

NOV 23 1999

R992577 page 1 of 2



P.O. Box 4002, Elkhart, IN 46514-0002 • (219) 264-3440 • FAX (219) 266-6222

510(k) SUMMARY

CIDEX®¹ OPA Solution Test Strips

SUBMITTED BY

James E. Christner
Serim Research Corporation
P.O. Box 4002
23565 Reedy Dr.
Elkhart, IN 46514

Phone: (219) 264-3440
Fax: (219) 266-6222
E-mail: jchristner@serim.com

Contact Person: James E. Christner

Date Prepared: July 7, 1999

DEVICE NAME

Trade Name: CIDEX® OPA Solution Test Strips
Common Name: Test Strips for *ortho*-Phthalaldehyde (OPA) in CIDEX® OPA Solution

Classification Name: Chemical Sterilization Process Indicator

PREDICATE DEVICE

Cidex® Solution Test Strips (K915170)

DESCRIPTION OF THE CIDEX® OPA SOLUTION TEST STRIP

The CIDEX® OPA Solution Test Strips consist of a 0.2 x 0.2-inch reagent-containing pad attached to one end of a 0.2 x 3.25-inch polystyrene handle. The indicator pad contains a color-forming reagent. It also contains an inhibiting compound that prevents visible reaction when the OPA concentration is at or below the MEC. When the OPA level is in sufficient excess of the MEC, the surplus reacts with the color-forming reagent.

The sample is placed in a 12 x 75-mm glass test tube. The indicator pad is immersed in the sample for 30 seconds, removed and allowed to react for an additional two and one-half

¹ © Advanced Sterilization Products, a Johnson & Johnson company, Division of Ethicon, Inc., Irvine, CA.

510(k) Summary – CIDEX® OPA Solution Test Strips

minutes at which time it is compared to a color standard. If the color of the entire pad is equal to or darker than the color standard, the concentration of *ortho*-phthalaldehyde (OPA) in CIDEX® OPA Solution is above the minimum effective concentration (MEC). If any part of the pad is lighter than the color standard, the CIDEX® OPA Solution should not be used.

INTENDED USE

CIDEX® OPA Solution Test Strips are semi-quantitative chemical indicators used to determine whether the concentration of OPA in CIDEX® OPA Solution is above or below the MEC. CIDEX® OPA Solution Test Strips cannot be used to validate the disinfection process.

TECHNOLOGICAL COMPARISON TO THE PREDICATE DEVICE

CIDEX® OPA Solution Test Strips are used for determining OPA in CIDEX® OPA Solution whereas the CIDEX® Solution Test Strips are used for determining glutaraldehyde levels in CIDEX® Activated Dialdehyde Solution. Both tests have dry, reagent-containing paper indicator pads attached to plastic handles. Both pads contain an inhibitor that prevents reaction with an indicator at ineffective active ingredient concentrations.

The reaction pad of the CIDEX® OPA Solution Test Strips is observed three minutes after the strip is immersed in the solution while that of CIDEX® Solution Test Strips is read between five and eight minutes after immersion. For interpretation of the result, the indicator pad of the CIDEX® OPA Solution Test Strip is compared with a standard color block. The CIDEX® Solution Test Strips use a visual standard for interpretation of the result.

STATEMENT OF SUBSTANTIAL EQUIVALENCE

Eight individuals used CIDEX® OPA Solution Test Strips from three trial production lots in blind studies to test CIDEX® OPA Solution standards. Three of the readers were inexperienced in laboratory techniques. A total of 324 results were obtained with each standard.

At the MEC (0.30% OPA), 324 results were FAIL giving a specificity (lack of false PASS results) of 1.00. At 0.40% and 0.45% OPA, 322 and 324 results, respectively, were PASS. These results show that the CIDEX® OPA Solution Test Strips effectively indicate when the OPA concentration in CIDEX® OPA Solution is at the MEC of 0.3%.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

NOV 23 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. James E. Christner
Vice President, Research & Development
Serim Research Corporation
P.O. Box 4002
23565 Reedy Drive
Elkhart, Indiana 46514

Re: K992341
Trade Name: CIDEX® OPA Solution Test Strips
Regulatory Class: II
Product Code: JOJ
Dated: October 22, 1999
Received: October 26, 1999

Dear Mr. Christner:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any

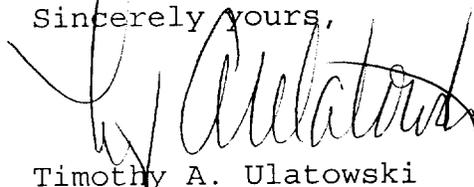
Page 2 - Mr. Christner

obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K992341

Device Name: CIDEX* OPA Solution Test Strips

Indications For Use:

CIDEX* OPA Solution Test Strips are semi-quantitative chemical indicators used to determine whether the concentration of active ingredient in CIDEX* OPA Solution is above or below the minimum effective concentration of 0.3% OPA. CIDEX* OPA Solution Test Strips cannot be used to validate the sterilization or disinfection process.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices



NOV 23 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. James E. Christner
Vice President, Research & Development
Serim Research Corporation
P.O. Box 4002
23565 Reedy Drive
Elkhart, Indiana 46514

Re: K992341
Trade Name: CIDEX® OPA Solution Test Strips
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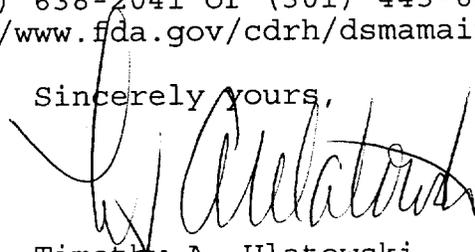
Page 2 - Mr. Christner

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Sincerely yours,



Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2

510(k) Number (if known): K992341

Device Name: CIDEX* OPA Solution Test Strips

Indications For Use:

CIDEX* OPA Solution Test Strips are semi-quantitative chemical indicators used to determine whether the concentration of active ingredient in CIDEX* OPA Solution is above or below the minimum effective concentration of 0.3% OPA. CIDEX* OPA Solution Test Strips cannot be used to validate the sterilization or disinfection process.

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

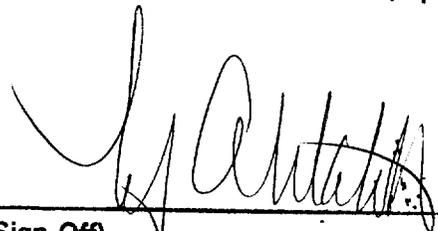
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)



(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOI@FDA.HHS.GOV or 301-796-8118

510(k) Number K992341

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Memorandum

From: Reviewer(s) - Name(s) November 13, 1999 Elaine S. Mayhall

Subject: 510(k) Number 159 52341/51

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.

De Novo Classification Candidate? YES NO

Other (e.g., exempt by regulation, not a device, duplicate, etc.)

- Is this device subject to 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

This 510(k) contains:

Truthful and Accurate Statement Requested Enclosed
(required for originals received 3-14-95 and after)

A 510(k) summary OR A 510(k) statement

The required certification and summary for class III devices

The indication for use form (required for originals received 1-1-96 and after)

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):

JOS Class II

Review: Elaine S. Mayhall
(Branch Chief)

ASCB
(Branch Code)

