



# U.S. Department of Health & Human Services

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Food and Drug Administration

## FOIA RESPONSE

**USER:** (ixg)  
**FOLDER:** K062925 - 349 pages (FOI:09002143)  
**COMPANY:** ROCHE DIAGNOSTICS CORP. (ROCHDIAGA)  
**PRODUCT:** TEST, TIME, PROTHROMBIN (GJS)  
**SUMMARY:** Product: COAGUCHEK XS SYSTEM

**DATE REQUESTED:** Mar 1, 2011

**DATE PRINTED:** Mar 25, 2011

**Note:** Releasable Version



# **Table of Contents**

<b>510K SUMMARY - 7 pages</b>	<b>1</b>
<b>AMENDMENT - 1 pages</b>	<b>8</b>
<b>CORRESPONDENCE - 10 pages</b>	<b>9</b>
<b>ORIGINAL - 117 pages</b>	<b>19</b>
<b>REVIEWER INFORMATION - 56 pages</b>	<b>136</b>
<b>SUPPLEMENT - 157 pages</b>	<b>192</b>

K062925

JAN 29 2007

## 510(k) Summary

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**Introduction** According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

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**1) Submitter name, address, contact** Roche Diagnostics Corporation  
9115 Hague Rd.  
Indianapolis, IN 46250

Contact Person: Luann Ochs

Date Prepared: January 29, 2007

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**2) Device name** Proprietary name: CoaguChek® XS System  
Common name: Prothrombin time test  
Classification name: Prothrombin time test

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**3) Predicate device** The Roche Diagnostics CoaguChek XS System (patient self-testing) is substantially equivalent in materials, design and function to other products that measure prothrombin time INR in human blood. Most notably, it is substantially equivalent to the Roche Diagnostics CoaguChek XS System (professional). In fact, it is identical in materials, design and function to the CoaguChek XS System (professional) except the labeling has been modified and validated for patient self-testing.

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**4) Device Description** The CoaguChek XS is a 3<sup>rd</sup> generation Roche Diagnostic's CoaguChek meter which was cleared for professional use under premarket notification K060978.

This premarket notification is being submitted to obtain clearance for patient self-testing.

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**5) Intended Use** The CoaguChek XS PT test strips are part of the CoaguChek XS System. The CoaguChek XS System measures blood-clotting time for people who are taking anticoagulation medications such as Coumadin® or warfarin. The CoaguChek XS System uses blood from a finger stick. The system is intended for properly selected and suitably trained users or their caregivers on the prescription or other order of the treating doctor. Users should be stabilized on anticoagulation medications such as Coumadin® or warfarin prior to self-testing with the CoaguChek XS System.

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**6) Comparison to Predicate Device** The following characteristics have been previously submitted, reviewed and cleared under the premarket notification for the CoaguChek XS System (K060978):

- Factor Sensitivity
- Heparin Sensitivity
- Hematocrit Effect
- Interfering Substances
- Normal Range
- Measuring Range
- Test Strip Stability
- Integrated Quality Control
- Instrument Failsafes
- Calibration
- Software Development

These characteristics are not impacted by the new user population.

The use of the system by self-testers was validated by an external user study that was conducted as the system is intended to be used. Following self-directed training, the subjects self-tested in the home setting for up to 8 weeks. The subjects also had 3 scheduled visits to their study site to collect user vs. technician data as well as user vs. reference method (Dade Innovin on a Sysmex analyzer) data.

The study results successfully demonstrated that self-trained subjects can obtain results that are equivalent to healthcare professionals and to the reference method. This study also demonstrated that self-tester results are consistent over time.

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**7) Performance characteristics** The performance characteristics that are impacted by the new user population were evaluated. The following information has been incorporated into our draft patient self-testing insert.

Claim	Statement															
<p><b>Accuracy</b></p>	<p>A study was conducted comparing test results obtained by self-trained patients with those obtained by healthcare professionals using the CoaguChek XS meter. The correlation was very good, as indicated by the following statistics: N = 258, Slope = 1.00, Intercept = 0.0 and Correlation Coefficient = 0.974. This study shows that self-trained patients are able to obtain results that are as accurate as those obtained by healthcare professionals trained in the use of the CoaguChek XS meter.</p>															
<p><b>Precision</b></p>	<p>A study was conducted and the precision of duplicates for capillary blood results was calculated for both self-trained patients and healthcare professionals. The following results were obtained:</p> <table border="1" data-bbox="662 1360 1377 1603"> <thead> <tr> <th></th> <th>Patient Results</th> <th>Professional Results</th> </tr> </thead> <tbody> <tr> <td><b>N</b></td> <td>222</td> <td>257</td> </tr> <tr> <td><b>Mean</b></td> <td>2.55</td> <td>2.50</td> </tr> <tr> <td><b>SD</b></td> <td>0.132</td> <td>0.135</td> </tr> <tr> <td><b>CV</b></td> <td>5.19</td> <td>5.38</td> </tr> </tbody> </table> <p>This study shows that self-trained patients are able to obtain results that are as precise as those obtained by healthcare professionals trained in the use of the CoaguChek XS meter.</p>		Patient Results	Professional Results	<b>N</b>	222	257	<b>Mean</b>	2.55	2.50	<b>SD</b>	0.132	0.135	<b>CV</b>	5.19	5.38
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

ROCHE Diagnostics Corp.  
C/O Jennifer Tribbett  
9115 Hague Road  
P.O. Box 50457  
Indianapolis, Indiana 46250

JAN 29 2007

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

Re: k062925

Trade/Device Name: CoaguChek® XS System for Patient Self-testing  
Regulation Number: 21 CFR 864.7750  
Regulation Name: Prothrombin Time Test  
Regulatory Class: Class II  
Product Code: GJS  
Dated: September 27, 2006  
Received: September 28, 2006

Dear Ms. Tribbett:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

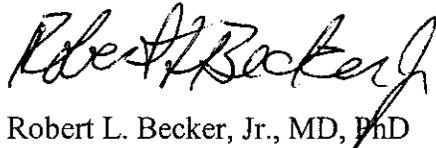
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally

Page 2 –

marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Robert L. Becker, Jr., MD, PhD

Director

Division of Immunology and Hematology

Office of In Vitro Diagnostic Device

Evaluation and Safety

Center for Devices and

Radiological Health

Enclosure

Page 3 –

cc: HFZ-401 DMC

HFZ-404 510(k) Staff  
HFZ- 440 Division  
D.O.

## Indications for Use

510(k) Number (if known): ~~K060978~~ K062925

Device Name: CoaguChek® XS System for Patient Self-Testing

### Indications For Use:

The CoaguChek XS PT test strips are part of the CoaguChek XS System. The CoaguChek XS System measures blood-clotting time for people who are taking anticoagulation medications such as Coumadin® or warfarin. The CoaguChek XS System uses blood from a finger stick. The system is intended for properly selected and suitably trained users or their caregivers on the prescription or other order of the treating doctor. Users should be stabilized on anticoagulation medications such as Coumadin® or warfarin prior to self-testing with the CoaguChek XS System.

Prescription Use  X   
(Part 21 CFR 801 Subpart D)

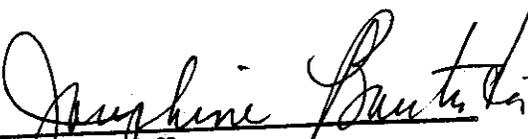
AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE  
IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
Division Sign-Off

Office of In Vitro Diagnostic Device  
Evaluation and Safety

510(k)  K062925





ROCHE Diagnostics Corp.  
C/O Jennifer Tribbett  
9115 Hague Road  
P.O. Box 50457  
Indianapolis, Indiana 46250

JAN 29 2007

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

Re: k062925

Trade/Device Name: CoaguChek® XS System for Patient Self-testing  
Regulation Number: 21 CFR 864.7750  
Regulation Name: Prothrombin Time Test  
Regulatory Class: Class II  
Product Code: GJS  
Dated: September 27, 2006  
Received: September 28, 2006

Dear Ms. Tribbett:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

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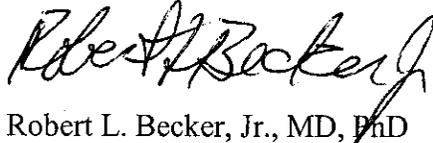
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Sincerely yours,



Robert L. Becker, Jr., MD, PhD  
Director  
Division of Immunology and Hematology  
Office of In Vitro Diagnostic Device  
Evaluation and Safety  
Center for Devices and  
Radiological Health

Enclosure

Page 3 –

cc: HFZ-401 DMC

HFZ-404 510(k) Staff

HFZ- 440 Division

D.O.

## Indications for Use

510(k) Number (if known): ~~K060978~~ 1K062925

Device Name: CoaguChek® XS System for Patient Self-Testing

### Indications For Use:

The CoaguChek XS PT test strips are part of the CoaguChek XS System. The CoaguChek XS System measures blood-clotting time for people who are taking anticoagulation medications such as Coumadin® or warfarin. The CoaguChek XS System uses blood from a finger stick. The system is intended for properly selected and suitably trained users or their caregivers on the prescription or other order of the treating doctor. Users should be stabilized on anticoagulation medications such as Coumadin® or warfarin prior to self-testing with the CoaguChek XS System.

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

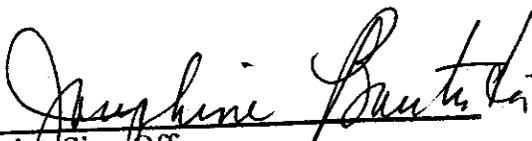
AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE  
IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
Division Sign/Off

Office of In Vitro Diagnostic Device  
Evaluation and Safety

510(k)   K062925

January 12, 2007

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Food and Drug Administration  
Center for Devices and  
Radiological Health  
Office of Device Evaluation  
Document Mail Center (HFZ-401)  
9200 Corporate Blvd.  
Rockville, Maryland 20850

ROCHE DIAGNOSTICS CORP.  
PROFESSIONAL DIAGNOSTICS  
9115 HAGUE RD.  
INDIANAPOLIS, IN 46256  
ATTN: THERESA BUSH

510(k) Number: K062925  
Product: COAGUCHEK XS  
SYSTEM

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST cite your 510(k) number and be sent in duplicate to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at [www.fda.gov/cdrh/ode/a02-01.html](http://www.fda.gov/cdrh/ode/a02-01.html).

The deficiencies identified represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: <http://www.fda.gov/cdrh/modact/leastburdensome.html>.

If after 30 days the additional information (AI), or a request for an extension of time, is not received, we will discontinue review of your submission and proceed to delete your file from our review system (21 CFR 807.87(1)). Please note our guidance document entitled, "Guidance for Industry and FDA Staff, FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request. The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at <http://www.fda.gov/cdrh/mdufma/guidance/1219.html>. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission. Please remember that the Safe Medical Devices Act of 1990 states that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

If you have procedural or policy questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (240)276-4040.

Sincerely yours,

Marjorie Shulman  
Supervisor Consumer Safety Officer  
Premarket Notification Section  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

November 14, 2006

Food and Drug Administration  
Center for Devices and  
Radiological Health  
Office of Device Evaluation  
Document Mail Center (HFZ-401)  
9200 Corporate Blvd.  
Rockville, Maryland 20850

ROCHE DIAGNOSTICS CORP.  
PROFESSIONAL DIAGNOSTICS  
9115 HAGUE RD.  
INDIANAPOLIS, IN 46256  
ATTN: JENNIFER TRIBBETT

510(k) Number: K062925  
Product: COAGUCHEK XS  
SYSTEM

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST cite your 510(k) number and be sent in duplicate to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at [www.fda.gov/cdrh/ode/a02-01.html](http://www.fda.gov/cdrh/ode/a02-01.html).

The deficiencies identified represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: <http://www.fda.gov/cdrh/modact/leastburdensome.html>.

If after 30 days the additional information (AI), or a request for an extension of time, is not received, we will discontinue review of your submission and proceed to delete your file from our review system (21 CFR 807.87(l)). Please note our guidance document entitled, "Guidance for Industry and FDA Staff, FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request. The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at <http://www.fda.gov/cdrh/mdufma/guidance/1219.html>. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission. Please remember that the Safe Medical Devices Act of 1990 states that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

If you have procedural or policy questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (240)276-4040.

Sincerely yours,

Marjorie Shulman  
Supervisor Consumer Safety Officer  
Premarket Notification Section  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Food and Drug Administration  
Center for Devices and  
Radiological Health  
Office of Device Evaluation  
Document Mail Center (HFZ-401)  
9200 Corporate Blvd.  
Rockville, Maryland 20850

September 28, 2006

ROCHE DIAGNOSTICS CORP.  
PROFESSIONAL DIAGNOSTICS  
9115 HAGUE RD.  
INDIANAPOLIS, IN 46256  
ATTN: JENNIFER TRIBBETT

510(k) Number: K062925  
Received: 28-SEP-2006  
Product: COAGUCHEK XS SYSTEM

The Center for Devices and Radiological Health (CDRH), Office of Device Evaluation (ODE), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in any future correspondence that relates to this submission. We will notify you when the processing of your premarket notification has been completed or if any additional information is required. **YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.**

On May 21, 2004, FDA issued a Guidance for Industry and FDA Staff entitled, "FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. Please review this document at <http://www.fda.gov/cdrh/mdufma/guidance/1219.html>.

In future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's eCopy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, HDE) with an electronic copy. For more information about the program, including the formatting requirements, please see [www.fda.gov/cdrh/electsub.html](http://www.fda.gov/cdrh/electsub.html).

The Clinical Laboratory Improvement Amendments of 1988 (CLIA) requires the categorization of commercially marketed test systems by level of complexity. If your device is a test system that requires categorization you will be notified of your complexity as an enclosure with any clearance letter.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC) (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review". Please refer to this guidance for information on current fax and e-mail practices at [www.fda.gov/cdrh/ode/a02-01.html](http://www.fda.gov/cdrh/ode/a02-01.html).

You should be familiar with the regulatory requirements for medical device available at Device Advice <http://www.fda.gov/cdrh/devadvice/>. If you have other procedural or policy questions, or want information on how to check on the status of your submission, please contact DSMICA at (301) 443-6597 or its toll-free number (800) 638-2041, or at their Internet address <http://www.fda.gov/cdrh/dsmamain.html> or me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman  
Supervisory Consumer Safety Officer  
Office of Device Evaluation  
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
FOOD AND DRUG ADMINISTRATION  
MEDICAL DEVICE USER FEE COVER SHEET

PAYMENT IDENTIFICATION NUMBER: (b)(4)(b)(4)  
Write the Payment Identification number on your check.

A completed Cover Sheet must accompany each original application or supplement subject to fees. The following actions must be taken to properly submit your application and fee payment:

1. Electronically submits the completed Cover Sheet to the Food and Drug Administration (FDA) before payment is sent.
2. Include printed copy of this completed Cover Sheet with a check made payable to the Food and Drug Administration. Remember that the Payment Identification Number must be written on the check.
3. Mail Check and Cover Sheet to the US Bank Lock Box, FDA Account, P.O. Box 956733, St. Louis, MO 63195-6733. (Note: In no case should payment be submitted with the application.)
4. If you prefer to send a check by a courier, the courier may deliver the check and Cover Sheet to: US Bank, Attn: Government Lockbox 956733, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This address is for courier delivery only. Contact the US Bank at 314-418-4821 if you have any questions concerning courier delivery.)
5. For Wire Transfer Payment Procedures, please refer to the MDUFMA Fee Payment Instructions at the following URL: <http://www.fda.gov/cdrh/mdufma/faqs.html#3a>. You are responsible for paying all fees associated with wire transfer.
6. Include a copy of the complete Cover Sheet in volume one of the application when submitting to the FDA at either the CBER or CDRH Document Mail Center.

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)

ROCHE DIAGNOSTICS CORP  
9115 Hague Road P.O. Box 50457  
Indianapolis IN 46250-0457  
US

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)

(b)(4)

2. CONTACT NAME

jennifer tribbett

2.1 E-MAIL ADDRESS

jennifer.tribbett@roche.com

2.2 TELEPHONE NUMBER (include Area code)

317-521-3742

2.3 FACSIMILE (FAX) NUMBER (Include Area code)

NO DATA

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: <http://www.fda.gov/dc/mdufma>)

Select an application type:

- Premarket notification(510(k)); except for third party
- Biologics License Application (BLA)
- Premarket Approval Application (PMA)
- Modular PMA
- Product Development Protocol (PDP)
- Premarket Report (PMR)

3.1 Select one of the types below

- Original Application

Supplement Types:

- Efficacy (BLA)
- Panel Track (PMA, PMR, PDP)
- Real-Time (PMA, PMR, PDP)
- 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)

- YES, I meet the small business criteria and have submitted the required qualifying documents to FDA
- NO, I am not a small business

4.1 If Yes, please enter your Small Business Decision Number:

5. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.

- This application is the first PMA submitted by a qualified small business, including any affiliates, parents, and partner firms
- The sole purpose of the application is to support conditions of use for a pediatric population
- This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only
- The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

6. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).)

- YES
- NO

7. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION (FOR FISCAL YEAR 2005)

(b)(4)

24-Jul-2006

HE II

FDNY  
2006  
AUG 28

**Premarket Notification, 510(k)**  
**for Roche Diagnostics**  
**CoaguChek® XS System for Patient Self-Testing**  
**Premarket Notification**

**September 27, 2006**

K24



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Roche Confidential

226

# Premarket Notification [510(k)]

## Table of Contents

Section	Page
Table of Contents .....	2
Premarket Notification, 510(k) for the CoaguChek® XS System for Patient Self Testing	
I. General Information .....	3
Premarket Submission Cover Sheet .....	8
Premarket Notification [510(k)] checklist for Acceptance Decision .....	14
II. Truthful and Accurate Statement .....	23
Indications for Use Statement .....	24
Clinical Investigator Financial Disclosure .....	25
III. 510(k) Summary .....	27
IV. External Patient Self-Testing Study .....	31
V. Instrument Features	
On-board Control .....	47
Automatic Meter Checks .....	63
VI. New Device Labeling	
Test Strip Insert .....	67
Instrument User's Manual .....	70
Training Video Script .....	94
Getting Started Guide .....	111
VII. Predicate Device Labeling .....	114



September 27, 2006

Food and Drug Administration  
Center for Devices and Radiological Health  
Office of Device Evaluations, Division of Clinical Laboratory Devices  
Document Mail Center (HFZ-401)  
9200 Corporate Boulevard  
Rockville, MD 20850

## Re: Premarket Notification for the CoaguChek® XS System

### Patient Self-Testing

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**Purpose** In accordance with 21 CFR 807.81(a)(2), Roche Diagnostics Corporation hereby submits official notification as required by Section 510(k) of the Federal Food, Drug and Cosmetics Act of our intention to market the device described in this Premarket Notification [510(k)].

---

**Introduction** The CoaguChek XS is a 3<sup>rd</sup> generation Roche Diagnostic's CoaguChek meter which was cleared for professional use under premarket notification K060978.

**This premarket notification is being submitted to obtain clearance for patient self-testing.**

The system is identical in materials (test strip and meter), design and function to the CoaguChek XS system described in K060978. However, the labeling has been modified for patient self-testing use.

The use of the system by self-testers was validated by an external user study that was conducted as the system is intended to be used. Following self-directed training, the subjects self-tested in the home setting for up to 8 weeks. The subjects also had 3 scheduled visits, to their study site, to collect user vs. technician data as well as user vs. reference method (Dade Innovin on a Sysmex analyzer) data.

The study results successfully demonstrated that self-trained subjects can obtain results that are equivalent to healthcare professionals and to the reference method. This study also demonstrated that self-tester results are consistent over time.

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*Continued on next page*

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**Device Name** Proprietary name: CoaguChek® XS System for Patient Self-Testing

Common name: Prothrombin time test

Classification name: Prothrombin time test

---

**Establishment registration** The CoaguChek XS System (meter and strip) will be manufactured in the Roche Diagnostics facility located in Mannheim Germany. The establishment registration number for this site is 9610126.

---

**Classification** Regulation Number: 21 CFR 864.7750

Identification: A prothrombin time test is a device used as a general screening procedure for the detection of possible clotting factor deficiencies in the extrinsic coagulation pathway, which involves the reaction between coagulation factors III and VII, and to monitor patients receiving coumarin therapy (the administration of one of the coumarin anticoagulants in the treatment of venous thrombosis or pulmonary embolism).

Panel	Classification Number	Class	Classification Name
Hematology	81 GJS	II	Prothrombin time test

---

**Performance Standards** To date, no performance standards that affect this device have been finalized under Section 514 of the Act.

---

**Proposed labeling** The instructions for use as required by 21 CFR 809.10 are provided in the

- Test Strip Insert
- Instrument User's Manual
- Training Video
- Getting Started Guide

All of these labeling pieces have been designed specifically for the patient self-testing population. They are included in Section VI of this submission.

We believe our draft labeling satisfies the intent of the regulation.

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*Continued on next page*

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229

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**Substantial  
equivalence**

The Roche Diagnostics CoaguChek XS System (patient self-testing) is substantially equivalent in materials, design and function to other products that measure prothrombin time INR in human blood. Most notably, it is substantially equivalent to the Roche Diagnostics CoaguChek XS System (professional). In fact, it is identical in materials, design and function to the CoaguChek XS System (professional) except the labeling has been modified and validated for patient self-testing.

---

**Evaluations  
Summary**

The following characteristics have been previously submitted, reviewed and cleared under the premarket notification for the CoaguChek XS System (K060978):

- Factor Sensitivity
- Heparin Sensitivity
- Hematocrit Effect
- Interfering Substances
- Normal Range
- Measuring Range
- Test Strip Stability
- Integrated Quality Control
- Instrument Failsafes
- Calibration
- Software Development

These characteristics are not impacted by the new user population.

The use of the system by self-testers was validated by an external user study that was conducted as the system is intended to be used. Following self-directed training, the subjects self-tested in the home setting for up to 8 weeks. The subjects also had 3 scheduled visits to their study site to collect user vs. technician data as well as user vs. reference method (Dade Innovin on a Sysmex analyzer) data.

The study results successfully demonstrated that self-trained subjects can obtain results that are equivalent to healthcare professionals and to the reference method. This study also demonstrated that self-tester results are consistent over time.

Section IV provides information regarding the testing protocol and results from this external user study.

---

**Performance characteristics**

The performance characteristics that are impacted by the new user population were evaluated as described in Section IV. The following information has been incorporated into our draft patient self-testing insert.

<b>Claim</b>	<b>Statement</b>															
<b>Accuracy</b>	<p>A study was conducted comparing test results obtained by self-trained patients with those obtained by healthcare professionals using the CoaguChek XS meter. The correlation was very good, as indicated by the following statistics: N = 258, Slope = 1.00, Intercept = 0.0 and Correlation Coefficient = 0.974. This study shows that self-trained patients are able to obtain results that are as accurate as those obtained by healthcare professionals trained in the use of the CoaguChek XS meter.</p>															
<b>Precision</b>	<p>A study was conducted and the precision of duplicates for capillary blood results was calculated for both self-trained patients and healthcare professionals. The following results were obtained:</p> <table border="1" data-bbox="680 1152 1372 1382"> <thead> <tr> <th></th> <th><b>Patient Results</b></th> <th><b>Professional Results</b></th> </tr> </thead> <tbody> <tr> <td><b>N</b></td> <td>222</td> <td>257</td> </tr> <tr> <td><b>Mean</b></td> <td>2.55</td> <td>2.50</td> </tr> <tr> <td><b>SD</b></td> <td>0.132</td> <td>0.135</td> </tr> <tr> <td><b>CV</b></td> <td>5.19</td> <td>5.38</td> </tr> </tbody> </table> <p>This study shows that self-trained patients are able to obtain results that are as precise as those obtained by healthcare professionals trained in the use of the CoaguChek XS meter.</p>		<b>Patient Results</b>	<b>Professional Results</b>	<b>N</b>	222	257	<b>Mean</b>	2.55	2.50	<b>SD</b>	0.132	0.135	<b>CV</b>	5.19	5.38
	<b>Patient Results</b>	<b>Professional Results</b>														
<b>N</b>	222	257														
<b>Mean</b>	2.55	2.50														
<b>SD</b>	0.132	0.135														
<b>CV</b>	5.19	5.38														

*Continued on next page*

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**Enhanced Meter  
Functions**

(b) (4)

(b)(4)

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**Confidentiality  
request**

Roche Diagnostics requests that FDA not disclose the nature or existence of the premarket notification until the substantial equivalence decision has been reached.

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**Closing**

We trust the information provided in this Premarket Notification [510(k)] will support an affirmative decision by the agency to extend the use of the CoaguChek XS System to patient self-testers.

If you should have questions or require further information, please do not hesitate to contact me.

- Phone: (317)-576-3742
- FAX: (317) 576-2324

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Sincerely,



Jennifer Tribbett  
Regulatory Affairs Principal

enclosures

007

**PREMARKET SUBMISSION COVER SHEET**

008

233

**CDRH PREMARKET REVIEW SUBMISSION COVER SHEET**

Date of Submission  
 September 27, 2006

User Fee Payment ID Number  
 MD6026741-956733

FDA Submission Document Number (if known)

**SECTION A TYPE OF SUBMISSION**

<p><b>PMA</b></p> <input type="checkbox"/> Original Submission <input type="checkbox"/> Premarket Report <input type="checkbox"/> Modular Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment <input type="checkbox"/> Licensing Agreement	<p><b>PMA &amp; HDE Supplement</b></p> <input type="checkbox"/> Regular (180 day) <input type="checkbox"/> Special <input type="checkbox"/> Panel Track (PMA Only) <input type="checkbox"/> 30-day Supplement <input type="checkbox"/> 30-day Notice <input type="checkbox"/> 135-day Supplement <input type="checkbox"/> Real-time Review <input type="checkbox"/> Amendment to PMA & HDE Supplement <input type="checkbox"/> Other	<p><b>PDP</b></p> <input type="checkbox"/> Original PDP <input type="checkbox"/> Notice of Completion <input type="checkbox"/> Amendment to PDP	<p><b>510(k)</b></p> <input checked="" type="checkbox"/> Original Submission: <input checked="" type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated (Complete section I, Page 5) <input type="checkbox"/> Additional Information <input type="checkbox"/> Third Party	<p><b>Meeting</b></p> <input type="checkbox"/> Pre-510(K) Meeting <input type="checkbox"/> Pre-IDE Meeting <input type="checkbox"/> Pre-PMA Meeting <input type="checkbox"/> Pre-PDP Meeting <input type="checkbox"/> Day 100 Meeting <input type="checkbox"/> Agreement Meeting <input type="checkbox"/> Determination Meeting <input type="checkbox"/> Other (specify):
<p><b>IDE</b></p> <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement	<p><b>Humanitarian Device Exemption (HDE)</b></p> <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment	<p><b>Class II Exemption Petition</b></p> <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	<p><b>Evaluation of Automatic Class III Designation (De Novo)</b></p> <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	<p><b>Other Submission</b></p> <input type="checkbox"/> 513(g) <input type="checkbox"/> Other (describe submission):

Have you used or cited Standards in your submission?  Yes  No (If Yes, please complete Section I, Page 5)

**SECTION B SUBMITTER, APPLICANT OR SPONSOR**

Company / Institution Name Roche Diagnostics	Establishment Registration Number (if known) 1823260		
Division Name (if applicable) Professional Diagnostics	Phone Number (including area code) ( 317 ) 521-3742		
Street Address 9115 Hague Road	FAX Number (including area code) ( 317 ) 521-2324		
City Indianapolis	State / Province IN	ZIP/Postal Code 46256	Country USA
Contact Name Jennifer Tribbett			
Contact Title Regulatory Affairs Principal		Contact E-mail Address Jennifer.tribbett@roche.com	

**SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)**

Company / Institution Name			
Division Name (if applicable)		Phone Number (including area code) ( )	
Street Address		FAX Number (including area code) ( )	
City	State / Province	ZIP/Postal Code	Country
Contact Name			
Contact Title		Contact E-mail Address	

**SECTION D1**

**REASON FOR APPLICATION - PMA, PDP, OR HDE**

- Withdrawal
- Additional or Expanded Indications
- Request for Extension
- Post-approval Study Protocol
- Request for Applicant Hold
- Request for Removal of Applicant Hold
- Request to Remove or Add Manufacturing Site

- Change in design, component, or specification:
  - Software / Hardware
  - Color Additive
  - Material
  - Specifications
  - Other (specify below)

- Location change:
  - Manufacturer
  - Sterilizer
  - Packager

- Process change:
  - Manufacturing
  - Sterilization
  - Packaging
  - Other (specify below)

- Labeling change:
  - Indications
  - Instructions
  - Performance
  - Shelf Life
  - Trade Name
  - Other (specify below)

- Report Submission:
  - Annual or Periodic
  - Post-approval Study
  - Adverse Reaction
  - Device Defect
  - Amendment

- Response to FDA correspondence:

- Change in Ownership
- Change in Correspondent
- Change of Applicant Address

- Other Reason (specify):

**SECTION D2**

**REASON FOR APPLICATION - IDE**

- New Device
- New Indication
- Addition of Institution
- Expansion / Extension of Study
- IRB Certification
- Termination of Study
- Withdrawal of Application
- Unanticipated Adverse Effect
- Notification of Emergency Use
- Compassionate Use Request
- Treatment IDE
- Continued Access

- Change in:
  - Correspondent / Applicant
  - Design / Device
  - Informed Consent
  - Manufacturer
  - Manufacturing Process
  - Protocol - Feasibility
  - Protocol - Other
  - Sponsor

- Repose to FDA Letter Concerning:
  - Conditional Approval
  - Deemed Approved
  - Deficient Final Report
  - Deficient Progress Report
  - Deficient Investigator Report
  - Disapproval
  - Request Extension of Time to Respond to FDA
  - Request Meeting
  - Request Hearing

- Report submission:
  - Current Investigator
  - Annual Progress Report
  - Site Waiver Report
  - Final

- Other Reason (specify):

**SECTION D3**

**REASON FOR SUBMISSION - 510(k)**

- New Device

- Additional or Expanded Indications

- Change in Technology

- Other Reason (specify):

010

**SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS**

Product codes of devices to which substantial equivalence is claimed				Summary of, or statement concerning, safety and effectiveness information	
1	GJS	2		3	
4		5		6	
7		8		9	
Information on devices to which substantial equivalence is claimed (if known)					
	510(k) Number		Trade or Proprietary or Model Name		Manufacturer
1	K060978	1	CoaguChek XS System	1	Roche Diagnostics
2		2		2	
3		3		3	
4		4		4	
5		5		5	
6		6		6	

**SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS**

Common or usual name or classification  
Prothrombin time test

Trade or Proprietary or Model Name for This Device	Model Number
CoaguChek® XS System	1
	2
	3
	4
	5

FDA document numbers of all prior related submissions (regardless of outcome)

1	2	3	4	5	6
K060978					
7	8	9	10	11	12

Data Included in Submission  
 Laboratory Testing     Animal Trials     Human Trials

**SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS**

Product Code GJS	C.F.R. Section (if applicable) 21 CFR 864.7750	Device Class <input type="checkbox"/> Class I <input checked="" type="checkbox"/> Class II <input type="checkbox"/> Class III <input type="checkbox"/> Unclassified
Classification Panel Hematology		

Indications (from labeling)  
**The CoaguChek XS System measures blood-clotting time (Prothrombin Time) for people who are taking anticoagulation medications such as Coumadin® or warfarin. The CoaguChek XS System measures blood-clotting time using blood from the gertip.**

(Wording has been simplified compared to the wording in the professional insert in order to achieve the appropriate reading level required for home testers.)

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.

FDA Document Number (if known)

**SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION**

<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	FDA Establishment Registration Number 9610126	<input checked="" type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Manufacturer	<input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Repackager / Relabeler
Company / Institution Name Roche Diagnostics GmbH		Establishment Registration Number 9610126	
Division Name (if applicable) Professional Diagnostics		Phone Number (including area code) ( 317 ) 521-3742 (in the U.S.)	
Street Address Sandhofer Strasse 116		FAX Number (including area code) ( 317 ) 521-2324 (in the U.S.)	
City Mannheim		State / Province	ZIP/Postal Code D-68298
		Country Germany	
Contact Name Jennifer Tribbett (in the U.S.)		Contact Title Regulatory Affairs Principal	Contact E-mail Address Jennifer.tribbett@roche.com

<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	FDA Establishment Registration Number	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Manufacturer	<input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Repackager / Relabeler
Company / Institution Name		Establishment Registration Number	
Division Name (if applicable)		Phone Number (including area code) ( )	
Street Address		FAX Number (including area code) ( )	
City		State / Province	ZIP/Postal Code
		Country	
Contact Name		Contact Title	Contact E-mail Address

<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	FDA Establishment Registration Number	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Manufacturer	<input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Repackager / Relabeler
Company / Institution Name		Establishment Registration Number	
Division Name (if applicable)		Phone Number (including area code) ( )	
Street Address		FAX Number (including area code) ( )	
City		State / Province	ZIP/Postal Code
		Country	
Contact Name		Contact Title	Contact E-mail Address

**SECTION I**

**UTILIZATION OF STANDARDS**

Note: Complete this section if your application or submission cites standards or includes a "Declaration of Conformity to a Recognized Standard" statement.

	Standards No.	Standards Organization	Standards Title	Version	Date
1					
2					
3					
4					
5					
6					
7					

Please include any additional standards to be cited on a separate page.

Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Food and Drug Administration  
 CDRH (HFZ-342)  
 9200 Corporate Blvd.  
 Rockville, MD 20850

... agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control

# SCREENING CHECKLIST FOR ALL PREMARKET NOTIFICATION [510(k)] SUBMISSIONS

**510(k) Number:** \_\_\_\_\_

The cover letter clearly identifies the type of 510(k) submission as **(Check the appropriate box)**:

- Special 510(k) - Do Sections 1 and 2
- Abbreviated 510(k) - Do Sections 1, 3 and 4
- Traditional 510(k) or no identification provided - Do Sections 1 and 4

**Section 1: Required Elements for All Types of 510(k) submissions:**

	Present or Adequate	Missing or Inadequate
Cover letter, containing the elements listed on page 3-2 of the Premarket Notification [510] Manual.		
Table of Contents.		
Truthful and Accurate Statement.		
Device's Trade Name, Device's Classification Name and Establishment Registration Number.		
Device Classification Regulation Number and Regulatory Status (Class I, Class II, Class III or Unclassified).		
Proposed Labeling including the material listed on page 3-4 of the Premarket Notification [510] Manual.		
Statement of Indications for Use that is on a separate page in the premarket submission.		
Substantial Equivalence Comparison, including comparisons of the new device with the predicate in areas that are listed on page 3-4 of the Premarket Notification [510] Manual.		
510(k) Summary or 510(k) Statement.		
Description of the device (or modification of the device) including diagrams, engineering drawings, photographs or service manuals.		
Identification of legally marketed predicate device. *		
Compliance with performance standards. * [See Section 514 of the Act and 21 CFR 807.87 (d).]		
Class III Certification and Summary. **		
Financial Certification or Disclosure Statement for 510(k) notifications with a clinical study. * [See 21 CFR 807.87 (i)]		
510(k) Kit Certification ***		

\* - May not be applicable for Special 510(k)s.  
 \*\* - Required for Class III devices, only.  
 \*\*\* - See pages 3-12 and 3-13 in the Premarket Notification [510] Manual and the Convenience Kits Interim Regulatory Guidance.

**Section 2: Required Elements for a SPECIAL 510(k) submission:**

	<b>Present</b>	<b>Inadequate or Missing</b>
Name and 510(k) number of the submitter's own, unmodified predicate device.		
A description of the modified device and a comparison to the sponsor's predicate device.		
A statement that the intended use(s) and indications of the modified device, as described in its labeling are the same as the intended uses and indications for the submitter's unmodified predicate device.		
Reviewer's confirmation that the modification has not altered the fundamental scientific technology of the submitter's predicate device.		
A Design Control Activities Summary that includes the following elements (a-c):		
a. Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis.		
b. Based on the Risk Analysis, an identification of the required verification and validation activities, including the methods or tests used and the acceptance criteria to be applied.		
c. A Declaration of Conformity with design controls that includes the following statements:		
A statement that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results of the activities demonstrated that the predetermined acceptance criteria were met. This statement is signed by the individual responsible for those particular activities.		
A statement that the manufacturing facility is in conformance with the design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review. This statement is signed by the individual responsible for those particular activities.		

**Section 3: Required Elements for an ABBREVIATED 510(k)\* submission:**

	<b>Present</b>	<b>Inadequate or Missing</b>
For a submission, which relies on a guidance document and/or special control(s), a summary report that describes how the guidance and/or special control(s) was used to address the risks associated with the particular device type. (If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.)		
For a submission, which relies on a recognized standard, a declaration of conformity [For a listing of the required elements of a declaration of conformity, <b>SEE Required Elements for a Declaration of Conformity to a Recognized Standard</b> , which is posted with the 510(k) boilers on the <b>H drive.</b> ]		
For a submission, which relies on a recognized standard without a declaration of conformity, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has <u>not</u> been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device <u>and</u> any additional information requested by the reviewer in order to determine substantial equivalence.		
Any additional information, which is not covered by the guidance document, special control, recognized standard and/or non-recognized standard, in order to determine substantial equivalence.		

\* - When completing the review of an abbreviated 510(k), please fill out an Abbreviated Standards Data Form (located on the H drive) and list all the guidance documents, special controls, recognized standards and/or non-recognized standards, which were noted by the sponsor.