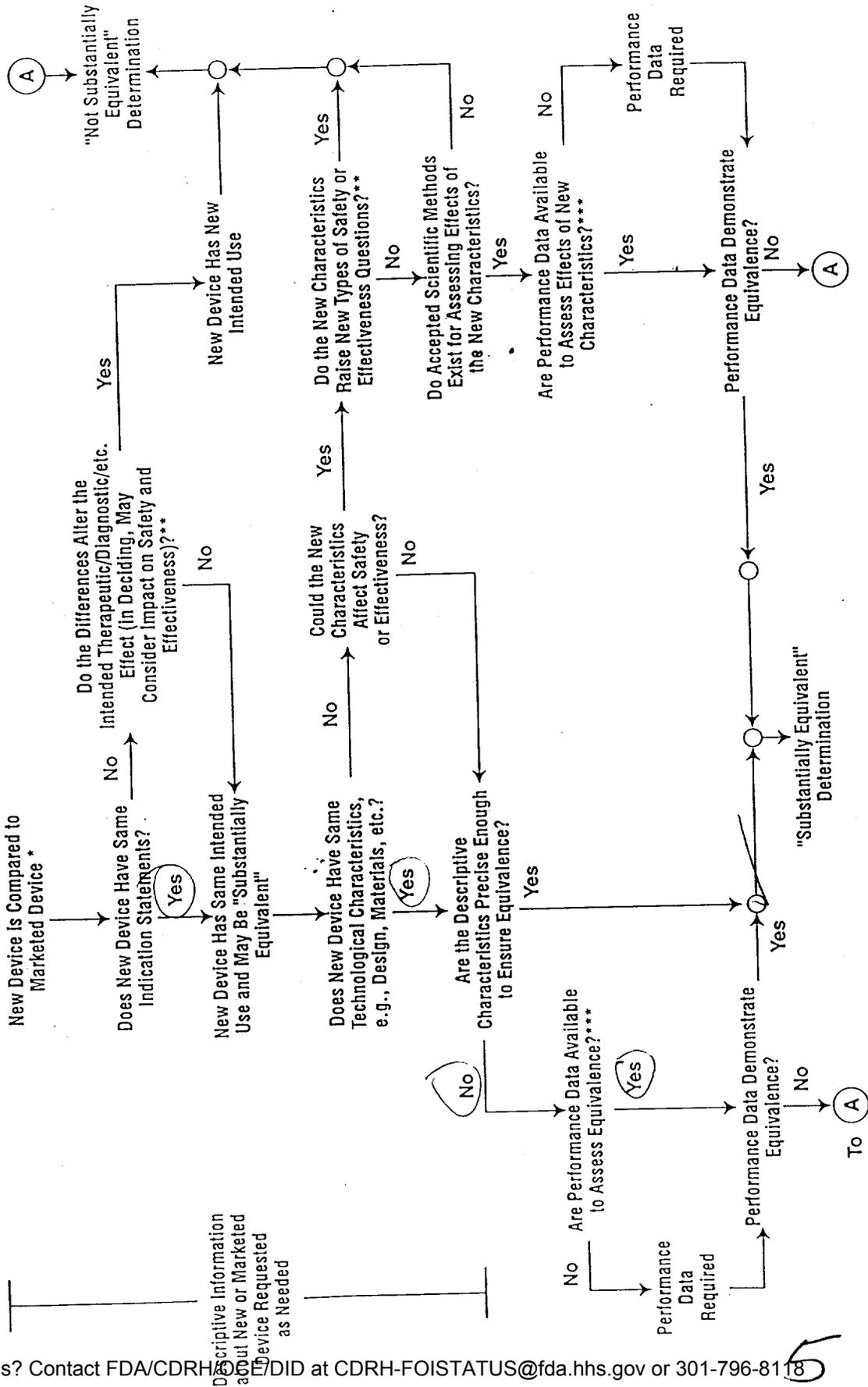
11-17-99
(Date)

Final Review: _____
(Division Director)

[Signature]
(Date) 11/18/99

Revised: 8/17/99

510(k) "Substantial Equivalence" Decision-Making Process (Detailed)



** 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.

* 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.

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION-MAKING DOCUMENTATION

510(k) Number: K992341

Reviewer: ELAINE SCHALK MAYHALL Division/Branch: DDIGD/INCB

Manufacturer Name: SERIM RESEARCH CORP.

Trade Name: CIDEX™ OPA SOLUTION TEST STRIP

Common Name: CHEMICAL INDICATOR

Products To Which Compared: CIDEX™ SOLUTION TEST STRIPS (K915170; A.K.A., PYMAH STERIOLOG INDICATOR STRIPS

	YES	NO	
1. IS PRODUCT A DEVICE?	<u>X</u>	—	IF NO STOP
2. DEVICE SUBJECT TO 510(K)?	<u>X</u>	—	IF NO STOP
3. SAME INDICATION STATEMENT?	<u>X</u>	—	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?	<u>X</u>	—	IF YES GO TO 7
6. COULD THE NEW CHARACTERISTICS AFFECT SAFETY OR EFFECTIVENESS?	— *	—	IF YES GO TO 8
7. DESCRIPTIVE CHARACTERISTICS PRECISE ENOUGH?	—	<u>X</u>	<u>IF YES STOP SE</u> <u>IF NO GO TO 10</u>
8. NEW TYPES OF SAFETY OR EFFECTIVENESS QUESTIONS?	—	—	IF YES STOP > NSE
9. ACCEPTED SCIENTIFIC METHODS EXIST?	—	—	IF NO STOP > NSE
10. PERFORMANCE DATA AVAILABLE?	<u>X</u>	—	IF NO REQUEST DATA
11. DATA DEMONSTRATE EQUIVALENCE?	<u>X</u>	—	> SE

* "yes" responses to 4, 6, 8, and 11, and every "no" response requires an explanation (see last page).

NARRATIVE DEVICE DESCRIPTION

1. **INTENDED USE:** The Cidex™ OPA Solution Test Strip is intended for monitoring the concentration of ortho-phthalaldehyde (OPA) in germicide solutions with a minimum effective concentration of 0.3% OPA. The indicator is dedicated for use with Cidex™ OPA Solution.
2. **DEVICE DESCRIPTION:** The Cidex™ OPA Solution Test Strips are chemical indicators used for determining whether the concentration of OPA in Cidex™ OPA Solution is above or below the minimum effective concentration of 0.3%. The indicator pad measures 0.2 inches x 0.2 inches and is attached to a 0.2 inch x 3.25 inch polystyrene handle. The strips are packaged in groups of 60 strips with a desiccant pack in containers made of HDPE. One 12x75 mm glass test tube is supplied with each bottle. The cap is made of HDPE with a cap liner consisting of pulpboard backing covered with vinyl coated aluminum foil. The formula is shown in Table 1.

Table 1. Formulation of the Strips

Ingredients	% by Weight
Sodium sulfite	32.2
Ammonium citrate	46.6
Gantrez	21.2
TOTAL	100%

Chemical principle: The OPA reacts with sodium sulfite to form an addition compound. The excess OPA then reacts with ammonium ions to form colored polymers. When the OPA concentration is 0.3% or less, it is entirely consumed with the sodium sulfite to produce colorless product. When its concentration is sufficient to overwhelm the sodium sulfite, the excess reacts with ammonium ions to produce colored polymers (brown/black). If the solution contains 0.3% OPA or less, the pad will be lighter than the color block on the package and should indicate FAIL. If the solution contains 0.45% OPA or more, the pad color will be equal to or darker than the color block and should indicate PASS. At intermediate concentrations of OPA, the test strip may indicate either PASS or FAIL.

A 12x75 glass test tube is provided with the strips for use in testing samples of Cidex™ OPA solutions. About 1 ml of Cidex™ OPA solution is placed in the glass test tube. After immersing the strip in the Cidex™ OPA solution for exactly 30 seconds, the test strip is removed by touching the side edge of the pad against the inside of the tube and is drawn upward for 2-3 seconds against the entire length of the test tube. The handle end of the strip is laid on a paper towel so that the indicator pad hangs over the edge to prevent further absorption. After 2.5 minutes following removal of the strip from the solution, the color of the indicator pad is compared to the color block on the container.


 Elaine Schalk Mayhall, Ph.D.

MEMORANDUM

DATE: November 15, 1999

FROM: Elaine Schalk Mayhall, Ph.D., Chemist, Infection Control Devices Branch,
DDIGD, HFZ-480

SUBJECT: K992341/S1
SERIM RESEARCH CORP.
CIDEX™ OPA SOLUTION TEST STRIP

CONTACT: James Christner
219-264-3440 (IN)
219-266-6222 fax

TO: The Record

The firm has provided additional information requested via fax and phone on 10/8/99.

Intended Use

The Cidex™ OPA Solution Test Strips are semi-quantitative chemical indicators used to determine whether the concentration of ortho-phthalaldehyde in Cidex™ OPA Solution is above or below the minimum effective concentration of 0.3%.

Background

Serim Research previously has submitted the following three 510(k)s for this product:

- K972739 - withdrawn by the firm in a letter dated 9/4/97 because the 510(k) for Cidex™ OPA Solution had been deleted.
- K983290 - withdrawn and deleted from the system by FDA because the submission for Cidex™ OPA Solution had significant deficiencies that could not be resolved within 30 days (letter dated 10/98).
- K983806 – withdrawn and deleted from the system by FDA because the submission for Cidex OPA Solution was deleted (letter dated /98); A list of our concerns about the indicator was sent to the firm via fax on 12/8/98.

Device Description

The Cidex™ OPA Solution Test Strips are chemical indicators used for determining whether the concentration of OPA in Cidex™ OPA Solution is above or below the minimum effective concentration of 0.3%. The indicator pad measures 0.2 inches x 0.2 inches and is attached to a 0.2 inch x 3.25 inch polystyrene handle. The strips are packaged in groups of 60 strips with a



desiccant pack in containers made of HDPE. One 12x75 mm glass test tube is supplied with each bottle. The cap is made of HDPE with a cap liner consisting of pulpboard backing covered with vinyl coated aluminum foil. The formula is shown in Table 1.

Table 1. Formulation of the Strips

Ingredients	% by Weight
Sodium sulfite	(b)(4)
Ammonium citrate	(b)(4)
Gantrez	(b)(4)
TOTAL	100%

Chemical principle: The OPA reacts with sodium sulfite to form an addition compound. The excess OPA then reacts with ammonium ions to form colored polymers. When the OPA concentration is 0.3% or less, it is entirely consumed with the sodium sulfite to produce colorless product. When its concentration is sufficient to overwhelm the sodium sulfite, the excess reacts with ammonium ions to produce colored polymers (brown/black). If the solution contains 0.3% OPA or less, the pad will be lighter than the color block on the package and should indicate FAIL. If the solution contains 0.45% OPA or more, the pad color will be equal to or darker than the color block and should indicate PASS. At intermediate concentrations of OPA, the test strip may indicate either PASS or FAIL.

A 12x75 glass test tube is provided with the strips for use in testing samples of Cidex™ OPA solutions. About 1 ml of Cidex™ OPA solution is placed in the glass test tube. After immersing the strip in the Cidex™ OPA solution for exactly 30 seconds, the test strip is removed by touching the side edge of the pad against the inside of the tube and is drawn upward for 2-3 seconds against the entire length of the test tube. The handle end of the strip is laid on a paper towel so that the indicator pad hangs over the edge to prevent further absorption. After 2.5 minutes following removal of the strip from the solution, the color of the indicator pad is compared to the color block on the container.

Comparison Products

The firm noted that the Cidex™ OPA Solution Test Strip is similar in design, composition and function to the Cidex™ Solution Test Strips (K915170; a.k.a., PyMah Sterilog Indicator Strips). The firm provided a table comparing the indicator strips.

RESPONSE

1. The firm revised the labeling as follows to emphasize the need for practicing the method before use:

(b) (4)



(b) (4)



These revisions are adequate to emphasize to the user the need to practice the technique before using the strips.

2. The firm revised the labeling as follows to reflect the test tube rinsing procedure used in the test tube reuse study:

(b) (4)



These directions do not agree with the process used in the test tube reuse study conducted by the firm. In the study, the firm demonstrated that rinsing the tube once with Enzol and then rinsing three times with tap water followed by rinsing three times with deionized water was adequate for at least 70 uses of the tube.

3. The firm indicated that because users do not use the strip as frequently as recommended by the manufacturer, the firm does not expect users to follow a recommendation to use three strips instead of one. The firm noted that the technique is similar to that used for the Bayer urine test strips and is considered a "Low Complexity" procedure under CLIA and thus is CLIA waived. The firm noted that because the directions for the reuse of the solution are to test the MEC before each use, the chance of a strip not showing fail in the last three days is extremely small. The firm also provided a statistical evaluation of the data and included the

article, "Assessing pass/fail testing when there are no failures to assess," by Thom R. Nichols and Sheldon Dummer along with expanded statistical tables. I asked Pamela Scott, OSB, to review the statistical information.

I discussed my concerns about this product with Dr. Chiu Lin. I noted that out of 6 lots of strips tested by the firm, 1 lot showed 2 false pass results and that the results are very technique sensitive. The firm beefed up the labeling recommending that the user practice using the strips before starting use of the strips. He indicated that he would have more confidence in the strip if the firm conducted additional testing of about 20 strips from 1 lot with Cidex OPA solution containing 0.2% OPA. I phoned Dr. Christner on 11/5/99 to request the following information:

(b) (4)



I requested that he send the information via fax followed by a hard copy to DMC.

Response to 11/5/99 phone request for additional information

(b) (4)



(b) (4)

A large rectangular area of the document is redacted with a solid grey fill.

RECOMMENDATION: Based on the liquid chemical germicide guidance document, I recommend that the Serim Cidex™ OPA Solution Test Strips be found SUBSTANTIALLY EQUIVALENT to the Cidex™ Solution Test Strips (K915170; a.k.a., PyMah Sterilog Indicator Strips).

Reviewed by

A handwritten signature in black ink that reads "Elaine S. Mayhall".

Elaine Schalk Mayhall, Ph.D.

Mayhall, Elaine

From: Scott, Pamela E
Sent: Friday, November 12, 1999 9:53 AM
To: Mayhall, Elaine
Cc: Lin, Chiu S.; Ulatowski, Tim; Barrick, Mary K.; Stein, Bridgette R.; Scott, Pamela E
Subject: Statistical review of sponsor's response to ODE's questions about K992341 Cidex OPA Solution Test Strips, Serim Research Corp.

Introduction

The sponsor states that the OPA Solution Test Strips are semi-quantitative chemical indicators used to determine whether the concentration of OPA, the active ingredient in the solution, is above the minimum effective concentration (MEC) of 0.3% OPA. The "color" developed on the Cidex OPA Solution Test Indicator Pad determines whether the concentration of OPA in the sample is above or below the minimum effective dose of 0.3%. If the "color" of the indicator pad is equal to or darker than the gray color block on the bottle label, then the solution is considered to "pass" and the concentration is above the MEC of 0.3% OPA. If the "color" of the indicator pad is lighter than the "color" block on the solution bottle label, then the solution is considered to "fail" and the concentration is at or below the MEC of 0.3% OPA and should be discarded.

Since the Division of Biostatistics did not perform a review of the original submission, my review is limited to the sponsor's response to your 10/8/1999 phone call. As a result, additional statistical issues may arise from a statistical review of the original submission.

Comments

(b)(4)



K992341/A-2



P.O. Box 4002, Elkhart, IN 46514-0002 • (800) 542-4670 • FAX (219) 266-6222

November 15, 1999

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

Re: K992341
510(k) Submission for Cidex® OPA Solution Test Strips

To Whom it May Concern:

The attached information regarding the above referenced Premarket Notification [510(k)] was requested by the Office of Device Evaluation.

Sincerely,

James E. Christner
Vice President, Research & Development
Serim Research Corporation
P.O. Box 4002
23565 Reedy Drive
Elkhart, IN 46514

NOV 16 09 55
FDA/CDRH/OCE/DHO

JK
8

14



P.O. Box 4002, Elkhart, IN 46514-0002 • (800) 542-4670 • FAX (219) 266-6222

November 15, 1999

Elaine S. Mayhall, Ph.D.
Chemist, Infection Control Devices Branch
Division of Dental, Infection Control and General Hospital Devices
Office of Device Evaluation
Center for Devices and Radiological Health
Fax: (301) 480-3002

Dear Dr. Mayhall:

The attached information is being submitted in response to your phone call of 11/12/99 regarding our 510(k) submission K992341 for OPA Solution Test Strips.

If you have any questions regarding the above please feel free to contact me at any time.

Sincerely,

A handwritten signature in cursive script that reads "James E. Christner".

James E. Christner, Ph.D.
Vice President of Research & Development

Serim Research Corporation
P.O. Box 4002
23565 Reedy Dr.
Elkhart, IN 46514

Phone: 219-264-3440
Fax: 219-266-6222
Email: jchristner@serim.com

10/15/99 05:55
FDA/OE/DC/ONE/DID

510(k) Number (if known): K992341

Device Name: CIDEX* OPA Solution Test Strips

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Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)



Records processed under FOIA Request # 2013-7845; Released by CDRH on 08-17-2015
Re: 510(k) for OPA Solution Test Strips - K992341

CONFIDENTIAL



P.O. Box 4002, Elkhart, IN 46514-0002 • (800) 542-4670 • FAX (219) 266-6222

November 15, 1999

Elaine S. Mayhall, Ph.D.
Chemist, Infection Control Devices Branch
Division of Dental, Infection Control and General Hospital Devices
Office of Device Evaluation
Center for Devices and Radiological Health
Fax: (301) 480-3002

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If you have any questions regarding the above please feel free to contact me at any time.

Sincerely,

A handwritten signature in cursive script that reads "James E. Christner".

James E. Christner, Ph.D.
Vice President of Research & Development

Serim Research Corporation
P.O. Box 4002
23565 Reedy Dr.
Elkhart, IN 46514

Phone: 219-264-3440
Fax: 219-266-6222
Email: jchristner@serim.com

510(k) Number (if known): K992341

Device Name: CIDEX* OPA Solution Test Strips

Indications For Use:

CIDEX* OPA Solution Test Strips are semi-quantitative chemical indicators used to determine whether the concentration of active ingredient in CIDEX* OPA Solution is above or below the minimum effective concentration of 0.3% OPA. CIDEX* OPA Solution Test Strips cannot be used to validate the sterilization or disinfection process.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)



P.O. Box 4002, Elkhart, IN 46514-0002 • (800) 542-4670 • FAX (219) 266-6222

November 9, 1999

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

Re: K992341
510(k) Submission for Cidex® OPA Solution Test Strips

To Whom it May Concern:

The attached information regarding the above referenced Premarket Notification [510(k)] was requested by the Office of Device Evaluation.

Sincerely,

James E. Christner
Vice President, Research & Development
Serim Research Corporation
P.O. Box 4002
23565 Reedy Drive
Elkhart, IN 46514

RECEIVED
NOV 11 1999 10 06
FDA/CDRH/OCE/DMD

SK
7



P.O. Box 4002, Elkhart, IN 46514-0002 • (800) 542-4670 • FAX (219) 266-6222

November 9, 1999

Elaine S. Mayhall, Ph.D.
Chemist, Infection Control Devices Branch
Division of Dental, Infection Control and General Hospital Devices
Office of Device Evaluation
Center for Devices and Radiological Health
Fax: (301) 480-3002

Dear Dr. Mayhall:

The attached information is being submitted in response to your phone call of 11/05/99 regarding our 510(k) submission K992341 for OPA Solution Test Strips.