**Section 4: Additional Requirements for ABBREVIATED and TRADITIONAL 510(k) submissions (If Applicable):**

	<b>Present</b>	<b>Inadequate or Missing</b>
a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation:		
b) Sterilization and expiration dating information:		
i) sterilization process		
ii) validation method of sterilization process		
iii) SAL		
iv) packaging		
v) specify pyrogen free		
vi) ETO residues		
vii) radiation dose		
viii) Traditional Method or Non-Traditional Method		
c) Software Documentation:		

*Items with checks in the “Present or Adequate” column do not require e additional information from the sponsor. Items with checks in the “Missing or Inadequate” column must be submitted before substantive review of the document.*

Passed Screening  Yes  No

Reviewer: \_\_\_\_\_

Concurrence by Review Branch: \_\_\_\_\_

Date: \_\_\_\_\_

The deficiencies identified above represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the “A Suggested Approach to Resolving Least Burdensome Issues” document. It is available on our Center web page at: <http://www.fda.gov/cdrh/modact/leastburdensome.html>

017

242

# Screening Checklist

## For all Premarket Notification 510(k) Submissions

<b>Device Name: CoaguChek XS System for Patient Self Testing</b>				<b>K</b>		
<b>Submitter (Company): Roche Diagnostics</b>						
<b>Items which should be included (circle missing &amp; needed information)</b>	<b>S P E C I A L</b>		<b>A B B R E V I A T E D</b>		<b>T R A D I T I O N A L</b>	<b>√ IF ITEM IS NEEDED AND IS MISSING</b>
	YES	NO	YES	NO	<input checked="" type="radio"/> YES	
<b>1. Cover Letter clearly identifies Submission as:</b>						
a) "Special 510(k): Device Modification"						
b) "Abbreviated 510(k)"						
c) Traditional 510(k)						
Go to # 2,4		Go to 3,4,5		Go to # 4, 5	Page 1	
<b>2. "SPECIALS" – ONLY FOR MODIFICATIONS TO MANUFACTURER'S OWN CLASS II, III OR RESERVED CLASS I DEVICE</b>						
a) Name & 510(k) number of legally marketed (unmodified) predicate device						
b) STATEMENT – INTENDED USE AND INDICATIONS FOR USE OF MODIFIED DEVICE AS DESCRIBED IN ITS LABELING HAVE NOT CHANGED*						
c) STATEMENT – FUNDAMENTAL SCIENTIFIC TECHNOLOGY OF THE MODIFIED DEVICE HAS NOT CHANGED*						
d) Design Control Activities Summary						
i) Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis.						
ii) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied.						
iii) A declaration of conformity with design controls. The declaration of conformity should include:						

018

243

<p>1) A statement signed by the individual responsible, that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(a) and the results demonstrated that the predetermined acceptance criteria were met.</p>				
<p>2) A statement signed by the individual responsible, that manufacturing facility is in conformance with design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review.</p>				

→ → → **CONTINUE TO SECTION 4** ← ← ←

	SPECIALS		ABBREVIATED		TRADITIONAL		√ IF ITEM IS NEEDED AND IS MISSING
	YES	NO	YES	NO	YES	NO	
<b>3. ABBREVIATED 510(K): SPECIAL CONTROLS/CONFORMANCE TO RECOGNIZED STANDARDS</b>							
a) For a submission, which relies on a guidance Document and/or special control(s), a summary report that describes how the guidance and/or special control(s) was used to address the risks associated with the particular device type.							
b) If a manufacturer elects to us an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.							
c) For a submission, which relies on a recognized standard, a declaration of conformity to the standard. The declaration should include the following:							
i) An identification of the applicable recognized consensus standards that were met							
ii) A specification, for each consensus standard, That all requirements were met, except for inapplicable requirements or deviations noted below							
iii) An identification, for each consensus standard, of any way(s) in which the standard may have been adapted for application to the device under review, e.g., an identification of an alternative series of tests that were performed.							
iv) An identification, for each consensus standard, of any requirements that were not applicable to the device							
v) A specification of any deviations from each applicable standard that were applied							
vi) A specification of the differences that may exist, if any, between the tested device and the device to be marketed and a justification of the test results in these areas of difference							
vii) Name/address of test laboratory/certification body involved in determining the conformance of the device with applicable consensus standards and a reference to any accreditations for those organizations							
d) Data/information to address issues not covered by guidance documents, special controls, and/or recognized standards							

→ → → CONTINUE TO SECTION 4 ← ← ←

020

245

<b>4. GENERAL INFORMATION; REQUIRED IN ALL 510(K) SUBMISSIONS</b>							
√ IF ITEM IS							
	SPECIALS		ABBREVIATED		TRADITIONAL		NEEDED AND IS MISSING
	YES	NO	YES	NO	YES	NO	
a) Trade name, classification name, establishment registration number, address of manufacturer, device class					X		Page 4
b) OR a statement that the device is not yet classified	FDA – may be a classification request; see coordinator						
c) Identification of legally marketed equivalent device		NA			X		Page 5
d) Compliance with Section 514 – performance standards		NA			X		Page 4
e) Address of manufacturer					X		Page 12
f) Truthful and Accurate Statement					X		Page 23
g) Indications for Use enclosure					X		Page 24
h) SMDA Summary or Statement (FOR ALL DEVICE CLASSES)					X		Page 27
i) Class III Certification & Summary (FOR ALL CLASS III DEVICES)					NA		
j) Description of device (or modification) including diagrams, engineering drawings, photographs, service manuals					X		Section VI
k) Proposed Labeling:					X		Section VI
i) Package labeling (user info)							
ii) statement of intended use							
iii) advertisements or promotional materials							
iv) MRI compatibility (if claimed)							
m) Comparison information (similarities and differences) to named legally marketed equivalent device (table preferred) should include:					X		Page 5
i) labeling							
ii) intended use							
iii) physical characteristics							
iv) anatomical sites of use							
v) performance (bench, animal, clinical) testing		NA					
vi) safety characteristics		NA					
n) If kit, kit certification						NA	
<b>5. Additional Considerations: (may be covered by Design Controls)</b>							
a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/ formulation:						NA	
i) component & material							
ii) identify patient-contacting materials							
iii) biocompatibility of final sterilized product							

b) Sterilization and expiration dating information-							
i) sterilization method							
ii) SAL							
iii) packaging							
iv) specify pyrogen free							
v) radiation dose							
c) Software validation & verification							Reviewed in K060978
i) hazard analysis							
ii) level of concern							
iii) development documentation							
iv) certification							

Items shaded under "NO" are necessary for that type of submission. Circled items and items with checks in the "Needed & Missing" column must be submitted before acceptance of the document.

Passed Screening \_\_\_\_\_ Yes \_\_\_\_\_ no

Reviewer: \_\_\_\_\_

Date: \_\_\_\_\_

Concurrence by Review

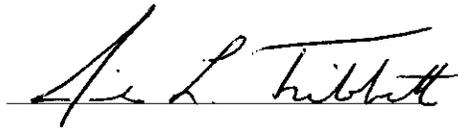
Branch: \_\_\_\_\_

**Premarket Notification**

**Truthful and Accurate Statement**

As required by 21 CFR 807.87:

I certify, in my capacity as Regulatory Affairs Principal for Roche Diagnostics, I believe to the best of my knowledge, that all data and information submitted in this premarket notification are truthful and accurate and that no material fact has been omitted.



Jennifer L. Tribbett, RAC

September 27, 2006

023

248

## Indications for Use

510(k) Number (if known): K062925

Device Name: CoaguChek® XS System for Patient Self-Testing

### Indications For Use:

The CoaguChek XS System measures blood-clotting time (Prothrombin Time) for people who are taking anticoagulation medications such as Coumadin® or warfarin. The CoaguChek XS System measures blood-clotting time using blood from the fingertip.

Prescription Use  X   
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

---

Concurrence of CDRH, Office of Device Evaluation (ODE)

### CERTIFICATION: FINANCIAL INTERESTS AND ARRANGEMENTS OF CLINICAL INVESTIGATORS

TO BE COMPLETED BY APPLICANT

With respect to all covered clinical studies (or specific clinical studies listed below (if appropriate)) submitted in support of this application, I certify to one of the statements below as appropriate. I understand that this certification is made in compliance with 21 CFR part 54 and that for the purposes of this statement, a clinical investigator includes the spouse and each dependent child of the investigator as defined in 21 CFR 54.2(d).

Please mark the applicable checkbox.

- (1) As the sponsor of the submitted studies, I certify that I have not entered into any financial arrangement with the listed clinical investigators (enter names of clinical investigators below or attach list of names to this form) whereby the value of compensation to the investigator could be affected by the outcome of the study as defined in 21 CFR 54.2(a). I also certify that each listed clinical investigator required to disclose to the sponsor whether the investigator had a proprietary interest in this product or a significant equity in the sponsor as defined in 21 CFR 54.2(b) did not disclose any such interests. I further certify that no listed investigator was the recipient of significant payments of other sorts as defined in 21 CFR 54.2(f).

(b)(6)

(b)(6)

- (2) As the applicant who is submitting a study or studies sponsored by a firm or party other than the applicant, I certify that based on information obtained from the sponsor or from participating clinical investigators, the listed clinical investigators (attach list of names to this form) did not participate in any financial arrangement with the sponsor of a covered study whereby the value of compensation to the investigator for conducting the study could be affected by the outcome of the study (as defined in 21 CFR 54.2(a)); had no proprietary interest in this product or significant equity interest in the sponsor of the covered study (as defined in 21 CFR 54.2(b)); and was not the recipient of significant payments of other sorts (as defined in 21 CFR 54.2(f)).

- (3) As the applicant who is submitting a study or studies sponsored by a firm or party other than the applicant, I certify that I have acted with due diligence to obtain from the listed clinical investigators (attach list of names) or from the sponsor the information required under 54.4 and it was not possible to do so. The reason why this information could not be obtained is attached.

NAME Jennifer Tribbett	TITLE Regulatory Affairs Principal
FIRM/ORGANIZATION Roche Diagnostics	
SIGNATURE 	DATE 09/27/2006

#### Paperwork Reduction Act Statement

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Public reporting burden for this collection of information is estimated to average 1 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the necessary data, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information to the address to the right:

Department of Health and Human Services  
Food and Drug Administration  
5600 Fishers Lane, Room 14C-03  
Rockville, MD 20857

025

### CERTIFICATION: FINANCIAL INTERESTS AND ARRANGEMENTS OF CLINICAL INVESTIGATORS

TO BE COMPLETED BY APPLICANT

With respect to all covered clinical studies (or specific clinical studies listed below (if appropriate)) submitted in support of this application, I certify to one of the statements below as appropriate. I understand that this certification is made in compliance with 21 CFR part 54 and that for the purposes of this statement, a clinical investigator includes the spouse and each dependent child of the investigator as defined in 21 CFR 54.2(d).

Please mark the applicable checkbox.

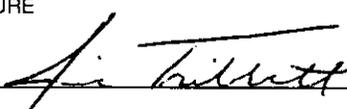
- (1) As the sponsor of the submitted studies, I certify that I have not entered into any financial arrangement with the listed clinical investigators (enter names of clinical investigators below or attach list of names to this form) whereby the value of compensation to the investigator could be affected by the outcome of the study as defined in 21 CFR 54.2(a). I also certify that each listed clinical investigator required to disclose to the sponsor whether the investigator had a proprietary interest in this product or a significant equity in the sponsor as defined in 21 CFR 54.2(b) did not disclose any such interests. I further certify that no listed investigator was the recipient of significant payments of other sorts as defined in 21 CFR 54.2(f).

(b) (6)

(b)(6)

- (2) As the applicant who is submitting a study or studies sponsored by a firm or party other than the applicant, I certify that based on information obtained from the sponsor or from participating clinical investigators, the listed clinical investigators (attach list of names to this form) did not participate in any financial arrangement with the sponsor of a covered study whereby the value of compensation to the investigator for conducting the study could be affected by the outcome of the study (as defined in 21 CFR 54.2(a)); had no proprietary interest in this product or significant equity interest in the sponsor of the covered study (as defined in 21 CFR 54.2(b)); and was not the recipient of significant payments of other sorts (as defined in 21 CFR 54.2(f)).

- (3) As the applicant who is submitting a study or studies sponsored by a firm or party other than the applicant, I certify that I have acted with due diligence to obtain from the listed clinical investigators (attach list of names) or from the sponsor the information required under 54.4 and it was not possible to do so. The reason why this information could not be obtained is attached.

NAME Jennifer Tribbett	TITLE Regulatory Affairs Principal
FIRM/ORGANIZATION Roche Diagnostics	
SIGNATURE 	DATE 09/27/2006

#### Paperwork Reduction Act Statement

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Public reporting burden for this collection of information is estimated to average 1 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the necessary data, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information to the address to the right:

Department of Health and Human Services  
Food and Drug Administration  
5600 Fishers Lane, Room 14C-03  
Rockville, MD 20857

026

## 510(k) Summary

027

252

## 510(k) Summary

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**Introduction** According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

---

**1) Submitter name, address, contact** Roche Diagnostics Corporation  
9115 Hague Rd.  
Indianapolis, IN 46250

Contact Person: Jennifer Tribbett

Date Prepared: September 27, 2006

---

**2) Device name** Proprietary name: CoaguChek® XS System  
Common name: Prothrombin time test  
Classification name: Prothrombin time test

---

**3) Predicate device** The Roche Diagnostics CoaguChek XS System (patient self-testing) is substantially equivalent in materials, design and function to other products that measure prothrombin time INR in human blood. Most notably, it is substantially equivalent to the Roche Diagnostics CoaguChek XS System (professional). In fact, it is identical in materials, design and function to the CoaguChek XS System (professional) except the labeling has been modified and validated for patient self-testing.

---

**4) Device Description** The CoaguChek XS is a 3<sup>rd</sup> generation Roche Diagnostic's CoaguChek meter which was cleared for professional use under premarket notification K060978.

This premarket notification is being submitted to obtain clearance for patient self-testing.

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028

258

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**5) Intended Use** The CoaguChek XS System measures blood-clotting time (Prothrombin Time) for people who are taking anticoagulation medications such as Coumadin® or warfarin. The CoaguChek XS System measures blood-clotting time using blood from the fingertip.

---

**6) Comparison to Predicate Device** The following characteristics have been previously submitted, reviewed and cleared under the premarket notification for the CoaguChek XS System (K060978):

- Factor Sensitivity
- Heparin Sensitivity
- Hematocrit Effect
- Interfering Substances
- Normal Range
- Measuring Range
- Test Strip Stability
- Integrated Quality Control
- Instrument Failsafes
- Calibration
- Software Development

These characteristics are not impacted by the new user population.

The use of the system by self-testers was validated by an external user study that was conducted as the system is intended to be used. Following self-directed training, the subjects self-tested in the home setting for up to 8 weeks. The subjects also had 3 scheduled visits to their study site to collect user vs. technician data as well as user vs. reference method (Dade Innovin on a Sysmex analyzer) data.

The study results successfully demonstrated that self-trained subjects can obtain results that are equivalent to healthcare professionals and to the reference method. This study also demonstrated that self-tester results are consistent over time.

---

**7) Performance characteristics**

The performance characteristics that are impacted by the new user population were evaluated. The following information has been incorporated into our draft patient self-testing insert.

Claim	Statement															
<p><b>Accuracy</b></p>	<p>A study was conducted comparing test results obtained by self-trained patients with those obtained by healthcare professionals using the CoaguChek XS meter. The correlation was very good, as indicated by the following statistics: N = 258, Slope = 1.00, Intercept = 0.0 and Correlation Coefficient = 0.974. This study shows that self-trained patients are able to obtain results that are as accurate as those obtained by healthcare professionals trained in the use of the CoaguChek XS meter.</p>															
<p><b>Precision</b></p>	<p>A study was conducted and the precision of duplicates for capillary blood results was calculated for both self-trained patients and healthcare professionals. The following results were obtained:</p> <table border="1" data-bbox="680 1122 1374 1349"> <thead> <tr> <th></th> <th>Patient Results</th> <th>Professional Results</th> </tr> </thead> <tbody> <tr> <td><b>N</b></td> <td>222</td> <td>257</td> </tr> <tr> <td><b>Mean</b></td> <td>2.55</td> <td>2.50</td> </tr> <tr> <td><b>SD</b></td> <td>0.132</td> <td>0.135</td> </tr> <tr> <td><b>CV</b></td> <td>5.19</td> <td>5.38</td> </tr> </tbody> </table> <p>This study shows that self-trained patients are able to obtain results that are as precise as those obtained by healthcare professionals trained in the use of the CoaguChek XS meter.</p>		Patient Results	Professional Results	<b>N</b>	222	257	<b>Mean</b>	2.55	2.50	<b>SD</b>	0.132	0.135	<b>CV</b>	5.19	5.38
	Patient Results	Professional Results														
<b>N</b>	222	257														
<b>Mean</b>	2.55	2.50														
<b>SD</b>	0.132	0.135														
<b>CV</b>	5.19	5.38														

## External Study

(b) (4)

(b)(4)

031

256

# Executive Summary

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**Study Objective**

(b) (4)

**Acceptance  
Criteria**

**Additional (for  
information  
only) analysis**

(b)(4)

**Conclusion**

---

*Continued on next page*

**032**

257

Pages 54 through 67 redacted for the following reasons:

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Study Data, b4

**On-Board (Built In) Quality Control**

**Previously Reviewed by FDA under K060978**

**047**

272

## On-board (built-in) Quality Control

**On-Board  
Quality Control  
(OBC)**

(b) (4)

(b)(4)

**Protocol  
Summary**

Pages 70 through 83 redacted for the following reasons:

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Technical Data, b4

**Automatic Meter Checks (Failsafes)**

**Previously Reviewed by FDA under K060978**

**063**

*288*

## Automatic Meter Checks (Failsafes)

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**Meter Failsafes**

(b) (4)

(b)(4)

**Failsafe List**

(b) (4)

(b)(4)

Pages 86 through 87 redacted for the following reasons:

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Study Data, b4

## **New Device Labeling**

### **Test Strip Insert**

067

# CoaguChek<sup>®</sup> XS PT Test



Test Strips and 1 Code Chip  
**PERSONAL USE**

## Purpose

The CoaguChek XS PT test strips are part of the CoaguChek XS System. The CoaguChek XS System measures blood-clotting time for people who are taking anticoagulation medications such as Coumadin<sup>®</sup> or warfarin. The CoaguChek XS System uses blood from a fingerstick.

**Caution: These test strips are for use outside the body only. Do not eat the test strips.**

## Before You Start Testing

If you are new to the CoaguChek XS System, watch the *CoaguChek XS System Video* and read the *CoaguChek XS System Getting Started* guide before testing.

## Storing the Test Strips

Store the test strips in their container, with the cap closed. You can store the test strips at room temperature (18-32°C or 65-90°F) or in the refrigerator (2-8°C or 36-46°F). When stored properly, the test strips can be used up until the expiration date printed on the test strip container. Throw the test strips away if they are past their "Use By" date.

## Handling the Test Strips

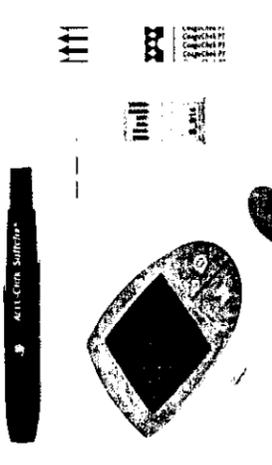
When you are ready to test, remove 1 test strip from the container. **Close the container tightly.**

You must use the test strip within 10 minutes of removing it from the container. Otherwise, you may get an error message and you will have to repeat the test.

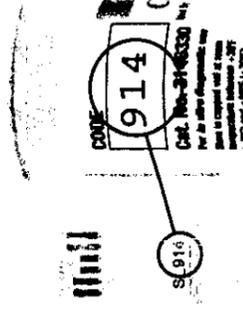
## Step 1: Getting Ready to Test

Gather supplies:

- CoaguChek XS Meter
- CoaguChek XS PT Test Strip
- Test Strip Code Chip
- Lancet (Follow the manufacturer's instructions to prepare the lancet for use.)



If you are using test strips from a new, unopened box, you will need to change the Test Strip Code Chip. The 3-number code on the test strip container must match the 3-number code on the code chip. To install the code chip, follow the instructions in the *Code Chip* section of the *CoaguChek XS System User Manual*.



Put the meter on a flat surface, like a table or countertop, that will not vibrate or move during testing, as this can result in an error message.

## Step 2: Testing Blood from a Fingertick

### Getting a Good Drop of Blood

Increasing the blood flow in your finger will help you get a good drop of blood. Before you lance your finger, try the following techniques until you see that your fingertip has good color:

- Warm your hand by holding it under your arm, use a hand warmer, and/or wash your hand with warm water.
- Hold your arm down to the side, so that your hand is below your waist.
- Massage your finger from its base.
- If needed, immediately after lancing, gently squeeze your finger from its base to encourage blood flow.

## Procedure

1. Wash your hands with warm, soapy water. Dry completely.
2. Take a test strip out of the container. **Close the container tightly.**
3. Insert a test strip as far as you can. The meter turns on.
4. Confirm that the number displayed matches the number on the test strip container, then press **M**. If the numbers are different, make sure you are using the code chip that came with the test strips you are using. If they still do not match, call the Roche Diagnostics Technical Service Center at 1-800-819-1106.



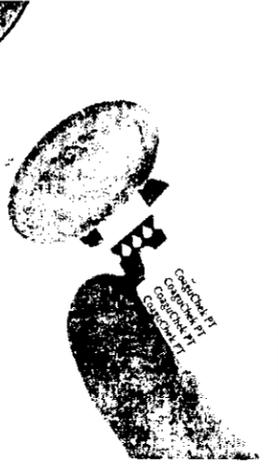
5. An hourglass appears as the meter warms up, which takes about 30 seconds.

6. When the meter is warmed up, a flashing test strip and blood drop symbol appear and the meter begins a countdown. You have 120 seconds to apply blood to the test strip.

7. Use the lancet to perform a fingerstick.

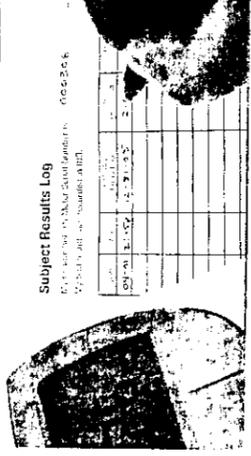


8. The meter must be on a table. Apply 1 drop of blood to the side of the target area. You must apply blood to the test strip within 15 seconds of lancing your finger.



9. Do not add more blood. Do not touch or remove the test strip when a test is in progress.

10. The result appears in about 1 minute. Record the result on the *Subject Results Log*.



11. Properly dispose of the used lancet and test strip.

12. Turn the meter off.

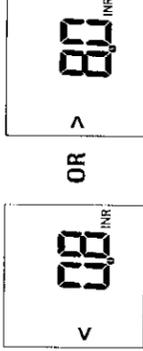
If you need to redo a test, use a new lancet, a new test strip, and a different finger.

### Additional Information

The *CoaguChek XS System User Manual* contains more information. If you need technical help, call the Roche Diagnostics Technical Service Center at 1-800-819-1106.

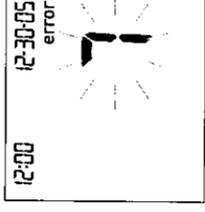
### Very Low or Very High Test Results

The CoaguChek XS PT test strips provide test results if the INR value is between 0.8 and 8.0. If the meter displays < (less than) **0.8** or > (greater than) **8.0**, repeat the test. If, when you repeat the test, you get the same display (either < **0.8** or > **8.0**), call the Roche Diagnostics Technical Service Center at 1-800-819-1106.



### Error Messages

If you see Error 7, repeat the test. Be sure to apply the blood drop to the test strip within 15 seconds of sticking the fingertip. If you still get Error 7, call the Roche Diagnostics Technical Service Center at 1-800-819-1106. If the meter displays any other error message, refer to the *Error Messages* section of the *CoaguChek XS System User Manual*.



### Built-In Controls

The CoaguChek XS System has built-in quality control functions in the meter and test strips. The meter automatically runs its own quality control test as part of every blood test, so you never have to run quality control tests with liquid quality controls. For more information about the built-in quality control functions, see the *CoaguChek XS System User Manual*.

### Performance Characteristics

**Measuring Range:** The measuring range of the CoaguChek XS meter is 0.8 – 8.0 INR (9.6 to 96.0 seconds).

**Accuracy:** A study was conducted comparing test results obtained by self-trained patients with those obtained by healthcare professionals using the CoaguChek XS meter. The correlation was very good, as indicated by the following statistics: N = 258, Slope = 1.00, Intercept = 0.0, and Correlation Coefficient = 0.974. This study shows that self-trained patients are able to obtain results that are as accurate as those obtained by healthcare professionals trained in the use of the CoaguChek XS meter.

**Precision:** A study was conducted and the precision of duplicates for capillary blood results was calculated for both self-trained patients and healthcare professionals. The following results were obtained:

	Patient Results	Professional Results
<b>N</b>	222	257
<b>Mean</b>	2.55	2.50
<b>SD</b>	0.132	0.135
<b>CV</b>	5.19	5.38

This study shows that self-trained patients are able to obtain results that are as precise as those obtained by healthcare professionals trained in the use of the CoaguChek XS meter.

The following U.S. patents have been granted or are pending for the CoaguChek XS System (meter and test strips): 6,652,439; 7,073,246; 2005/0103824; 6,881,376; 6,207,000; 2005/0214171; 2005/0123441; 6,645,368; 2004/0157339; 2005/0129574; 2005/0135988

COAGUCHEK is a trademark of Roche.

Manufactured for:  
Roche Diagnostics  
9115 Hague Road  
Indianapolis, IN 46256

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573-33595-0909



**New Device Labeling**  
**Instrument User's Manual**

070

295

# CoaguChek<sup>®</sup> XS System

User Manual



071

# Table of Contents

<b>About this Manual</b> .....	<b>1</b>
Symbols and Abbreviations.....	1
<b>User Resources</b> .....	<b>2</b>
Video.....	2
Getting Started.....	2
User Manual.....	2
Test Strip Package Inserts.....	2
Lancet Device Package Inserts.....	2
<b>The CoaguChek XS System</b> .....	<b>3</b>
Anticoagulation Medication.....	3
Blood-clotting Time.....	3
How the System Works.....	4
The CoaguChek XS Meter.....	5
Operating Conditions.....	6
<b>Getting Started</b> .....	<b>7</b>
Batteries.....	7
Installing (or Replacing) Batteries.....	8
Meter Setup.....	9
Setting the Date and Time.....	9
The Meter's Display.....	12
Code Chip.....	12
Inserting a New Code Chip.....	13
Integrated Quality Controls.....	14

The following patents have been granted or are pending for the CoaguChek XS System (meter and test strips): EP 1042667 A, EP 1218732 A, EP 1039298 B, EP 0949002 A, WO 03/095092, DE 10356452.7, DE 10359303.9, DE 10346863.3, DE 102004011648.2, PCT/US2004/19691.

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# About this Manual

<b>Testing a Blood Sample</b> .....	15
Tips for a Good Fingertick .....	15
Important Notes About Blood Testing .....	16
Always .....	16
Never .....	16
Infection Control .....	17
Preparing for a Test .....	18
Performing a Test .....	20
Very Low or Very High Test Results .....	24
<b>Memory</b> .....	25
Storing Test Results in Memory .....	25
Reviewing Stored Test Results .....	25
Erasing Stored Test Results .....	27
<b>Cleaning the Meter</b> .....	29
Cleaning the Exterior .....	29
Cleaning the Test Strip Guide .....	30
<b>Error Messages</b> .....	32

## Symbols and Abbreviations

The test strip insert, the label on the back of the meter, the User Manual, and other packaging material may contain the following symbols or abbreviations:

 Use by/Expiration date

 Lot number

 For in vitro diagnostic use

 This product fulfills the requirements of Directive 98/79/EC on in vitro diagnostic medical devices

REF Catalog number

 Please read instructions for use

 Caution (refer to accompanying documents).  
Please refer to safety-related notes in the manual accompanying this instrument

 Manufactured by

 Store at

## User Resources

Several resources are available to help you use and maintain the CoaguChek XS System.

### Video

The CoaguChek XS System Video is for new users of the CoaguChek XS System. The video will help you get comfortable with the CoaguChek XS Meter and the testing procedure.

### Getting Started

The Getting Started guide shows you how to perform your first coagulation test on the CoaguChek XS Meter.

### User Manual

This CoaguChek XS System User Manual is a comprehensive guide to the meter and test strips. It is designed to provide answers to your questions about the meter's operation and use. **Read this entire manual carefully, and refer to it as necessary.**

### Test Strip Package Inserts

Be sure to read the test strip package insert for important updates and keep the insert from your current test strip package for future reference.

### Lancet Device Package Inserts

Be sure to read the lancet device package insert to learn how to use the lancet device and for important updates. Keep the insert from your current lancet device package for future reference.

## The CoaguChek XS System

The CoaguChek XS System measures blood-clotting time (Prothrombin Time) for people who are taking anticoagulation medications such as Coumadin® or warfarin. The CoaguChek XS System measures blood-clotting time using blood from the fingertip.

### Anticoagulation Medication

Anticoagulation medications, also known as blood thinners, are prescribed to avoid unwanted clots. Your blood-clotting time must be monitored to ensure that your medication dosage is correct.

### Blood-clotting Time

The rate at which blood clots is measured in units called INR. It is very important that you stay within your target INR range. If your INR is too low, the risk of blood clots increases. If your INR is too high, the risk for internal bleeding increases.

Everyone's INR is different. Your doctor determines the best INR range for you, depending on why you are taking anticoagulants and how you react to them. Your doctor also determines how often your blood should be tested. Your doctor needs to know your blood-clotting time in order to successfully treat you.

## How the System Works

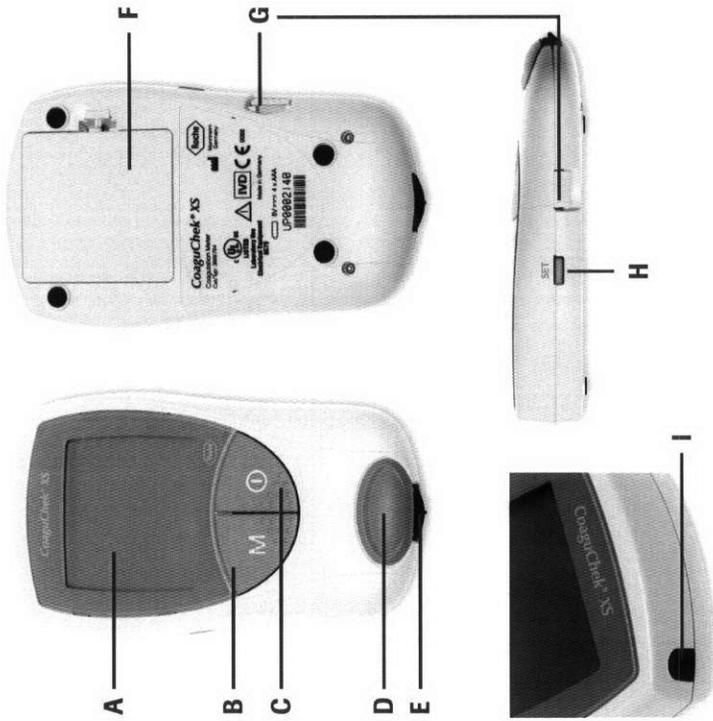
The CoaguChek XS System includes a meter and CoaguChek XS PT test strips. Each box of test strips has its own code chip that you insert into the meter. The code chip contains important information about the test strips such as their expiration date and lot number.

The CoaguChek XS System makes measuring blood-clotting time easy. The display on the meter guides you through the testing process. With the code chip inserted in the meter, you simply insert a test strip and apply a blood sample when the meter is ready. The meter displays the result in about a minute. The meter automatically stores the result in memory so that you can easily recall results.

The CoaguChek XS PT test strip contains various ingredients. When a blood drop is applied, the meter starts the test and the blood mixes with the ingredients on the test strip. When the meter determines that the blood has clotted, it stops the measurement and calculates the result.

## The CoaguChek XS Meter

- A Display
- B M (Memory) Button
- C ON-OFF Button
- D Test Strip Guide Cover
- E Test Strip Guide
- F Battery Compartment Cover
- G Code Chip Slot
- H SET Button
- I Data Port



# Getting Started

## Operating Conditions

To ensure that the CoaguChek XS Meter functions correctly, follow these guidelines:

- Use the meter at room temperature, between 65°F and 90°F (18°C and 32°C).
- Use the meter at a relative humidity of less than 85%, without condensation.
- When testing, keep the meter level.
- If you store the meter for a period of time, remove the batteries.
- Do not use the meter at an altitude higher than 14,000 feet (4,300 meters).
- Do not use the meter near a strong magnetic field, such as a microwave oven, as this may interfere with the meter's proper operation.

*Note: The CoaguChek XS Meter automatically shuts off after 3 minutes if no buttons have been pushed.*

Refer to the Getting Started guide to learn how to set up the meter and prepare for and run your first blood-clotting-time test.

## Batteries

The CoaguChek XS Meter uses 4 AAA batteries. The recommended batteries, alkaline-manganese batteries, should last for approximately 60 tests.

When you turn the meter on, the display briefly shows the battery symbol. The battery symbol is divided into 4 segments. With new, fresh batteries in the meter, the battery symbol shows all 4 segments.



When only 1 segment appears, replace the batteries. When only 1 segment appears you can still access results stored in the meter's memory.



If you insert new batteries within 1 minute of removing the old batteries, the date and time settings will remain in memory. But if you do need to reset the date and time, refer to the Meter Setup section in this manual.

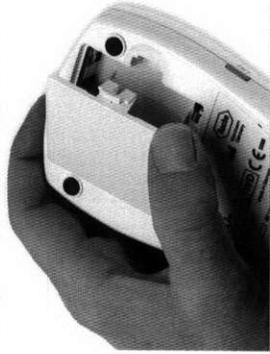
The meter saves battery power by automatically turning off after 3 minutes, unless you press a button or insert a test strip. Even when the batteries are removed, the test results are saved in memory.

## Installing (or Replacing) Batteries

Have ready 4 AAA batteries.

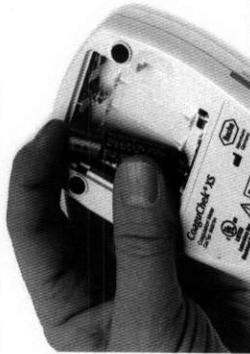
### 1. Open Battery Compartment

With the meter turned off, turn it over. Press the latch gently inward and lift the cover. Remove the old batteries, if necessary.



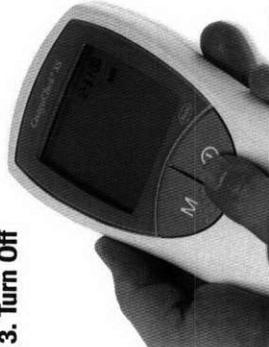
### 2. Insert New Batteries

Position the batteries according to the diagram inside the battery compartment. Replace the cover. Turn the meter back over.



### 3. Turn Off

Turn the meter off .



## Meter Setup

The CoaguChek XS Meter is preset with the U.S. date format (month-day-year) and U.S. time format (12-hour as opposed to 24-hour).

Before you use the meter for the first time—or if there is no battery power for more than 1 minute—you'll have to set the current date and time.

## Setting the Date and Time

The date and time settings are important. Each time you run a test, the meter compares its date with the test strip's expiration date. If the test strips are expired, the meter displays an error message and prevents you from running a test.

Whenever you put batteries in the meter, it automatically goes to Setup mode (where you set the date and time). You can also go to Setup mode at any time by pressing the SET button (.

To set the date and time, you'll use these buttons:

-  to change a setting.
-  (SET) to accept a setting.



### 1. Go to Setup Mode

If the meter is not already in Setup mode, press the SET button .



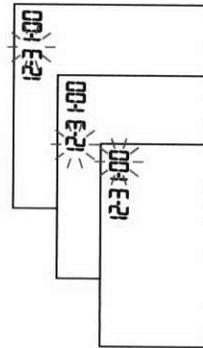
The date format flashes in the upper-right corner.

### 2. Set Today's Date

Press the SET button .  
Press the M button  to change the year. Press the SET button .

Press the M button  to change the month. Press the SET button .

Press the M button  to change the day. Press the SET button .

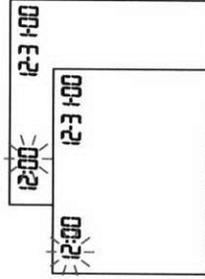


### 3. Set Current Time

Press the SET button .

Press the M button  to change the hour. Press the SET button .

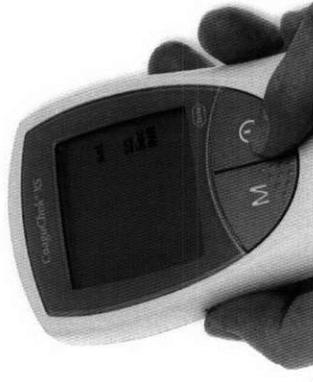
Press the M button  to change the minutes. Press the SET button .



### 4. Turn Off

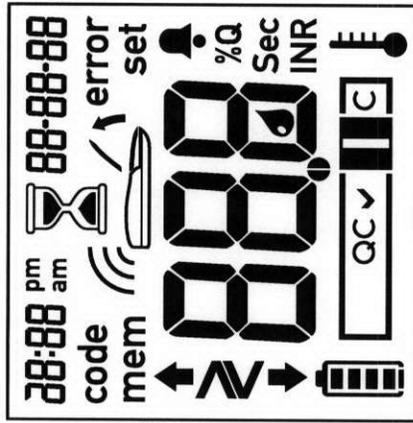
Turn the meter off .

If, in the future, you need to change the date and time, press the SET button  to re-enter Setup mode. After you change the date and time, just turn the meter off .



## The Meter's Display

When you turn the meter on, it briefly shows all the display's letters, numbers, and symbols. Regularly check that all segments of each letter, number, and symbol appear. Please compare your meter's display to the meter display shown here on this page.



You can display all the letters, numbers, and symbols for a longer time to allow comparison. To do this, you will turn the meter on and then hold down the ON-OFF button .

The full display should appear as shown at left.

## Code Chip

Each box of test strips comes with its own code chip. The code chip provides the meter with information such as the lot number and expiration date of the test strips.

Before each test, make sure the correct code chip is in the meter. Each time you open a new box of test strips, replace the old code chip with the new one.

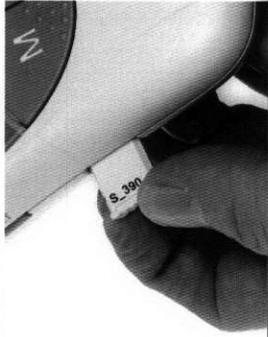
Protect the code chip from moisture and also from equipment that produces magnetic fields, such as a microwave oven.

## Inserting a New Code Chip

Have the correct code chip ready.