(b) (4)

A large rectangular area of the document is redacted with a solid grey fill. The redaction covers the majority of the page's content, leaving only the header, footer, and signature blocks visible.

If you have any questions regarding the above please feel free to contact me at any time.

Sincerely,

A handwritten signature in cursive script that reads "James E. Christner".

James E. Christner, Ph.D.
Vice President of Research & Development

Serim Research Corporation
P.O. Box 4002
23565 Reedy Dr.
Elkhart, IN 46514

Phone: 219-264-3440
Fax: 219-266-6222
Email: jchristner@serim.com

10 NOV 10 06
FDA/CDRH/OCE/DID

Table 1

**Blind Study Results
Measuring OPA in Cidex OPA Solutions
with Cidex OPA Solution Test Strips**

(b) (4)



CIDEX® OPA Solution Test Strips - Package Insert

Final 11/08/99

MASTER DRAFT
3rd 510K Submission
11/99

CIDEX® OPA Solution Test Strips

INTENDED USE

CIDEX® OPA Solution Test Strips are semi-quantitative chemical indicators used to indicate whether the concentration of ortho-phthalaldehyde, the active ingredient in CIDEX® OPA Solution, is above the minimum effective concentration (MEC) of 0.3% OPA. It is recommended that CIDEX® OPA Solutions be tested before each usage with CIDEX® OPA Solution Test Strips.

WARNING: CIDEX® OPA Solution Test Strips cannot be used to validate the disinfection process. Do not use CIDEX® OPA Solutions beyond the 14-day maximum use life even if the test strip shows the solution is above the MEC.

CHEMICAL PRINCIPLES OF THE TEST

The filter paper square (indicator pad) mounted on the end of plastic strip comprises the reactive portion of the CIDEX® OPA Solution Test Strip. The indicator pad contains an inhibitor and a color-forming reagent. If the concentration of OPA is at or below the MEC, the inhibitor will prevent any color formation. If the concentration of OPA is present in excess of the inhibitor, it reacts with the color-forming reagent to form colored pigments.

STORAGE

- CIDEX® OPA Solution Test Strips must be kept in the original bottle with the cap tightly closed.
- Store in a dry place at controlled room temperature; 16°-32° C (61°-90° F).
- Protect strips from exposure to extremes of heat, light and moisture.
- Do not remove the desiccant pack. Keep desiccant out of reach of children.
- Use within 90 days after first opening the bottle.
- Always write the "Date Opened" in the space provided on the bottle label.
- Do not use test strips (from an opened or unopened bottle) after the expiration date.

DIRECTIONS FOR USE

IMPORTANT: Prior to starting routine use of the CIDEX® OPA Solution Test Strips, it is advisable to **practice the testing technique** using control solutions (the preparation of which is described in the "QUALITY CONTROL" section). Familiarity with the proper testing technique will increase user proficiency, minimize procedural errors and assist in interpretation of results.

Sample Collection

Collect approximately 1 mL of room temperature CIDEX® OPA Solution into the 12x75-mm glass test tube provided. The tube should be approximately 1/5 full allowing the indicator pad on the test strip to be fully immersed in the sample.

Testing Procedure

1. Dispense approximately 1-mL of CIDEX® OPA Solution into the 12x75-mm glass test tube provided.
2. Dip the test strip into the sample *for exactly 30 seconds*.
3. Remove the test strip by touching the side edge of the indicator pad against the inside of the test tube and draw upward (for approximately 2-3 seconds) *against the entire length of the test tube*, gradually removing excess sample. (See Figure 1.)

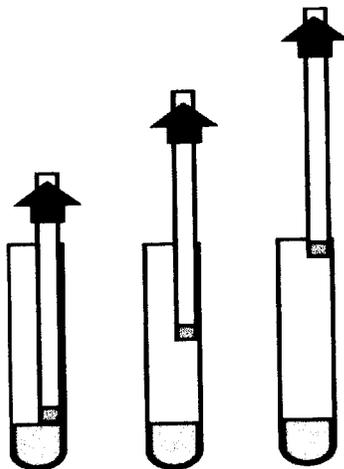


Figure 1

4. Lay the handle end of the test strip on a paper towel so that the indicator pad hangs over the edge of the towel to prevent absorption of the sample solution.
5. Compare the color of the indicator pad to the color block on the bottle label at exactly 3 minutes after the test was started (2½ minutes after removing the strip from the test tube.)
6. Use the logbook in CIDEX® Solutions Information Station (Reorder No. 20251) to record results.
7. Discard the test strip and CIDEX® OPA Solution test sample in accordance with federal, state, local and institution guidelines.
8. Clean the test tube with Enzol® or an equivalent detergent, then rinse the test tube thoroughly with three changes of tap water followed by three distilled water rinses. Dry completely prior to next use.

INTERPRETATION OF TEST RESULTS

The color developed on the CIDEX® OPA Solution Test Strip Indicator Pad is used to determine whether the concentration of OPA in the sample is above or below the MEC of 0.3%.

- For a “PASS”, the entire indicator pad should be equal to or darker than the gray color block on the bottle label.
- If the entire indicator pad is lighter than the color block on the label or distinct areas of lighter color are observed, the result is a “FAIL”. The CIDEX® OPA Solution is at or below the

MEC and must be discarded.

At concentrations slightly above the MEC the indicator pad may have a mottled appearance. However, if any portion of the indicator pad is lighter than the color block, the results should be considered a "FAIL".

NOTE: False "FAILS" may occur as the MEC is approached. This is due in part to a safety margin provided by the test strip ensuring that solutions at or below the MEC will "FAIL" virtually 100% of the time.

MATERIAL REQUIRED

The following materials are not provided for the CIDEX OPA Test Strips but will be needed for the test:

- Watch or Timer

QUALITY CONTROL

Testing Frequency

Each facility should determine the frequency of control testing for its own QC program. All personnel responsible for monitoring disinfectants should practice testing the positive and negative controls prior to starting routine use of CIDEX OPA Solution. Regular testing of the control solutions will increase user proficiency, minimize procedural errors and protect against the inadvertent use of outdated product or product that has deteriorated due to improper storage or handling.

Preparation and Testing of Control Solutions

Verify that the CIDEX® OPA Solution has an acceptable expiration date. Label two tubes, one for the positive control and one for the negative control. To prepare a positive control use fresh, full strength solution. To prepare a negative control, dilute one part of full strength solution with one part of distilled water. Following the "Directions for Use", dip one test strip in the positive control and one in the negative control.

Results for Control Solutions:

Refer to the color block on the test strip bottle for interpretation of results.

- At 3 minutes, the test strip dipped in the full strength positive control solution should exhibit a completely gray/black color on the indicator pad equal to or darker than the color block on the bottle label indicating a PASS result.
- The test strip dipped in the negative control should show a color lighter than the color block on the bottle label when read at 3 minutes indicating a FAIL result.

If the results obtained from using the positive and negative controls indicate the test strip is not performing as expected, **do not use** the remaining strips, but retain them for possible return to Product Quality Services. For technical product information and support, contact Advanced Sterilization Products at 1-888-783-7723.

CIDEX® OPA Solution Test Strips - Package Insert

Final 11/08/99

PERFORMANCE CHARACTERISTICS

The performance characteristics of CIDEX® OPA Solution Test Strips are based on testing samples of CIDEX® OPA Solution of known *ortho*-phthalaldehyde concentrations that are at and above the MEC. The analytical method used to determine the *ortho*-phthalaldehyde concentration in these samples is High Pressure Liquid Chromatography with UV detection. The CIDEX® OPA Solution Test Strips have been designed to indicate "FAIL" virtually 100% of the time at and below the MEC of 0.3% *ortho*-phthalaldehyde (OPA).

WARNINGS AND PRECAUTIONS

- Prior to first using Cidex OPA Test Strips, read the product insert thoroughly and practice the testing technique to ensure user proficiency.
- The user **MUST** adhere to the "Directions for Use" since any modification may affect the performance of the test.
- Replace and tighten cap immediately after removing a strip.
- Do not touch the indicator pad.
- Protect strips from chemicals or contaminated surfaces.
- Do not ingest the strip or allow the indicator pad to come in contact with the eye.
- Only use the 12 x 75mm test tubes provided and use a new test tube when opening a new bottle of strips.
- The reusable 12 x 75mm test tubes must be thoroughly cleaned with detergent, rinsed well and dried between uses.
- Discard used or expired CIDEX® OPA Solution Test Strips in an appropriate waste receptacle in accordance with federal, state and local laws and your facility's regulations.
- CIDEX® OPA Solution Test Strips cannot be used as a means of validating the disinfection process.
- CIDEX® OPA Solution Test Strips are designed specifically to detect *ortho*-phthalaldehyde. They cannot be used to measure other disinfectants and should only be used to test CIDEX® OPA Solution.