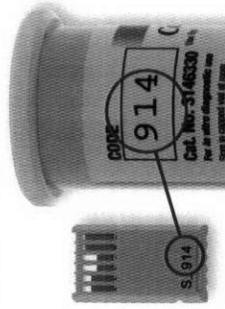
### 1. Remove Old Code Chip

With the meter turned off, remove the old code chip and throw it away.



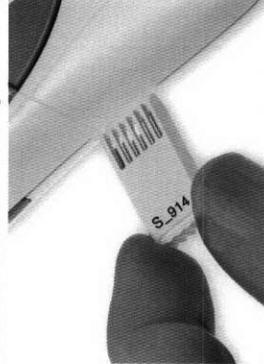
### 2. Match Codes

Make sure that the 3-number code on the new test strip container matches the 3-number code on the new code chip.



### 3. Insert New Code Chip

Slide the new code chip into the code chip slot until it snaps into place.



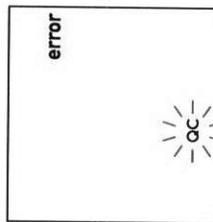
# Testing a Blood Sample

## Integrated Quality Controls

The CoaguChek XS System has built-in quality control functions in the meter and test strips. The meter automatically runs its own quality control test as part of every blood test, so you never have to run quality control tests with liquid quality controls.

When the quality control test runs, the letters **QC** flash on the meter's display. When the quality control test is finished, a checkmark (✓) appears following the letters **QC**. Then the meter continues to run the blood test.

If the quality control test fails, the meter displays the following error message. See the Error Messages section in this manual for an explanation of this (and other) error messages and what to do when they occur.

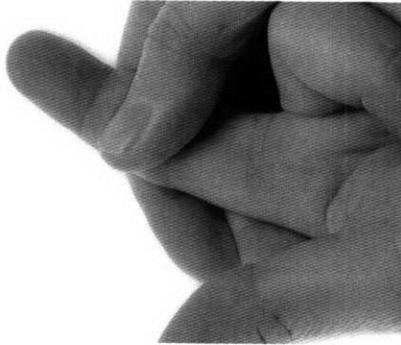


## Tips for a Good Fingertick

For fingertick blood testing, increasing the blood flow in your finger will help you get a good drop of blood. Before you prick your finger, try the following techniques until you see that your fingertip has good color:

- Warm your hand by holding it under your arm, use a hand warmer, and/or wash your hand with warm water.
- Hold your arm down by your side, so that your hand is below your waist.
- Massage your finger from its base.

*If needed, immediately after pricking, gently squeeze your finger from the base to encourage blood to flow.*



3051

## Important Notes About Blood Testing

### Always

- Operate the meter at temperatures between 65°F and 90°F (18°C and 32°C).
- Refer to the test strip package insert for proper use and handling of test strips.
- Keep the test strip guide and meter clean. See the Cleaning the Meter section in this manual for more information.

### Never

- Store the meter in extreme temperatures (below 65°F or above 90°F).
- Store the meter in damp or humid conditions (greater than 85% humidity).
- Remove or insert the code chip while the meter is performing a test.
- Use a code chip from a box of test strips other than the one in use.
- Touch or remove the test strip during a test.
- Wait more than 15 seconds after sticking your fingertip before applying the blood.
- Add more blood after the test has begun.
- Touch any buttons while a test is in progress.
- Perform a test with a drop of blood from a previous fingerstick.

### Infection Control

The ACCU-CHEK® Softclix lancet device is intended for use by a single person and is not suitable for use where testing different persons with the same device may lead to infections.

## Preparing for a Test

### 1. Gather Items



Gather the following items:

- CoaguChek XS Meter
- Container of test strips
- Test strip code chip
- ACCU-CHEK Softclix lancet device and lancet

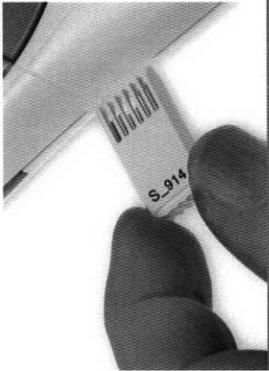
*Each box of test strips comes with a matching code chip. Every time you open a new box of test strips, you must replace the code chip.*

### 2. Match Codes



Make sure the code number on the test strip container and the code chip match.

### 3. Insert Code Chip



Make sure the meter is turned off. With the code number facing up, insert the code chip into the code chip slot until it snaps into place.

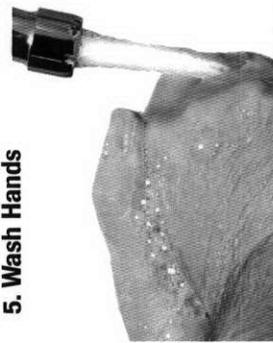
### 4. Prepare Lancet Device



Pull off the cap of the lancet device. Insert a new lancet. Twist off the lancet's protective cap. Put the cap back on the lancet device. Line up the notches for the cap to fit. Select the penetration depth.

Press the plunger. A yellow dot appears in the release button.

### 5. Wash Hands



Wash your hands in warm, soapy water.

*Make sure your fingertip is thoroughly dry.*

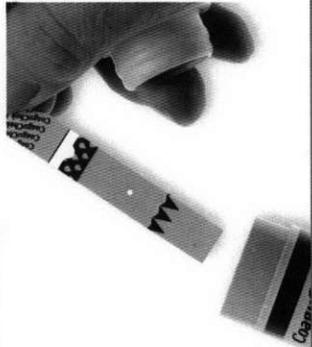
## Performing a Test

### 1. Get Ready

Take a test strip out of the container.

#### **Close the container tightly.**

*You have 10 minutes to use a test strip once you remove it from the container.*



### 2. Insert Strip

Slide the test strip into the test strip guide in the direction of the arrows until it stops.

The meter turns on. The code number of the inserted code chip flashes on the display.



### 3. Match the Code

Confirm that the number displayed matches the number on the test strip container, then press the M button .

*If the numbers are different, make sure you are using the code chip that came with the test strips you are using.*

An hourglass appears as the meter warms up, which takes about thirty seconds

When the meter is warmed up a flashing test strip appears and the meter begins a countdown. You have 120 seconds to apply blood to the test strip.



### 4. Collect the Blood

Massage your finger until you see increased color in your fingertip.

Keeping your hand down, press the tip of the lancet firmly against the side of your fingertip. Press the release button.

*Gently squeeze from the base of your finger to develop a hanging drop of blood.*



308

### 5. Identify the Target Area

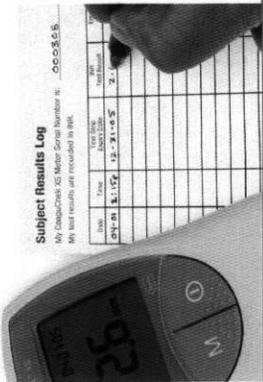
Find the target area on the test strip.

To prevent error messages, the meter must be on a table free of vibrations.



### 7. Record Result

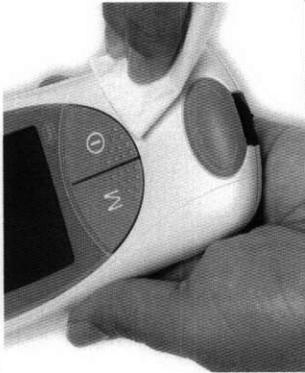
Record the result on the Subject Results Log.



### 8. Clean Up

Remove the lancet from the lancet device. Place the used test strip and lancet in a puncture-proof container with a lid. Turn the meter off.

*If the meter is dirty, wipe it clean with a lint-free tissue and an approved cleaning solution.*



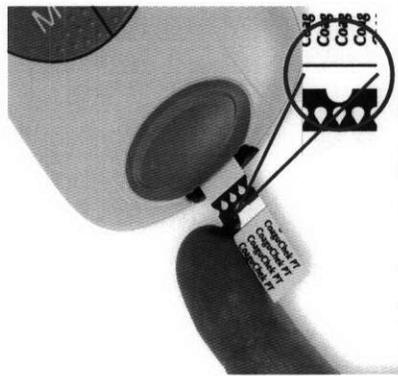
### 6. Apply the Blood

Within 15 seconds of sticking your fingertip, apply the blood to the target area of the test strip—from the side of the test strip.

- Hold the blood drop to the test strip until you hear a beep. The flashing blood drop symbol disappears.

**Do not add more blood to the test strip. Do not touch the test strip.**

- The result appears in about 1 minute.

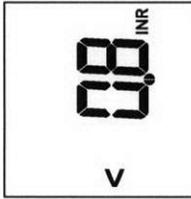


309

# Memory

## Very Low or Very High Test Results

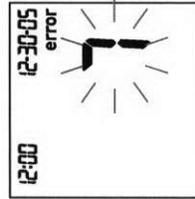
The CoaguChek XS PT test strips provide test results if the INR value is between 0.8 and 8.0. If the meter displays < (less than) **0.8** or > (greater than) **8.0**, repeat the test. If, when you repeat the test, you get the same result (either < **0.8** or > **8.0**), call the Roche Diagnostics Technical Service Center at 1-800-819-1106.



OR



If you see Error 7, repeat the test. Be sure to apply the blood drop to the test strip within 15 seconds of sticking your fingertip. If you still get Error 7, call the Roche Diagnostics Technical Service Center at 1-800-819-1106.



## Storing Test Results in Memory

The CoaguChek XS Meter automatically stores up to 100 test results and their dates and times in its memory. If the memory is full when you perform a test, the oldest result is automatically deleted. The most recent result is always saved.

*Note: All test results remain in memory even when the meter is without batteries.*

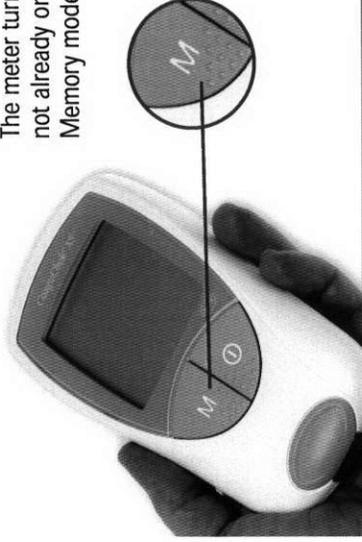
## Reviewing Stored Test Results

You can review stored test results even when the meter's battery power is low.

To review results in memory:

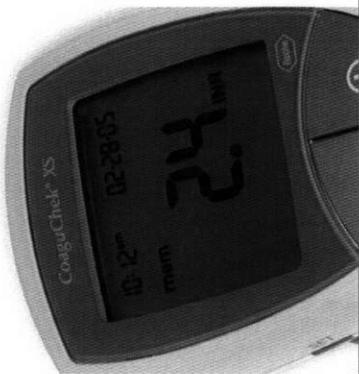
### 1. Access the Memory

Press the M button . The meter turns on, if it is not already on, and goes to Memory mode.



## 2. View Most Recent Result

The most recent test result appears. The letters **mem** indicate that you are viewing a result in memory. The time and date of the test also appear. If there are no results in memory, a **0** appears in the display's top-right corner.



## 3. View Earlier Results

To view earlier results, press the **M** button again. After you have viewed all the results in the memory, 3 dashes appear.



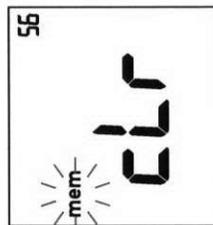
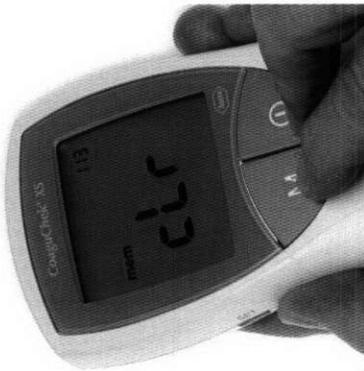
## Erasing Stored Test Results

You can erase all of the test results that are stored in the meter's memory. You cannot, however, erase individual test results.

To erase all stored results:

### 1. Go to Erase mode.

With the meter turned off, press **and hold down** the **M** button. While you are holding down the **M** button, press the **ON-OFF** button and then hold down both buttons for at least 5 seconds.



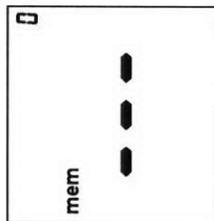
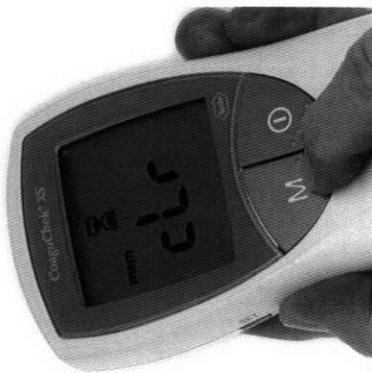
The meter displays **mem** (flashing) and **clr**. The number of results in memory is shown in the top-right corner of the display.

# Cleaning the Meter

## 2. Confirm

Press the M button  to confirm that you want to erase the entire memory.

*Note: To exit Erase mode without erasing the results, press the ON-OFF button instead.*



The hourglass symbol flashes while the test results are being erased. Then, the counter is set to 0 and 3 dashes appear.

It is important to keep the meter clean. Clean the meter whenever it looks dirty or, if you prefer a regular schedule, clean the meter each time you open a new box of test strips.

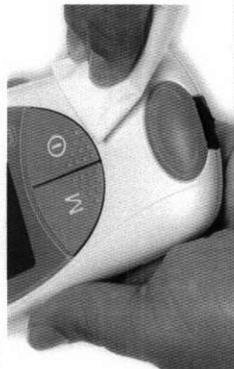
Use only the following products to clean the meter:

- 10% bleach solution (1 part bleach and 9 parts water)
- 70% isopropyl alcohol solution
- lint-free tissues
- cotton swabs

**Caution: Do not spray any cleaning solution on the meter. Never use a spray of any type.**

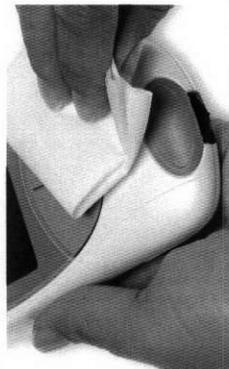
## Cleaning the Exterior

### 1. Clean the Exterior



With the meter turned off, wipe the meter's exterior clean.

### 2. Dry the Exterior

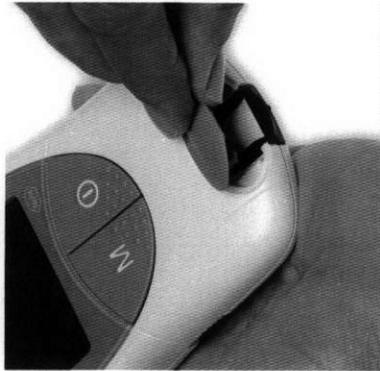


With a lint-free tissue, dry the meter.

## Cleaning the Test Strip Guide

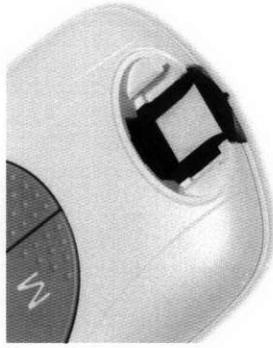
### 1. Open the Cover

With the meter turned off, use your thumbnail to open the cover of the test strip guide by pressing its front edge upward. Move the cover safely away from the meter. Then rinse the cover with water or wipe it clean.



### 3. Allow to Dry

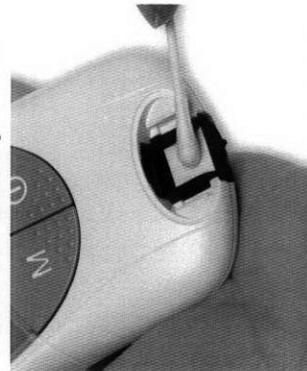
With the cover off, allow the test strip guide to dry for about 10 minutes.



### 2. Clean the Test Strip Guide

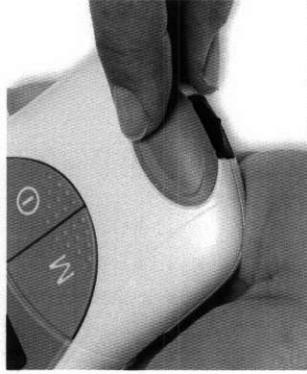
Clean the easily accessible areas with a cotton swab.

**Caution: Do not insert any objects into the test strip guide. Doing so could damage the electrical contacts behind the test strip guide.**



### 4. Close the Cover

Close the cover, and make sure it snaps into place.



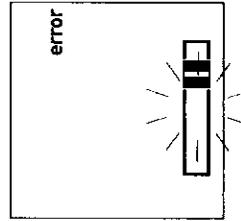
# Error Messages

You may see the following error messages while using the CoaguChek XS Meter. If you see an error message, first try to correct the problem using the solution described below. If the problem persists, call the Roche Diagnostics Technical Service Center at 1-800-819-1106.

## Error: Test Strip

Possible causes:

- A test strip was already inserted when the meter was turned on.
- The meter timed out after you inserted the test strip.
- The test strip is unusable.
- The test strip is not a CoaguChek XS PT test strip.

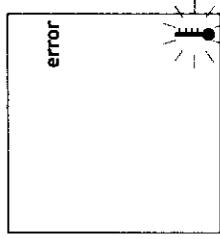


## Solution:

Remove the test strip. Then repeat the test with a new CoaguChek XS PT test strip.

## Error: Meter Temperature

The meter is too cold or too warm to measure correctly.

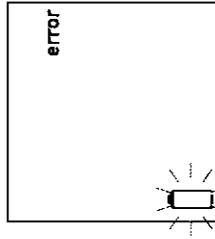


## Solution:

Turn the meter off and allow it to stand for about 30 minutes at room temperature (between 65°F and 90°F).

## Error: Battery

The battery level is too low.

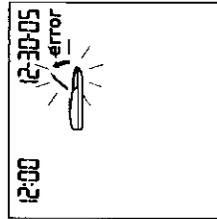


## Solution:

Replace the batteries. See the Batteries section of this manual.

**Error: Test Strip Guide Cover**

The test strip guide cover is not properly closed.

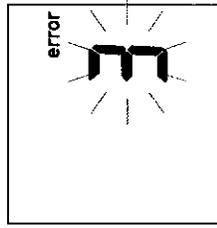


**Solution:**

Close the test strip guide cover.

**Error: Test Strip Expired**

The test strip has expired.

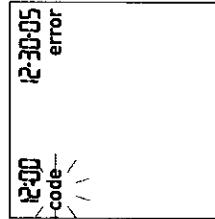


**Solution:**

Check the meter's date setting. If it is not correct, set the correct date. For more information, see the Meter Setup section of this manual. If the date is correct, turn the meter off and remove the code chip and the test strip. Then use the code chip and a test strip from a new box of test strips.

**Error: Code Chip**

The code chip is missing, not properly inserted, or damaged.

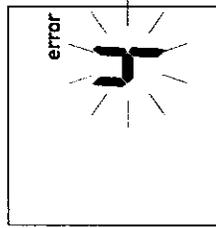


**Solution:**

Check to see if you have the correct code chip properly inserted in the meter. For more information, see the Code Chip section of this manual. If the code chip is damaged, call the Roche Diagnostics Technical Service Center at 1-800-819-1106.

**Error: Test Strip Unusable**

The test strip is unusable.



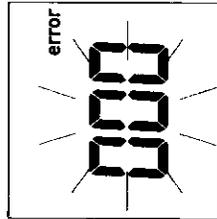
**Solution:**

Turn the meter off, remove the test strip, and then re-insert it. If the error message reappears, discard the unusable test strip and use a new one.

315

**Error: Time Exceeded**

You did not apply blood to the test strip within 2 minutes after the blood drop symbol appeared.

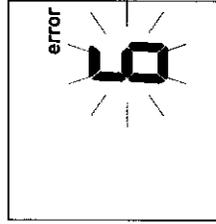


**Solution:**

Turn the meter off and remove the test strip. Repeat the test using the same test strip and blood taken from a new fingerstick from a different finger.

**Error: Test Strip Interference**

The test strip was touched or removed during the test.

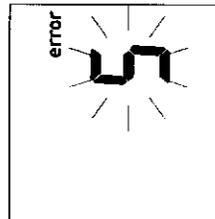


**Solution:**

Turn the meter off and remove the test strip. Repeat the test using a new test strip and blood taken from a new fingerstick from a different finger.  
Do not touch or remove the test strip when a test is in progress.

**Error: Blood Application**

Error applying blood to the test strip.

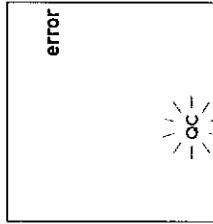


**Solution:**

Turn the meter off and remove the test strip.  
Repeat the test using a new test strip and blood taken from a new fingerstick from a different finger.

**Error: Quality Control Failure**

The test strip failed the internal quality control check. The test strip is unusable.

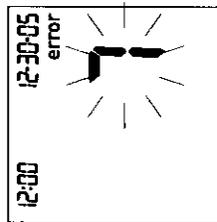


**Solution:**

Turn the meter off and remove the test strip. Repeat the test using a new test strip and blood taken from a new fingerstick from a different finger.

316

**Error: Measurement Error**  
Measurement error caused by the blood sample.

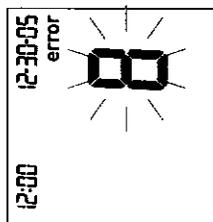


**Solution:**

Be sure to apply the blood drop to the test strip within 15 seconds of sticking the fingertip.  
Repeat the test. If you still get Error 7, call the Roche Diagnostics Technical Service Center at 1-800-819-1106.

**Error: Internal Error**

An error occurred during the internal diagnostic test.



**Solution:**

Turn the meter off and remove the batteries. Wait at least 1 minute before re-inserting the batteries in the battery compartment. Re-set the date and time as described in the Meter Setup section of this manual.

**Caution: The date and time must be set correctly.**

Repeat the test. If you see the same error message again, the meter has a defect. Call the Roche Diagnostics Technical Service Center at 1-800-819-1106.



Diagnostics

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**New Device Labeling  
Training Video Script**

## I. Introduction

### Narrator voice over

The CoaguChek XS System from Roche Diagnostics measures blood-clotting time for people who are taking anticoagulation medications such as Coumadin or warfarin.

It's easy to use... you just insert a test strip, apply the blood sample, and read the result.

The meter automatically runs its own self check at the beginning of every blood test.

With the CoaguChek XS System, you no longer have to travel to and from a lab... and wait for the results. You can self-test anywhere... any time.

In this program, we'll give you a quick overview... to get you started using the CoaguChek XS System to perform blood tests.

Then, we'll take a closer look at setting up, using, and maintaining the system.

Remember, never adjust your anticoagulation medication yourself. Always consult with your physician.

1. Product shot.

2. Preview of scenes from the remaining modules of the program.

Graphic text to emphasize disclaimer.

326

## II. Parts of the System

Voice over

Let's look closely at the parts of the CoaguChek XS System.

The CoaguChek XS Care Kit includes...

the meter ...

4 triple-A batteries ...

the lancet device...

instructional materials... and the Log Sheet.

Additional parts of the system include ...

test strips ... a test strip code chip ... and the test strip package insert.

Now let's look at the parts of the meter itself.

Here is the display...

the ON-OFF button...

the M button...

and the test strip guide.

On the side is the code chip slot...

and the SET button...

3. Product shot.

4. Beauty shots.

Show Soft-Clix.

5. Product shot.

6. Indicating the parts of the meter or graphics highlighting them.

---

At the back is the data port... which is an infrared window for data transfer.

On the bottom of the meter you'll see the battery compartment.

---

(For the video at launch include this copy) the unit's serial number...

and the Roche Diagnostics Technical Service Center phone number.

### III. Quick Start

Voice over

This section will provide you with a quick overview... to get you started using the CoaguChek XS System to perform blood tests.

Keep in mind that we are about to show you... very simply... how to perform a blood test... and that the remainder of this program includes more details about setting up your meter, getting a blood sample, and testing. So be sure to watch the entire program if this is the first time you're doing a test.

Then, you can refer to the CoaguChek XS System User Manual and the package insert. If you still have questions, call the Roche Diagnostics Technical Service Center at 1-800-819-1106.

To perform a blood test, you'll need the following items...

The CoaguChek XS Meter...

a test strip...

the test strip code chip...

a lancet device... and lancet.

7. Product shot.

Add bullet graphics:

Other modules in this program:

- Setting Up the Meter
- Getting a Blood Sample
- Performing a Blood Test
- Cleaning the Meter

8. Highlighting each item.

323

9. Washing hands.

First, wash your hands in warm, soapy water. Or, clean your fingertip with an alcohol wipe.  
Make sure your fingertip is thoroughly dry.
- 9a. Inserting code chip.

To insert the code chip, first make sure the meter is off.  
Then insert the code chip ... with the code number facing up... until you feel it snap into place.
10. Inserting test strip (meter turns on) and confirming that codes match.

To begin a test, insert the test strip to turn the meter on.  
The meter will display the code chip number. Match the three-number code on the display with the three-number code on the test strip container.  
Confirm that the codes match, then press the M button.
11. The meter's display: hourglass.

An hourglass appears as the meter warms up... which takes about 30 seconds.  
While you're waiting, make sure the meter shows today's date and the correct time.
12. Flashing strip and countdown.

When the meter is warmed-up, a flashing test strip appears and the meter begins a countdown.  
You have 120 seconds to apply the blood drop.
13. Massaging finger to prepare for finger stick.

Gently massage your finger from the base of the knuckle... and let your hand hang loosely ...

324

099

- 
14. Applying the blood (from top, slightly to the side).  
Perform the fingerstick.  
Then, apply the blood drop to the target area of the test strip.  
It's important to apply only one drop of blood – don't add more.
15. Meter display.  
The countdown disappears, and the blood test begins.
16. Meter display: QC test.  
In a few seconds, as part of the testing process, the meter automatically performs a self-check.
17. The result on the display.  
In about a minute, the result appears on the display.  
Show result from 2.3 to 2.6 INR.
18. Recording the result.  
Be sure to record your result on your Log Sheet and dispose of the strip and lancet properly.  
Turn the meter off.
- 

325

#### IV. Setting Up the Meter

Voice over

The CoaguChek XS System is simple to set up for the first time. All you need to do is install the batteries... and set the date and time.

Let's take a look at how to do this.

Remove the battery compartment cover on the bottom of the meter... install the batteries... and replace the cover.

When you install the batteries, the meter automatically enters setup mode.

All settings are changed with the M button... and accepted with the SET button.

The date format flashes. Press the SET button.

The year flashes. Press the M button to change the year. Press the SET button to accept the year and move on to the month.

Press the M button to change the month. Press the SET button to accept the month and move on to the day.

Press the M button to change the day. Press the SET button to accept the day and move on to the

19. Product shot.

20. Installing batteries.

21. Meter display

22. M button, and SET button.

23. Changing the settings (the default date and time format is U.S.).

time format.

The time format flashes. Press the SET button.

The hour flashes. Press the M button to change the hour. Press the SET button to accept the hour and move on to the minutes.

Press the M button to change the minutes. Press the SET button to accept the minutes.

INR... which is the default unit of measurement... flashes. Turn the meter off.

24. Holding down ON-OFF button; revealing full display.  
Show meter next to User Manual opened to reference page.

Then turn the meter back over and hold down the ON-OFF button to check that all the letters, numbers, and symbols on the display appear as shown in the User Manual.

25. Pressing SET.

You can repeat this process, any time, to change the meter's settings.

To enter setup mode at other times, simply press the SET button on the side of the meter.

## V. Getting a Blood Sample

### Voice over

One of the most important parts of testing is getting a drop of blood.

Our lancet device helps ensure that you consistently get a good drop... quickly and easily.

The lancet device has 11 depth settings, so you can use the setting that works best for you. The higher the number, the deeper the penetration.

The first time you use it, try a depth setting of 5. See if the blood drop you get is sufficient for the test. If it's not, try a higher setting. Or, if your skin is softer-than-average, try a lower setting.

Let's look at how to prepare the lancet device.

First, pull off the cap.

Then, insert a new lancet until it snaps into place. Twist the lancet's protective cap and pull gently to remove it.

Put the cap back onto the lancet device. The cap fits only when the notch on the cap aligns with the center of the semi-circle.

Turn the dial so that the center of the semi-circle points to 5.

26. Lancing a finger and getting a blood drop.

27. The device, set to a depth setting of 5.

28. Preparing the lancet device.

328

Press the plunger until it clicks. A yellow dot appears in the center of the clear button... indicating that the lancet device is ready. Set it aside while you prepare for the fingerstick.

Wash your hands in warm, soapy water.

The warmth of the water helps draw blood into the fingers... which makes getting a good drop of blood easier.

Make sure your fingertip is thoroughly dry.

Gently massage your finger from the base of the knuckle ... like this ...

Then let your hand hang loosely for 10 to 30 seconds... to bring blood into the fingertips.

Press the lancet device against the side of your finger... and press the trigger button.

Now you can very gently massage your finger starting at the base until a drop of blood appears... but don't excessively squeeze your finger... because this could interfere with the test.

29. Washing hands.

30. Massaging, hanging the hand.

31. Lancing the fingertip.

Show the meter with a strip in it in the background.

32. Massaging to get the blood drop. (Show the "squeeze and release" technique.)

## VI. Performing a Blood Test

### Voice over

33. Meter on a table.
34. Preparing for the blood test.
35. Insert the code chip.
36. Opening the container and removing a strip. C.U. of replacing the cap—for emphasis.
37. Inserting the test strip.
- Now let's look at the complete blood test procedure.
- The correct code chip must be in the meter. The code chip automatically provides the meter with information that is specific to each lot of test strips.
- Each box of test strips comes with a matching code chip. Every time you open a new box of test strips, you will replace the code chip.
- To insert the code chip, first make sure the meter is off.
- Then insert the code chip ... with the code number facing up... until you feel it snap into place.
- Remove a test strip from the container.
- Test strips are sensitive to humidity. So be sure to replace the cap after you've removed the test strip.
- Insert the test strip into the meter with the printed side up... in the direction of the arrows... as far as it goes.
- The meter turns on and displays the code chip number.
- Match the three-number code on the display with the three-number code on the test strip container.

---

<p>38. The meter's display.</p>	<p>Confirm that the codes match, then press the M button.</p> <p>An hourglass appears as the meter warms up... which takes about 30 seconds.</p> <p>While you're waiting, make sure the meter shows today's date and the correct time.</p>
<p>39. Inserting the test strip. Sound effects: meter beeps</p>	<p>When the meter is warmed-up, a flashing strip appears and the meter begins a countdown.</p> <p>You have 120 seconds to collect and apply the blood drop.</p>
<p>40. Applying the blood: show patient's hand resting on table and other hand bringing meter to the finger.</p>	<p>Once you have a hanging drop of blood... apply it to the target area of the test strip.</p> <p>It's important to apply only one drop of blood – don't add more.</p> <p>The countdown disappears, and the blood test begins.</p>
<p>41. Meter display: QC</p>	<p>In a few seconds, as part of the testing process, the meter automatically performs a self-check.</p>
<p>42. The result on the display.</p>	<p>In about a minute, the result appears on the display.</p> <p>If the meter displays an error message rather than a test result... refer to the Error Messages section of the user manual to learn what to do next.</p> <p>If you need to run a new test, use a new test strip and a different finger.</p>

43. Disposing of the used strip.

Once you're finished... remove the test strip and discard it along with your lancet in a puncture-proof container, such as an empty coffee can.

44. Recording result.

Record the result on your Log Sheet... and turn the meter off.

Note: In the final video for launch, the patient will be asked to record the result and call their doctor with the result.

The CoaguChek XS Meter automatically stores 100 results, with the date and time, in its memory.

332

## VII. Cleaning the Meter

### Voice over

45. Product shot.  
Cleaning the meter is simple. You should clean it each time you open a new box of test strips... or whenever it looks dirty.
46. Add text graphics.  
Use only these approved cleaning solutions... a 70% isopropyl alcohol solution or a 10% bleach solution...  
Do not spray any cleaning solution on the meter. Do not use a spray of any type.  
Use a soft towel or cotton swab... and a lint-free tissue.
47. Cleaning the exterior.  
Just wipe the exterior.  
Then let it air dry or dry it with a lint-free tissue.
48. Cleaning the interior.  
To clean the interior, first turn the meter off.  
Remove the test strip guide cover by lifting the front of the cover. Clean the cover with an approved cleaning solution.  
Carefully clean the test strip guide with a lint-free wipe, or swab. Do not let any liquid enter the meter, as it will damage the electrical contacts behind the test strip guide.

---

Let the test strip guide air dry thoroughly before  
replacing the cover.

It's that easy.

---

### VIII. Conclusion

Voice over

In this video program, you've seen how easy it is to use the CoaguChek XS System.

Keep in mind that every step is described in detail in the CoaguChek XS System User Manual...

If you still have questions after reviewing the manual, call the Roche Diagnostics Technical Service Center at 1-800-819-1106.

That's how easy it is to test with the CoaguChek XS System...

... from Roche Diagnostics.

53. Roche logo.  
COAGUCHEK is a trademark of a Member of the Roche Group.  
© 2005 Roche Diagnostics. All rights reserved.

49. Product shot.

50. Instructional materials.

51. 1-800-819-1106

52. Product shot.

335

**New Device Labeling  
Getting Started Guide**

# CoaguChek<sup>®</sup> XS System

## Getting Started



## GETTING STARTED ►

### Follow these steps to get started using the meter:

1. Watch the *CoaguChek XS System Video*. It will help you get comfortable with the CoaguChek XS Meter and the testing procedure.
2. Read the Accu-Chek<sup>®</sup> Softclix lancet device package insert.
3. With this *CoaguChek XS System Getting Started* guide by the meter, follow the steps to perform your first test.

### Then, as necessary, refer to the User Manual:

The *CoaguChek XS System User Manual* is a comprehensive guide to the meter and test strips. It is designed to provide answers to your questions about the meter's operation and use.

## INSTALLING BATTERIES & SETUP ►

### 1. Open Compartment



Open the battery compartment on the back of the meter.

### 2. Insert Batteries



Insert 4 AAA batteries according to the diagram inside the battery compartment.

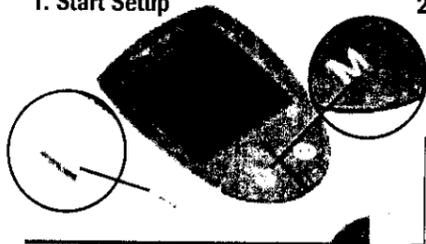
Right after you insert the batteries, you'll need to set the date and time.

The date and time settings are important. Each time you run a test, the meter compares its date with the test strip's expiration date. If the test strip is expired, the meter displays an error message and prevents you from running a test.

Whenever you put batteries in the meter, it automatically goes to Setup mode (where you set the date and time). You can also go to Setup mode at any time by pressing the SET button (◻).

## SETTING DATE AND TIME ►

### 1. Start Setup

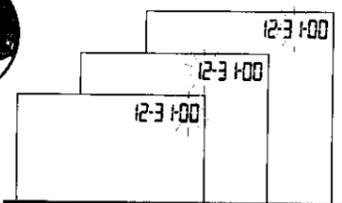


To set the date and time, you'll use these buttons: **M** to change a setting or **◻** (SET) to accept a setting.

If the meter is not already in Setup mode, press **◻**.

The date format flashes in the upper right corner.

### 2. Set Date



Press **◻**. The year flashes.

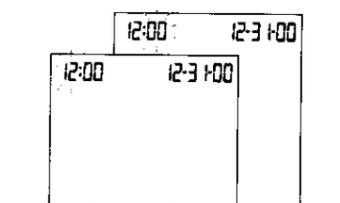
**M** to change the year then **◻**.

**M** to change the month then **◻**.

**M** to change the day then **◻**.

The time format flashes in the upper left corner.

### 3. Set Time



Press **◻**. The hour flashes.

**M** to change the hour then **◻**.

**M** to change the minutes then **◻**.

Turn the meter off **Ⓚ**.

### 4. Check Display



Press and hold the ON-OFF button **Ⓚ**.

Make sure all the letters, numbers, and symbols on the display appear correctly. See *The Meter's Display* section in the *User Manual* to see the full display.

Release **Ⓚ**.

Turn the meter off **Ⓚ**.

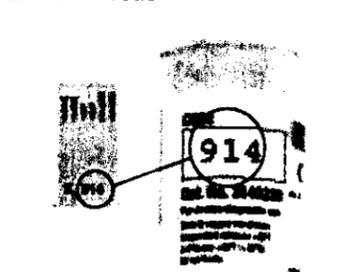
## PREPARING FOR A TEST ►

### 1. Gather Items



- CoaguChek XS Meter
- Container of test strips
- Test strip code chip
- Accu-Chek Softclix lancet device and

### 2. Match Code



The code number on the test strip container and the code chip must match.

Each box of test strips comes with a matching code chip. Every time you open

### 3. Insert Code Chip



Make sure the meter is off.

With the code number facing up, insert the code chip into the code chip slot until it snaps into place.

### 4. Prepare Lancet Device



Pull off the cap of the lancet device. Insert a new lancet. Twist off the lancet's protective cap. Put the cap back on the lancet device. Line up the notches for the cap to fit. Select the

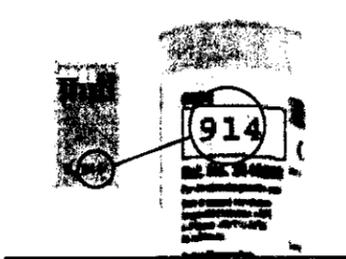
337

122

111



- CoaguChek XS Meter
- Container of test strips
- Test strip code chip
- Accu-Chek Softclix lancet device and lancet



The code number on the test strip container and the code chip must match.

*Each box of test strips comes with a matching code chip. Every time you open a new box of test strips, you must replace the code chip.*



Make sure the meter is off. With the code number facing up, insert the code chip into the code chip slot until it snaps into place.



Pull off the cap of the lancet device. Insert a new lancet. Twist off the lancet's protective cap. Put the cap back on the lancet device. Line up the notches for the cap to fit. Select the penetration depth.

Press the plunger. A yellow dot appears in the release button.

## TESTING ▶



### Before continuing, review these tips for getting a good blood drop.

Increasing the blood flow in your finger will help you get a good drop of blood:

- Warm your hand. Hold it under your arm, use a hand warmer, and/or wash with warm water.
- Let your arm hang by your side.
- Massage your finger from its base.

*Use these techniques until your fingertip has good color.*

### 1. Wash Hands



Wash your hands in warm, soapy water.

*Make sure the fingertip is thoroughly dry.*

### 2. Get Ready



Take a test strip out of the container.

**Close the container tightly.**

*You have 10 minutes to use a test strip once you remove it from the container.*

### 3. Insert Test Strip

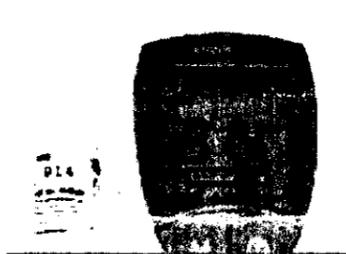


Slide the test strip into the test strip guide in the direction of the arrows until it stops.

*The meter turns on.*

*The code number of the inserted code chip flashes on the display.*

### 4. Match Code



Confirm that the number displayed matches the number on the test strip container, then press **M**.

*If the numbers are different, first make sure that the correct code chip is inserted. If the numbers still don't match, call the Roche Diagnostics Technical Service Center at 1-800-819-1106.*

*An hourglass appears as the meter warms up. A flashing test strip and blood drop appear when the meter is ready for a sample.*

*You have 120 seconds to apply blood to the test strip.*

### 5. Collect Sample

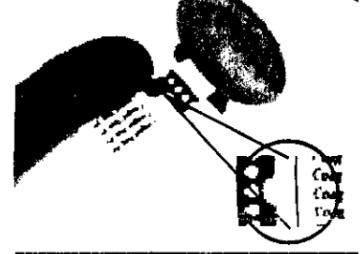


*Massage the finger until you see increased color in the fingertip.*

Keeping the hand down, press the tip of the lancet firmly against the side of the fingertip. Press the release button.

*Gently squeeze from the base of the finger to develop a hanging drop of blood.*

### 6. Apply Sample



The meter must be on a table. Find the target area on the test strip. Dose the test strip from the side. *See the User Manual for more information.*

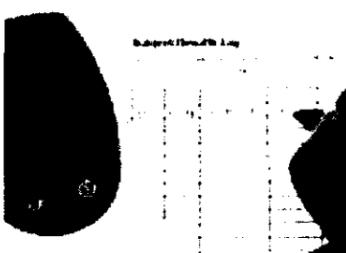
Within 15 seconds of sticking your fingertip, apply the blood to the target area on the test strip.

*Hold the blood drop to the test strip until you hear a beep. The flashing blood drop symbol will disappear.*

**Do not add more blood to the test strip. Do not touch the test strip.**

*The result appears in about 1 minute.*

### 7. Record Result



Record the result on the *Subject Results Log*.

*Note: If during testing the meter displays an error message, refer to the Error Messages section of the User Manual for what to do next.*

### 8. Clean Up



Remove the lancet from the lancet device. Place the used test strip and lancet in a puncture-proof container with a lid.

Turn the meter off. **⓪**

*If the meter is dirty, wipe it clean with a lint-free tissue and an approved cleaning solution.*

*Note: See Cleaning the Meter in the User Manual for more information.*

328

113

## **Predicate Device Labeling**

## CoagChek<sup>®</sup> XS PT Test

Lot: 140231149  
48 Test Strips, 1 Color Chip



These test strips are to be used with the CoagChek XS System.

### Purpose

The CoagChek XS System is intended for use by professional healthcare providers for quantitative pathologic time testing for the monitoring of low fibrin therapy. The CoagChek XS System uses a latex agglutination immunoassay with a whole blood

sample. These test strips are for use outside the body only. Do not use the test strips.

### Before You Start Testing

For all use with the CoagChek XS System, wash the CoagChek XS System Vials and read the CoagChek XS System Order Sheet before testing.

### Storing the Test Strips

Store the test strips in their container, with the cap closed. You can store the test strips at room temperature or in the refrigerator (2 to 30°C or 36 to 86°F). When stored properly, the test strips can be used until the expiration date printed on the test strip container. Discard all test strips if they are past their "Use By" date.

### Handling the Test Strips

When you are ready to test, remove 1 test strip from the container. Do not open a vial of test strips. Do not touch the test strip with wet hands or gloves. The only change the test strips receive is the ambient light.

You must use the test strip within 10 minutes of removing it from the container. Otherwise, you may get an error message and you will have to repeat the test.

## Sample Collection and Preparation

The steps that follow apply to collecting a blood sample from a fingerstick. Optionally, you may use a capillary tube to collect the fingerstick blood sample. You may also use the CoagChek XS System to collect a blood sample. Obtain the following materials at the CoagChek XS System User Assembly Site. See the User Manual for more information on sample, follow universal blood collection procedures and guidelines.

### Step 1: Getting Ready to Test

- CoagChek XS Meter
- CoagChek XS PT Test Strip
- Test Strip Color Chip
- Lancet (follow the manufacturer's instructions to prepare the lancet for use.)

If you are using test strips from a new, unopened box, you will need to change the 3-number code on the color chip. The 3-number code on the test strip container must match the 3-number code on the color chip. To reset the code chip, follow the instructions in the Color Chip section of the CoagChek XS System User Manual.

Put the meter on a flat surface, like a table, in a counter-top area with no water or noise during testing, so this can result in an error message.

### Step 2: Testing Blood from a Fingerstick

1. **Washing a Good Drop of Blood**  
Wash your hands with soap and water. Then, use a clean, dry paper towel to dry your hands. Use the following instructions to prepare a good drop of blood. Hold the finger over the target. Do the following steps quickly and you will see that the fingerstick has good color:

- Warm the hand by having the patient hold it under 15 or 20 °C (60 or 68 °F) for a minute, use a hand warmer, and/or wrap the hand with a warm towel.
- Have the patient hold his or her arm down to the side, so that the hand is below the wrist.
- Massage the finger from its base.
- If needed, immediately after lancing, gently squeeze the finger from its base to encourage blood flow.

## Procedure

1. Wash the patient's hands well with warm, soapy water or wipe the finger with alcohol. Allow the patient's finger to dry completely before performing the fingerstick.
  2. Take a test strip out of the container. Close the container tightly.
  3. Insert a test strip as far as you can. The meter turns on.
  4. Confirm that the patient's blood is visible in the window on the test strip container. Then press **M**. If the numbers are different, make sure you are using the color chip that came with the test strips as a reference.
  5. An hourglass appears as the meter warms up, which takes about 15 seconds.
  6. When the meter is warmed up, a flashing test strip and blood drop symbol appear and the meter begins a countdown. You have 100 seconds to apply blood to the test strip.
  7. Use the lancet to perform a fingerstick.
  8. Apply 1 drop of blood to the top or side of the target area. You must apply blood to the test strip or thin. It is accurate if touching the finger.
  9. Do not add more blood. Do not touch or remove the test strip when a result is in progress.
  10. The result appears in about 1 minute. Record the result.
  11. Properly dispose of the used lancet and test strip.
  12. Turn the meter off.
- If you need to redo a test, use a new lancet, a new test strip, and a different finger.

## Technical Information

**How the Test Works**  
The CoagChek XS PT Test, used as directed with the CoagChek XS Meter, will provide an biochemical measurement of prothrombin time following activation of fibrin coagulation with human recombinant thromboplastin. In simple terms, blood works with the meter to make a small amount of fibrin. The meter then measures how long it takes to measure blood clotting time.

## Contents of the Test Strip

The test strip contains reagent (human recombinant thromboplastin), as well as stabilizers, preservatives, and additives.

## Limitations of Procedure

- The CoagChek XS PT Test uses only fresh, healthy, or non-wedged, dried venous whole blood. Plasma or serum cannot be used.
- The only device syringes without anticoagulants in addition, clear, clear or syringes must not be used.
- The liquid alone must be a minimum of 10 µl. If volume low, sample volume will cause an error message.
- Never add more blood to test strip after test has begun or perform another test using the same fingerstick.
- When a patient is on intravenous infusion therapy, do not collect a single test strip (receiving the infusion line).
- Hematocrit ranges between 20-50% do not significantly affect test results.
- Testing performed with the following factors below will affect or make your analysis (Physicians) indicated as significant affect on test results:
  - Alcohol (up to 20 mg/dL)
  - Hemoglobin up to 150 mg/dL
  - The results are unaffected by hemoglobin concentrations up to 0.6 L/hL.
  - The CoagChek XS PT Test is insensitive to low molecular weight heparins (LMWH) up to 275 IU/hL under the following:
    - The presence of anti-thrombin III (AT-III) such as Urokinase and heparin (U) can occasionally lead to prolonged clotting times, i.e., elevated fibrin values. A comparison to an AT-III activity laboratory method is recommended if the presence of AT-III is known or suspected.
    - In case cases, patients with long acting Heparin (Heparin) may require an FESB0017 message on the meter display. If this error message appears, again when the test is repeated, the result must be checked using another method.

## Expected Results

The CoagChek XS Meter displays test results in units equivalent to laboratory PT/INR measurements. Results may be displayed in the International Normalized Ratio (INR) or PT/INR (Normal PT/INR), seconds, and % Check to unit used mainly by healthcare professionals (Europe).

Each lot of test strips is calibrated to a reference lot that is traceable to the WHO International Reference Preparation. Normal INR levels vary from patient to patient. The normal INR range for patients on low-dose warfarin therapy is 2.0 to 3.0. The normal INR range for patients on high-dose warfarin therapy is 3.0 to 4.5. The normal INR range from 0.8 to 1.1. For the purpose of providing universal INR results, the Mean Normal Prothrombin Time (MNPT) has been established as 17 seconds for healthy volunteers and the International Sensitivity Index (ISI) for the system has been established as 1.

The physician must determine the test INR level depending on the report for a therapeutic treatment and how each individual responds to treatment (based on Prothrombin Time). Each physician should establish expected values for INR or INR patient population or practice present.

Differences in reagents, exposure to, and one-way variables can affect prothrombin test results. These factors should be considered when comparing different populations and test methods.

## Unusual Results

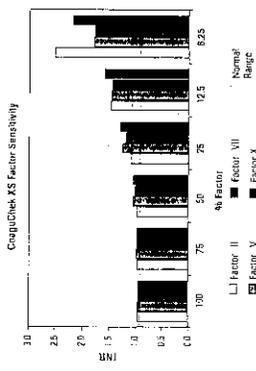
- The meter displays an error message, refer to the *From Message Section* of the CoagChek XS System User Manual. If the meter displays an unusual test result (but not an error message), check the following items:
  - Is the correct code chip in the meter? The 3-number code on the test strip container must match the 3-number code on the color chip.
  - Is the meter set up with the correct date and time?
- Certain factors may affect results by affecting reaction phenomenon. The potential effect of a drug interaction with warfarin at the effect of underlying diseases, or a liver disease, congestive heart failure) must be considered when interpreting a result.

370

Also, changes in the patient's clinical cause usually low or high results. Any unusual result should always be followed up with appropriate coagulation tests and reported to the clinician to follow the course of the unusual result. If the track does not match the clinical symptoms, repeat the patient test to rule out analytical error.

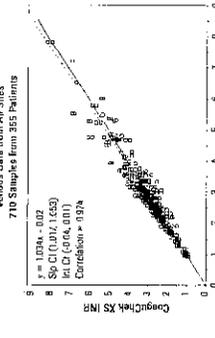
**Performance Characteristics**

**Measuring Range:** The CoagCheck XS System has a measurable range of 10 to 8.6 INR. **Sensitivity:** The CoagCheck XS PT Test is sensitive to various clotting factors as determined by an in-house single factor diagnostic plasma was combined with a normal plasma to create a series of representative plasmas. The results, as seen in the graph below, represent the typical CoagCheck XS PT Test sensitivity to Factor II, Factor VII, Factor X, Factor V, Factor VIII, and X.



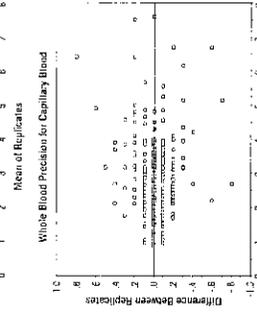
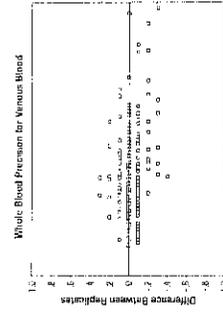
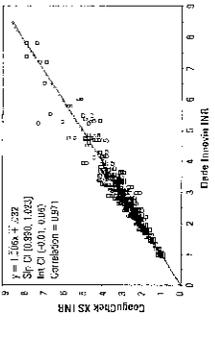
Accuracy: 710 venous samples were collected from 355 patients at three external sites. The INR of each sample was compared to the INR of a venous plasma sample analyzed on a standard laboratory instrument. The following table shows the conditions included (number of patients) normal - red to white (R2), high fibrinogen (F9), other replacement (F5), stroke (F4) (F3), DVT (F1), other heart related disorders (F6), other clotting disorders (F8), other (F0).

Site	N	Slope	Intercept	Correlation
Site 1	232	1.178	0.19	0.973
Site 2	229	1.111	-0.11	0.971
Site 3	49	0.934	0.03	0.988
All	710	1.054	-0.02	0.974



Accuracy: 707 capillary samples were collected from 357 individuals at three external sites. Capillary blood samples were analyzed on the CoagCheck XS meter with the capillary blood test plasma. The following table shows the conditions included (number of patients) normal - red to white (R2), high fibrinogen (F9), other replacement (F5), stroke (F4) (F3), DVT (F1), other heart related disorders (F6), other clotting disorders (F8), other (F0).

Site	N	Slope	Intercept	Correlation
Site 1	230	1.111	-0.10	0.973
Site 2	229	1.081	-0.068	0.978
Site 3	241	1.092	0.02	0.985
All	700	1.098	0.022	0.971



**Built-In Controls and Diagnostics**

The CoagCheck XS System has quality control functions integrated into the meter and test strips, so you never have to run quality control tests with liquid quality controls. The meter automatically runs its own quality control test as part of every blood test. For more information about the built-in quality control functions, see the CoagCheck XS System User Manual.

**References**  
 1. Mørk S and Thiel, H. "Measuring Warfarin Therapy in Patients with LULAS Anticoagulants." *Annals of Internal Medicine* 1997; 127: 177-182.  
 2. Longtin LA, van den Broekbeek AMTP and Leek SM. "Reliability and Clinical Impact of the Normalization of the Prothrombin Time in Oral Anticoagulant Control." *Thromb Haemostas*. 1985; 54: 140-144.

**Return Policy**  
 If due to a problem with the CoagCheck XS PT Test Strip, you may be asked to return it along with the test strip to the factory. If the problem is not related to the strip, call Roche Diagnostics, Inc. for more information. The return policy for the meter is outlined in the return authorization table, which must be put on the shipping carton.

**Additional Information**  
 The CoagCheck XS System User Manual contains more information. If you still have questions, call Roche Diagnostics Technical Service Center at 1-800-498-4374, 24 hours a day, 7 days a week.

Roche Diagnostics, Inc. is a subsidiary of Roche Holding AG, a Swiss company. Roche Diagnostics, Inc. is a subsidiary of Roche Holding AG, a Swiss company. Roche Diagnostics, Inc. is a subsidiary of Roche Holding AG, a Swiss company.



341

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration  
Memorandum

From: Reviewer(s) - Name(s) Valerie A. Gnyard

Subject: 510(k) Number K062925/S2

To: The Record - It is my recommendation that the subject 510(k) Notification:

- Refused to accept.
- Requires additional information (other than refuse to accept).
- Is substantially equivalent to marketed devices.
- NOT substantially equivalent to marketed devices.
- Other (e.g., exempt by regulation, not a device, duplicate, etc.)

- Is this device subject to Section 522 Postmarket Surveillance?  YES  NO
- Is this device subject to the Tracking Regulation?  YES  NO
- Was clinical data necessary to support the review of this 510(k)?  YES  NO
- Is this a prescription device?  YES  NO
- Was this 510(k) reviewed by a Third Party?  YES  NO
- Special 510(k)?  YES  NO
- Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers  YES  NO

- Truthful and Accurate Statement  Requested  Enclosed
- A 510(k) summary OR  A 510(k) statement
- The required certification and summary for class III devices NIA
- The indication for use form

Combination Product Category (Please see algorithm on H drive 510k/Boilers) N

Animal Tissue Source  YES  NO Material of Biological Origin  YES  NO

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

- No Confidentiality  Confidentiality for 90 days  Continued Confidentiality exceeding 90 days

Predicate Product Code with class: GJS Additional Product Code(s) with panel (optional):

Class II 21 CFR 814.7750

Review: Josephine Bantini (Branch Chief) DIHD (Branch Code) 1/29/07 (Date)

Final Review: Robert Beeler (Division Director) 27 Jan 2007 (Date)

**"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION**

**K062925**

Reviewer: **VALERIE R. GINYARD**

Division/Branch: **DIHD**

Device Name: **COAGUCHEK XS SYSTEM (PATIENT SELF-TESTING)**

Product To Which Compared (510(K) Number If Known): **COAGUCHEK XS SYSTEM (PROFESSIONAL) (K060978)**

	YES	NO	
1. Is Product A Device	<b>X</b>		If <b>NO</b> = Stop
2. Is Device Subject To 510(k)?	<b>X</b>		If <b>NO</b> = Stop
3. Same Indication Statement?			If <b>YES</b> = Go To 5
4. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?	<b>X</b>		If <b>YES</b> = Stop <b>NE</b>
5. Same Technological Characteristics?	<b>X</b>		If <b>YES</b> = Go To 7
6. Could The New Characteristics Affect Safety Or Effectiveness?			If <b>YES</b> = Go To 8
7. Descriptive Characteristics Precise Enough?		<b>X</b>	If <b>NO</b> = Go To 10 If <b>YES</b> = Stop <b>SE</b>
8. New Types Of Safety Or Effectiveness Questions?			If <b>YES</b> = Stop <b>NE</b>
9. Accepted Scientific Methods Exist?			If <b>NO</b> = Stop <b>NE</b>
10. Performance Data Available?	<b>X</b>		If <b>NO</b> = Request Data
11. Data Demonstrate Equivalence?	<b>X</b>		Final Decision: <b>SE</b>

1. **Intended Use:** The CoaguChek XS System (patient self-testing) is intended for properly selected and suitably trained users or their caregivers on the prescription or other order of the treating doctor. Users should be stabilized on anticoagulation medications such as Coumadin® or warfarin prior to self-testing with the CoaguChek XS System. The system uses capillary blood.

2. **Device Description:** Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. Is the device life-supporting or life sustaining? Is the device implanted (short-term or long-term)? Does the device design use software? Is the device sterile? Is the device for single use? Is the device over-the-counter or prescription use? Does the device contain drug or biological product as a component? Is this device a kit? Provide a summary about the devices design, materials, physical properties and toxicology profile if important.

**Summary:** The Coaguchek XS System (patient self-testing) is prothrombin time testing system intended for home users.

The CoaguChek® XS System includes a meter and CoaguChek® XS PT test strips. The test strip contains a human recombinant tissue factor, and is calibrated to an ISI of 1.0. The test strip incorporates quality control material that accesses strip integrity. The CoaguChek® XS meter automatically stores up to 100 test results along with their dates and times in memory.

(b)(4), (b)(5)

(b)(4), (b)(5)

To support substantial equivalence, the Sponsor presented precision and comparison studies. All Studies demonstrated acceptable performance.

7. **Explain how descriptive characteristics are not precise enough:**

(b)(4), (b)(5)

(b)(4), (b)(5)

by the Sponsor.

11. **Explain how the performance data demonstrates that the device is or is not substantially equivalent:** Performance data demonstrated that the device is substantially equivalent to a legally marketed device.

(b)(4), (b)(5)

(b)(4), (b)(5)

(b)(4), (b)(5)

(b)(4), (b)(5)

Analytical performance was demonstrated in K060978.

All results demonstrated acceptable results.

*Valerie R. Genjand*

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION  
DECISION SUMMARY  
ASSAY AND INSTRUMENT COMBINATION TEMPLATE**

**A. 510(k) Number:**

K062925

**B. Purpose for Submission:**

Clearance of a new instrument and test strip

**C. Measurand:**

Prothrombin Time

**D. Type of Test:**

Electrochemical

**E. Applicant:**

Roche Diagnostics

**F. Proprietary and Established Names:**

CoaguChek® XS System (Patient Self-testing)

**G. Regulatory Information:**

1. Regulation section:

21 CFR 864.7750

2. Classification:

Class II

3. Product code:

GJS

4. Panel:

81 Hematology

**H. Intended Use:**

1. Intended use(s):

The CoaguChek XS System is intended for properly selected and suitably trained users or their caregivers on the prescription or other order of the treating doctor. Users should be stabilized on anticoagulation medications such as Coumadin® or warfarin prior to self-testing with the CoaguChek XS System. The system uses blood from a finger stick

2. Indication(s) for use:

3. Special conditions for use statement(s):

Intended for home use

4. Special instrument requirements:

**I. Device Description:**

The CoaguChek® XS System includes a meter and CoaguChek® XS PT test strips. The test strip contains a human recombinant tissue factor, and is calibrated to an ISI of 1.0.

The test strip incorporates quality control material that accesses strip integrity.

The CoaguChek® XS meter automatically stores up to 100 test results along with their dates and times in memory.

**J. Substantial Equivalence Information:**

1. Predicate device name(s):

Roche Diagnostics CoaguChek XS System

2. Predicate 510(k) number(s):

K060978

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended Use	Measure prothrombin time	same
Technology	Electrochemical with amperometric detection of thrombin activity	same
Dosing	Top and side dosing	same

Differences		
Item	Device	Predicate
Indications	Home users	Professional use

**K. Standard/Guidance Document Referenced (if applicable):**

**L. Test Principle:**

When a blood sample is applied to the test strip, thromboplastin activates the coagulation cascade which leads to the formation of thrombin. Thrombin cleaves the thrombin substrate creating an electrochemically active peptide, which generates an electrical signal. The signal is converted to an INR value and displayed by the CoaguChek XS System.

The on-board quality control is a bi-level control that accesses test strip integrity. The PT test and QC testing are performed simultaneously. The test system determines whether the quality control is within preset limits. If it is, the meter displays a short term "QC✓", and then the PT test result. If the QC is not within limits, the meter displays "error QC", and no PT test result will be displayed.

**M. Performance Characteristics (if/when applicable):**

1. Analytical performance:

Pages 145 through 146 redacted for the following reasons:

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Test Data, b4

calibration results using serial infrared communication in a protected mode, reading and storage of specific information for strip LOT from code key, calculation of PT time based on data received from measurement cycle, and checks for failsafe in order to recognize malfunctions of the measurement electronics or malfunctions within the strip used for testing.

FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types:

Yes  or No

3. Specimen Identification:

Date and time of testing is recorded by the CoaguChek XS meter

4. Specimen Sampling and Handling:

Whole blood is manually applied to the target area of the test strip either from the top or side of the strip.

5. Calibration:

The CoaguChek XS Test strips are calibrated to a master reagent lot which has in turn been calibrated to a WHO International Reference Preparations (rTF/95) using the manual tilt tube method.

6. Quality Control:

The CoaguChek XS System incorporates a bi-level on-board quality control (OBC) within the CoaguChek XS test strip that monitors test strip integrity.

Level 1 OBC detects strip defects such as reagent defects, capillary compression and electrode defects. Level 2 OBC directly measures strip damage due to such things as exposure to increased humidity, light, and temperature.

The pre-determined OBC ranges are programmed into the lot specific code chip that is packaged with the matching test strip lot.

Acceptable data was presented validating the OBC.

**P. Other Supportive Instrument Performance Characteristics Data Not Covered In the "Performance Characteristics" Section above:**

An instrument failsafe checklist was presented outlining the QC check made by the CoaguChek XS meter.

**Q. Proposed Labeling:**

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

**R. Conclusion:**

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.

**S. Other Supportive Device and Instrument Information:**

**T. Administrative Information:**

1. Applicant Contact Information:

a. *Name of applicant:*

Roche Diagnostics Inc.

b. *Mailing address:*

9115 Hauge Road

Indianapolis, IN 46256

c. *Phone #:*

317-521-3742

d. *Fax #:*

317-521-2324

e. *E-mail address (optional):*

tracy.bush@roche.com

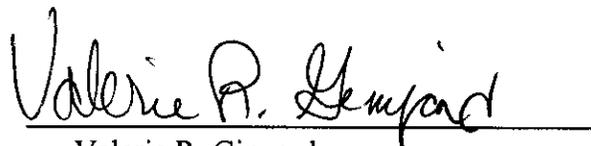
f. *Contact:*

Tracy Bush

2. Review Documentation:

28 September 2006	Submission received in DMC
29 September 2006	Submission received in OIVD
3 October 2006	Submission assigned to Reviewer
13 November 2006	Submission placed on hold
12 December 2006	Requested additional information received
18 December 2006	Additional information received by Reviewer
10 January 2007	Email correspondence
10 January 2007	Submission placed on hold
18 January 2007	Additional information received by Reviewer
29 January 2007	Request for labeling modifications
29 January 2007	labeling modifications received
29 January 2007	SE

**U. Reviewer Name and Signature:**

  
Valerie R. Ginyard  
CDRH/OIVD/DIHD

## Indications for Use

510(k) Number (if known): ~~K060978~~ 1K062925

Device Name: CoaguChek® XS System for Patient Self-Testing

### Indications For Use:

The CoaguChek XS PT test strips are part of the CoaguChek XS System. The CoaguChek XS System measures blood-clotting time for people who are taking anticoagulation medications such as Coumadin® or warfarin. The CoaguChek XS System uses blood from a finger stick. The system is intended for properly selected and suitably trained users or their caregivers on the prescription or other order of the treating doctor. Users should be stabilized on anticoagulation medications such as Coumadin® or warfarin prior to self-testing with the CoaguChek XS System.

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

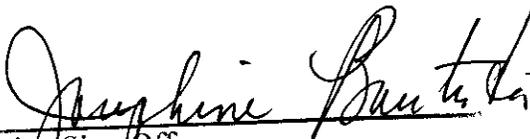
AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
Division Sign/Off

Office of In Vitro Diagnostic Device  
Evaluation and Safety

510(k)           K062925          

18

## **510(k) Summary**

## 510(k) Summary

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**Introduction** According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

---

**1) Submitter name, address, contact** Roche Diagnostics Corporation  
9115 Hague Rd.  
Indianapolis, IN 46250

Contact Person: Luann Ochs

Date Prepared: January 29, 2007

---

**2) Device name** Proprietary name: CoaguChek® XS System  
Common name: Prothrombin time test  
Classification name: Prothrombin time test

---

**3) Predicate device** The Roche Diagnostics CoaguChek XS System (patient self-testing) is substantially equivalent in materials, design and function to other products that measure prothrombin time INR in human blood. Most notably, it is substantially equivalent to the Roche Diagnostics CoaguChek XS System (professional). In fact, it is identical in materials, design and function to the CoaguChek XS System (professional) except the labeling has been modified and validated for patient self-testing.

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**4) Device Description** The CoaguChek XS is a 3<sup>rd</sup> generation Roche Diagnostic's CoaguChek meter which was cleared for professional use under premarket notification K060978.

This premarket notification is being submitted to obtain clearance for patient self-testing.

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**5) Intended Use** The CoaguChek XS PT test strips are part of the CoaguChek XS System. The CoaguChek XS System measures blood-clotting time for people who are taking anticoagulation medications such as Coumadin® or warfarin. The CoaguChek XS System uses blood from a finger stick. The system is intended for properly selected and suitably trained users or their caregivers on the prescription or other order of the treating doctor. Users should be stabilized on anticoagulation medications such as Coumadin® or warfarin prior to self-testing with the CoaguChek XS System.

---

**6) Comparison to Predicate Device** The following characteristics have been previously submitted, reviewed and cleared under the premarket notification for the CoaguChek XS System (K060978):

- Factor Sensitivity
- Heparin Sensitivity
- Hematocrit Effect
- Interfering Substances
- Normal Range
- Measuring Range
- Test Strip Stability
- Integrated Quality Control
- Instrument Failsafes
- Calibration
- Software Development

These characteristics are not impacted by the new user population.

The use of the system by self-testers was validated by an external user study that was conducted as the system is intended to be used. Following self-directed training, the subjects self-tested in the home setting for up to 8 weeks. The subjects also had 3 scheduled visits to their study site to collect user vs. technician data as well as user vs. reference method (Dade Innovin on a Sysmex analyzer) data.

The study results successfully demonstrated that self-trained subjects can obtain results that are equivalent to healthcare professionals and to the reference method. This study also demonstrated that self-tester results are consistent over time.

---

**7) Performance characteristics** The performance characteristics that are impacted by the new user population were evaluated. The following information has been incorporated into our draft patient self-testing insert.

Claim	Statement															
<p><b>Accuracy</b></p>	<p>A study was conducted comparing test results obtained by self-trained patients with those obtained by healthcare professionals using the CoaguChek XS meter. The correlation was very good, as indicated by the following statistics: N = 258, Slope = 1.00, Intercept = 0.0 and Correlation Coefficient = 0.974. This study shows that self-trained patients are able to obtain results that are as accurate as those obtained by healthcare professionals trained in the use of the CoaguChek XS meter.</p>															
<p><b>Precision</b></p>	<p>A study was conducted and the precision of duplicates for capillary blood results was calculated for both self-trained patients and healthcare professionals. The following results were obtained:</p> <table border="1" data-bbox="678 1327 1384 1589"> <thead> <tr> <th></th> <th>Patient Results</th> <th>Professional Results</th> </tr> </thead> <tbody> <tr> <td><b>N</b></td> <td>222</td> <td>257</td> </tr> <tr> <td><b>Mean</b></td> <td>2.55</td> <td>2.50</td> </tr> <tr> <td><b>SD</b></td> <td>0.132</td> <td>0.135</td> </tr> <tr> <td><b>CV</b></td> <td>5.19</td> <td>5.38</td> </tr> </tbody> </table> <p>This study shows that self-trained patients are able to obtain results that are as precise as those obtained by healthcare professionals trained in the use of the CoaguChek XS meter.</p>		Patient Results	Professional Results	<b>N</b>	222	257	<b>Mean</b>	2.55	2.50	<b>SD</b>	0.132	0.135	<b>CV</b>	5.19	5.38
	Patient Results	Professional Results														
<b>N</b>	222	257														
<b>Mean</b>	2.55	2.50														
<b>SD</b>	0.132	0.135														
<b>CV</b>	5.19	5.38														

**Ginyard, Valerie**

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**From:** Ochs, Luann [luann.ochs@roche.com]  
**Sent:** Monday, January 29, 2007 10:36 AM  
**To:** Ginyard, Valerie  
**Subject:** RE: K062925  
**Attachments:** Indications for Use.doc; 510k Summary.doc

Dear Valerie,

Here are the two documents you requested.

Kind regards,  
Luann

Luann Ochs, MS  
Director, U.S. Regulatory Affairs  
Roche Diagnostics Corporation  
tel: 317-521-7399  
fax: 317-521-4103

-----Original Message-----

**From:** Ginyard, Valerie [mailto:valerie.ginyard@fda.hhs.gov]  
**Sent:** Monday, January 29, 2007 10:28 AM  
**To:** Ochs, Luann {D147~Indianapolis}  
**Subject:** RE: K062925

Here it is:

The CoaguChek XS PT test strips are apart of the CoaguChek XS System. The CoaguChek XS System measures blood-clotting time for people who are taking anticoagulation medications such as Coumadin® or warfarin. The CoaguChek XS System uses blood from a finger stick. The system is intended for properly selected and suitably trained users or their caregivers on the prescription or other order of the treating doctor. Users should be stabilized on anticoagulation medications such as Coumadin® or warfarin prior to self-testing with the CoaguChek XS System.

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**From:** Ochs, Luann [mailto:luann.ochs@roche.com]  
**Sent:** Monday, January 29, 2007 10:21 AM  
**To:** Ginyard, Valerie  
**Subject:** RE: K062925

Yes, please send me the wording and I will get the documents right to you.

-----Original Message-----

**From:** Ginyard, Valerie [mailto:valerie.ginyard@fda.hhs.gov]  
**Sent:** Monday, January 29, 2007 10:18 AM  
**To:** Ochs, Luann {D147~Indianapolis}  
**Subject:** RE: K062925

23

No-oo. It is the IU found in the strip labeling under Purpose. If you need me to I will send you the wording. Thanks.

---

**From:** Ochs, Luann [mailto:luann.ochs@roche.com]  
**Sent:** Monday, January 29, 2007 10:15 AM  
**To:** Ginyard, Valerie  
**Subject:** RE: K062925

Valerie,

(b)(4), (b)(5)

(b)(4), (b)(5)

-----Original Message-----

**From:** Ginyard, Valerie [mailto:valerie.ginyard@fda.hhs.gov]  
**Sent:** Monday, January 29, 2007 5:23 AM  
**To:** Bush, Tracy {D147~Indianapolis}  
**Cc:** Ochs, Luann {D147~Indianapolis}  
**Subject:** K062925

Hi Tracy

Please modify your 510(k) summary and Indications for Use statement to reflect the updated intended use statement. Forward to me via email ASAP.

Thanks!

Valerie

## Ginyard, Valerie

---

**From:** Ginyard, Valerie  
**Sent:** Monday, January 29, 2007 5:23 AM  
**To:** 'Bush, Tracy'  
**Cc:** 'Ochs, Luann'  
**Subject:** K062925

Hi Tracy

Please modify your 510(k) summary and Indications for Use statement to reflect the updated intended use statement. Forward to me via email ASAP.

Thanks!

Valerie

From: Reviewer(s) - Name(s) Valerie Ginyard  
Subject: 510(k) Number K062925/S'

To: The Record - It is my recommendation that the subject 510(k) Notification:

- Refused to accept.
- Requires additional information (other than refuse to accept).
- Is substantially equivalent to marketed devices.
- NOT substantially equivalent to marketed devices.
- Other (e.g., exempt by regulation, not a device, duplicate, etc.)

- Is this device subject to Section 522 Postmarket Surveillance?  YES  NO
- Is this device subject to the Tracking Regulation?  YES  NO
- Was clinical data necessary to support the review of this 510(k)?  YES  NO
- Is this a prescription device?  YES  NO
- Was this 510(k) reviewed by a Third Party?  YES  NO
- Special 510(k)?  YES  NO
- Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers  YES  NO

- Truthful and Accurate Statement  Requested  Enclosed
- A 510(k) summary OR  A 510(k) statement
- The required certification and summary for class III devices
- The indication for use form

Combination Product Category (Please see algorithm on H drive 510k/Boilers) \_\_\_\_\_

Animal Tissue Source  YES  NO Material of Biological Origin  YES  NO

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

- No Confidentiality  Confidentiality for 90 days  Continued Confidentiality exceeding 90 days

Predicate Product Code with class: \_\_\_\_\_ Additional Product Code(s) with panel (optional): \_\_\_\_\_

Review: \_\_\_\_\_  
 (Branch Chief) (Branch Code) (Date)

Final Review: \_\_\_\_\_  
 (Division Director) (Date)

## Ginyard, Valerie

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**From:** Ginyard, Valerie  
**Sent:** Wednesday, January 10, 2007 1:39 PM  
**To:** 'Ochs, Luann'  
**Subject:** K062925

Hi LuAnn;

As I mentioned in my phone message earlier today, we have a few additional concerns we need you to address.

(b) (4), (b) (5)

(b)(4), (b)(5)

Please respond to these issues in writing to

Food and Drug Administration  
Center for Devices and Radiological Health  
Office of In Vitro Device Evaluation and Safety  
Document Mail Center (HFZ-401)  
9200 Corporate Blvd  
Rockville, Maryland 20850

The submission will be placed on hold pending receipt of the requested additional information.

If you have any questions, please feel free to contact me.

Sincerely,

Valerie R. Ginyard  
Scientific Reviewer  
Division of Immunology and Hematology Devices  
Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)  
(240) 276-0443, X153  
fax: (240) 276-0663

THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify us by email or telephone.

## Ginyard, Valerie

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**From:** Russek-Cohen, Estelle  
**Sent:** Friday, January 05, 2007 5:26 PM  
**To:** Ginyard, Valerie  
**Cc:** DBS Reviews; Vishnuvajjala, R. Lakshmi; Bautista, Josephine  
**Subject:** Review of Roche Patient self-test K062925/S1

**Attachments:** review 010507.doc



review 010507.doc  
(38 KB)

Hi Valerie:

(b)(4), (b)(5)

(b)(4), (b)(5)

Josie: I probably need to talk with you about the HW assignment for the chempa submission...welcome back, happy new year and the vacation is over!

**Estelle Russek-Cohen, Ph.D.**

Team Leader and Mathematical Statistician  
Diagnostic Devices Branch  
Division of Biostatistics HFZ-550  
Office of Surveillance and Biometrics  
Center for Devices and Radiological Health  
1350 Piccard Drive  
Rockville MD 20850

eyr@cdrh.fda.gov  
Estelle.Russek-Cohen@fda.hhs.gov  
Phone 240-276-3043  
Fax 240-276-3131  
Division phone number 240-276-3133

Date: January 5, 2007

From: Mathematical Statistician (Estelle Russek-Cohen, PhD), HFZ-550  
DXDB/DBS/OSB

To: Valerie Dada  
DIHD/OIVD

Re: Statistical review of Response by Sponsor  
Roche CoaguChek XS System for Patient Self-Testing  
510(k) K062925/S1

Background

There were 11 questions posed by the sponsor. Only a few were related to statistics issues and I will focus my review on these (b)(4), (b)(5)

(b)(4), (b)(5) (b)(4), (b)(5)

Question 1 (b)(4), (b)(5) (b)(4), (b)(5)

(b)(4), (b)(5)  
(b)(4), (b)(5)

(b)(4), (b)(5)

Question 3. (b)(4), (b)(5) (b)(4), (b)(5)

(b)(4), (b)(5)  
(b)(4), (b)(5)

Question 4. (b)(4), (b)(5) (b)(4), (b)(5)  
(b)(4), (b)(5) (b)(4), (b)(5)

Question 5. (b)(4) (b)(4)  
(b)(4), (b)(5) (b)(4), (b)(5)  
(b)(4) (b)(4)

Question 7. (b)(4), (b)(5) (b)(4), (b)(5)

Question 8. (b)(4), (b)(5) (b)(4), (b)(5)  
(b)(4), (b)(5) (b)(4), (b)(5)

Question 9. (b)(4), (b)(5) (b)(4), (b)(5)  
(b)(4), (b)(5) (b)(4), (b)(5)

If I can be of any assistance, please do not hesitate to contact me at [eyr@cdrh.fda.gov](mailto:eyr@cdrh.fda.gov).