HOW SUPPLIED

Product Code	Description	Package Information
20392	CIDEX® OPA Solution Test Strips Glass test tubes (12x75 mm)	60 strips/bottle; 2 bottles/case 2 tubes per case

Distributed by:
 ADVANCED STERILIZATION PRODUCTS
 a Johnson & Johnson Company
 Irvine, CA 92618.
 For technical information and/or information regarding
 safety and effectiveness, call 1-888-783-7723.

4 25

UNDERSTANDING THE TESTING TECHNIQUE:

The “*Directions for Use*” **MUST** be followed closely to achieve optimal test results. Outlined below is an explanation of the significance of the technique for each step in the Test Procedure. This information may be useful for training and troubleshooting.

- Leaving the test strip in the sample of CIDEX® OPA Solution for longer than 30 seconds or swirling the strip vigorously could cause excess color development. This could lead to a false “PASS” result, i.e., the concentration of OPA in the solution is truly below the MEC, but due to improper technique the test strip gives a “PASS” result.
- Removing the test strip too soon from the solution or blotting the indicator pad with an absorbent material such as a paper towel could cause insufficient color development. This could cause a false “FAIL” result when the solution would normally pass.
- It is important to use the 12x75-mm glass test tube provided. The procedure and timing were optimized using this specific test tube
- Failure to draw the side edge of the indicator pad slowly (for 2-3 seconds) up the inside of the test tube could lead to a false “PASS” due to retention of excess sample.
- Thoroughly clean, rinse and dry the test tube between each use. For optimal results, use a new test tube with each new bottle of strips.
- Although excess sample solution must be allowed to drain from the indicator pad, it is important not to remove too much solution. Therefore it is recommended that once the test strip is removed from the test tube, the indicator pad should not come in contact with an absorbent surface. The test tube wall removes the proper amount of sample as opposed to paper towels, which have a tendency to absorb an excessive amount of solution from the indicator pad.
The use of this test tube/sample removal technique provides significantly improved and consistent results when compared to alternate sample removal methods used with other tests (i.e., blotting or shaking excess liquid from the indicator pad).
- It is important to interpret the results of the test strip exactly 3 minutes after starting the test (dip for 30 seconds, then allow reaction to develop for an additional 2½ minutes).
 - If the test is read in less than 3 minutes, the color change may be incomplete and a solution could give a false “FAIL” result.
 - If the test is read after 3 minutes, excess color may develop and the solution could yield a false “PASS” result.
- The test strip may take on a mottled appearance as it approaches the MEC. Appearance of distinct areas of color lighter than the color block is considered a “FAIL” result.
- Only one test strip per one mL of sample may be dipped. If the test is repeated, 1 mL of fresh sample is required.

Developed exclusively for testing
CIDEX, OPA Solution



OPA

Solution

Test Strips

60 STRIPS

ADVANCED STERILIZATION
PRODUCTS

CONTROL
NO.

IMPORTANT:
*Read Package Insert Thoroughly
Before Use*

Composition: CIDEX™ OPA
Solution Test Strips consist of
an inhibitor and a color-forming
reagent impregnated and dried
on filter paper.

STORAGE: Keep cap tightly
closed. Store bottle at controlled
room temperature 16°- 32°C
(61°- 90°F) and in a dry place.
Do not remove desiccant.

CAUTION: Do not use after
90 days of opening the bottle.

Date Opened _____

Do Not Use After _____

Distributed by
ADVANCED STERILIZATION
PRODUCTS
a Johnson & Johnson company
Division of Ethicon Inc., Irvine, CA 92618
For technical information and/or information
regarding safety and effectiveness,
call 1-800-783-7723
*TRADEMARK © ASP 1997

UNOPENED
EXP. DATE

DIRECTIONS FOR USE:

1. Dispense ~~at least~~ a 1 mL sample of CIDEX OPA Solution into a ~~clean~~ 12x75mm glass test tube.
2. Dip the Test Strip into the sample for exactly 30 seconds making sure that the Indicator Pad is fully immersed.
3. At 30 seconds, remove the Test Strip from the sample and draw the side edge of the Indicator Pad upward (for 2-3 seconds) against the entire length of the test tube to gradually remove excess sample.
4. Lay the handle end of the Test Strip on a paper towel so that the Indicator Pad hangs over the edge to prevent further absorption of the sample solution.
5. Compare the color of the Indicator Pad to the color block on the bottle label at exactly 3 minutes after the test was started (2-1/2 minutes after removing the strip from the test tube.) If the Indicator Pad is equal in color or darker than the color block on the bottle label, the result is "PASS" (the CIDEX OPA Solution is above the MEC). If the Indicator Pad is lighter than the color block ("FAIL"), the CIDEX OPA Solution should be discarded.



PASS
11745 7/96

CONFIDENTIAL



P.O. Box 4002, Elkhart, IN 46514-0002 • (800) 542-4670 • FAX (219) 266-6222

November 9, 1999

Elaine S. Mayhall, Ph.D.
Chemist, Infection Control Devices Branch
Division of Dental, Infection Control and General Hospital Devices
Office of Device Evaluation
Center for Devices and Radiological Health
Fax: (301) 480-3002

Dear Dr. Mayhall:

The attached information is being submitted in response to your phone call of 11/05/99 regarding our 510(k) submission K992341 for OPA Solution Test Strips.

(b) (4)



If you have any questions regarding the above please feel free to contact me at any time.

Sincerely,

James E. Christner, Ph.D.
Vice President of Research & Development

Serim Research Corporation
P.O. Box 4002
23565 Reedy Dr.
Elkhart, IN 46514

Phone: 219-264-3440
Fax: 219-266-6222
Email: jchristner@serim.com

28

CONFIDENTIAL

Re: 510(k) for OPA Solution Test Strips - K992341

Table 1

**Blind Study Results
Measuring OPA in Cidex OPA Solutions
with Cidex OPA Solution Test Strips**

(b) (4)



29

CIDEX® OPA Solution Test Strips – Package Insert**Final 11/08/99****MASTER DRAFT
3rd 510K Submission
11/99**

CIDEX® OPA Solution Test Strips

CIDEX® OPA Solution Test Strips are semi-quantitative chemical indicators used to indicate whether the concentration of ortho-phthalaldehyde, the active ingredient in CIDEX® OPA Solution, is above the minimum effective concentration (MEC) of 0.3% OPA. It is recommended that CIDEX® OPA Solutions be tested before each usage with CIDEX® OPA Solution Test Strips.

WARNING: CIDEX® OPA Solution Test Strips cannot be used to validate the disinfection process. Do not use CIDEX® OPA Solutions beyond the 14-day maximum use life even if the test strip shows the solution is above the MEC.

The filter paper square (indicator pad) mounted on the end of plastic strip comprises the reactive portion of the CIDEX® OPA Solution Test Strip. The indicator pad contains an inhibitor and a color-forming reagent. If the concentration of OPA is at or below the MEC, the inhibitor will prevent any color formation. If the concentration of OPA is present in excess of the inhibitor, it reacts with the color-forming reagent to form colored pigments.

- CIDEX® OPA Solution Test Strips must be kept in the original bottle with the cap tightly closed.
- Store in a dry place at controlled room temperature; 16°-32° C (61°-90° F).
- Protect strips from exposure to extremes of heat, light and moisture.
- Do not remove the desiccant pack. Keep desiccant out of reach of children.
- Use within 90 days after first opening the bottle.
- Always write the "Date Opened" in the space provided on the bottle label.
- Do not use test strips (from an opened or unopened bottle) after the expiration date.

IMPORTANT: Prior to starting routine use of the CIDEX® OPA Solution Test Strips, it is advisable to practice the testing technique using control solutions (the preparation of which is described in the "QUALITY CONTROL" section). Familiarity with the proper testing technique will increase user proficiency, minimize procedural errors and assist in interpretation of results.

Sample Collection

Collect approximately 1 mL of room temperature CIDEX® OPA Solution into the 12x75-mm glass test tube provided. The tube should be approximately 1/5 full allowing the indicator pad on the test strip to be fully immersed in the sample.

CIDEX® OPA Solution Test Strips -- Package Insert**Final 11/08/99****Testing Procedure**

1. Dispense approximately 1-mL of CIDEX® OPA Solution into the 12x75-mm glass test tube provided.
2. Dip the test strip into the sample *for exactly 30 seconds*.
3. Remove the test strip by touching the side edge of the indicator pad against the inside of the test tube and draw upward (for approximately 2-3 seconds) *against the entire length of the test tube*, gradually removing excess sample. (See Figure 1.)