Cc: R. Lakshmi Vishnuvajjala  
J. Bautista

**CONSULTATIVE REVIEW MEMORANDUM**

DATE: January 04, 2007

TO: Valerie Dada  
Scientific Reviewer  
Hematology,DIHD,OIVD

FROM: Dave Li, M.D.  
Medical Officer  
OIVD/DIHD/IMDB  
Telephone: (240)276-0443 Ext. 151  
E-mail: [dai.li@fda.hhs.gov](mailto:dai.li@fda.hhs.gov)

SUBJECT: Review Issues K062925 S001  
Device Name: Roche Diagnostics CoaguChek<sup>®</sup> XS System for Patient  
Self-testing: Prothrombin Time

CONTACT: Jennifer Tribbert  
Regulatory Affair Principal  
Roche Diagnostics  
915 Hague Road  
P.O. Box 50457  
Indianapolis, IN 46250-0457  
Phone 317-576-3742  
Fax 317-576-2324

RECEIVED: December 13, 2006

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**I. BACKGROUND**

**A. Device description and principle**

A prothrombin time test is a device used as a general screening procedure for the detection of possible clotting factor deficiencies in the extrinsic coagulation pathway, which involves the reaction between coagulation factors III and VII, and to monitor patients receiving coumarin therapy (the administration of one of the coumarin anticoagulants in the treatment of venous thrombosis or pulmonary embolism).

The Roche Diagnostics CoaguChek<sup>®</sup> XS System is a third generation Roche Diagnostics's CoaguChek meter which was cleared for professional use under pre-market notification K060978.

## Ginyard, Valerie

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**From:** Li, Dai  
**Sent:** Thursday, January 04, 2007 11:37 AM  
**To:** Ginyard, Valerie  
**Cc:** Bautista, Josephine; Becker, Robert; Chan, Maria M  
**Subject:** K062925 S001 Roche Diagnostics CoaguChek® XS System for Patient Self-testing: Prothrombin Time

**Attachments:** K062925 S001 Roche CoaguCheckXS System PT for Patient Self Testing Review Issues 20070104.doc

Attached please find my comments on the Roche 510K.

Thanks,



K062925 S001  
Roche CoaguCheckX.

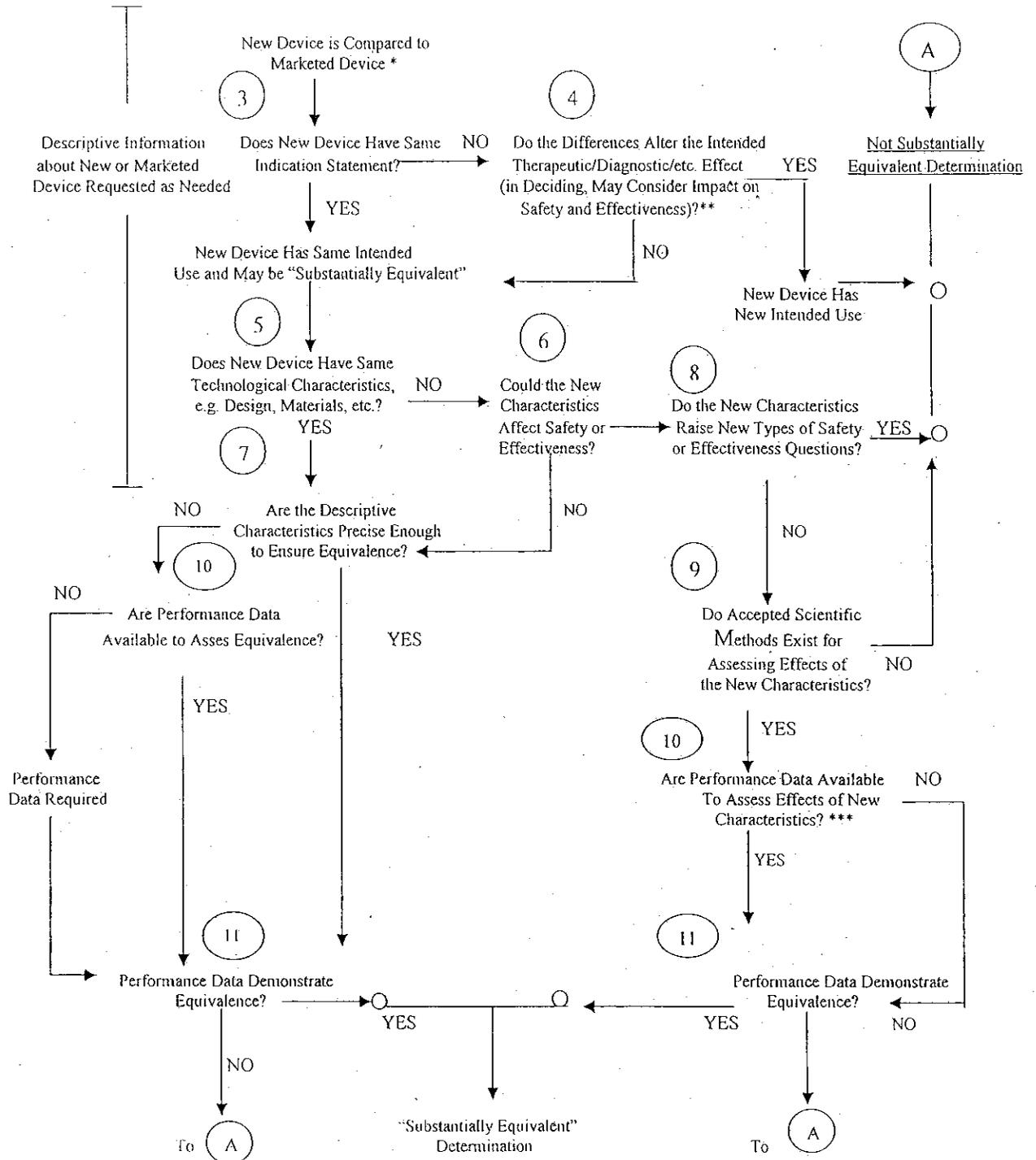
(b)(4), (b)(5)

(b)(4), (b)(5)

(b)(4), (b)(5)

(b)(4), (b)(5)

## 510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



\* 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

\*\* This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

\*\*\* Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.

REVISED:3/14/95

THE 510(K) DOCUMENTATION FORMS ARE AVAILABLE ON THE LAN UNDER 510(K) BOILERPLATES TITLED "DOCUMENTATION" AND MUST BE FILLED OUT WITH EVERY FINAL DECISION (SE, NSE, NOT A DEVICE, ETC.).

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K \_\_\_\_\_

Reviewer: \_\_\_\_\_

Division/Branch: \_\_\_\_\_

Device Name: \_\_\_\_\_

Product To Which Compared (510(K) Number If Known): \_\_\_\_\_

YES NO

	YES	NO	
1. Is Product A Device			If NO = Stop
2. Is Device Subject To 510(k)?			If NO = Stop
3. Same Indication Statement?			If YES = Go To 5
4. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If YES = Stop NE
5. Same Technological Characteristics?			If YES = Go To 7
6. Could The New Characteristics Affect Safety Or Effectiveness?			If YES = Go To 8
7. Descriptive Characteristics Precise Enough?			If NO = Go To 10 If YES = Stop SE
8. New Types Of Safety Or Effectiveness Questions?			If YES = Stop NE
9. Accepted Scientific Methods Exist?			If NO = Stop NE
10. Performance Data Available?			If NO = Request Data
11. Data Demonstrate Equivalence?			Final Decision:

Note: In addition to completing the form on the LAN, "yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation.

1. Intended Use:
2. Device Description: Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. Is the device life-supporting or life sustaining? Is the device implanted (short-term or long-term)? Does the device design use software? Is the device sterile? Is the device for single use? Is the device over-the-counter or prescription use? Does the device contain drug or biological product as a component? Is this device a kit? Provide a summary about the devices design, materials, physical properties and toxicology profile if important.

EXPLANATIONS TO "YES" AND "NO" ANSWERS TO QUESTIONS ON PAGE 1 AS NEEDED

1. Explain why not a device:
2. Explain why not subject to 510(k):
3. How does the new indication differ from the predicate device's indication:
4. Explain why there is or is not a new effect or safety or effectiveness issue:
5. Describe the new technological characteristics:
6. Explain how new characteristics could or could not affect safety or effectiveness:
7. Explain how descriptive characteristics are not precise enough:
8. Explain new types of safety or effectiveness questions raised or why the questions are not new:
9. Explain why existing scientific methods can not be used:
10. Explain what performance data is needed:
11. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

ATTACH ADDITIONAL SUPPORTING INFORMATION

## Internal Administrative Form

	YES	NO
1. Did the firm request expedited review?		
2. Did we grant expedited review?		
3. Have you verified that the Document is labeled Class III for GMP purposes?		
4. If, not, has POS been notified?		
5. Is the product a device?		
6. Is the device exempt from 510(k) by regulation or policy?		
7. Is the device subject to review by CDRH?		
8. Are you aware that this device has been the subject of a previous NSE decision?		
9. If yes, does this new 510(k) address the NSE issue(s), (e.g., performance data)?		
10. Are you aware of the submitter being the subject of an integrity investigation?		
11. If, yes, consult the ODE Integrity Officer.		
12. Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #191-2 and Federal Register 90N0332, September 10, 1991.		

## Dada, Valerie

---

**From:** Dada, Valerie  
**Sent:** Monday, November 13, 2006 11:10 AM  
**o:** 'Tribbett, Jennifer'  
**subject:** K062925- CoaguChek Home Use

Good Morning Jennifer;

I have completed my initial review of the Tina-Quant D-Dimer submission, and have the following concerns:

1. (b)(4), (b)(5)
2. (b)(4), (b)(5)
- 3.
- 4.
- 5.
- 6.
- 7.

- 8. (b)(4), (b)(5)
- 9. (b)(4), (b)(5)
- 10.
- 11.

Please respond to these issues in writing to

Food and Drug Administration  
Center for Devices and Radiological Health  
Office of In Vitro Device Evaluation and Safety  
Document Mail Center (HFZ-401)  
9200 Corporate Blvd  
Rockville, Maryland 20850

The submission will be placed on hold pending receipt of the requested additional information.

If you have any questions, please feel free to contact me.

Sincerely,

Valerie R. Dada Ginyard  
Scientific Reviewer  
Division of Immunology and Hematology Devices  
Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)  
(240) 276-0443, X153  
fax: (240) 276-0663

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration  
Center for Devices and Radiologic Health

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**Date:** 6 Nov 2006 **MEMORANDUM**

**To:** FILE K062925  
COAGUCHEK® XS SYSTEM  
ROCHE DIAGNOSTICS

**Subject:** Request for additional information

**From:** Valerie R. Dada Ginyard, DIHD Reviewer

The Roche CoaguChek XS is a portable prothrombin time (PT) meter intended to monitor patients on anticoagulation therapy (warfarin). It is intended for home users.

The device consists of a meter with and test strips. The test strips are made of human recombinant thromboplastin and incorporates on-board integrated quality controls which use electrochemical signals to detect test strip integrity.

(b)(4), (b)(5)

(b)(4), (b)(5)

The Sponsor will be asked to address the following:

1. (b)(4), (b)(5)

(b)(4), (b)(5)

2.

3.

**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service  
Food and Drug Administration  
Center for Devices and Radiological Health  
Office of In Vitro Diagnostic Device Evaluation and Safety

To: Lu Ann Ochs, Director Regulatory Affairs  
Roche Diagnostics

From: Valerie R. Dada  
Scientific Reviewer, DIHD

RE: I050128  
CoaguChek XS

Date: 26 May 2005

---

Dear Ms. Ochs,

Thank you for submitting this premarket application for our review. The purpose of the premarket application review by FDA staff is to give manufacturers an idea of the types of questions or concerns the agency is likely to express during the review of a submission. As a rule, FDA review of premarket applications lead to better prepared submissions and shorter review time.

This is an informal communication that represents the best judgment of the (Hematology/Pathology) staff and consultants who reviewed the submitted information. It does not constitute an advisory opinion and does not bind or otherwise obligate or commit the agency to the views expressed, as per 21 CFR 10.85(k).

With the understanding that the study for which you have submitted this protocol has not yet started, we have provided the following evaluation of your proposed protocol.

**Comments:**

1. (b)(4), (b)(5)  

(b)(4), (b)(5)
- 2.

3. (b)(4), (b)(5)

4.

(b)(4), (b)(5)

5.

6.

(b)(4), (b)(5)

(b)(4), (b)(5)

You have also requested to be exempt from conducting a post-market study for this device. Because this will be a newly marketed device with new technology and you are proposing a patient self training program, we feel that post market studies are warranted for this device.

Thank you for allowing us to assist you with your protocol. Our comments and suggestions are strictly for your assistance. You are not required to respond. However, if you would like to respond please submit any revisions in triplicate to the address below. Please reference the pre-IDE number above to facilitate processing:

Document Mail Center (HFZ-401)  
Center for Devices and Radiological Health  
Food and Drug Administration  
9200 Corporate Blvd.  
Rockville, MD 20850

If you have any questions or comments regarding this review, please contact Valerie R. Dada at 240-276-0443 ext.162.

Date: October 30, 2006

From: Mathematical Statistician (Estelle Russek-Cohen, PhD), HFZ-550  
DXDB/DBS/OSB

To: Valerie Dada  
DIHD/OIVD

Re: Statistical Review of 510(k) K062925  
Coaguchek XS PST  
Roche Diagnostics Corp, Indianapolis, IN 46250

### Background

The Roche Coaguchek XS PST is a submission for an already 510(k) cleared device. The purpose of this submission is to extend the intended use of the device for patient self-testing. The device measures prothrombin time and INR (an index calculated from the prothrombin time result).

(b)(4), (b)(5)

(b)(4), (b)(5)

Pages 178 through 180 redacted for the following reasons:

-----  
Study Data, b4

**CONSULTATIVE REVIEW MEMORANDUM**

DATE: November 3, 2006

TO: Valerie Dada  
Scientific Reviewer  
Hematology,DIHD,OIVD

FROM: Dave Li, M.D., Ph.D., FACB  
Medical Officer  
OIVD/DIHD/IMDB  
Telephone: (240)276-0443 Ext. 151  
E-mail: [dai.li@fda.hhs.gov](mailto:dai.li@fda.hhs.gov)

SUBJECT: Review Issues K062925  
Device Name: Roche Diagnostics CoaguChek<sup>®</sup> XS System for Patient  
Self-testing: Prothrombin Time

CONTACT: Jennifer Tribbert  
Regulatory Affair Principal  
Roche Diagnostics  
915 Hague Road  
P.O. Box 50457  
Indianapolis, IN 46250-0457  
Phone 317-576-3742  
Fax 317-576-2324

RECEIVED: October 18, 2006

---

**I. BACKGROUND**

**A. Device description and principle**

A prothrombin time test is a device used as a general screening procedure for the detection of possible clotting factor deficiencies in the extrinsic coagulation pathway, which involves the reaction between coagulation factors III and VII, and to monitor patients receiving coumarin therapy (the administration of one of the coumarin anticoagulatants in the treatment of venous thrombosis or pulmonary embolism).

The Roche Diagnostics CoaguChek<sup>®</sup> XS System is a third generation Roche Diagnostics's CoaguChek meter which was cleared for professional use under pre-market notification K060978.

This system is identical in materials (test strip and meter), design and function to the CoaguChek XS system described in K060978. However, the labeling has been modified for patient self-testing use.

**B. Intended use**

The CoaguChek XS System measures blood-clotting time (Prothrombin Time) for people who are taking anticoagulation medications such as Coumadin<sup>®</sup> or warfarin. The CoaguChek XS System measures blood-clotting time using blood from the fingertip.

**C. Reason for submission**

This pre-marker notification is being submitted to obtain clearance for patient testing.

**D. Predicate device**

Roche Diagnostics CoaguChek<sup>®</sup> XS System (professional) K060978.

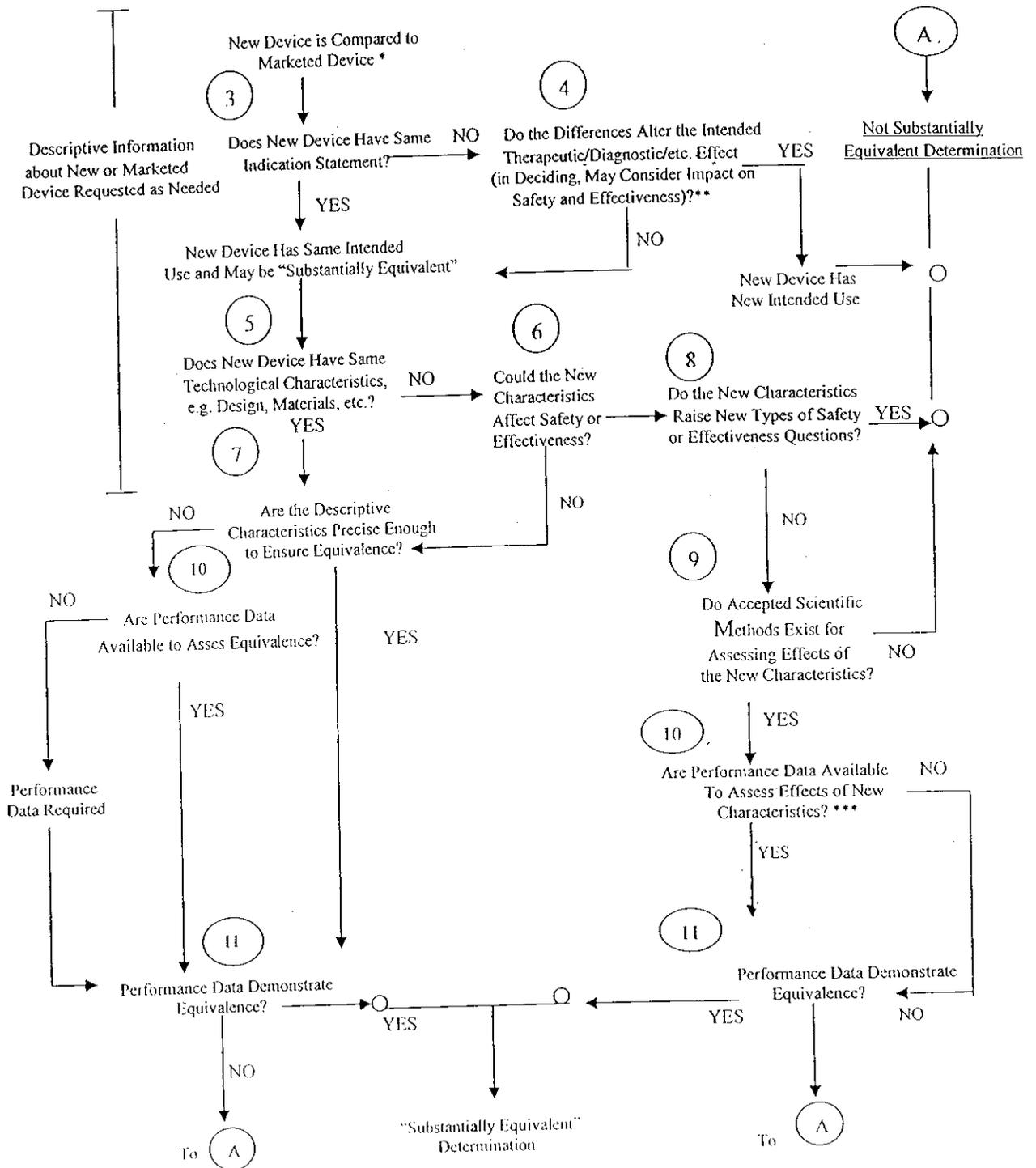
(b)(4), (b)(5)

(b)(4), (b)(5)

(b)(4), (b)(5)

(b)(4), (b)(5)

## 510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



- \* 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.
- \*\* This decision is normally based on descriptive information alone, but limited testing information is sometimes required.
- \*\*\* Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.

## Internal Administrative Form

	YES	NO
1. Did the firm request expedited review?		
2. Did we grant expedited review?		
3. Have you verified that the Document is labeled Class III for GMP purposes?		
4. If, not, has POS been notified?		
5. Is the product a device?		
6. Is the device exempt from 510(k) by regulation or policy?		
7. Is the device subject to review by CDRH?		
8. Are you aware that this device has been the subject of a previous NSE decision?		
9. If yes, does this new 510(k) address the NSE issue(s), (e.g., performance data)?		
10. Are you aware of the submitter being the subject of an integrity investigation?		
11. If, yes, consult the ODE Integrity Officer.		
12. Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #I91-2 and Federal Register 90N0332, September 10, 1991.		

**SCREENING CHECKLIST  
FOR ALL PREMARKET NOTIFICATION [510(k)] SUBMISSIONS**

510(k) Number: \_\_\_\_\_

The cover letter clearly identifies the type of 510(k) submission as (Check the appropriate box):

- Special 510(k) - Do Sections 1 and 2
- Abbreviated 510(k) - Do Sections 1, 3 and 4
- Traditional 510(k) or no identification provided - Do Sections 1 and 4

**Section 1: Required Elements for All Types of 510(k) submissions:**

	Present or Adequate	Missing or Inadequate
Cover letter, containing the elements listed on page 3-2 of the Premarket Notification [510] Manual.		
Table of Contents.		
Truthful and Accurate Statement.		
Device's Trade Name, Device's Classification Name and Establishment Registration Number.		
Device Classification Regulation Number and Regulatory Status (Class I, Class II, Class III or Unclassified).		
Proposed Labeling including the material listed on page 3-4 of the Premarket Notification [510] Manual.		
Statement of Indications for Use that is on a separate page in the premarket submission.		
Substantial Equivalence Comparison, including comparisons of the new device with the predicate.		
510(k) Summary or 510(k) Statement.		
Description of the device (or modification of the device) including diagrams, engineering drawings, photographs or service manuals.		
Identification of legally marketed predicate device. *		
Compliance with performance standards. * [See Section 514 of the Act and 21 CFR 807.87 (d).]		
Class III Certification and Summary. **		
Financial Certification or Disclosure Statement for 510(k) notifications with a clinical study. * [See 21 CFR 807.87 (i)].		
510(k) Kit Certification ***		

- \* - May not be applicable for Special 510(k)s.
- \*\* - Required for Class III devices, only.
- \*\*\* - See pages 3-12 and 3-13 in the Premarket Notification [510] Manual and the Convenience Kits Interim Regulatory Guidance.

**Section 2: Required Elements for a SPECIAL 510(k) submission:**

	Present	Inadequate or Missing
Name and 510(k) number of the submitter's own, unmodified predicate device.		
A description of the modified device and a comparison to the sponsor's predicate device.		
A statement that the intended use(s) and indications of the modified device, as described in its labeling are the same as the intended uses and indications for the submitter's unmodified predicate device.		
Reviewer's confirmation that the modification has not altered the fundamental scientific technology of the submitter's predicate device.		
A Design Control Activities Summary that includes the following elements (a-c):		
a. Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis.		
b. Based on the Risk Analysis, an identification of the required verification and validation activities, including the methods or tests used and the acceptance criteria to be applied.		
c. A Declaration of Conformity with design controls that includes the following statements:		
A statement that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results of the activities demonstrated that the predetermined acceptance criteria were met. This statement is signed by the individual responsible for those particular activities.		
A statement that the manufacturing facility is in conformance with the design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review. This statement is signed by the individual responsible for those particular activities.		

**Section 3: Required Elements for an ABBREVIATED 510(k)\* submission:**

	Present	Inadequate or Missing
For a submission, which relies on a guidance document and/or special control(s), a summary report that describes how the guidance and/or special control(s) was used to address the risks associated with the particular device type. (If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.)		
For a submission, which relies on a recognized standard, a declaration of conformity [For a listing of the required elements of a declaration of conformity, SEE Required Elements for a Declaration of Conformity to a Recognized Standard, which is posted with the 510(k) boilers on the H drive.]		

For a submission, which relies on a recognized standard without a declaration of conformity, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has <u>not</u> been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device and any additional information requested by the reviewer in order to determine substantial equivalence.		
Any additional information, which is not covered by the guidance document, special control, recognized standard and/or non-recognized standard, in order to determine substantial equivalence.		

- \* - When completing the review of an abbreviated 510(k), please fill out an Abbreviated Standards Data Form (located on the H drive) and list all the guidance documents, special controls, recognized standards and/or non-recognized standards, which were noted by the sponsor.

**Section 4: Additional Requirements for ABBREVIATED and TRADITIONAL 510(k) submissions (If Applicable):**

	Present	Inadequate or Missing
a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation:		
b) Sterilization and expiration dating information:		
i) sterilization process		
ii) validation method of sterilization process		
iii) SAL		
iv) packaging		
v) specify pyrogen free		
vi) ETO residues		
vii) radiation dose		
viii) Traditional Method or Non-Traditional Method		
c) Software Documentation:		

*Items with checks in the "Present or Adequate" column do not require e additional information from the sponsor. Items with checks in the "Missing or Inadequate" column must be submitted before substantive review of the document.*

Passed Screening \_\_\_ Yes \_\_\_ No

Reviewer: \_\_\_\_\_

Concurrence by Review Branch: \_\_\_\_\_

Date: \_\_\_\_\_

The deficiencies identified above represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: <http://www.fda.gov/cdrh/modact/leastburdensome.html>

THE 510(K) DOCUMENTATION FORMS ARE AVAILABLE ON THE LAN UNDER 510(K) BOILERPLATES TITLED "DOCUMENTATION" AND MUST BE FILLED OUT WITH EVERY FINAL DECISION (SE, NSE, NOT A DEVICE, ETC.).

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K \_\_\_\_\_

Reviewer: \_\_\_\_\_

Division/Branch: \_\_\_\_\_

Device Name: \_\_\_\_\_

Product To Which Compared (510(K) Number If Known): \_\_\_\_\_

	YES	NO	
1. Is Product A Device			If NO = Stop
2. Is Device Subject To 510(k)?			If NO = Stop
3. Same Indication Statement?			If YES = Go To 5
4. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If YES = Stop NE
5. Same Technological Characteristics?			If YES = Go To 7
6. Could The New Characteristics Affect Safety Or Effectiveness?			If YES = Go To 8
7. Descriptive Characteristics Precise Enough?			If NO = Go To 10 If YES = Stop SE
8. New Types Of Safety Or Effectiveness Questions?			If YES = Stop NE
9. Accepted Scientific Methods Exist?			If NO = Stop NE
10. Performance Data Available?			If NO = Request Data
11. Data Demonstrate Equivalence?			Final Decision:

Note: In addition to completing the form on the LAN, "yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation.

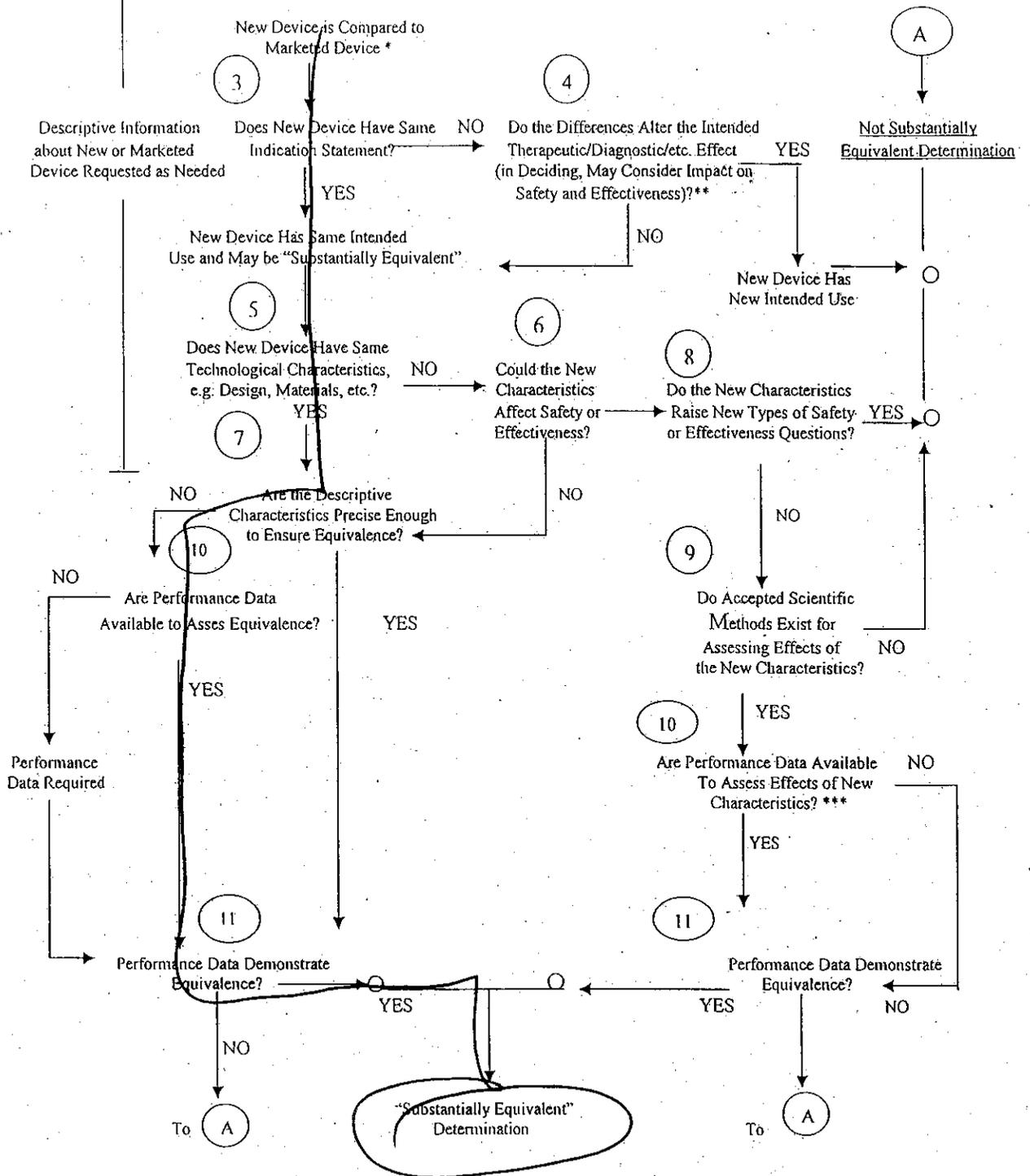
1. Intended Use:
2. Device Description: Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. Is the device life-supporting or life sustaining? Is the device implanted (short-term or long-term)? Does the device design use software? Is the device sterile? Is the device for single use? Is the device over-the-counter or prescription use? Does the device contain drug or biological product as a component? Is this device a kit? Provide a summary about the device's design, materials, physical properties and toxicology profile if important.

EXPLANATIONS TO "YES" AND "NO" ANSWERS TO QUESTIONS ON PAGE 1 AS NEEDED

1. Explain why not a device:
2. Explain why not subject to 510(k):
3. How does the new indication differ from the predicate device's indication:
4. Explain why there is or is not a new effect or safety or effectiveness issue:
5. Describe the new technological characteristics:
6. Explain how new characteristics could or could not affect safety or effectiveness:
7. Explain how descriptive characteristics are not precise enough:
8. Explain new types of safety or effectiveness questions raised or why the questions are not new:
9. Explain why existing scientific methods can not be used:
10. Explain what performance data is needed:
11. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

ATTACH ADDITIONAL SUPPORTING INFORMATION

## 510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



\* 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

\*\* This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

\*\*\* Data may be in the 510(k), other 510(k)s, the Center's classification files, or the literature.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration  
Memorandum

From: Reviewer(s) - Name(s) Valerie B. Doda  
Subject: 510(k) Number 1K062925

To: The Record - It is my recommendation that the subject 510(k) Notification:

- Refused to accept.
- Requires additional information (other than refuse to accept).
- Is substantially equivalent to marketed devices.
- NOT substantially equivalent to marketed devices.
- Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Is this device subject to Section 522 Postmarket Surveillance?	<input type="checkbox"/> YES	<input type="checkbox"/> NO
Is this device subject to the Tracking Regulation?	<input type="checkbox"/> YES	<input type="checkbox"/> NO
Was clinical data necessary to support the review of this 510(k)?	<input type="checkbox"/> YES	<input type="checkbox"/> NO
Is this a prescription device?	<input type="checkbox"/> YES	<input type="checkbox"/> NO
Was this 510(k) reviewed by a Third Party?	<input type="checkbox"/> YES	<input type="checkbox"/> NO
Special 510(k)?	<input type="checkbox"/> YES	<input type="checkbox"/> NO
Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers	<input type="checkbox"/> YES	<input type="checkbox"/> NO

- Truthful and Accurate Statement  Requested  Enclosed
- A 510(k) summary OR  A 510(k) statement
- The required certification and summary for class III devices
- The indication for use form

Combination Product Category (Please see algorithm on H drive 510k/Boilers) \_\_\_\_\_

Animal Tissue Source  YES  NO Material of Biological Origin  YES  NO

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

- No Confidentiality
- Confidentiality for 90 days
- Continued Confidentiality exceeding 90 days

Predicate Product Code with class: \_\_\_\_\_ Additional Product Code(s) with panel (optional): \_\_\_\_\_

Review: \_\_\_\_\_ (Branch Chief) \_\_\_\_\_ (Branch Code) \_\_\_\_\_ (Date)

Final Review: \_\_\_\_\_ (Division Director) \_\_\_\_\_ (Date)

---

Food and Drug Administration  
Center for Devices and  
Radiological Health  
Office of Device Evaluation  
Document Mail Center (HFZ-401)  
9200 Corporate Blvd.  
Rockville, Maryland 20850

December 12, 2006

ROCHE DIAGNOSTICS CORP.  
PROFESSIONAL DIAGNOSTICS  
9115 HAGUE RD.  
INDIANAPOLIS, IN 46256  
ATTN: THERESA BUSH

510(k) Number: K062925  
Product: COAGUCHEK XS  
SYSTEM

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at [www.fda.gov/cdrh/ode/a02-01.html](http://www.fda.gov/cdrh/ode/a02-01.html). On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at <http://www.fda.gov/cdrh/ode/guidance/1567.html>. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so in 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

If you have procedural or policy questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (240)276-4040.

Sincerely yours,

Marjorie Shulman  
Supervisory Consumer Safety Officer  
Premarket Notification Section  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

K062925/S1

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION <b>CDRH PREMARKET REVIEW SUBMISSION COVER SHEET</b>	Form Approval OMB No. 9010-0120 Expiration Date: May 31, 2007. See OMB Statement on page 5.
--	--

Date of Submission December 11, 2006	User Fee Payment ID Number n/a	FDA Submission Document Number (if known) K062925
---	-----------------------------------	--

SECTION A					TYPE OF SUBMISSION				
<b>PMA</b> <input type="checkbox"/> Original Submission <input type="checkbox"/> Premarket Report <input type="checkbox"/> Modular Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment <input type="checkbox"/> Licensing Agreement	<b>PMA &amp; HDE Supplement</b> <input type="checkbox"/> Regular (180 day) <input type="checkbox"/> Special <input type="checkbox"/> Panel Track (PMA Only) <input type="checkbox"/> 30-day Supplement <input type="checkbox"/> 30-day Notice <input type="checkbox"/> 135-day Supplement <input type="checkbox"/> Real-time Review <input type="checkbox"/> Amendment to PMA & HDE Supplement <input type="checkbox"/> Other	<b>PDP</b> <input type="checkbox"/> Original PDP <input type="checkbox"/> Notice of Completion <input type="checkbox"/> Amendment to PDP	<b>510(k)</b> <input type="checkbox"/> Original Submission: <input type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated (Complete section I, Page 5) <input checked="" type="checkbox"/> Additional Information <input type="checkbox"/> Third Party	<b>Meeting</b> <input type="checkbox"/> Pre-510(K) Meeting <input type="checkbox"/> Pre-IDE Meeting <input type="checkbox"/> Pre-PMA Meeting <input type="checkbox"/> Pre-PDP Meeting <input type="checkbox"/> Day 100 Meeting <input type="checkbox"/> Agreement Meeting <input type="checkbox"/> Determination I <input type="checkbox"/> Other (specify):					
<b>IDE</b> <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement	<b>Humanitarian Device Exemption (HDE)</b> <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment	<b>Class II Exemption Petition</b> <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	<b>Evaluation of Automatic Class III Designation (De Novo)</b> <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	<b>Other Submis:</b> <input type="checkbox"/> 513(g) <input type="checkbox"/> Other (describe subn)					

Have you used or cited Standards in your submission?  Yes  No (If Yes, please complete Section I, Page 5)

SECTION B	SUBMITTER, APPLICANT OR SPONSOR
-----------	---------------------------------

Company / Institution Name Roche Diagnostics	Establishment Registration Number (if known) 1823260		
Division Name (if applicable) Professional Diagnostics	Phone Number (including area code) ( 317 ) 521-3742		
Street Address 9115 Hague Road	FAX Number (including area code) ( 317 ) 521-2324		
City Indianapolis	State / Province IN	ZIP/Postal Code 46256	Country USA
Contact Name Tracy Bush / Luann Ochs			
Contact Title Regulatory Affairs Principal	Contact E-mail Address Tracy.bush@roche.com; luann.ochs@roche.com		

SECTION C	APPLICATION CORRESPONDENT (e.g., consultant, if different from above)
-----------	---

Company / Institution Name			
Division Name (if applicable)	Phone Number (including area code) ( )		
Street Address	FAX Number (including area code) ( )		

K22

City	State / Province	ZIP/Postal Code	Country
Contact Name			
Contact Title	Contact E-mail Address		

**SECTION D1**

**REASON FOR APPLICATION - PMA, PDP, OR HDE**

<input type="checkbox"/> Withdrawal <input type="checkbox"/> Additional or Expanded Indications <input type="checkbox"/> Request for Extension <input type="checkbox"/> Post-approval Study Protocol <input type="checkbox"/> Request for Applicant Hold <input type="checkbox"/> Request for Removal of Applicant Hold <input type="checkbox"/> Request to Remove or Add Manufacturing Site	<input type="checkbox"/> Change in design, component, or specification: <input type="checkbox"/> Software / Hardware <input type="checkbox"/> Color Additive <input type="checkbox"/> Material <input type="checkbox"/> Specifications <input type="checkbox"/> Other ( <i>specify below</i> )  Other ( <i>specify below</i> )	<input type="checkbox"/> Location change: <input type="checkbox"/> Manufacturer <input type="checkbox"/> Sterilizer <input type="checkbox"/> Packager
<input type="checkbox"/> Process change: <input type="checkbox"/> Manufacturing <input type="checkbox"/> Sterilization <input type="checkbox"/> Packaging <input type="checkbox"/> Other ( <i>specify below</i> )	<input type="checkbox"/> Labeling change: <input type="checkbox"/> Indications <input type="checkbox"/> Instructions <input type="checkbox"/> Performance <input type="checkbox"/> Shelf Life <input type="checkbox"/> Trade Name <input type="checkbox"/> Other ( <i>specify below</i> )	<input type="checkbox"/> Report Submission: <input type="checkbox"/> Annual or Periodic <input type="checkbox"/> Post-approval Study <input type="checkbox"/> Adverse Reaction <input type="checkbox"/> Device Defect <input type="checkbox"/> Amendment
<input type="checkbox"/> Response to FDA correspondence:		<input type="checkbox"/> Change in Ownership <input type="checkbox"/> Change in Correspondent <input type="checkbox"/> Change of Applicant Address
<input type="checkbox"/> Other Reason ( <i>specify</i> ):		

**SECTION D2**

**REASON FOR APPLICATION - IDE**

<input type="checkbox"/> New Device <input type="checkbox"/> New Indication <input type="checkbox"/> Addition of Institution <input type="checkbox"/> Expansion / Extension of Study <input type="checkbox"/> IRB Certification <input type="checkbox"/> Termination of Study <input type="checkbox"/> Withdrawal of Application <input type="checkbox"/> Unanticipated Adverse Effect <input type="checkbox"/> Notification of Emergency Use <input type="checkbox"/> Compassionate Use Request <input type="checkbox"/> Treatment IDE <input type="checkbox"/> Continued Access  Request for Removal of Applicant Hold	<input type="checkbox"/> Change in: <input type="checkbox"/> Correspondent / Applicant <input type="checkbox"/> Design / Device <input type="checkbox"/> Informed Consent <input type="checkbox"/> Manufacturer <input type="checkbox"/> Manufacturing Process <input type="checkbox"/> Protocol - Feasibility <input type="checkbox"/> Protocol - Other <input type="checkbox"/> Sponsor  <input type="checkbox"/> Report submission: <input type="checkbox"/> Current Investigator <input type="checkbox"/> Annual Progress Report <input type="checkbox"/> Site Waiver Report <input type="checkbox"/> Final	<input type="checkbox"/> Repose to FDA Letter Concerning: <input type="checkbox"/> Conditional Approval <input type="checkbox"/> Deemed Approved <input type="checkbox"/> Deficient Final Report <input type="checkbox"/> Deficient Progress Report <input type="checkbox"/> Deficient Investigator Report <input type="checkbox"/> Disapproval <input type="checkbox"/> Request Extension of Time to Respond to FDA <input type="checkbox"/> Request Meeting <input type="checkbox"/> Request Hearing  Manufacturer
<input type="checkbox"/> Other Reason ( <i>specify</i> ):		

SECTION D3

REASON FOR SUBMISSION - 510(k)

New Device

Additional or Expanded Indications

Change in Technology

Other Reason (*specify*):

**SECTION E**

**ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS**

Product codes of devices to which substantial equivalence is claimed

1	GJS	2		3		4	
5		6		7		8	

Summary of, or statement conc

safety and effectiveness info

- 510 (k) summary attached
- 510 (k) statement

Information on devices to which substantial equivalence is claimed (if known)

	510(k) Number		Trade or Proprietary or Model Name		Manufacturer
1	K060978	1	CoaguChek XS System	1	Roche Diagnostics
2		2		2	
3		3		3	
4		4		4	
5		5		5	
6		6		6	

**SECTION F**

**PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS**

Common or usual name or classification

Prothrombin time test

	Trade or Proprietary or Model Name for This Device		Model Number
1	CoaguChek® XS System	1	
2		2	
3		3	
4		4	
5		5	

FDA document numbers of all prior related submissions (regardless of outcome)

1	K060978	2		3		4		5		6	
---	---------	---	--	---	--	---	--	---	--	---	--

98

7	8	9	10	11	12
---	---	---	----	----	----

Data Included in Submission

Laboratory Testing

Animal Trials

Human Trials

**SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS**

Product Code

GJS

C.F.R. Section (if applicable)

21 CFR 864.7750

Device Class

Class I

Class II

Class III

Unclassified

Classification Panel

Hematology

Indications (from labeling)

**The CoaguChek XS System measures blood-clotting time (Prothrombin Time) for people who are taking anticoagulation medications such as Coumadin® or warfarin. The CoaguChek XS System measures blood clotting time using blood from the fingertip.**

(Wording has been simplified compared to the wording in the professional insert in order to achieve the appropriate reading level required for home testers.)

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.

FDA Document Number (if known)

**SECTION HMANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION**

<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		FDA Establishment Registration Number <b>9610126</b>		<input checked="" type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler	
Company / Institution Name <b>Roche Diagnostics GmbH</b>			Establishment Registration Number <b>9610126</b>		
Division Name (if applicable) <b>Professional Diagnostics</b>			Phone Number (including area code) <b>( 317 ) 521-3742 (in the U.S.)</b>		
Street Address <b>Sandhofer Strasse 116</b>			FAX Number (including area code) <b>( 317 ) 521-2324 (in the U.S.)</b>		
City <b>Mannheim</b>		State / Province	ZIP/Postal Code <b>D-68298</b>	Country <b>German</b>	
Contact Name <b>Jennifer Tribbett (in the U.S.)</b>		Contact Title <b>Regulatory Affairs Principal</b>		Contact E-mail Address <b>Jennifer.tribbett@roche.</b>	

**SECTION HMANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION**

<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		FDA Establishment Registration Number		<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler	
Company / Institution Name			Establishment Registration Number		
Division Name (if applicable)			Phone Number (including area code) (   )		
Street Address			FAX Number (including area code) (   )		
City		State / Province	ZIP/Postal Code	Country	
Contact Name		Contact Title		Contact E-mail Address	

**SECTION HMANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION**

<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		FDA Establishment Registration Number		<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler	
Company / Institution Name			Establishment Registration Number		
Division Name (if applicable)			Phone Number (including area code)		

		(      )	
Street Address		FAX Number <i>(including area code)</i> (      )	
City		State / Province	ZIP/Postal Code      Country
Contact Name	Contact Title	Contact E-mail Address	



**SECTION I**

**UTILIZATION OF STANDARDS**

Note: Complete this section if your application or submission cites standards or includes a "Declaration of Conformity to a Recognized Standard" statement.

1	Standards No.	Standards Organization	Standards Title	Version	Date
2	Standards No.	Standards Organization	Standards Title	Version	Date
3	Standards No.	Standards Organization	Standards Title	Version	Date
4	Standards No.	Standards Organization	Standards Title	Version	Date
5	Standards No.	Standards Organization	Standards Title	Version	Date
6	Standards No.	Standards Organization	Standards Title	Version	Date

	Standards No.	Standards Organization	Standards Title	Version	Date
7					

Please include any additional standards to be cited on a separate page.

**Public reporting burden for this collection of information** is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Food and Drug Administration  
 CDRH (HFZ-342)  
 9200 Corporate Blvd.  
 Rockville, MD 20850

*An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control*

## **Additional Information for K062925 (Roche Diagnostics CoaguChek XS System for Patient Self-Testing)**

---

**Overview** This additional information supplement contains the answers to the questions posed by Valerie Dada via e-mail on November 10, 2006

---

### **FDA Question 1**

---

**Question 1** You propose to eliminate the training provided by the health care provider, and allow patients to self-train, which is a significant departure from current recommendations, and raises new concerns of safety and effectiveness

We currently recommend that manufacturers of home use PT devices provide training material to healthcare providers (HCP) to ensure that potential users are properly trained to use the PT device. Given that the CoaguChek XS has just recently been cleared by the FDA (August 2006) and we have no history of performance for the device, and that the CoaguChek XS incorporates a new technology for you, and given the compliance and post-market study issues with your previous home use PT device, we have concerns regarding the safe use of this device.

Therefore, we recommend that you provide a training guide to be used by the healthcare professional to train potential patients. This manual should follow 21 CFR 809.10(b), and should include information describing the clinical trial (patient demographics, failure rates, etc.), the intended target population, and device performance related to the clinical trial. The manual should state that patients should be stabilized on oral anticoagulation therapy before being trained for this device, describe the patient training program, and state that patients should undergo training, demonstrate proficiency, and have at least two follow-up visits prior to being allowed to self-test unsupervised. The Professional training manual should also include a recommendation that proficiency checks should be performed at six-month intervals in which the HCP checks the patient's monitor and observes the patient performing a blood test. Include a log sheet/checklist outlining all elements that the patient must demonstrate proficiency before being allowed to self-test.

---

**Roche response** Attached please find a health care provider training manual containing the requested information.

Please note that six pages are blank. These pages are 'left-hand/ facing' pages and will remain blank in the assembled, double-sided guide; except for a page number.

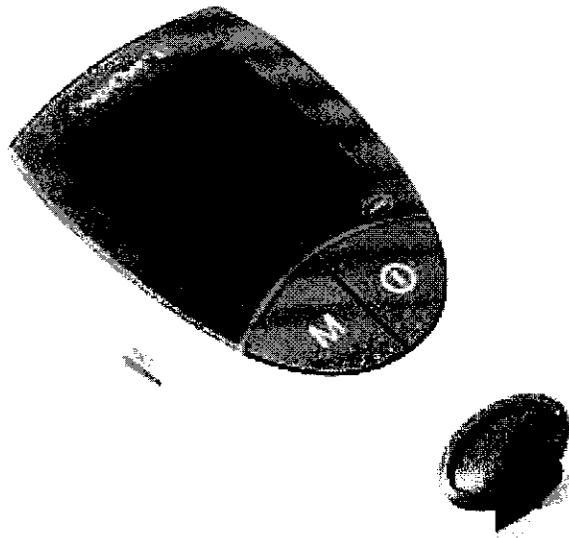
---

# CoaguChek<sup>®</sup> XS System

Professional

Training Manual

for Self-Testing



# Table of Contents

	<b>Introduction .....</b>	<b>1</b>
<b>1</b>	<b>Overview of Warfarin Therapy and the CoaguChek XS System.....</b>	<b>3</b>
<b>2</b>	<b>Materials for User Training .....</b>	<b>5</b>
<b>3</b>	<b>User Selection Guidelines .....</b>	<b>7</b>
	Overview .....	7
	Clinical Study .....	8
	Performance Characteristics.....	9
<b>4</b>	<b>Training Users for Self-Testing .....</b>	<b>11</b>
	Preparation .....	11
	Supplies .....	11
	Training Outline .....	12
	Testing the Trainees.....	18
	<i>Certificate of Completion</i> .....	18
	Follow-up Visits .....	18
<b>5</b>	<b>Proficiency Checks.....</b>	<b>19</b>
<b>6</b>	<b>Forms .....</b>	<b>21</b>

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573-34375

## Introduction

### Introduction

Roche Diagnostics is pleased to present this guide to assist you in training individuals in the use of the CoaguChek® XS System. The guide contains a variety of materials to help you plan the curriculum:

- an overview of the CoaguChek XS System
- a description of training materials available from Roche Diagnostics
- a guide to selecting appropriate individuals to participate in self-testing
- a suggested outline for the training class
- *Skills Checklist* and *Knowledge Test*
- *Certificate of Completion* to be given to trainees
- suggestions for refresher training.

If you have questions, please contact the Roche Diagnostics Technical Service Center 1-800-428-4674, 24 hours a day, 7 days a week, 365 days a year.

### Obtaining CoaguChek XS Meters for Users

Roche Diagnostics uses a network of certified national distributors to assist you with acquiring a CoaguChek XS System for your users. Contact your Roche Account Manager or the Roche Diagnostics Technical Service Center at 1-800-428-4674, 24 hours a day, 7 days a week, 365 days a year. Potential users who will be self-testing must have a doctor's prescription for the CoaguChek XS meter and complete a training program offered through an approved Roche distributor.



## Overview of Warfarin Therapy and the CoaguChek XS System

### OVERVIEW

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The CoaguChek XS System from Roche Diagnostics measures blood-clotting time for people who are taking anticoagulation medications such as warfarin (for example Coumadin®). Warfarin is an oral anticoagulant that changes the formation of certain blood factors produced in the liver in such a way that the clotting time is slowed. (Refer to the latest warfarin package insert for contraindications.) The goal is to prevent clots from forming or moving. At the same time, however, it is important to avoid excessive anticoagulation, or blood thinning, which carries a risk of hemorrhage.

People on warfarin therapy must be monitored closely for two reasons. First, as indicated above, it is very important to keep blood coagulation time within an optimal therapeutic, or target, range. Second, each individual reacts differently to warfarin, and the medication's ability to prevent a clot is affected by a person's metabolism, diet, and other medications.

The variability of laboratory results due to reagent differences is a common problem. The CoaguChek XS System minimizes the variability that is seen with traditional PT/INR assay reagents. Each lot of test strips is compared to a reference material by Roche Diagnostics. The strips are then assigned a "code," which standardizes the reported result via a mathematical algorithm, thus minimizing lot-to-lot variability. No manual calibration of the system is required; each lot of strips comes with a code chip that stores the information needed for automatic calibration.

The CoaguChek XS System offers significant advantages in both convenience and reliability. It is a hand-held, battery-operated system that can perform a PT/INR blood test on a fresh whole blood sample from a fingerstick. A test strip is inserted into the meter and a blood sample applied to the strip. The test result is displayed in about one minute. The need for trips to the laboratory or for venipuncture is virtually eliminated.

The CoaguChek System by Roche Diagnostics has been used successfully since 1994 by health care professionals in anticoagulation clinics, physicians' offices, and home health agencies and since 1997 for self-testing. Now, there is the CoaguChek XS System available for self-testing. The materials that follow are designed to help you select appropriate users and train them to use the CoaguChek XS System properly.

158

# 2

## Materials for User Training

Roche Diagnostics has developed the following materials, provided in the product care kit, specifically for your use in training new users to self-test with the CoaguChek XS System:

### **Training DVD**

This program, which runs approximately 15 minutes, provides step-by-step instruction in setting up the meter, preparing for and performing a fingerstick blood test, running quality control checks, and cleaning the meter. It is intended to be the basis of the training session. You may also use the DVD as a trainee selection aid; individuals who are unsure of what self-testing involves may be shown the DVD to help them decide if they want to go through training and try self-testing.

### **CoaguChek XS System User Manual**

A copy of the manual is provided with each CoaguChek XS Meter. It is intended to be used as an ongoing reference guide by users, but should also be used in training to familiarize trainees with the content and structure of the manual and make them comfortable with referring to it.

### **Getting Started Guide**

A Getting Started reference guide is included in each CoaguChek XS System Care Kit. It provides an easy reference for testing.

### **Package Inserts**

Both the test strips and lancet device have package inserts with information about proper storage and use. It is important to call the users' attention to the inserts during training.

To order additional copies of any of these materials, or to make comments or suggestions about the training materials, please contact the Roche Diagnostics Technical Service Center 1-800-428-4674, 24 hours a day, 7 days a week, 365 days a year.

# 3

## User Selection Guidelines

### OVERVIEW

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It is important that users be screened carefully before beginning a self-testing program. The following questions are designed to guide the physician, clinic nurse, or other health care professional in determining an individual's suitability for self-testing.

**Are specific diagnoses more appropriate for self-testing?**

No, the specific diagnosis is not necessarily indicative of who should or should not self-test. However, prior to beginning self-testing, users should be stabilized on anticoagulation medications such as warfarin. People with chronic conditions (for example, congestive heart failure, atrial fibrillation, prosthetic heart valve replacement) who will need frequent monitoring over a long period of time are certainly candidates for self-testing.

**What personal characteristics must the potential user have?**

The person must be reliable, compliance-oriented, and able to follow instructions.

**What do I look for in judging these characteristics?**

Consider the following:

- Does the person keep appointments?
- Does he or she comply with medication dosing and other elements of the treatment regimen?
- Is he or she capable of understanding the importance of testing and the details of the testing procedure?
- Are vision and motor skills adequate?

**What else should I consider?**

Look for motivated individuals who want to take an active part in managing their condition. Lifestyle factors may be important; people who travel, work, or find it difficult to get to the laboratory may be especially motivated to learn self-testing.

**Which individuals probably should not self-test?**

- It is up to the attending physician to determine which individuals are eligible for self-testing.
- Refer to the test strip package insert for current limitations of procedure.

**Is it appropriate to train a third-party tester?**

Motivated parents of children who need testing or caregivers for other individuals (for example, a spouse) may be trained. The caregiver should be screened using the same criteria.

**Once the potential user has passed the initial screening, what do we do next?**

Explain to the person in general terms what will be involved and provide an opportunity to ask questions. If he or she expresses interest, send a copy of the training DVD home or show it in the office. Stress that this overview is only intended to give a better idea of what self-testing involves and that more detailed training and follow-up support will be provided. Each potential user will be instructed on the fingerstick procedure and perform a fingerstick as part of the screening. If the person wants to continue participation after seeing the DVD and performing a fingerstick, he or she should be enrolled in a training class.

**Clinical Study Information**

A clinical study was conducted by Roche Diagnostics consisting of four visits to the clinical site. Informed consent and randomization occurred at Visit 1. Testing began at Visit 2. Ninety-one individuals completed at least one visit after Visit 1. The following table outlines the demographic information for the users who completed at least one visit after Visit 1.

Demographic	Number	Percent
Total number of users	91	100%
Caregivers	4	4.4%
Males	51	56%
Females	40	44%
Age range	32 – 89	100%
Mean Age	64 years	N/A
Age 65 - 69 years	16	17.6%
Age 70 - 74 years	13	14.3%
Age 75 years and up	16	17.6%
Education Level- Eighth grade or less through advanced college degree	91	100%
Median Education Level	Some college	N/A
On warfarin 3 - 12 months	19	20.9%
On warfarin 1 - 2 years	22	24.2%
On warfarin 3 - 5 years	23	25.3%
On warfarin > 5 years	27	29.7%
Atrial fibrillation	38	41.8%
Valve replacement	25	27.5%
Stroke/stroke prevention	7	7.7%
DVT	5	5.5%
Other heart conditions	6	6.6%
Other clotting disorders	10	11%

There were 107 people enrolled. A total of 88 people completed all four visits to the site. The reasons for drop-outs were as follows:

Reason for Drop-Out	# of Subjects
Felt it was too stressful	2
Didn't have time	3
Didn't want to use meter on his own	1
Didn't think he could learn to use meter	1
Was having knee surgery	1
Study terminated prior to Visit 4	1
Unknown	7
Disqualified due to target INR range outside of study protocol	3

## PERFORMANCE CHARACTERISTICS

### Measuring Range:

The CoaguChek XS PT System has a PT/INR measuring range of 0.8–8.0 INR and 9.6–96.0 seconds.

### Accuracy:

A study was conducted comparing test results obtained by trained users with those obtained by healthcare professionals, when both were using the CoaguChek XS System. The correlation was very good, as indicated by the following statistics: N=463, Slope=1.000, Intercept=0.0 and Correlation Coefficient=0.977. This study shows that trained users are able to obtain results that are as accurate as those obtained by healthcare professionals trained in the use of the CoaguChek XS System.

### Precision:

A study was conducted and the precision of duplicates for capillary blood results was calculated for both trained users and healthcare professionals. The following results were obtained:

	User Results	Professional Results
N	214	249
Mean	2.57	2.52
SD	0.13	0.13
CV	5.13	5.36

This study shows that trained users are able to obtain results that are as precise as those obtained by healthcare professionals trained in the use of the CoaguChek XS System.

During the study, the following error rates were observed:

		Visit 1	Visit 2	Visit 3	Overall
Error 6	Test Strip Interference	0.8%	0.9%	0.5%	0.7%
Error 5	Blood Application	31.7%	23.9%	18.9%	25.2%
Error 4	Test Strip Unusable	0.8%	0.0%	2.8%	1.1%
Error 000	Time Exceeded	1.5%	1.3%	0.0%	1.0%
Error QC	Quality Control Failure	1.1%	0.0%	0.0%	0.4%
	Unknown Error	1.1%	0.0%	0.5%	0.6%

# 4

## Training Users for Self-Testing

### PREPARATION

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The suggested time for each training session is two hours. If you prefer, you may break this into two one-hour sessions. Some trainers have found that it works well to have one educational session and one hands-on practice session. However the training is scheduled, it is important to allow plenty of time for trainees to practice the testing procedure and ask questions.

Training is mandatory. Users should not be permitted to take a meter home without satisfactorily completing a training session and passing the *Knowledge Test* and *Skills Checklist*.

Schedule training in a room free of distractions and with adequate facilities for trainees to take notes and practice with the meters.

Limit training classes to small groups so trainees can have individual attention during the practice session. It may be helpful to have an assistant.

Organize the presentation, gather the needed supplies, and make sure the meters are operational.

### SUPPLIES

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#### CoaguChek XS Testing Supplies

(one set for each trainee plus one for demonstration)

- CoaguChek XS System Care Kit, consisting of:
  - CoaguChek XS Meter
  - 4 AAA batteries
  - CoaguChek XS System User Manual
  - CoaguChek XS System Getting Started Guide
  - CoaguChek XS System Prothrombin Time Self-Testing Log Book
  - ACCU-CHEK® Softclix lancet device and lancets
  - CoaguChek XS System Training DVD
  
- CoaguChek XS Test Kit, consisting of:
  - A container of test strips
  - A test strip code chip
  - The test strip package insert

## 4 Training Users for Self-Testing

### Other Supplies

- Alcohol wipes
- Cotton balls or tissue
- Pre-packaged towelettes such as CoaguWipes\* or 10% bleach solution (1 part bleach to 9 parts water)
- Biohazard waste and sharps containers for disposal of supplies and lancets used during practice
- Disposable gloves for instructor and assistants to wear when assisting trainees in practicing fingersticks
- DVD player
- TV monitor
- Sufficient copies of the class outline, *Knowledge Test*, *Skills Checklist*, Log Book, *Certificate of Completion*, and key sections of the *CoaguChek XS User Manual*, especially the *Error Messages* section

## TRAINING OUTLINE

### User Training CoaguChek XS System

Topic	Time to Present/Practice
Introduction and Overview of Training Session	5 minutes
CoaguChek XS System Training DVD	15 minutes
Review of CoaguChek XS System and Operating Guidelines	10 minutes
Review System Set-Up	5 minutes
Testing Fingerstick Samples (including practice and completion of <i>Skills Checklist</i> )	40 minutes
Documenting Results on Log Book	5 minutes
Review Built-In Quality Control	10 minutes
Cleaning the CoaguChek XS System	5 minutes
<i>Knowledge Test</i>	10 minutes
Local Information and Wrap-Up	10 minutes

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**Introduction and Overview of Training Session**

1. Explain the importance of regular PT/INR testing.
2. Review the policy for certification. Explain that each trainee will be asked to successfully complete a *Knowledge Test* and *Skills Checklist*.
3. Review the agenda for the training session. (This outline may be copied and distributed to attendees as a detailed reference.)

**CoaguChek XS System Training DVD**

Show the 15-minute Training DVD, which gives an overview of the testing procedure, built-in quality control testing, and maintenance.

**Review of CoaguChek XS System and Operating Guidelines**

1. Review components of the CoaguChek XS Meter
  - Display panel
  - M (memory) button
  - ON-OFF button
  - Test strip guide cover
  - Test strip guide
  - Battery compartment cover
  - Code chip slot
  - SET button
  - Data port
2. Review contents of the Test Kit
  - A container of 6 test strips
  - The test strip code chip
  - The test strip package insert
3. Review operating conditions of the meter and proper storage conditions of test strips
  - Operate meter at room temperature, 65°–90° F (18°–32° C).
  - Operate meter with 10% to 85% relative humidity, without condensation.
  - Avoid bright sunlight.
  - Operate the meter on a flat surface, free of vibrations.

- Use well-protected carrying case.
- Read the information packaged with the test strips regarding up to date product specifications and limitations.
- Read the latest warfarin package insert for contraindications.

### Review System Set-Up

1. The CoaguChek XS System uses four AAA alkaline batteries, inserted into the battery compartment on the back of the meter. Explain the importance of entering the correct date and time. (Each time you run a test, the meter compares its date with the test strip's expiration date. If the test strip is expired, the meter displays an error message and prevents you from running a test.)
2. Discuss the purpose of the code chip included with each test kit. The code number on the test strip container must match the code chip number.
3. Review how to insert the code chip. Make sure the meter is off. Insert the code chip with the code number facing up until it snaps into place.
- 4 Explain that the meter has set-up options that users will not be asked to change. Appropriate settings have been programmed before they receive their meters.

### Testing Fingertick Samples

(Including practice and completion of *Skills Checklist*)

**Important:** If a caregiver assists with the testing procedure, it is recommended that the caregiver wash hands thoroughly and wear disposable gloves to prevent contact with the blood sample.

1. Review supplies needed for performing a self-test:
  - CoaguChek XS meter
  - Container of test strips
  - Test strip code chip
  - ACCU-CHEK Softclix lancet device and lancet
2. Review how to prepare the lancet device.

Users pull off the cap and insert a new lancet. Provide these instructions: Twist off the lancet's protective cap. Put the cap back on the lancet device. To place the cap back on, line up the notch on the cap with the center of the semi-circle. Turn the dial so that the center of the semi-circle points to 5. (The lancet device has multiple depth settings, so the user can use the setting

that works best. The higher the number, the deeper the penetration. The first time a person uses it, try a depth setting of 5. If the blood drop you get is not sufficient, try a higher setting.)

Instruct the user to press the plunger. A yellow dot appears in the release button, telling the user that the device is ready. Tell the user to set it aside while preparing for the fingerstick.

3. Review how to prepare for a fingerstick, instructing the user to:

- Wash the hand in warm, soapy water. This cleans and warms the hand.
- Massage the finger from its base.
- Let the hand hang loosely at his or her side for 10 to 30 seconds.
- Use these techniques until the fingertip has good color.

4. Review testing procedures, instructing the user to follow this process:

- The correct code chip must be in the meter. The code chip automatically provides the meter with the information that is specific to each lot of test strips. Each box of test strips comes with a matching code chip. Every time users open a new box of test strips, they will replace the code chip.
- Take a strip out of the test strip container. Close the container tightly.
- Slide the test strip into the meter's test strip guide in the direction of the arrows until it stops. The meter will turn on and the code number of the inserted code chip will flash on the display.
- Be sure the code number on the display matches the number on the test strip container, then press **M**.
- After **M** is pressed, an hourglass appears as the meter warms up. A flashing test strip and blood drop appear when the meter is ready for a sample. The user has 120 seconds to apply a blood drop to the test strip.

5. Review collecting and applying the sample, instructing the user to follow this process:

- Massage the finger from the base until there is increased color in the fingertip. Keeping the hand down, press the tip of the lancet firmly against the side of the fingertip. Press the release button.
- The meter must be on a table. Find the target area on the test strip.
- Within 15 seconds of sticking the fingertip, apply the blood drop from the fingertip to the target area from the side. See the user manual for more information.

- Hold the blood drop to the test strip until the meter beeps. The flashing blood drop symbol will disappear and the result will appear on the display, which takes about a minute. **Do not add more blood or touch the test strip.**
- If the meter displays an error message rather than a test result, refer to the *Error Messages* section of the user manual to learn what to do next.
- To run a new test, use a new test strip and a different finger.

6. Review final testing steps, instructing the user to:

- Record the result in the Log Book. The meter will automatically store 100 results, with the date and time, in its memory.
- Clean up: remove the lancet from the lancet device. Place the used test strip and lancet in a puncture-proof waste container with a lid. Turn the meter off. If the meter is dirty, wipe it with a lint-free tissue and an approved cleaning solution.
- Always call their doctor with their test results.
- If the result is outside the therapeutic range, call the doctor immediately.

7. Review the procedure to follow if the test results are not in the accepted PT/INR range:

- Explain to the user that a PT/INR result outside the therapeutic range is a result that is above or below the immediate follow-up values set by their doctor or designated healthcare professional. The user must contact his or her doctor immediately if this occurs. Include clear instructions on how the user is to contact his or her doctor and what the user is to do if the doctor is not immediately available. The user's doctor should write these immediate follow-up values and follow-up instructions in the appropriate section of the user's Log Book.

**NOTE:** *Be sure the meter is properly set up, including date, time, and units of measurement, before the training session ends.*

### Review Built-In Quality Control

The CoaguChek XS System has built-in quality control functions in the meter and test strips. The meter automatically runs its own quality control test as part of every blood test, so you never have to run quality control tests with liquid quality controls.

When the quality control test runs, the letters **QC** flash on the meter's display. When the quality control test is finished, a check mark (✓) appears following the letters **QC**. Then the meter continues to run the blood test.

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The built-in quality control helps you know that your test strip has not been damaged. If you receive a test error, look in the manual for an explanation of all test errors.

### **Cleaning the CoaguChek XS System**

Review cleaning procedures with the user, instructing them to follow this process: A user should clean the meter whenever it looks dirty or each time he or she opens a new box of test strips, whichever the user prefers.

Use only the following products to clean the meter:

- pre-packaged bleach towelettes such as CoaguWipes® or 10% bleach solution (1 part bleach and 9 parts water)
- 70% isopropyl alcohol solution
- lint-free tissues
- cotton swabs.

Do not spray any cleaning solution on the meter. Never use a spray of any type.

To clean the exterior of the meter:

1. With the meter turned off, wipe the meter's exterior clean.
2. With a lint-free tissue, dry the meter.

To clean the test strip guide:

1. Open and clean the cover. With the meter turned off, use your thumbnail to open the cover of the test strip guide by pressing its front edge upward. Move the cover safely away from the meter. Then rinse the cover with water or wipe it clean.
2. Clean the test strip guide. Clean the easily accessible areas with a cotton swab. Do not insert any objects into the test strip guide.
3. Allow the test strip guide to dry, with the cover off, for about 10 minutes.
4. Close the cover, and make sure it snaps into place.

## TESTING THE TRAINEES

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1. Complete the *Skills Checklist*, included in this package, after observing each trainee during the hands-on practice session. One or more assistants may be helpful in completing the checklists without slowing down the class.
2. Have trainees complete the *Knowledge Test*, included in this package, at the end of the training presentation and practice sessions.
3. Score the test with the answer key and review any areas of confusion.
4. Develop a plan before the training class for remedial action if trainees do not perform adequately on either of the tests. In some cases, it may be necessary to return the trainee to a laboratory testing regimen.

The *Skills Checklist* and *Knowledge Test* master forms can be copied as needed and are included in the back of this manual.

## CERTIFICATE OF COMPLETION

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Each trainee who successfully completes the class and the tests should be given a certificate. A certificate that can be copied as needed is included in the *Forms* section at the back of this binder.

## FOLLOW-UP VISITS

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Remind all trainees they are required to return for two follow-up visits where they will demonstrate their knowledge of self-testing with the CoaguChek XS System.

# 5

## Proficiency Checks

After completing the training class and beginning self-testing, users should be monitored periodically by a trained healthcare professional to be sure their testing technique is correct and the meter is performing properly. Suggested frequency for monitoring is every six months. The following procedure may be useful:

- Establish a reminder system that prompts you to contact each user at 6-month intervals.
- Make an appointment for the user to come to the clinic or office.
- Ask the user to bring the CoaguChek XS meter, testing supplies, and Log Book.
- During the interview, record your observations on the 6-month Performance Evaluation form.
- Inspect the meter thoroughly.
- Observe the user cleaning the CoaguChek XS meter. If necessary, stress the importance of maintaining a regular cleaning schedule.
- Observe the user performing a blood test. If necessary, offer suggestions for improvement. A 2-week follow-up is recommended whenever competency needs reassessment.
- The healthcare professional will perform a user blood test after the trainee performs a self-test. The test should match within 30%; this verifies that the meter is performing properly. If this test indicates a problem with the meter or test strips, repeat the test. If the result is still in question, please contact the Roche Diagnostics Technical Service Center 1-800-428-4674, 24 hours a day, 7 days a week, 365 days a year.
- If the test result is within range and the user performs all tests satisfactorily, make an appointment for six months in the future.

# 6

## Forms

### OVERVIEW

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The following forms are included as part of the CoaguChek XS System training for self-testing.

These forms should be used as originals. Please feel free to copy them as needed.

- *Skills Checklist*
- *Knowledge Test*
- *Answer Key*
- *Certificate of Completion*

## COAGUCHEK XS SYSTEM SKILLS CHECKLIST

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Trainer should check each activity as it is demonstrated or described.

### User Assemble Equipment

- CoaguChek XS meter
- Container of test strips
- Test strip code chip
- ACCU-CHEK Softclix lancet device and lancet

### User Reviews Procedure

- States when coding is needed
- Turns meter off before inserting or removing code chip
- Removes old code chip if one is installed
- Inserts new code chip until it snaps into place

### Performs Test Procedure

- Properly prepares lancet device
- Turns meter on
- Inserts test strip
- Obtains blood sample correctly
- Applies blood to test strip correctly
- Reads result
- Records result
- Tries to correct any problem should there be an error message, using the solutions described in the user manual
- Is aware of the 24-hour Technical Service number at 1-800-428-4674 if problem persists
- Properly discards used test strip and blood-drawing supplies

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573-34375



## COAGUCHEK XS SYSTEM SKILLS CHECKLIST

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- Recalls Results from Memory**     Correctly recalls results stored in memory
- Problem Solving**     Refers to *Error Messages* in the user manual when a problem occurs
- Cleaning**
- States minimum cleaning frequency
  - Demonstrates exterior cleaning procedure as stated in the user manual
  - Properly cleans test strip guide
- Battery Replacement**     Demonstrates removal and replacement of batteries

Trainee Name: \_\_\_\_\_

Training Date: \_\_\_\_\_

Training Site: \_\_\_\_\_

Trainer Name: \_\_\_\_\_

Trainer Signature: \_\_\_\_\_ Date: \_\_\_\_\_

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125

## COAGUCHEK XS SYSTEM KNOWLEDGE TEST

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**Mark "T" if the statement is true and "F" if the statement is false.**

- \_\_\_ 1. When coding the CoaguChek XS Meter, you must use the code chip from the same test strip container that you are using.
- \_\_\_ 2. After removing a test strip from the container, it is important to close the cap tightly.
- \_\_\_ 3. When performing a blood test, it is important to hold the finger to the strip until the meter beeps.
- \_\_\_ 4. The sample must be applied to the test strip within five minutes of removing it from the container.
- \_\_\_ 5. INR is a reporting format that stands for International Normalized Ratio.
- \_\_\_ 6. Every time a blood test is performed, the meter also performs a built-in quality control test.
- \_\_\_ 7. If the built-in quality control test fails, the meter will still give a test result.
- \_\_\_ 8. The most recent user result appears first when reviewing memory.
- \_\_\_ 9. CoaguChek XS test strips may be stored at room temperature until the expiration date printed on the container.
- \_\_\_ 10. The CoaguChek XS Meter stores up to 50 results with time and date.

**Please answer the following questions:**

11. What is used to clean the exterior of the CoaguChek XS Meter?

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## COAGUCHEK XS SYSTEM KNOWLEDGE TEST

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12. What would cause Error 3 to appear on the display?

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13. What would cause Error 5 to appear on the display?

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14. After inserting a test strip, the code flashes on the display. What is the next step?

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15. Why is it important to apply blood to the test strip within 15 seconds of sticking the finger?

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Trainee Name: \_\_\_\_\_

Training Date: \_\_\_\_\_

Training Site: \_\_\_\_\_

Trainer Name: \_\_\_\_\_

Trainer Signature: \_\_\_\_\_ Date: \_\_\_\_\_



## ANSWER KEY

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### For CoaguChek XS System Knowledge Test

1. T
2. T
3. T
4. F – The sample must be applied to the test strip within 10 minutes of removing the strip from the container.
5. T
6. T
7. F – If the built-in quality control does not pass, a flashing “QC” will appear on the display.
8. T
9. T
10. F – The CoaguChek XS Meter stores up to 100 test results with time and date
11. The CoaguChek XS Meter can be cleaned with 10% bleach solution or 70% isopropyl alcohol.
12. Error 3 indicates that the strip is expired. Ensure that the date is set correctly on the meter. If it is incorrect, set the correct date. If the date is correct, turn the meter off and remove the code chip and the test strip. Use the code chip and a test strip from a new box of test strips.
13. Error 5 indicates an error applying blood to the test strip. It is caused by not having a large enough drop of blood. When applying blood to the test strip, massage your finger until you have a good blood drop and hold your finger against the test strip until the meter beeps.
14. Confirm that the code flashing on the display matches the code on the container of test strips you are using. Then press the **M** button to continue the testing process.
15. After 15 seconds your blood may begin to clot, which could lead to an incorrect result.



# CoaguChek<sup>®</sup> XS System



*Certificate of Completion*  
presented to

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for successfully completing Self-Testing training on the

***CoaguChek<sup>®</sup> XS System***

Dated: \_\_\_\_\_

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Certified Training Consultant

## FDA Question 2

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**Question 2**      Modify the intended use statement to specify that patients for this device should be selected and trained by the healthcare provider.

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**Roche response**      The intended use statement will be modified to the following:

The CoaguChek XS System measures blood-clotting time for people who are taking anticoagulation medications such as Coumadin or warfarin. The CoaguChek XS System uses blood from a fingerstick. The system is intended for properly selected and suitably trained users or their caregivers on the prescription or other order of the treating doctor. Users should be stabilized on anticoagulation medications such as Coumadin or warfarin prior to self-testing with the CoaguChek XS System.

Please see the modified package insert on the following pages.

A modified indications for use page is also provided.