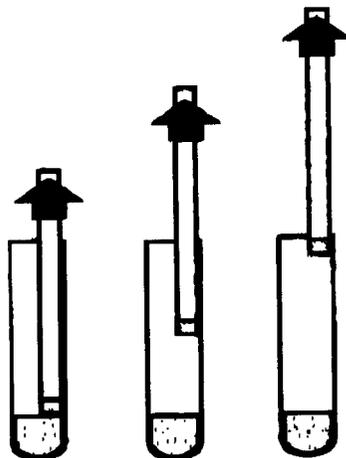


Figure 1

4. Lay the handle end of the test strip on a paper towel so that the indicator pad hangs over the edge of the towel to prevent absorption of the sample solution.
5. Compare the color of the indicator pad to the color block on the bottle label at exactly 3 minutes after the test was started (2½ minutes after removing the strip from the test tube.)
6. Use the logbook in CIDEX® Solutions Information Station (Reorder No. 20251) to record results.
7. Discard the test strip and CIDEX® OPA Solution test sample in accordance with federal, state, local and institution guidelines.
8. Clean the test tube with Enzol® or an equivalent detergent, then rinse the test tube thoroughly with three changes of tap water followed by three distilled water rinses. Dry completely prior to next use.

The color developed on the CIDEX® OPA Solution Test Strip Indicator Pad is used to determine whether the concentration of OPA in the sample is above or below the MEC of 0.3%.

- For a "PASS", the entire indicator pad should be equal to or darker than the gray color block on the bottle label.
- If the entire indicator pad is lighter than the color block on the label or distinct areas of lighter color are observed, the result is a "FAIL". The CIDEX® OPA Solution is at or below the

CIDEX® OPA Solution Test Strips – Package Insert**Final 11/08/99**

MEC and must be discarded.

At concentrations slightly above the MEC the indicator pad may have a mottled appearance. However, if any portion of the indicator pad is lighter than the color block, the results should be considered a "FAIL".

NOTE: False "FAILS" may occur as the MEC is approached. This is due in part to a safety margin provided by the test strip ensuring that solutions at or below the MEC will "FAIL" [virtually 100% of the time.

The following materials are not provided for the CIDEX OPA Test Strips but will be needed for the test:

- Watch or Timer

Testing Frequency

Each facility should determine the frequency of control testing for its own QC program. All personnel responsible for monitoring disinfectants should practice testing the positive and negative controls prior to starting routine use of CIDEX OPA Solution. Regular testing of the control solutions will increase user proficiency, minimize procedural errors and protect against the inadvertent use of outdated product or product that has deteriorated due to improper storage or handling.

Preparation and Testing of Control Solutions

Verify that the CIDEX® OPA Solution has an acceptable expiration date. Label two tubes, one for the positive control and one for the negative control. To prepare a positive control use fresh, full strength solution. To prepare a negative control, dilute one part of full strength solution with one part of distilled water. Following the "Directions for Use", dip one test strip in the positive control and one in the negative control.

Results for Control Solutions:

Refer to the color block on the test strip bottle for interpretation of results.

- At 3 minutes, the test strip dipped in the full strength positive control solution should exhibit a completely gray/black color on the indicator pad equal to or darker than the color block on the bottle label indicating a PASS result.
- The test strip dipped in the negative control should show a color lighter than the color block on the bottle label when read at 3 minutes indicating a FAIL result.

If the results obtained from using the positive and negative controls indicate the test strip is not performing as expected, do not use the remaining strips, but retain them for possible return to Product Quality Services. For technical product information and support, contact Advanced Sterilization Products at 1-888-783-7723.

CIDEX® OPA Solution Test Strips -- Package Insert

Final 11/08/99

The performance characteristics of CIDEX® OPA Solution Test Strips are based on testing samples of CIDEX® OPA Solution of known *ortho*-phthalaldehyde concentrations that are at and above the MEC. The analytical method used to determine the *ortho*-phthalaldehyde concentration in these samples is High Pressure Liquid Chromatography with UV detection. The CIDEX® OPA Solution Test Strips have been designed to indicate "FAIL" virtually 100% of the time at and below the MEC of 0.3% *ortho*-phthalaldehyde (OPA).

- Prior to first using Cidex OPA Test Strips, read the product insert thoroughly and practice the testing technique to ensure user proficiency.
- The user **MUST** adhere to the "Directions for Use" since any modification may affect the performance of the test.
- Replace and tighten cap immediately after removing a strip.
- Do not touch the indicator pad.
- Protect strips from chemicals or contaminated surfaces.
- Do not ingest the strip or allow the indicator pad to come in contact with the eye.
- Only use the 12 x 75mm test tubes provided and use a new test tube when opening a new bottle of strips.
- The reusable 12 x 75mm test tubes must be thoroughly cleaned with detergent, rinsed well and dried between uses.
- Discard used or expired CIDEX® OPA Solution Test Strips in an appropriate waste receptacle in accordance with federal, state and local laws and your facility's regulations.
- CIDEX® OPA Solution Test Strips cannot be used as a means of validating the disinfection process.
- CIDEX® OPA Solution Test Strips are designed specifically to detect *ortho*-phthalaldehyde. They cannot be used to measure other disinfectants and should only be used to test CIDEX® OPA Solution.

Product Code	Description	Package Information
20392	CIDEX® OPA Solution Test Strips Glass test tubes (12x75 mm)	60 strips/bottle; 2 bottles/case 2 tubes per case

Distributed by:
ADVANCED STERILIZATION PRODUCTS
 a Johnson & Johnson Company
 Irvine, CA 92618.
 For technical information and/or information regarding safety and effectiveness, call 1-888-783-7723.

Printed in the U.S.A.

11026 7/99

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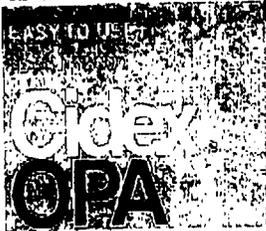
CIDEX® OPA Solution Test Strips -- Package Insert**Final 11/08/99**

The "*Directions for Use*" **MUST** be followed closely to achieve optimal test results. Outlined below is an explanation of the significance of the technique for each step in the Test Procedure. This information may be useful for training and troubleshooting.

- Leaving the test strip in the sample of CIDEX® OPA Solution for longer than 30 seconds or swirling the strip vigorously could cause excess color development. This could lead to a false "PASS" result, i.e., the concentration of OPA in the solution is truly below the MEC, but due to improper technique the test strip gives a "PASS" result.
- Removing the test strip too soon from the solution or blotting the indicator pad with an absorbent material such as a paper towel could cause insufficient color development. This could cause a false "FAIL" result when the solution would normally pass.
- It is important to use the 12x75-mm glass test tube provided. The procedure and timing were optimized using this specific test tube
- Failure to draw the side edge of the indicator pad slowly (for 2-3 seconds) up the inside of the test tube could lead to a false "PASS" due to retention of excess sample.
- Thoroughly clean, rinse and dry the test tube between each use. For optimal results, use a new test tube with each new bottle of strips.
- Although excess sample solution must be allowed to drain from the indicator pad, it is important not to remove too much solution. Therefore it is recommended that once the test strip is removed from the test tube, the indicator pad should not come in contact with an absorbent surface. The test tube wall removes the proper amount of sample as opposed to paper towels, which have a tendency to absorb an excessive amount of solution from the indicator pad.
The use of this test tube/sample removal technique provides significantly improved and consistent results when compared to alternate sample removal methods used with other tests (i.e., blotting or shaking excess liquid from the indicator pad).
- It is important to interpret the results of the test strip exactly 3 minutes after starting the test (dip for 30 seconds, then allow reaction to develop for an additional 20 minutes).
 - If the test is read in less than 3 minutes, the color change may be incomplete and a solution could give a false "FAIL" result.
 - If the test is read after 3 minutes, excess color may develop and the solution could yield a false "PASS" result.
- The test strip may take on a mottled appearance as it approaches the MEC. Appearance of distinct areas of color lighter than the color block is considered a "FAIL" result.
- Only one test strip per one mL of sample may be dipped. If the test is repeated, 1 mL of fresh sample is required.

Developed exclusively for testing
CIDEX OPA Solution

EASY TO USE



Solution

Test Strips

60 STRIPS

ADVANCED STERILIZATION PRODUCTS

CONTING. NO. _____

UNOPENED EXPIRES _____

COMPOSITION: CIDEX OPA Solution Test Strips consist of an indicator and a color-forming reagent impregnated and dried on fiber paper.

STORAGE: Keep cap tightly closed. Store bottle at controlled room temperature 16°-32° C (61°-90°F) and in a dry place. Do not remove desiccant.

CAUTION: Do not use after 60 days of opening the bottle.

Date Opened _____

Do Not Use After _____

Distributed by:
ADVANCED STERILIZATION PRODUCTS
a Johnson & Johnson Company
Member of Ethicon Inc., Irvine, CA 92714
For technical information and literature, contact:
1-800-735-7776
TRADEMARK © ASP 1997

DIRECTIONS FOR USE:

- Dispense at least a 1 mL sample of CIDEX OPA Solution into a clean 1.2x75mm glass test tube.
- Dip the Test Strip into the sample for exactly 30 seconds making sure that the Indicator Pad is fully immersed.
- At 30 seconds, remove the Test Strip from the sample and draw the side edge of the Indicator Pad upward (for 2-3 seconds) against the entire length of the test tube to gradually remove excess sample.
- Lay the handle end of the Test Strip on a paper towel so that the Indicator Pad hangs over the edge to prevent further absorption of the sample solution.
- Compare the color of the Indicator Pad to the color block on the bottle label at exactly 3 minutes after the test was started (2-1/2 minutes after removing the strip from the test tube). If the Indicator Pad is equal in color or darker than the color block on the bottle label, the result is "PASS" (the CIDEX OPA Solution is above the MEC). If the Indicator Pad is lighter than the color block ("FAIL"), the CIDEX OPA Solution should be discarded.