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# CoaguChek<sup>®</sup> XS PT Test

Test Strips and 1 Code Chip  
PERSONAL USE

## Purpose

The CoaguChek XS PT test strips are part of the CoaguChek XS System. The CoaguChek XS System measures blood-clotting time for people who are taking anticoagulation medications such as Coumadin<sup>®</sup> or warfarin. The CoaguChek XS System uses blood from a fingerstick. The system is intended for properly selected and suitably trained users or their caregivers on the prescription or other order of the treating doctor. Users should be stabilized on anticoagulation medications such as Coumadin or warfarin prior to self-testing with the CoaguChek XS System.

**Caution: These test strips are for use outside the body only. Do not eat the test strips.**

## Before You Start Testing

If you are new to the CoaguChek XS System, watch the *CoaguChek XS System Video* and read the *CoaguChek XS System Getting Started* guide before testing.

## Storing the Test Strips

Store the test strips in their container, with the cap closed. You can store the test strips at room temperature (18–32°C or 65–90°F) or in the refrigerator (2–8°C or 36–46°F). When stored properly, the test strips can be used until the expiration date printed on the test strip container.

Throw the test strips away if they are past their “Use By” date.

## Handling the Test Strips

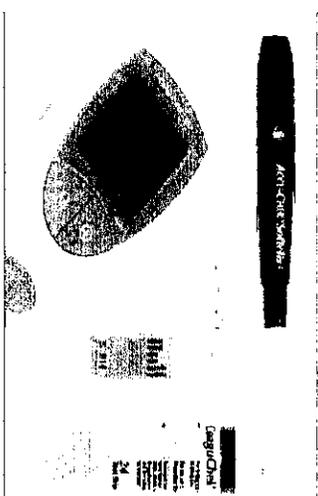
When you are ready to test, remove 1 test strip from the container. **Close the container tightly.**

You must use the test strip within 10 minutes of removing it from the container. Otherwise, you may get an error message and you will have to repeat the test.

## Step 1: Getting Ready to Test

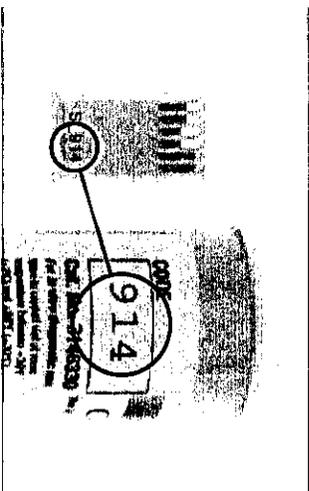
Gather supplies:

- CoaguChek XS Meter
- Container of CoaguChek XS PT Test Strips
- Test Strip Code Chip
- ACCU-CHEK<sup>®</sup> Softclix Lancing Device and Lancing



Put the meter on a flat surface, like a table or countertop, that will not vibrate or move during testing. Movement can result in an error message.

If you are using test strips from a new, unopened box, you will need to change the test strip code chip. The 3-number code on the test strip container must match the 3-number code on the code chip. To install the code chip, follow the instructions in the *Code Chip* section of the *CoaguChek XS System User Manual*.



## Step 2: Testing Blood from a Fingertick

### Getting a Good Drop of Blood

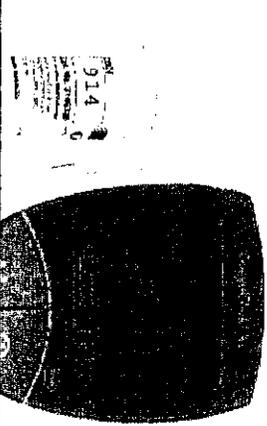
Increasing the blood flow in your finger will help you get a good drop of blood. Before you lance your finger, try the following techniques until you see that your fingertip has good color:

- Warm your hand by holding it under your arm, using a hand warmer, and/or washing your hand with warm water.
- Hold your arm down to the side so that your hand is below your waist.
- Massage your finger from its base.
- If needed, immediately after lancing, gently squeeze your finger from its base to encourage blood flow.

### Procedure

1. Wash your hands with warm, soapy water. Dry completely.
2. Take a test strip out of the container. **Close the container tightly.**
3. Insert a test strip as far as you can into the meter. The meter turns on.

4. Confirm that the number displayed matches the number on the test strip container, then press **M**. If the numbers are different, make sure you are using the code chip that came with the test strips you are using. If they still do not match, call the Roche Diagnostics Technical Service Center at 1-800-428-4674, 24 hours a day, 7 days a week.



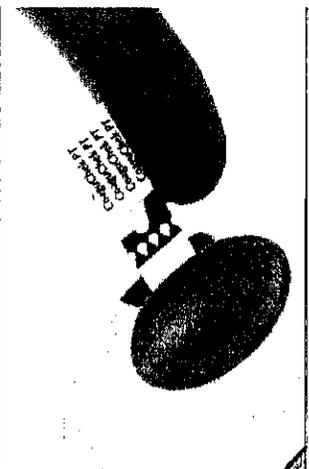
5. An hourglass appears as the meter warms up, which takes about 30 seconds.
6. When the meter is warmed up, a flashing test strip and blood drop symbol appear and the meter begins a countdown. You have 120 seconds to apply blood to the test strip.

7. Use the lancet device to perform a fingerstick. **Set the penetration depth to 5.** See the *CoaguChek XS System User Manual* for more information. After sticking your finger, you have 15 seconds to apply blood to the test strip. If it takes longer to form a good drop of blood, lance a different finger for the test.

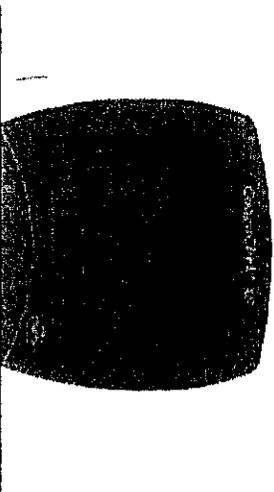


8. The meter must be on a table. Apply 1 drop of blood to the side of the test strip.

*It's important to hold the blood drop to the test strip until you hear a beep.*



1. You'll see the hourglass when the blood test begins. Then, pull your finger away from the test strip.



Remember to apply only one drop of blood—don't add more. Do not touch or remove the test strip when a test is in progress.

*The result appears in about 1 minute.*

10. Record the result on the *CoaguChek XS System Prothrombin Time Self-Testing Log Book*. Call your doctor with the test result.
11. Properly dispose of the used lancet and test strip.
12. Turn the meter off.

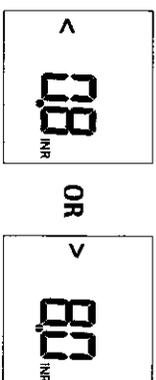
If you need to redo a test, use a new lancet, a new test strip, and a different finger.

### Additional Information

The *CoaguChek XS System User Manual* contains more information. If you need technical help, call the Roche Diagnostics Technical Service Center at 1-800-428-4674, 24 hours a day, 7 days a week.

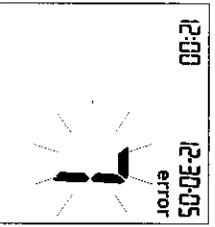
### Very Low or Very High Test Results

The CoaguChek XS PT test strips provide test results if the INR value is between 0.8 and 8.0. If the meter displays < (less than) **0.8** or > (greater than) **8.0**, repeat the test. If, when you repeat the test, you get the same display (either < **0.8** or > **8.0**), call your doctor.



## Error Messages

If you see Error 7, repeat the test. Be sure to apply the blood drop to the test strip within 15 seconds of sticking the fingertip. If you still get Error 7, call the Roche Diagnostics Technical Service Center at 1-800-428-4674. If the meter displays any other error message, refer to the *Error Messages* section of the *CoaguChek XS System User Manual*.



## Built-In Controls

The CoaguChek XS System has built-in quality control functions in the meter and test strips. The meter automatically runs its own quality control test as part of every blood test, so you never have to run quality control tests with liquid quality controls. For more information about the built-in quality control functions, see the *CoaguChek XS System User Manual*.

## Performance Characteristics

**Measuring Range:** The CoaguChek XS PT System has a PT measuring range of 0.8–8.0 INR and 9.6–96.0 seconds.

**Accuracy:** A study was conducted comparing test results obtained by trained users with those obtained by healthcare professionals, when both were using the CoaguChek XS System. The correlation was very good, as indicated by the following statistics:  $N=463$ ,  $Slope=1.000$ ,  $Intercept=0.0$  and  $Correlation Coefficient=0.977$ . This study shows that trained users are able to obtain results that are as accurate as those obtained by healthcare professionals trained in the use of the CoaguChek XS System.

**Study User Demographics:** A clinical study was conducted by Roche Diagnostics, consisting of four visits to the clinical site. Informed consent and randomization occurred at Visit 1. Testing began at Visit 2. Ninety-one patients completed at least one visit after Visit 1. The following table outlines the demographic information for the trained users who completed at least one visit after Visit 1.

Demographic	Number	Percent
Total number of users	91	100%
Caregivers	4	4.4%
Males	51	56%
Females	40	44%
Age range	32 - 89	100%
Mean Age	64 years	N/A
Age 65 - 69 years	16	17.6%
Age 70 - 74 years	13	14.3%
Age 75 years and up	16	17.6%
Education Level- Eighth grade or less through advanced college degree	91	100%
Median Education Level	Some college	N/A
On warfarin 3 - 12 months	19	20.9%
On warfarin 1 - 2 years	22	24.2%
On warfarin 3 - 5 years	23	25.3%
On warfarin > 5 years	27	29.7%
Atrial fibrillation	38	41.8%
Valve replacement	25	27.5%
Stroke/stroke prevention	7	7.7%
DVT	5	5.5%
Other heart conditions	6	6.6%
Other clotting disorders	10	11%

There were 107 patients enrolled. A total of 88 patients completed all four visits to the site. The reasons for drop-outs were as follows:

Reason for Drop-Out	# of Subjects
Felt it was too stressful	2
Didn't have time	3
Didn't want to use meter on his own	1
Didn't think he could learn to use meter	1
Was having knee surgery	1
Study terminated prior to Visit 4	1
Unknown	7
Disqualified due to target INR range outside of study protocol	3

**Precision:** A study was conducted and the precision of duplicates for capillary blood results was calculated for both trained users and healthcare professionals. The following results were obtained:

	User Results	Professional Results
N	214	249
Mean	2.57	2.52
SD	0.13	0.13
CV	5.13	5.36

This study shows that trained users are able to obtain results that are as precise as those obtained by healthcare professionals trained in the use of the CoaguChek XS System.

### Limited Warranty

Roche Diagnostics warrants that your CoaguChek XS PT test strips will be free from defects in materials and workmanship until the product expiration date printed on the label if the test strips are used and stored in the manner described in this package insert and in your CoaguChek XS System User Manual. If, prior to the expiration date of the test strips, there is a defect in materials or workmanship, Roche Diagnostics will replace the test strips free of charge. Your sole and exclusive remedy with respect to the strips shall be replacement. Any warranty claim should be directed to the Roche Diagnostics Technical Service Center at 1-800-428-4674.

THE ABOVE WARRANTY IS EXCLUSIVE OF ALL OTHER WARRANTIES, AND ROCHE DIAGNOSTICS MAKES NO OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION THE IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. IN NO EVENT SHALL ROCHE DIAGNOSTICS BE LIABLE TO THE PURCHASER OR ANY OTHER PERSON FOR ANY INCIDENTAL, CONSEQUENTIAL, INDIRECT, SPECIAL OR PUNITIVE DAMAGES ARISING FROM OR IN ANY WAY CONNECTED WITH THE PURCHASE

OR USE OF THE TEST STRIPS. NO WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, IF ANY IS IMPLIED FOR THE SALE OF THE TEST STRIPS, SHALL EXTEND FOR A LONGER DURATION THAN THE EXPIRATION DATE OF THE TEST STRIPS.

The following U.S. patents have been granted or are pending for the CoughCheck XS System (meter and test strips): 6,862,439; 7,073,246; 2005/0108624; 6,881,378; 6,207,000; 2005/0214171; 2005/0123441; 6,645,388; 2004/0157339; 2005/0129574; 2005/0135968

COAGUCHEK, ACQUICHEK and SOFTCLIX are trademarks of Roche. All other product names and trademarks are the property of their respective owners.

Manufactured for:  
Roche Diagnostics  
9115 Heigle Road  
Indianapolis, IN 46258

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573-34943-1208



## Indications for Use

510(k) Number (if known):

Device Name: CoaguChek® XS System for Patient Self-Testing

Indications For Use:

The CoaguChek XS System measures blood-clotting time (prothrombin time) for people who are taking anticoagulation medications such as Coumadin or warfarin. The CoaguChek XS System uses blood from a fingerstick. The system is intended for properly selected and suitably trained users or their caregivers on the prescription or other order of the treating doctor. Users should be stabilized on anticoagulation medications such as Coumadin or warfarin prior to self-testing with the CoaguChek XS System.

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

## FDA Question 3

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**Question 3** The comparison study initially enrolled 107 subject with 91 subjects completed all four visits. Based on the protocol, there should be a total of 546 (91 x 6) data points. Final data analyses were conducted with only n = 161 data points. A significant number of data (70.5%) were missing and not included in the final analysis. Provide a full explanation of data exclusion for the regression analyses.

---

**Roche response** The subject vs. lab-based regression analysis was originally conducted using 166 data points. Analysis of subject vs. lab-based reference was only conducted during visits 2 & 4; no lab-based reference was collected on visit 3. Not all available subject results were used, but rather the first result.

We have repeated the regression analyses using all available subject results, with detailed explanations of data exclusion.

Three new regression plots are provided on the next pages, followed by a full explanation of any data exclusion.

- Regression plot of subject results vs. laboratory reference result
- Regression plot of technician results vs laboratory reference result
- Regression plot of subject results (all individual results) vs. technician results (average of both results)

The data and summary in the package insert (see question 2) has been adjusted, and a corrected 510(k) summary is included below, reflecting the correct count.

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Pages 241 through 243 redacted for the following reasons:

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Technical Data, b4

## 510(k) Summary

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**Introduction** According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

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**1) Submitter name, address, contact** Roche Diagnostics Corporation  
9115 Hague Rd.  
Indianapolis, IN 46250

Contact Person: Tracy Bush/ Luann Ochs

Date Prepared: December 4, 2006

---

**2) Device name** Proprietary name: CoaguChek® XS System  
Common name: Prothrombin time test  
Classification name: Prothrombin time test

---

**3) Predicate device** The Roche Diagnostics CoaguChek XS System (patient self-testing) is substantially equivalent in materials, design and function to other products that measure prothrombin time INR in human blood. Most notably, it is substantially equivalent to the Roche Diagnostics CoaguChek XS System (professional). In fact, it is identical in materials, design and function to the CoaguChek XS System (professional) except the labeling has been modified and validated for patient self-testing.

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**4) Device Description** The CoaguChek XS is a 3<sup>rd</sup> generation Roche Diagnostic's CoaguChek meter which was cleared for professional use under premarket notification K060978.

This premarket notification is being submitted to obtain clearance for patient self-testing.

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**5) Intended Use** The CoaguChek XS System measures blood-clotting time for people who are taking anticoagulation medications such as Coumadin or warfarin. The CoaguChek XS System uses blood from a fingerstick. The system is intended for properly selected and suitably trained users or their caregivers on the prescription or other order of the treating doctor. Users should be stabilized on anticoagulation medications such as Coumadin or warfarin prior to self-testing with the CoaguChek XS System.

---

**6) Comparison to Predicate Device** The following characteristics have been previously submitted, reviewed and cleared under the premarket notification for the CoaguChek XS System (K060978):

- Factor Sensitivity
- Heparin Sensitivity
- Hematocrit Effect
- Interfering Substances
- Normal Range
- Measuring Range
- Test Strip Stability
- Integrated Quality Control
- Instrument Failsafes
- Calibration
- Software Development

These characteristics are not impacted by the new user population.

The use of the system by self-testers was validated by an external user study that was conducted as the system is intended to be used. Following self-directed training, the subjects self-tested in the home setting for up to 8 weeks. The subjects also had 3 scheduled visits to their study site to collect user vs. technician data as well as user vs. reference method (Dade Innovin on a Sysmex analyzer) data.

The study results successfully demonstrated that self-trained subjects can obtain results that are equivalent to healthcare professionals and to the reference method. This study also demonstrated that self-tester results are consistent over time.

---

**7) Performance characteristics**

The performance characteristics that are impacted by the new user population were evaluated. The following information has been incorporated into our draft patient self-testing insert.

Claim	Statement															
<p><b>Accuracy</b></p>	<p>A study was conducted comparing test results obtained by self-trained patients with those obtained by healthcare professionals using the CoaguChek XS meter. The correlation was very good, as indicated by the following statistics: N = 463, Slope = 1.00, Intercept = 0.0 and Correlation Coefficient = 0.977 This study shows that self-trained patients are able to obtain results that are as accurate as those obtained by healthcare professionals trained in the use of the CoaguChek XS meter.</p>															
<p><b>Precision</b></p>	<p>A study was conducted and the precision of duplicates for capillary blood results was calculated for both self-trained patients and healthcare professionals. The following results were obtained:</p> <table border="1" data-bbox="641 1060 1339 1281"> <thead> <tr> <th></th> <th>Patient Results</th> <th>Professional Results</th> </tr> </thead> <tbody> <tr> <td><b>N</b></td> <td>214</td> <td>249</td> </tr> <tr> <td><b>Mean</b></td> <td>2.57</td> <td>2.52</td> </tr> <tr> <td><b>SD</b></td> <td>0.13</td> <td>0.13</td> </tr> <tr> <td><b>CV</b></td> <td>5.13</td> <td>5.36</td> </tr> </tbody> </table> <p>This study shows that self-trained patients are able to obtain results that are as precise as those obtained by healthcare professionals trained in the use of the CoaguChek XS meter.</p>		Patient Results	Professional Results	<b>N</b>	214	249	<b>Mean</b>	2.57	2.52	<b>SD</b>	0.13	0.13	<b>CV</b>	5.13	5.36
	Patient Results	Professional Results														
<b>N</b>	214	249														
<b>Mean</b>	2.57	2.52														
<b>SD</b>	0.13	0.13														
<b>CV</b>	5.13	5.36														

## FDA Question 4

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Question 4

(b)(4), (b)(5)

Roche response

(b)(4), (b)(5)

# FDA Question 5

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**Question 5**

(b)(4), (b)(5)

**Roche response**

(b)(4), (b)(5)

(b)(4), (b)(5)

(b)(4), (b)(5)

## FDA Question 6

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**Question 6**

(b)(4), (b)(5)

**Roche response**

(b)(4), (b)(5)

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# FDA Question 7

Question 7

(b)(4), (b)(5)

Roche response

(b)(4), (b)(5)

# FDA Question 8

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**Question 8**

(b)(4), (b)(5)

**Roche response**

(b)(4), (b)(5)

(b)(4), (b)(5)

(b)(4), (b)(5)

Pages 253 through 255 redacted for the following reasons:

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Technical Data, b4

# FDA Question 9

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**Question 9**

(b)(4), (b)(5)

**Roche response**

(b)(4), (b)(5)

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(b)(4), (b)(5)

(b)(4), (b)(5)

# FDA Question 10

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**Question 10**

(b)(4), (b)(5)

(b)(4), (b)(5)

**Roche response**

(b)(4), (b)(5)

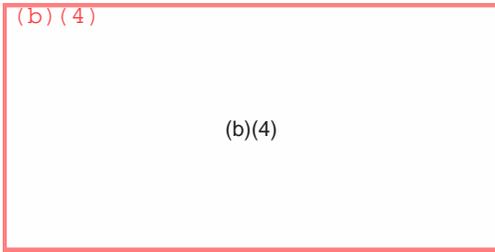
(b)(4), (b)(5)

(b) (4)



Diagnostics

(b) (4)



(b)(4)

(b) (4)



(b)(4)

Pages 259 through 275 redacted for the following reasons:

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Technical Report, b4

# Report

Reliability Test Report\_CC-XS\_AHein

(b) (4) (b)(4)

CoaguChek XS (0/1 Series)

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# Report

(b) (4)

(b)(4)

## CoaguChek XS (0/1 Series)

Version 1.0 [01.09.2005]

**Note:**

***This document is a translation of the German original document,  
File: PB058510.doc "Dauertest Gerät".***

***The translation is carried out by RWS Group GmbH Berlin,  
a worldwide leading company for professional translations.***

Pages 277 through 297 redacted for the following reasons:

-----  
Technical Report, b4

# Memo



Diagnostics

To: Dr. Füllemann

Copies:

From: Andreas Heinrich Bldg 072 / 3.5.3  
Tel. 0621 / 759-4528  
Fax 3009

Date: 22 November 2006

CoaguChek XS: Verification (b)(4), (b)(5)

(b)(4), (b)(5)

(b)(4), (b)(5)

(b)(4), (b)(5)

1/1

196

# FDA Question 11

**Question 11**

(b)(4), (b)(5)

**Roche response**

(b)(4), (b)(5)

Food and Drug Administration  
Center for Devices and  
Radiological Health  
Office of Device Evaluation  
Document Mail Center (HFZ-401)  
9200 Corporate Blvd.  
Rockville, Maryland 20850

January 17, 2007

ROCHE DIAGNOSTICS CORP.  
PROFESSIONAL DIAGNOSTICS  
9115 HAGUE RD.  
INDIANAPOLIS, IN 46256  
ATTN: THERESA BUSH

510(k) Number: K062925  
Product: COAGUCHEK XS  
SYSTEM

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at [www.fda.gov/cdrh/ode/a02-01.html](http://www.fda.gov/cdrh/ode/a02-01.html). On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at <http://www.fda.gov/cdrh/ode/guidance/1567.html>. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so in 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

If you have procedural or policy questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (240)276-4040.

Sincerely yours,

Marjorie Shulman  
Supervisory Consumer Safety Officer  
Premarket Notification Section  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

K062925/S2

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
FOOD AND DRUG ADMINISTRATION

**CDRH PREMARKET REVIEW SUBMISSION COVER SHEET**

Form Approval  
OMB No. 9010-0120  
Expiration Date: May 31, 2007.  
See OMB Statement on page 5.

Date of Submission January 12, 2006 <sup>7</sup>	User Fee Payment ID Number n/a	FDA Submission Document Number (if known) K062925
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SECTION A					TYPE OF SUBMISSION				
<b>PMA</b> <input type="checkbox"/> Original Submission <input type="checkbox"/> Premarket Report <input type="checkbox"/> Modular Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment <input type="checkbox"/> Licensing Agreement	<b>PMA &amp; HDE Supplement</b> <input type="checkbox"/> Regular (180 day) <input type="checkbox"/> Special <input type="checkbox"/> Panel Track (PMA Only) <input type="checkbox"/> 30-day Supplement <input type="checkbox"/> 30-day Notice <input type="checkbox"/> 135-day Supplement <input type="checkbox"/> Real-time Review <input type="checkbox"/> Amendment to PMA & HDE Supplement <input type="checkbox"/> Other	<b>PDP</b> <input type="checkbox"/> Original PDP <input type="checkbox"/> Notice of Completion <input type="checkbox"/> Amendment to PDP	<b>510(k)</b> <input type="checkbox"/> Original Submission: <input type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated (Complete section I, Page 5) <input checked="" type="checkbox"/> Additional Information <input type="checkbox"/> Third Party	<b>Meeting</b> <input type="checkbox"/> Pre-510(K) Meeting <input type="checkbox"/> Pre-IDE Meeting <input type="checkbox"/> Pre-PMA Meeting <input type="checkbox"/> Pre-PDP Meeting <input type="checkbox"/> Day 100 Meeting <input type="checkbox"/> Agreement Meeting <input type="checkbox"/> Determination Meeting <input type="checkbox"/> Other (specify)	<b>IDE</b> <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement	<b>Humanitarian Device Exemption (HDE)</b> <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment	<b>Class II Exemption Petition</b> <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	<b>Evaluation of Automatic Class III Designation (De Novo)</b> <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	<b>Other Submission</b> <input type="checkbox"/> 513(g) <input type="checkbox"/> Other (describe submission)
<b>IDE</b> <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement	<b>Humanitarian Device Exemption (HDE)</b> <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment	<b>Class II Exemption Petition</b> <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	<b>Evaluation of Automatic Class III Designation (De Novo)</b> <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	<b>Other Submission</b> <input type="checkbox"/> 513(g) <input type="checkbox"/> Other (describe submission)					

Have you used or cited Standards in your submission?     Yes     No    (If Yes, please complete Section I, Page 5)

**SECTION B                      SUBMITTER, APPLICANT OR SPONSOR**

Company / Institution Name Roche Diagnostics	Establishment Registration Number (if known) 1823260		
Division Name (if applicable) Professional Diagnostics	Phone Number (including area code) ( 317 ) 521-3742		
Street Address 9115 Hague Road	FAX Number (including area code) ( 317 ) 521-2324		
City Indianapolis	State / Province IN	ZIP/Postal Code 46256	Country USA
Contact Name Tracy Bush / Luann Ochs			
Contact Title Regulatory Affairs Principal	Contact E-mail Address Tracy.bush@roche.com; luann.ochs@roche.com		

**SECTION C                      APPLICATION CORRESPONDENT (e.g., consultant, if different from above)**

Company / Institution Name	
Division Name (if applicable)	Phone Number (including area code) (       )
Street Address	FAX Number (including area code) (       )

28

City	State / Province	ZIP/Postal Code	Country
Contact Name			
Contact Title		Contact E-mail Address	

K-19

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 2007 JAN 16 A 11:13  
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**SECTION D1**

**REASON FOR APPLICATION - PMA, PDP, OR HDE**

- Withdrawal
- Additional or Expanded Indications
- Request for Extension
- Post-approval Study Protocol
- Request for Applicant Hold
- Request for Removal of Applicant Hold
- Request to Remove or Add Manufacturing Site

- Change in design, component, or specification:
  - Software / Hardware
  - Color Additive
  - Material
  - Specifications
  - Other (specify below)

- Location change:
  - Manufacturer
  - Sterilizer
  - Packager

Other (specify below)

- Process change:
  - Manufacturing
  - Sterilization
  - Packaging
  - Other (specify below)

- Labeling change:
  - Indications
  - Instructions
  - Performance
  - Shelf Life
  - Trade Name
  - Other (specify below)

- Report Submission:
  - Annual or Periodic
  - Post-approval Study
  - Adverse Reaction
  - Device Defect
  - Amendment

- Response to FDA correspondence:

- Change in Ownership
- Change in Correspondent
- Change of Applicant Address

- Other Reason (specify):

**SECTION D2**

**REASON FOR APPLICATION - IDE**

- New Device
- New Indication
- Addition of Institution
- Expansion / Extension of Study
- IRB Certification
- Termination of Study
- Withdrawal of Application
- Unanticipated Adverse Effect
- Notification of Emergency Use
- Compassionate Use Request
- Treatment IDE
- Continued Access

- Change in:
  - Correspondent / Applicant
  - Design / Device
  - Informed Consent
  - Manufacturer
  - Manufacturing Process
  - Protocol - Feasibility
  - Protocol - Other
  - Sponsor

- Repose to FDA Letter Concerning:
  - Conditional Approval
  - Deemed Approved
  - Deficient Final Report
  - Deficient Progress Report
  - Deficient Investigator Report
  - Disapproval
  - Request Extension of Time to Respond to FDA
  - Request Meeting
  - Request Hearing

Request for Removal of Applicant Hold

- Report submission:
  - Current Investigator
  - Annual Progress Report
  - Site Waiver Report
  - Final

Manufacturer

- Other Reason (specify):

SECTION D3

REASON FOR SUBMISSION - 510(k)

New Device

Additional or Expanded Indications

Change in Technology

Other Reason (*specify*):

**SECTION E**

**ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS**

Product codes of devices to which substantial equivalence is claimed								Summary of, or statement concerning safety and effectiveness information <input checked="" type="checkbox"/> 510 (k) summary attached <input type="checkbox"/> 510 (k) statement
1	GJS	2		3		4		
5		6		7		8		

Information on devices to which substantial equivalence is claimed (if known)

	510(k) Number		Trade or Proprietary or Model Name		Manufacturer
1	K060978	1	CoaguChek XS System	1	Roche Diagnostics
2		2		2	
3		3		3	
4		4		4	
5		5		5	
6		6		6	

**SECTION F**

**PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS**

Common or usual name or classification

Prothrombin time test

	Trade or Proprietary or Model Name for This Device		Model Number
1	CoaguChek® XS System	1	
2		2	
3		3	
4		4	
5		5	

FDA document numbers of all prior related submissions (regardless of outcome)

1	2	3	4	5	6
K060978					

7	8	9	10	11	12
---	---	---	----	----	----

**Data Included in Submission**

Laboratory Testing
  Animal Trials
  Human Trials

**SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS**

**Product Code**  
GJS

**C.F.R. Section (if applicable)**  
21 CFR 864.7750

**Device Class**

Class I
  Class II  
 Class III
  Unclassified

**Classification Panel**  
Hematology

**Indications (from labeling)**

**The CoaguChek XS System measures blood-clotting time (Prothrombin Time) for people who are taking anticoagulation medications such as Coumadin® or warfarin. The CoaguChek XS System measures blood-clotting time using blood from the fingertip.**

(Wording has been simplified compared to the wording in the professional insert in order to achieve the appropriate reading level required for home testers.)

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.

FDA Document Number (if known)

**SECTION HMANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION**

<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		FDA Establishment Registration Number 9610126		<input checked="" type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler	
Company / Institution Name Roche Diagnostics GmbH			Establishment Registration Number 9610126		
Division Name (if applicable) Professional Diagnostics			Phone Number (including area code) ( 317 ) 521-3742 (in the U.S.)		
Street Address Sandhofer Strasse 116			FAX Number (including area code) ( 317 ) 521-2324 (in the U.S.)		
City Mannheim		State / Province	ZIP/Postal Code D-68298	Country German	
Contact Name Jennifer Tribbett (in the U.S.)		Contact Title Regulatory Affairs Principal		Contact E-mail Address Jennifer.tribbett@roche.	

<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		FDA Establishment Registration Number		<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler	
Company / Institution Name			Establishment Registration Number		
Division Name (if applicable)			Phone Number (including area code) (   )		
Street Address			FAX Number (including area code) (   )		
City		State / Province	ZIP/Postal Code	Country	
Contact Name		Contact Title		Contact E-mail Address	

<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		FDA Establishment Registration Number		<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler	
Company / Institution Name			Establishment Registration Number		
Division Name (if applicable)			Phone Number (including area code)		

		( )	
Street Address		FAX Number (including area code) ( )	
City		State / Province	ZIP/Postal Code Country
Contact Name	Contact Title	Contact E-mail Address	



**SECTION I**

**UTILIZATION OF STANDARDS**

Note: Complete this section if your application or submission cites standards or includes a "Declaration of Conformity to a Recognized Standard" statement.

1	Standards No.	Standards Organization	Standards Title	Version	Date
2	Standards No.	Standards Organization	Standards Title	Version	Date
3	Standards No.	Standards Organization	Standards Title	Version	Date
4	Standards No.	Standards Organization	Standards Title	Version	Date
5	Standards No.	Standards Organization	Standards Title	Version	Date
6	Standards No.	Standards Organization	Standards Title	Version	Date

	Standards No.	Standards Organization	Standards Title	Version	Date
7					

Please include any additional standards to be cited on a separate page.

**Public reporting burden for this collection of information** is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Food and Drug Administration  
 CDRH (HFZ-342)  
 9200 Corporate Blvd.  
 Rockville, MD 20850

*An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control*

## Additional Information #2 for K062925 (Roche Diagnostics CoaguChek XS System for Patient Self-Testing)

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**Overview** This additional information supplement contains the answers to the questions posed by Valerie Dada Ginyard via e-mail on January 10, 2007

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### FDA Question 1

---

**Question 1** For the user vs technician comparison study, you stated that per ISO 17593 values not falling between 2.0 and 4.5 INR were excluded from analysis. The ISO document that you cited is still in development, and has not been reviewed or recognized by the FDA. Therefore, we request that you reanalyze this data, including the 18 values that were eliminated because subjects did not meet the ISO 17593 target INR range.

---

**Roche response** In our answer to question 4 we did state that values outside 2.0 - 4.5 were eliminated from what we considered our main analyses ( we considered the bias calculations from ISO to be our 'main analysis') - but all values were included in the regression analyses (even those outside the 2.0 - 4.5 range). The regression analyses, found in our answer question 3, are the analyses shown in the labeling

The 18 results (3 patients X 3 values X 2 values per visit) in the regression analysis in question 3 were eliminated not because their actual results fell out of the range, but because those three patients did not meet the inclusion criteria (of having the right target INR value). In our e-mail conversation this morning (Jan 11, 2007), you agreed that it was correct to exclude these results

---

### FDA Question 2

---

**Question 2** The device labeling and HCP manual should be modified to include the graph and regression statistics for the user vs laboratory data, and the reanalyzed (from Q#1 above) user vs technician data.

---

**Roche response** The device labeling and HCP manual have been modified as requested and are attached.

---

# CoaguChek<sup>®</sup> XS PT Test

Test Strips and 1 Code Chip  
PERSONAL USE

## Purpose

The CoaguChek XS PT test strips are part of the CoaguChek XS System. The CoaguChek XS System measures blood-clotting time for people who are taking anticoagulation medications such as Coumadin<sup>®</sup> or warfarin. The CoaguChek XS System uses blood from a fingerstick. The system is intended for properly selected and suitably trained users or their caregivers on the prescription or other order of the treating doctor. Users should be stabilized on anticoagulation medications such as Coumadin or warfarin prior to self-testing with the CoaguChek XS System.

**Caution: These test strips are for use outside the body only. Do not eat the test strips.**

## Before You Start Testing

If you are new to the CoaguChek XS System, watch the *CoaguChek XS System Video* and read the *CoaguChek XS System Getting Started* guide before testing.

## Storing the Test Strips

Store the test strips in their container, with the cap closed. You can store the test strips at room temperature (18–32°C or 65–90°F) or in the refrigerator (2–8°C or 36–46°F). When stored properly, the test strips can be used until the expiration date printed on the test strip container.

Throw the test strips away if they are past their “Use By” date.

## Handling the Test Strips

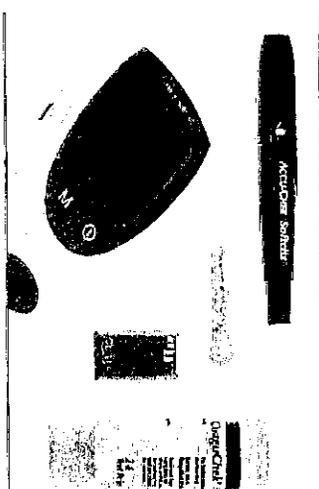
When you are ready to test, remove 1 test strip from the container. **Close the container tightly.**

You must use the test strip within 10 minutes of removing it from the container. Otherwise, you may get an error message and you will have to repeat the test.

## Step 1: Getting Ready to Test

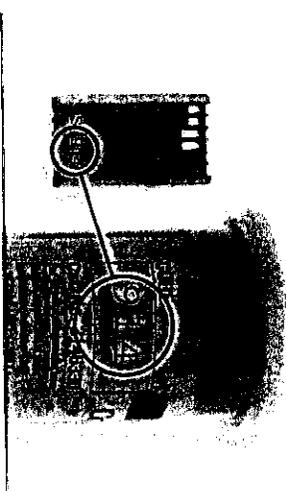
Gather supplies:

- CoaguChek XS Meter
- Container of CoaguChek XS PT Test Strips
- Test Strip Code Chip
- ACCU-CHEK<sup>®</sup> Softclix Lancing Device and Lancing



Put the meter on a flat surface, like a table or countertop, that will not vibrate or move during testing. Movement can result in an error message.

If you are using test strips from a new, unopened box, you will need to change the test strip code chip. The 3-number code on the test strip container must match the 3-number code on the code chip. To install the code chip, follow the instructions in the *Code Chip* section of the *CoaguChek XS System User Manual*.



## Step 2: Testing Blood from a Fingertick

### Getting a Good Drop of Blood

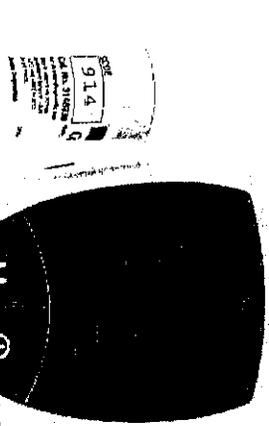
Increasing the blood flow in your finger will help you get a good drop of blood. Before you lance your finger, try the following techniques until you see that your fingertip has good color:

- Warm your hand by holding it under your arm, using a hand warmer, and/or washing your hand with warm water.
- Hold your arm down to the side so that your hand is below your waist.
- Massage your finger from its base.
- If needed, immediately after lancing, gently squeeze your finger from its base to encourage blood flow.

### Procedure

1. Wash your hands with warm, soapy water. Dry completely.
2. Take a test strip out of the container. **Close the container tightly.**
3. Insert a test strip as far as you can into the meter. The meter turns on.

4. Confirm that the number displayed matches the number on the test strip container, then press **M**. If the numbers are different, make sure you are using the code chip that came with the test strips you are using. If they still do not match, call the Roche Diagnostics Technical Service Center at 1-800-428-4674, 24 hours a day, 7 days a week.



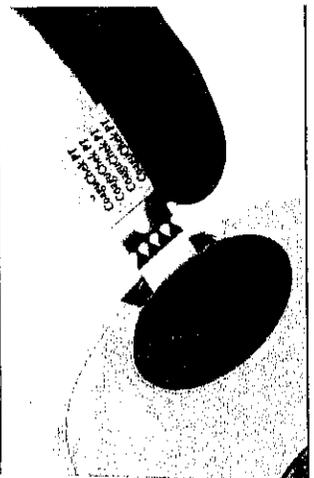
5. An hourglass appears as the meter warms up, which takes about 30 seconds.
6. When the meter is warmed up, a flashing test strip and blood drop symbol appear and the meter begins a countdown. You have 120 seconds to apply blood to the test strip.

7. Use the lancet device to perform a fingertick. **Set the penetration depth to 5.** See the *CoaguChek XS System User Manual* for more information. After sticking your finger, you have 15 seconds to apply blood to the test strip. If it takes longer to form a good drop of blood, lance a different finger for the test.