35

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

October 26, 1999

SERIM RESEARCH CORP.
23565 REEDY DRIVE
P.O. BOX 4002
ELKHART, IN 46514
ATTN: JAMES E. CHRISTNER

510(k) Number: K992341
Product: CIDEX OPA
SOLUTION TEST
STRIP

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. Because of equipment and personnel limitations we cannot accept telefaxed material as part of your official premarket notification submission, unless specifically requested of you by an FDA official.

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 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 Assistance at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

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

K992341/51



P.O. Box 4002, Elkhart, IN 46514-0002 • (800) 542-4670 • FAX (219) 266-6222

October 22, 1999

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

Re: K992341
510(k) Submission for Cidex® OPA Solution Test Strips

To Whom it May Concern:

The above referenced Premarket Notification [510(k)] is being held for 30 days pending receipt of this additional information which was requested by the Office of Device Evaluation.

Sincerely,

James E. Christner
James E. Christner
Vice President, Research & Development
Serim Research Corporation
P.O. Box 4002
23565 Reedy Drive
Elkhart, IN 46514

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FDA/CDRH/OCE/DHO

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P.O. Box 4002, Elkhart, IN 46514-0002 • (800) 542-4670 • FAX (219) 266-6222

October 18, 1999

Elaine S. Mayhall, Ph.D.
Chemist, Infection Control Devices Branch
Division of Dental, Infection Control and General Hospital Devices
Office of Device Evaluation
Center for Devices and Radiological Health
Fax: (301) 480-3002

Dear Dr. Mayhall:

This letter is being written in response to your phone call of 10/8/99 regarding 510(k) submission K992341 for OPA Solution Test Strips.

Summary of events leading up to your 10/8/99 phone call

(b) (4)



Your telephone call of 10/8/99

(b) (4)



Our Reply to the Telephone Call of 10/8/99

(b) (4)



¹ Based on the estimated number of disinfectant baths and the number of strips sold, it can be calculated that the testing frequency averages about one test/week/bath.

(b) (4)



² Guidance on the Content and Format of Premarket Notification [510(k)] Submissions for Liquid Chemical Germicides, Draft released for comment on December 6, 1996, Developed by Infection Control Devices Branch, Div. Dental, Infection Control and General Hospital Devices, ODR, CDRH.

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(b) (4)



If you have any questions regarding the above please feel free to contact me at any time.

Sincerely,



James E. Christner, Ph.D.
Vice President of Research & Development

Serim Research Corporation
P.O. Box 4002
23565 Reedy Dr.
Elkhart, IN 46514

Phone: 219-264-3440
Fax: 219-266-6222
Email: jchristner@serim.com

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Assessing Pass/Fail Testing When There Are No Failures to Assess

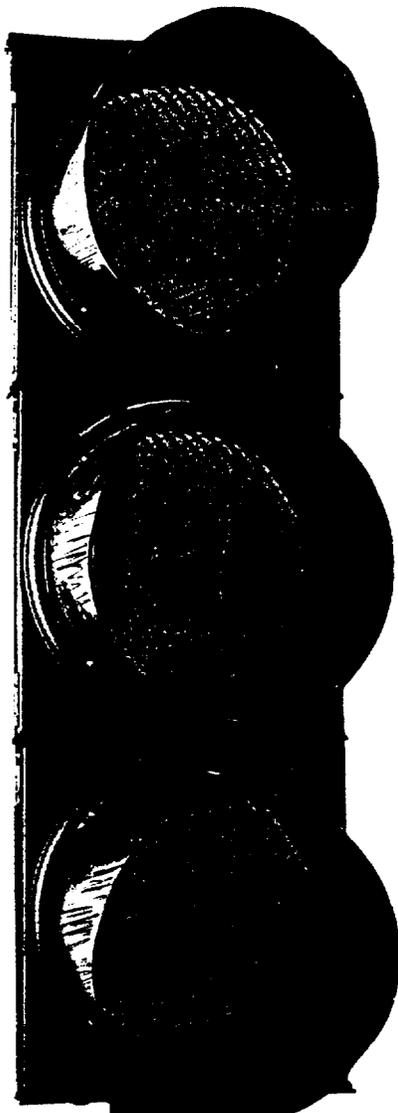
Sometimes pass/fail testing of a sample of products or components goes too smoothly. A zero failure rate can lead to a false sense of security if sample size isn't taken into account.

{ Thom R. Nichols and Sheldon Dummer }

In the course of their work, persons involved in manufacturing medical devices are often required to sample and test products or product components. Often this testing involves the collection of what are known as *variable data*. Variable data are continuous, quantitative data regarding such things as temperature, pressure, and efficiency. By their nature, these types of data provide an enviable precision in measurement, which in turn provides product developers the luxury of small sample sizes without a concomitant loss of statistical power. With such precise data the risk of making a wrong decision concerning products being tested is minimized.

However, quite often product development personnel are called on to sample and test a product, or product component, in which the only information gathered is whether it meets one of two possible outcomes, such as passing or failing a test. This category of information is known as *attribute data*. Attribute data are a discontinuous form of data resulting in the assignment of discrete values, such as yes or no, go or no-go, 0 or 1, or pass or fail.

Attribute data are often collected by engineers, product designers, product/project managers, and others who require initial basic information about a material or product component in order to judge its suitability for use in a medical device. The usefulness of attribute data in pass/fail testing



lies in its allowing user-defined failure criteria to be easily incorporated into research tests or product development laboratory tests—tests whose results, as a rule, are easy to observe and record. In general, if one observes that the test product meets defined criteria, the observation is recorded as a “pass”; if it does not, the observation is recorded as a “fail.” The number of passes and fails are then added up, descriptive statistics presented, conclusions drawn, and manufacturing decisions made.

A FALSE SENSE OF SECURITY

However, the results of such attribute tests can be misleading because the risk associated with decision making on the basis of them is often understated, or misunderstood. This is particularly true when samples are tested and no failure events are observed. When failure is observed in a product being tested the logical course of action is to proceed with caution in drawing conclusions about the acceptability of the test product. In other words, there is a recognition of risk brought about by the observation of one or more failures. Conversely, a zero failure rate observed during testing generally leads to a decision to proceed with the product being investigated.

However, there is a risk in drawing conclusions about a product when no testing failures are observed. Zero failure brings about a sense of security that is often false.

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Sample Size	Failure	90% Confidence Interval	95% Confidence Interval
10	0	25.9%	30.8%
	1	39.4%	44.5%
20	0	13.9%	16.8%
	1	21.6%	24.8%
30	0	9.5%	11.6%
	1	14.9%	17.2%
40	0	7.2%	8.8%
	1	11.3%	13.1%
60	0	4.9%	6.0%
	1	7.7%	9.0%
100	0	3.0%	3.6%
	1	4.7%	5.4%
150	0	2.0%	2.4%
	1	3.1%	3.7%
200	0	1.5%	1.8%
	1	2.4%	2.8%
250	0	1.2%	1.5%
	1	1.9%	2.2%
300	0	1.0%	1.2%
	1	1.6%	1.8%
400	0	0.8%	0.9%
	1	1.2%	1.4%

cause there is always risk involved.

For further reference, Table I presents the upper limits of expected failure when zero or one occurrence of failure is observed during testing.

CONCLUSION

Statistical analysis shows that in both attributes and variables testing, as the amount of valid information increases, the associated risk in making a decision based on that information decreases. In pass/fail testing this means that the ability to estimate with confidence the upper bounds of the true failure rate when the observed failure rate is zero is critically dependent upon sample size. Thus, decision making is also critically dependent on sample size.

REFERENCES

1. Collet D. *Modeling Binary Data*, New York, Chapman & Hall, 1991.
2. Fisher RA, and Yates F. *Statistical Tables for Biological, Agricultural, and Medical Research*, 6th ed. Edinburgh, Oliver and Boyd, 1963.

Thom R. Nichols is senior research statistician and Sheldon Dummer is senior quality engineer at Hollister, Inc. (Libertyville, IL). ■ 847/680-1000

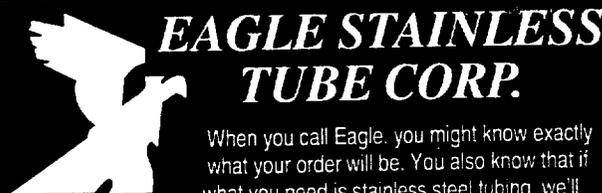
A hypertext version of this article will be available on Medical Device Link, <http://www.devicelink.com/mddi>, by July 1.