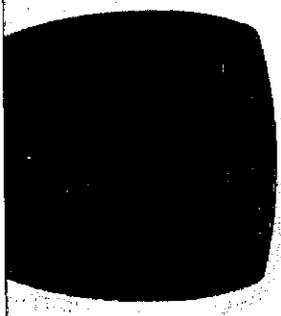


8. The meter must be on a table. Apply 1 drop of blood to the side of the test strip.

*It's important to hold the blood drop to the test strip until you hear a beep.*



9. You'll see the hourglass when the blood test begins. Then, pull your finger away from the test strip.



Remember to apply only one drop of blood—don't add more. Do not touch or remove the test strip when a test is in progress.

*The result appears in about 1 minute.*

10. Record the result on the *CoaguChek XS System Prothrombin Time Self-Testing Log Book*. Call your doctor with the test result.

11. Properly dispose of the used lancet and test strip.

12. Turn the meter off.

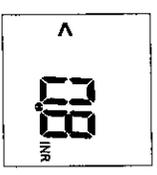
If you need to redo a test, use a new lancet, a new test strip, and a different finger.

### Additional Information

The *CoaguChek XS System User Manual* contains more information. If you need technical help, call the Roche Diagnostics Technical Service Center at 1-800-428-4674, 24 hours a day, 7 days a week.

### Very Low or Very High Test Results

The CoaguChek XS PT test strips provide test results if the INR value is between 0.8 and 8.0. If the meter displays < (less than) **0.8** or > (greater than) **8.0**, repeat the test. If, when you repeat the test, you get the same display (either < **0.8** or > **8.0**), call your doctor.

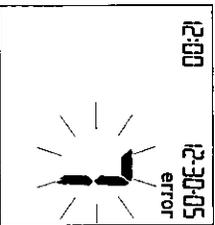


OR



## Error Messages

If you see Error 7, repeat the test. Be sure to apply the blood drop to the test strip within 15 seconds of sticking the fingertip. If you still get Error 7, call the Roche Diagnostics Technical Service Center at 1-800-428-4674. If the meter displays any other error message, refer to the *Error Messages* section of the *CoaguChek XS System User Manual*.



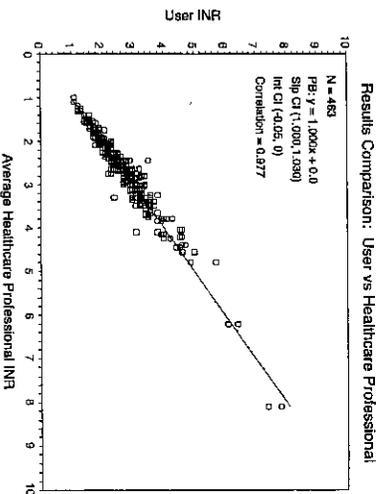
## Built-In Controls

The CoaguChek XS System has built-in quality control functions in the meter and test strips. The meter automatically runs its own quality control test as part of every blood test, so you never have to run quality control tests with liquid quality controls. For more information about the built-in quality control functions, see the *CoaguChek XS System User Manual*.

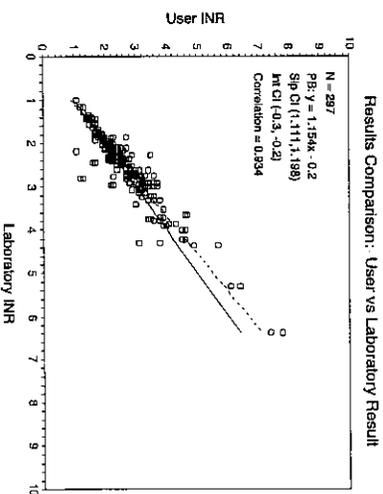
## Performance Characteristics

**Measuring Range:** The CoaguChek XS PT System has a PT measuring range of 0.8-8.0 INR and 9.6-96.0 seconds.

**Accuracy:** A study was conducted comparing test results obtained by trained users with those obtained by healthcare professionals, when both were using the CoaguChek XS System. The correlation was very good, as indicated by the following statistics:  $N=463$ ,  $Slope=1.000$ ,  $Intercept=0.0$  and  $Correlation\ Coefficient=0.977$ . This study shows that trained users are able to obtain results that are as accurate as those obtained by healthcare professionals trained in the use of the CoaguChek XS System.



The test results obtained by trained users were also compared to results obtained using a laboratory-based reference method. Results are shown in the plot below.



## Study User Demographics: A clinical

study was conducted by Roche Diagnostics, consisting of four visits to the clinical site. Informed consent and randomization occurred at Visit 1. Testing began at Visit 2. Ninety-one patients completed at least one visit after Visit 1. The following table outlines the demographic information for the trained users who completed at least one visit after Visit 1.

Demographic	Number	Percent
Total number of users	91	100%
Caregivers	4	4.4%
Males	51	56%
Females	40	44%
Age range	32 - 89	100%
Mean Age	64 years	N/A
Age 65 - 69 years	16	17.6%
Age 70 - 74 years	13	14.3%
Age 75 years and up	16	17.6%
Education Level - Eighth grade or less through advanced college degree	91	100%
Median Education Level	Some college	N/A
On warfarin 3 - 12 months	19	20.9%
On warfarin 1 - 2 years	22	24.2%
On warfarin 3 - 5 years	23	25.3%
On warfarin > 5 years	27	29.7%
Atrial fibrillation	38	41.8%
Valve replacement	25	27.5%
Stroke/stroke prevention	7	7.7%
DVT	5	5.5%
Other heart conditions	6	6.6%
Other clotting disorders	10	11%

There were 107 patients enrolled. A total of 88 patients completed all four visits to the site. The reasons for drop-outs were as follows:

Reason for Drop-Out	# of Subjects
Felt it was too stressful	2
Didn't have time	3
Didn't want to use meter on his own	1
Didn't think he could learn to use meter	1
Was having knee surgery	1
Study terminated prior to Visit 4	1
Unknown	7
Disqualified due to target INR range outside of study protocol	3

**Precision:** A study was conducted and the precision of duplicates for capillary blood results was calculated for both trained users and healthcare professionals. The following results were obtained:

User Results	Professional Results
<b>N</b> 214	249
<b>Mean</b> 2.57	2.52
<b>SD</b> 0.13	0.13
<b>CV</b> 5.13	5.36

This study shows that trained users are able to obtain results that are as precise as those obtained by healthcare professionals trained in the use of the CoaguChek XS System.

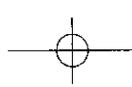
**Limited Warranty**

Roche Diagnostics warrants that your CoaguChek XS PT test strips will be free from defects in materials and workmanship until the product expiration date printed on the label if the test strips are stored and used in the manner described in this package insert and in your CoaguChek XS System User Manual. If, prior to the expiration date of the test strips there is a defect in materials or workmanship, Roche Diagnostics will replace the test strips free of charge. Your sole and exclusive remedy with respect to the strips shall be replacement. Any warranty claim should be directed to the Roche Diagnostics Technical Service Center at 1-800-428-4674.

THE ABOVE WARRANTY IS EXCLUSIVE OF ALL OTHER WARRANTIES, AND ROCHE DIAGNOSTICS MAKES NO OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION THE IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. IN NO EVENT SHALL ROCHE DIAGNOSTICS BE LIABLE TO THE PURCHASER OR ANY OTHER PERSON FOR ANY INCIDENTAL, CONSEQUENTIAL, INDIRECT, SPECIAL OR PUNITIVE DAMAGES ARISING FROM OR IN ANY WAY CONNECTED WITH THE PURCHASE OR USE OF THE TEST STRIPS.

NO WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. IF ANY IS IMPLIED FOR THE SALE OF THE TEST STRIPS, SHALL EXTEND FOR A LONGER DURATION THAN THE EXPIRATION DATE OF THE TEST STRIPS.

The following U.S. patents have been granted or are pending for the CoaguChek XS System (meter and test strips): 6,602,438; 7,073,246; 7,051,103; 6,981,378; 6,207,000; 2005/0214171; 2005/0123441; 6,646,388; 2004/0197339; 2005/0129574; 2005/0135988  
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Manufactured for:  
Roche Diagnostics  
9115 Hague Road  
Indianapolis, IN 46259  
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579-35204-0107



# CoaguChek<sup>®</sup> XS System

**Professional**

**Training Manual**

**for Self-Testing**



45



# Table of Contents

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	<b>Introduction.....</b>	<b>1</b>
<b>1</b>	<b>Overview of Warfarin Therapy and the CoaguChek XS System.....</b>	<b>3</b>
<b>2</b>	<b>Materials for User Training .....</b>	<b>5</b>
<b>3</b>	<b>User Selection Guidelines .....</b>	<b>7</b>
	Overview.....	7
	Clinical Study.....	8
	Performance Characteristics .....	9
<b>4</b>	<b>Training Users for Self-Testing .....</b>	<b>13</b>
	Preparation.....	13
	Supplies.....	13
	Training Outline.....	14
	Testing the Trainees.....	20
	<i>Certificate of Completion</i> .....	20
	Follow-up Visits.....	20
<b>5</b>	<b>Proficiency Checks.....</b>	<b>21</b>
<b>6</b>	<b>Forms.....</b>	<b>23</b>

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## Introduction

### Introduction

Roche Diagnostics is pleased to present this guide to assist you in training individuals in the use of the CoaguChek® XS System. The guide contains a variety of materials to help you plan the curriculum:

- an overview of the CoaguChek XS System
- a description of training materials available from Roche Diagnostics
- a guide to selecting appropriate individuals to participate in self-testing
- a suggested outline for the training class
- *Skills Checklist and Knowledge Test*
- *Certificate of Completion* to be given to trainees
- suggestions for refresher training.

If you have questions, please contact the Roche Diagnostics Technical Service Center 1-800-428-4674, 24 hours a day, 7 days a week, 365 days a year.

### Obtaining CoaguChek XS Meters for Users

Roche Diagnostics uses a network of certified national distributors to assist you with acquiring a CoaguChek XS System for your users. Contact your Roche Account Manager or the Roche Diagnostics Technical Service Center at 1-800-428-4674, 24 hours a day, 7 days a week, 365 days a year. Potential users who will be self-testing must have a doctor's prescription for the CoaguChek XS meter and complete a training program offered through an approved Roche distributor.



# 1 Overview of Warfarin Therapy and the CoaguChek XS System

## OVERVIEW

---

The CoaguChek XS System from Roche Diagnostics measures blood-clotting time for people who are taking anticoagulation medications such as warfarin (for example Coumadin®). Warfarin is an oral anticoagulant that changes the formation of certain blood factors produced in the liver in such a way that the clotting time is slowed. (Refer to the latest warfarin package insert for contraindications.) The goal is to prevent clots from forming or moving. At the same time, however, it is important to avoid excessive anticoagulation, or blood thinning, which carries a risk of hemorrhage.

People on warfarin therapy must be monitored closely for two reasons. First, as indicated above, it is very important to keep blood coagulation time within an optimal therapeutic, or target, range. Second, each individual reacts differently to warfarin, and the medication's ability to prevent a clot is affected by a person's metabolism, diet, and other medications.

The variability of laboratory results due to reagent differences is a common problem. The CoaguChek XS System minimizes the variability that is seen with traditional PT/INR assay reagents. Each lot of test strips is compared to a reference material by Roche Diagnostics. The strips are then assigned a "code," which standardizes the reported result via a mathematical algorithm, thus minimizing lot-to-lot variability. No manual calibration of the system is required; each lot of strips comes with a code chip that stores the information needed for automatic calibration.

The CoaguChek XS System offers significant advantages in both convenience and reliability. It is a hand-held, battery-operated system that can perform a PT/INR blood test on a fresh whole blood sample from a fingerstick. A test strip is inserted into the meter and a blood sample applied to the strip. The test result is displayed in about one minute. The need for trips to the laboratory or for venipuncture is virtually eliminated.

The CoaguChek System by Roche Diagnostics has been used successfully since 1994 by health care professionals in anticoagulation clinics, physicians' offices, and home health agencies and since 1997 for self-testing. Now, there is the CoaguChek XS System available for self-testing. The materials that follow are designed to help you select appropriate users and train them to use the CoaguChek XS System properly.





## Materials for User Training

Roche Diagnostics has developed the following materials, provided in the product care kit, specifically for your use in training new users to self-test with the CoaguChek XS System:

### **Training DVD**

This program, which runs approximately 15 minutes, provides step-by-step instruction in setting up the meter, preparing for and performing a fingerstick blood test, running quality control checks, and cleaning the meter. It is intended to be the basis of the training session. You may also use the DVD as a trainee selection aid; individuals who are unsure of what self-testing involves may be shown the DVD to help them decide if they want to go through training and try self-testing.

### **CoaguChek XS System User Manual**

A copy of the manual is provided with each CoaguChek XS Meter. It is intended to be used as an ongoing reference guide by users, but should also be used in training to familiarize trainees with the content and structure of the manual and make them comfortable with referring to it.

### **Getting Started Guide**

A Getting Started reference guide is included in each CoaguChek XS System Care Kit. It provides an easy reference for testing.

### **Package Inserts**

Both the test strips and lancet device have package inserts with information about proper storage and use. It is important to call the users' attention to the inserts during training.

To order additional copies of any of these materials, or to make comments or suggestions about the training materials, please contact the Roche Diagnostics Technical Service Center 1-800-428-4674, 24 hours a day, 7 days a week, 365 days a year.





## User Selection Guidelines

### OVERVIEW

---

It is important that users be screened carefully before beginning a self-testing program. The following questions are designed to guide the physician, clinic nurse, or other health care professional in determining an individual's suitability for self-testing.

- Are specific diagnoses more appropriate for self-testing?** No, the specific diagnosis is not necessarily indicative of who should or should not self-test. However, prior to beginning self-testing, users should be stabilized on anticoagulation medications such as warfarin. People with chronic conditions (for example, congestive heart failure, atrial fibrillation, prosthetic heart valve replacement) who will need frequent monitoring over a long period of time are certainly candidates for self-testing.
- What personal characteristics must the potential user have?** The person must be reliable, compliance-oriented, and able to follow instructions.
- What do I look for in judging these characteristics?** Consider the following:
- Does the person keep appointments?
  - Does he or she comply with medication dosing and other elements of the treatment regimen?
  - Is he or she capable of understanding the importance of testing and the details of the testing procedure?
  - Are vision and motor skills adequate?
- What else should I consider?** Look for motivated individuals who want to take an active part in managing their condition. Lifestyle factors may be important; people who travel, work, or find it difficult to get to the laboratory may be especially motivated to learn self-testing.
- Which individuals probably should not self-test?**
- It is up to the attending physician to determine which individuals are eligible for self-testing.
  - Refer to the test strip package insert for current limitations of procedure.
- Is it appropriate to train a third-party tester?** Motivated parents of children who need testing or caregivers for other individuals (for example, a spouse) may be trained. The caregiver should be screened using the same criteria.

### 3 User Selection Guidelines

**Once the potential user has passed the initial screening, what do we do next?**

Explain to the person in general terms what will be involved and provide an opportunity to ask questions. If he or she expresses interest, send a copy of the training DVD home or show it in the office. Stress that this overview is only intended to give a better idea of what self-testing involves and that more detailed training and follow-up support will be provided. Each potential user will be instructed on the fingerstick procedure and perform a fingerstick as part of the screening. If the person wants to continue participation after seeing the DVD and performing a fingerstick, he or she should be enrolled in a training class.

#### **Clinical Study Information**

A clinical study was conducted by Roche Diagnostics consisting of four visits to the clinical site. Informed consent and randomization occurred at Visit 1. Testing began at Visit 2. Ninety-one individuals completed at least one visit after Visit 1. The following table outlines the demographic information for the users who completed at least one visit after Visit 1.

Demographic	Number	Percent
Total number of users	91	100%
Caregivers	4	4.4%
Males	51	56%
Females	40	44%
Age range	32 - 89	100%
Mean Age	64 years	N/A
Age 65 - 69 years	16	17.6%
Age 70 - 74 years	13	14.3%
Age 75 years and up	16	17.6%
Education Level- Eighth grade or less through advanced college degree	91	100%
Median Education Level	Some college	N/A
On warfarin 3 - 12 months	19	20.9%
On warfarin 1 - 2 years	22	24.2%
On warfarin 3 - 5 years	23	25.3%
On warfarin > 5 years	27	29.7%
Atrial fibrillation	38	41.8%
Valve replacement	25	27.5%
Stroke/stroke prevention	7	7.7%
DVT	5	5.5%
Other heart conditions	6	6.6%
Other clotting disorders	10	11%

There were 107 people enrolled. A total of 88 people completed all four visits to the site. The reasons for drop-outs were as follows:

Reason for Drop-Out	# of Subjects
Felt it was too stressful	2
Didn't have time	3
Didn't want to use meter on his own	1
Didn't think he could learn to use meter	1
Was having knee surgery	1
Study terminated prior to Visit 4	1
Unknown	7
Disqualified due to target INR range outside of study protocol	3

## PERFORMANCE CHARACTERISTICS

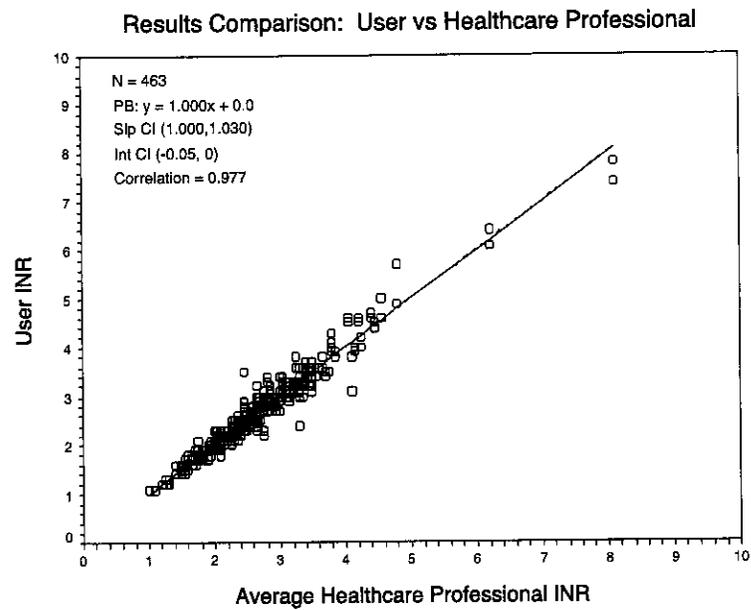
### Measuring Range:

The CoaguChek XS PT System has a PT/INR measuring range of 0.8–8.0 INR and 9.6–96.0 seconds.

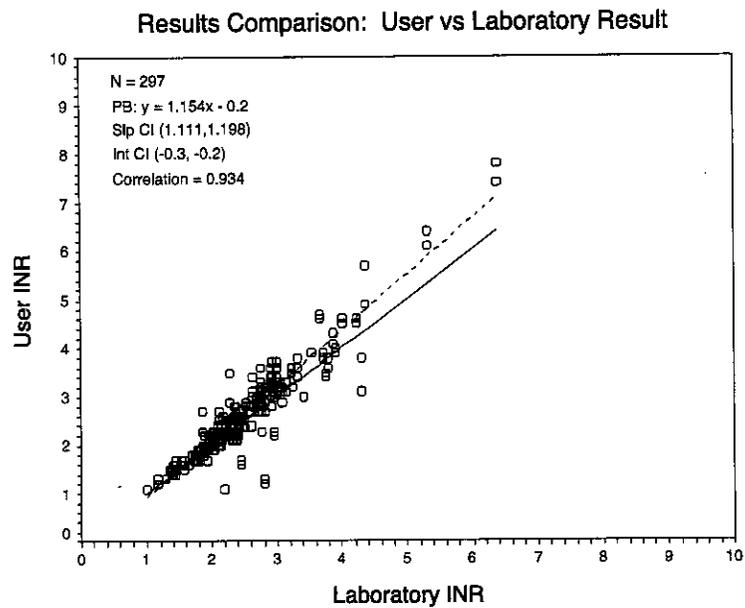
### Accuracy:

A study was conducted comparing test results obtained by trained users with those obtained by healthcare professionals, when both were using the CoaguChek XS System. The correlation was very good, as indicated by the following statistics: N=463, Slope=1.000, Intercept=0.0 and Correlation Coefficient=0.977. This study shows that trained users are able to obtain results that are as accurate as those obtained by healthcare professionals trained in the use of the CoaguChek XS System.

Accuracy:



The test results obtained by trained users were also compared to results obtained using a laboratory-based reference method. Results are shown in the plot below.



**Precision:**

A study was conducted and the precision of duplicates for capillary blood results was calculated for both trained users and healthcare professionals. The following results were obtained:

	<b>User Results</b>	<b>Professional Results</b>
N	214	249
Mean	2.57	2.52
SD	0.13	0.13
CV	5.13	5.36

This study shows that trained users are able to obtain results that are as precise as those obtained by healthcare professionals trained in the use of the CoaguChek XS System.

During the study, the following error rates were observed:

		<b>Visit 1</b>	<b>Visit 2</b>	<b>Visit 3</b>	<b>Overall</b>
Error 6	Test Strip Interference	0.8%	0.9%	0.5%	0.7%
Error 5	Blood Application	31.7%	23.9%	18.9%	25.2%
Error 4	Test Strip Unusable	0.8%	0.0%	2.8%	1.1%
Error 000	Time Exceeded	1.5%	1.3%	0.0%	1.0%
Error QC	Quality Control Failure	1.1%	0.0%	0.0%	0.4%
	Unknown Error	1.1%	0.0%	0.5%	0.6%



## 4 Training Users for Self-Testing

### PREPARATION

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The suggested time for each training session is two hours. If you prefer, you may break this into two one-hour sessions. Some trainers have found that it works well to have one educational session and one hands-on practice session. However the training is scheduled, it is important to allow plenty of time for trainees to practice the testing procedure and ask questions.

Training is mandatory. Users should not be permitted to take a meter home without satisfactorily completing a training session and passing the *Knowledge Test* and *Skills Checklist*.

Schedule training in a room free of distractions and with adequate facilities for trainees to take notes and practice with the meters.

Limit training classes to small groups so trainees can have individual attention during the practice session. It may be helpful to have an assistant.

Organize the presentation, gather the needed supplies, and make sure the meters are operational.

### SUPPLIES

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#### CoaguChek XS Testing Supplies

(one set for each trainee  
plus one for demonstration)

- CoaguChek XS System Care Kit, consisting of:
  - CoaguChek XS Meter
  - 4 AAA batteries
  - CoaguChek XS System User Manual
  - CoaguChek XS System Getting Started Guide
  - CoaguChek XS System Prothrombin Time Self-Testing Log Book
  - ACCU-CHEK® Softclix lancet device and lancets
  - CoaguChek XS System Training DVD
  
- CoaguChek XS Test Kit, consisting of:
  - A container of test strips
  - A test strip code chip
  - The test strip package insert

**Other Supplies**

- Alcohol wipes
- Cotton balls or tissue
- Pre-packaged towelettes such as CoaguWipes® or 10% bleach solution (1 part bleach to 9 parts water)
- Biohazard waste and sharps containers for disposal of supplies and lancets used during practice
- Disposable gloves for instructor and assistants to wear when assisting trainees in practicing fingersticks
- DVD player
- TV monitor
- Sufficient copies of the class outline, *Knowledge Test*, *Skills Checklist*, Log Book, *Certificate of Completion*, and key sections of the *CoaguChek XS User Manual*, especially the *Error Messages* section

**TRAINING OUTLINE**

**User Training  
CoaguChek XS System**

Topic	Time to Present/Practice
Introduction and Overview of Training Session	5 minutes
CoaguChek XS System Training DVD	15 minutes
Review of CoaguChek XS System and Operating Guidelines	10 minutes
Review System Set-Up	5 minutes
Testing Fingerstick Samples (including practice and completion of <i>Skills Checklist</i> )	40 minutes
Documenting Results on Log Book	5 minutes
Review Built-In Quality Control	10 minutes
Cleaning the CoaguChek XS System	5 minutes
<i>Knowledge Test</i>	10 minutes
Local Information and Wrap-Up	10 minutes

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**Introduction and Overview of Training Session**

1. Explain the importance of regular PT/INR testing.
2. Review the policy for certification. Explain that each trainee will be asked to successfully complete a *Knowledge Test* and *Skills Checklist*.
3. Review the agenda for the training session. (This outline may be copied and distributed to attendees as a detailed reference.)

**CoaguChek XS System Training DVD**

Show the 15-minute Training DVD, which gives an overview of the testing procedure, built-in quality control testing, and maintenance.

**Review of CoaguChek XS System and Operating Guidelines**

1. Review components of the CoaguChek XS Meter
  - Display panel
  - M (memory) button
  - ON-OFF button
  - Test strip guide cover
  - Test strip guide
  - Battery compartment cover
  - Code chip slot
  - SET button
  - Data port
2. Review contents of the Test Kit
  - A container of 6 test strips
  - The test strip code chip
  - The test strip package insert
3. Review operating conditions of the meter and proper storage conditions of test strips
  - Operate meter at room temperature, 65°–90° F (18°–32° C).
  - Operate meter with 10% to 85% relative humidity, without condensation.
  - Avoid bright sunlight.
  - Operate the meter on a flat surface, free of vibrations.

- Use well-protected carrying case.
- Read the information packaged with the test strips regarding up to date product specifications and limitations.
- Read the latest warfarin package insert for contraindications.

### Review System Set-Up

1. The CoaguChek XS System uses four AAA alkaline batteries, inserted into the battery compartment on the back of the meter. Explain the importance of entering the correct date and time. (Each time you run a test, the meter compares its date with the test strip's expiration date. If the test strip is expired, the meter displays an error message and prevents you from running a test.)
2. Discuss the purpose of the code chip included with each test kit. The code number on the test strip container must match the code chip number.
3. Review how to insert the code chip. Make sure the meter is off. Insert the code chip with the code number facing up until it snaps into place.
- 4 Explain that the meter has set-up options that users will not be asked to change. Appropriate settings have been programmed before they receive their meters.

### Testing Fingerstick Samples

(including practice and completion of *Skills Checklist*)

**Important:** If a caregiver assists with the testing procedure, it is recommended that the caregiver wash hands thoroughly and wear disposable gloves to prevent contact with the blood sample.

1. Review supplies needed for performing a self-test:
  - CoaguChek XS meter
  - Container of test strips
  - Test strip code chip
  - ACCU-CHEK Softclix lancet device and lancet
2. Review how to prepare the lancet device.

Users pull off the cap and insert a new lancet. Provide these instructions: Twist off the lancet's protective cap. Put the cap back on the lancet device. To place the cap back on, line up the notch on the cap with the center of the semi-circle. Turn the dial so that the center of the semi-circle points to 5. (The lancet device has multiple depth settings, so the user can use the setting

that works best. The higher the number, the deeper the penetration. The first time a person uses it, try a depth setting of 5. If the blood drop you get is not sufficient, try a higher setting.)

Instruct the user to press the plunger. A yellow dot appears in the release button, telling the user that the device is ready. Tell the user to set it aside while preparing for the fingerstick.

3. Review how to prepare for a fingerstick, instructing the user to:

- Wash the hand in warm, soapy water. This cleans and warms the hand.
- Massage the finger from its base.
- Let the hand hang loosely at his or her side for 10 to 30 seconds.
- Use these techniques until the fingertip has good color.

4. Review testing procedures, instructing the user to follow this process:

- The correct code chip must be in the meter. The code chip automatically provides the meter with the information that is specific to each lot of test strips. Each box of test strips comes with a matching code chip. Every time users open a new box of test strips, they will replace the code chip.
- Take a strip out of the test strip container. Close the container tightly.
- Slide the test strip into the meter's test strip guide in the direction of the arrows until it stops. The meter will turn on and the code number of the inserted code chip will flash on the display.
- Be sure the code number on the display matches the number on the test strip container, then press **M**.
- After **M** is pressed, an hourglass appears as the meter warms up. A flashing test strip and blood drop appear when the meter is ready for a sample. The user has 120 seconds to apply a blood drop to the test strip.

5. Review collecting and applying the sample, instructing the user to follow this process:

- Massage the finger from the base until there is increased color in the fingertip. Keeping the hand down, press the tip of the lancet firmly against the side of the fingertip. Press the release button.
- The meter must be on a table. Find the target area on the test strip.
- Within 15 seconds of sticking the fingertip, apply the blood drop from the fingertip to the target area from the side. See the user manual for more information.

- Hold the blood drop to the test strip until the meter beeps. The flashing blood drop symbol will disappear and the result will appear on the display, which takes about a minute. **Do not add more blood or touch the test strip.**
- If the meter displays an error message rather than a test result, refer to the *Error Messages* section of the user manual to learn what to do next.
- To run a new test, use a new test strip and a different finger.

6. Review final testing steps, instructing the user to:

- Record the result in the Log Book. The meter will automatically store 100 results, with the date and time, in its memory.
- Clean up: remove the lancet from the lancet device. Place the used test strip and lancet in a puncture-proof waste container with a lid. Turn the meter off. If the meter is dirty, wipe it with a lint-free tissue and an approved cleaning solution.
- Always call their doctor with their test results.
- If the result is outside the therapeutic range, call the doctor immediately.

7. Review the procedure to follow if the test results are not in the accepted PT/INR range:

- Explain to the user that a PT/INR result outside the therapeutic range is a result that is above or below the immediate follow-up values set by their doctor or designated healthcare professional. The user must contact his or her doctor immediately if this occurs. Include clear instructions on how the user is to contact his or her doctor and what the user is to do if the doctor is not immediately available. The user's doctor should write these immediate follow-up values and follow-up instructions in the appropriate section of the user's Log Book.

NOTE: *Be sure the meter is properly set up, including date, time, and units of measurement, before the training session ends.*

## Review Built-In Quality Control

The CoaguChek XS System has built-in quality control functions in the meter and test strips. The meter automatically runs its own quality control test as part of every blood test, so you never have to run quality control tests with liquid quality controls.

When the quality control test runs, the letters **QC** flash on the meter's display. When the quality control test is finished, a check mark (✓) appears following the letters **QC**. Then the meter continues to run the blood test.

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The built-in quality control helps you know that your test strip has not been damaged. If you receive a test error, look in the manual for an explanation of all test errors.

### **Cleaning the CoaguChek XS System**

Review cleaning procedures with the user, instructing them to follow this process: A user should clean the meter whenever it looks dirty or each time he or she opens a new box of test strips, whichever the user prefers.

Use only the following products to clean the meter:

- pre-packaged bleach towelettes such as CoaguWipes® or 10% bleach solution (1 part bleach and 9 parts water)
- 70% isopropyl alcohol solution
- lint-free tissues
- cotton swabs.

Do not spray any cleaning solution on the meter. Never use a spray of any type.

To clean the exterior of the meter:

1. With the meter turned off, wipe the meter's exterior clean.
2. With a lint-free tissue, dry the meter.

To clean the test strip guide:

1. Open and clean the cover. With the meter turned off, use your thumbnail to open the cover of the test strip guide by pressing its front edge upward. Move the cover safely away from the meter. Then rinse the cover with water or wipe it clean.
2. Clean the test strip guide. Clean the easily accessible areas with a cotton swab. Do not insert any objects into the test strip guide.
3. Allow the test strip guide to dry, with the cover off, for about 10 minutes.
4. Close the cover, and make sure it snaps into place.

## TESTING THE TRAINEES

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1. Complete the *Skills Checklist*, included in this package, after observing each trainee during the hands-on practice session. One or more assistants may be helpful in completing the checklists without slowing down the class.
2. Have trainees complete the *Knowledge Test*, included in this package, at the end of the training presentation and practice sessions.
3. Score the test with the answer key and review any areas of confusion.
4. Develop a plan before the training class for remedial action if trainees do not perform adequately on either of the tests. In some cases, it may be necessary to return the trainee to a laboratory testing regimen.

The *Skills Checklist* and *Knowledge Test* master forms can be copied as needed and are included in the back of this manual.

## CERTIFICATE OF COMPLETION

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Each trainee who successfully completes the class and the tests should be given a certificate. A certificate that can be copied as needed is included in the *Forms* section at the back of this binder.

## FOLLOW-UP VISITS

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Remind all trainees they are required to return for two follow-up visits where they will demonstrate their knowledge of self-testing with the CoaguChek XS System.



## Proficiency Checks

After completing the training class and beginning self-testing, users should be monitored periodically by a trained healthcare professional to be sure their testing technique is correct and the meter is performing properly. Suggested frequency for monitoring is every six months. The following procedure may be useful:

- Establish a reminder system that prompts you to contact each user at 6-month intervals.
- Make an appointment for the user to come to the clinic or office.
- Ask the user to bring the CoaguChek XS meter, testing supplies, and Log Book.
- During the interview, record your observations on the 6-month Performance Evaluation form.
- Inspect the meter thoroughly.
- Observe the user cleaning the CoaguChek XS meter. If necessary, stress the importance of maintaining a regular cleaning schedule.
- Observe the user performing a blood test. If necessary, offer suggestions for improvement. A 2-week follow-up is recommended whenever competency needs reassessment.
- The healthcare professional will perform a user blood test after the trainee performs a self-test. The test should match within 30%; this verifies that the meter is performing properly. If this test indicates a problem with the meter or test strips, repeat the test. If the result is still in question, please contact the Roche Diagnostics Technical Service Center 1-800-428-4674, 24 hours a day, 7 days a week, 365 days a year.
- If the test result is within range and the user performs all tests satisfactorily, make an appointment for six months in the future.





## Forms

### OVERVIEW

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The following forms are included as part of the CoaguChek XS System training for self-testing.

These forms should be used as originals. Please feel free to copy them as needed.

- *Skills Checklist*
- *Knowledge Test*
- *Answer Key*
- *Certificate of Completion*

## COAGUCHEK XS SYSTEM SKILLS CHECKLIST

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Trainer should check each activity as it is demonstrated or described.

### User Assemble Equipment

- CoaguChek XS meter
- Container of test strips
- Test strip code chip
- ACCU-CHEK Softclix lancet device and lancet

### User Reviews Procedure

- States when coding is needed
- Turns meter off before inserting or removing code chip
- Removes old code chip if one is installed
- Inserts new code chip until it snaps into place

### Performs Test Procedure

- Properly prepares lancet device
- Turns meter on
- Inserts test strip
- Obtains blood sample correctly
- Applies blood to test strip correctly
- Reads result
- Records result
- Tries to correct any problem should there be an error message, using the solutions described in the user manual
- Is aware of the 24-hour Technical Service number at 1-800-428-4674 if problem persists
- Properly discards used test strip and blood-drawing supplies

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71



## COAGUCHEK XS SYSTEM SKILLS CHECKLIST

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**Recalls Results from Memory**     Correctly recalls results stored in memory

**Problem Solving**     Refers to *Error Messages* in the user manual when a problem occurs

**Cleaning**

- States minimum cleaning frequency
- Demonstrates exterior cleaning procedure as stated in the user manual
- Properly cleans test strip guide

**Battery Replacement**     Demonstrates removal and replacement of batteries

Trainee Name: \_\_\_\_\_

Training Date: \_\_\_\_\_

Training Site: \_\_\_\_\_

Trainer Name: \_\_\_\_\_

Trainer Signature: \_\_\_\_\_ Date: \_\_\_\_\_

## COAGUCHEK XS SYSTEM KNOWLEDGE TEST

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**Mark "T" if the statement is true and "F" if the statement is false.**

- \_\_\_ 1. When coding the CoaguChek XS Meter, you must use the code chip from the same test strip container that you are using.
- \_\_\_ 2. After removing a test strip from the container, it is important to close the cap tightly.
- \_\_\_ 3. When performing a blood test, it is important to hold the finger to the strip until the meter beeps.
- \_\_\_ 4. The sample must be applied to the test strip within five minutes of removing it from the container.
- \_\_\_ 5. INR is a reporting format that stands for International Normalized Ratio.
- \_\_\_ 6. Every time a blood test is performed, the meter also performs a built-in quality control test.
- \_\_\_ 7. If the built-in quality control test fails, the meter will still give a test result.
- \_\_\_ 8. The most recent user result appears first when reviewing memory.
- \_\_\_ 9. CoaguChek XS test strips may be stored at room temperature until the expiration date printed on the container.
- \_\_\_ 10. The CoaguChek XS Meter stores up to 50 results with time and date.

**Please answer the following questions:**

11. What is used to clean the exterior of the CoaguChek XS Meter?

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# COAGUCHEK XS SYSTEM KNOWLEDGE TEST

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12. What would cause Error 3 to appear on the display?

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13. What would cause Error 5 to appear on the display?

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14. After inserting a test strip, the code flashes on the display. What is the next step?

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15. Why is it important to apply blood to the test strip within 15 seconds of sticking the finger?

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Trainee Name: \_\_\_\_\_

Training Date: \_\_\_\_\_

Training Site: \_\_\_\_\_

Trainer Name: \_\_\_\_\_

Trainer Signature: \_\_\_\_\_ Date: \_\_\_\_\_



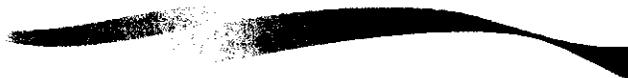
## ANSWER KEY

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### For CoaguChek XS System Knowledge Test

1. T
2. T
3. T
4. F - The sample must be applied to the test strip within 10 minutes of removing the strip from the container.
5. T
6. T
7. F - If the built-in quality control does not pass, a flashing "QC" will appear on the display.
8. T
9. T
10. F - The CoaguChek XS Meter stores up to 100 test results with time and date
11. The CoaguChek XS Meter can be cleaned with 10% bleach solution or 70% isopropyl alcohol.
12. Error 3 indicates that the strip is expired. Ensure that the date is set correctly on the meter. If it is incorrect, set the correct date. If the date is correct, turn the meter off and remove the code chip and the test strip. Use the code chip and a test strip from a new box of test strips.
13. Error 5 indicates an error applying blood to the test strip. It is caused by not having a large enough drop of blood. When applying blood to the test strip, massage your finger until you have a good blood drop and hold your finger against the test strip until the meter beeps.
14. Confirm that the code flashing on the display matches the code on the container of test strips you are using. Then press the **M** button to continue the testing process.
15. After 15 seconds your blood may begin to clot, which could lead to an incorrect result.

# CoaguChek<sup>®</sup> XS System



*Certificate of Completion*  
presented to

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for successfully completing Self-Testing training on the

**CoaguChek<sup>®</sup> XS System**

Dated: \_\_\_\_\_

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Certified Training Consultant