Table I. Upper boundary of expected failure from 90 and 95% confidence intervals in which true failure probability is expected to be exhibited. The probability of the upper boundary is equal to $\alpha/2$.

observed? The answer is 100, found by following the 90% confidence limit curve downward until it crosses the 3% probability line. The point of intersection corresponds to 100 on the sample axis.

Example 3. A sample size of 150 is tested with 0 failures observed. From the graph you find that there is a 95% chance that true failure will occur within an interval bounded by an upper limit of 2.4% failure. The question you must ask yourself is this: Am I willing to proceed knowing that I have a 95% chance of product failure that could be as great as 2.4%? In other words, does this risk analysis represent sufficient information about the product under development?

The colors of the graphs range from red (danger) to yellow (proceed with caution). If you are pass/fail sampling and observe zero failures from a sample of size n during the test, you should determine where on the confidence limit curves your upper range of failure exists. To do this, locate on the x-axis the number of samples you have tested, then move vertically until you cross either the 90 or 95% confidence curve. The color area you are in will give you a subjective determination of the risk of failure if you proceed with the development of this product (with red equaling higher risk and yellow equaling caution, or lower risk). You may then locate along the y-axis the upper probability of failure occurring when all that you know about this product is that zero failures occurred in your sample size. Notice that the graphs do not contain the color green (go). This is because



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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOI@FDA.hhs.gov or 301-796-8118

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TABLES OF EXPECTED PROBABILITY OF FAILURE

The following tables present the expected probability of failure when a failure is observed within a sample of size n . The probabilities are based upon the upper 5 percent, 2.5 percent, and 1 percent confidence intervals. As an example, if one wanted to know the upper limit percentage of failure that could be expected when 3 failures were detected from a sample of size 20, at the 95 percent confidence interval, the table would indicate 37.9 percent. This is found by intersecting the upper 2.5 percent column with the sample size=20, failure=3 row. The condition under which the distribution of failure probabilities are calculated is that the only information available to the investigator is that of pass/fail, or accept/reject status. In other words, such information as mode of failure, or time to failure, are not a criteria.

The expected probabilities of failure are exact probabilities and are based on the following equation which is a modification of that given by Collett¹.

$$P_f = 1 - P_L, \text{ where } P_L = y[y+(n-y+1)F_{2(n-y+1), 2y}(\alpha/2)]^{-1}$$

In the above equation P_f is the probability of failure, n is the sample size, and y is the observed number of non-failures. The value F is taken from the F distribution with numerator and denominator degrees of freedom given as $2(n-y+1)$ and $2y$ respectively.

Table 1. Sample sizes less than 1000.

Sample size	Failure	Expected Probability Of Failure		
		upper 5%	upper 2.5%	upper 1%
10	0	25.9	30.8	36.9
10	1	39.4	44.5	50.4
10	2	50.7	55.6	61.2
10	3	60.7	65.2	70.3
10	4	69.6	73.7	78.2
10	5	77.7	81.3	84.9
20	0	13.9	16.8	20.6
20	1	21.6	24.8	28.9
20	2	28.2	31.7	35.8
20	3	34.3	37.9	42.1
20	4	40.1	43.7	47.8
20	5	45.5	49.1	53.2
20	6	50.7	54.2	58.2
20	7	55.8	59.2	63.1
20	8	60.6	63.9	67.7
20	9	65.3	68.5	71.9
20	10	69.8	72.8	76.1

(continued)

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TABLES OF EXPECTED PROBABILITY OF FAILURE

Sample size	Failure	Expected Probability of Failure		
		upper 5%	upper 2.5%	upper 1%
30	0	9.5	11.6	14.2
30	1	14.9	17.2	20.2
30	2	19.5	22.0	25.2
30	3	23.8	26.6	29.8
30	4	27.9	30.7	34.0
30	5	31.9	34.8	38.1
30	6	35.7	38.5	42.0
30	7	39.3	42.3	45.7
30	8	43.0	45.8	49.2
30	9	46.4	49.4	52.7
30	10	49.9	52.8	56.1
30	11	53.3	56.2	59.4
30	12	56.7	59.3	62.6
30	13	59.8	62.6	65.6
30	14	63.0	65.7	68.7
30	15	66.1	68.7	71.6
40	0	7.2	8.8	10.9
40	1	11.3	13.1	15.5
40	2	14.9	16.9	19.4
40	3	18.3	20.4	23.0
40	4	21.4	23.6	26.4
40	5	24.5	26.8	29.6
40	6	27.5	29.8	32.7
40	7	30.4	32.8	35.6
40	8	33.2	35.6	38.5
40	9	36.0	38.5	41.4
40	10	38.7	41.2	44.1
40	11	41.4	43.9	46.8
40	12	44.0	46.5	49.5
40	13	46.6	49.1	52.0
40	14	49.2	51.6	54.6
40	15	51.7	54.2	57.1
60	0	4.9	6.0	7.4
60	1	7.7	9.0	10.6
60	2	10.1	11.5	13.3
60	3	12.4	13.9	15.8
60	4	14.6	16.2	18.1
60	5	16.7	18.4	20.4
60	6	18.8	20.5	22.6
60	7	20.8	22.6	24.7
60	8	22.7	24.6	26.8
60	9	24.7	26.5	28.8
60	10	26.6	28.5	30.8
60	11	28.5	30.5	32.8
60	12	30.4	32.3	34.7
60	13	32.3	34.1	36.5
60	14	34.0	36.1	38.4
60	15	35.8	37.8	40.2
60	16	37.6	39.6	42.1
60	17	39.4	41.4	43.8
60	18	41.2	43.2	45.6
60	19	42.9	44.9	47.3
60	20	44.7	46.7	49.0

(continued)

TABLES OF EXPECTED PROBABILITY OF FAILURE

Sample size	Failure	Expected Probability Of Failure		
		upper 5%	upper 2.5%	upper 1%
100	0	3.0	3.6	4.5
100	1	4.7	5.4	6.5
100	2	6.2	7.0	8.2
100	3	7.6	8.5	9.7
100	4	8.9	9.9	11.2
100	5	10.2	11.3	12.6
100	6	11.5	12.6	14.0
100	7	12.8	13.9	15.3
100	8	14.0	15.2	16.6
100	9	15.2	16.4	17.9
100	10	16.4	17.6	19.2
100	11	17.6	18.8	20.4
100	12	18.7	20.0	21.6
100	13	19.9	21.2	22.8
100	14	21.0	22.4	24.0
100	15	22.1	23.5	25.2
100	20	27.7	29.2	30.9
100	25	33.1	34.7	36.4
150	0	2.0	2.4	3.0
150	1	3.1	3.7	4.3
150	2	4.1	4.7	5.5
150	3	5.1	5.8	6.5
150	4	6.0	6.7	7.5
150	5	6.9	7.6	8.5
150	6	7.8	8.5	9.4
150	7	8.6	9.4	10.3
150	8	9.4	10.2	11.2
150	9	10.2	11.1	12.1
150	10	11.0	11.9	13.0
150	11	11.9	12.7	13.8
150	12	12.7	13.5	14.6
150	13	13.4	14.4	15.5
150	14	14.2	15.2	16.3
150	15	15.0	15.9	17.1
150	20	18.8	19.8	21.2
150	25	22.6	23.7	25.0
150	30	26.1	27.2	28.7

(continued)

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TABLES OF EXPECTED PROBABILITY OF FAILURE

Sample size	Failure	Expected Probability Of Failure		
		upper 5%	upper 2.5%	upper 1%
200	0	1.5	1.8	2.3
200	1	2.4	2.8	3.3
200	2	3.1	3.6	4.1
200	3	3.8	4.3	4.9
200	4	4.5	5.0	5.7
200	5	5.2	5.7	6.4
200	6	5.8	6.4	7.1
200	7	6.5	7.1	7.8
200	8	7.1	7.7	8.5
200	9	7.7	8.4	9.2
200	10	8.3	9.0	9.8
200	11	9.0	9.6	10.5
200	12	9.5	10.2	11.1
200	13	10.2	10.9	11.8
200	14	10.7	11.4	12.4
200	15	11.4	12.1	13.0
200	20	14.2	15.1	16.0
200	25	17.0	17.9	18.9
200	30	19.8	20.7	21.8
200	35	22.5	23.5	24.7
200	40	25.3	26.3	27.4
250	0	1.2	1.5	1.8
250	1	1.9	2.2	2.6
250	2	2.5	2.9	3.3
250	3	3.1	3.5	4.0
250	4	3.6	4.0	4.6
250	5	4.2	4.6	5.2
250	6	4.7	5.1	5.7
250	7	5.2	5.7	6.3
250	8	5.7	6.2	6.8
250	9	6.2	6.7	7.4
250	10	6.7	7.2	7.9
250	11	7.2	7.7	8.4
250	12	7.7	8.2	8.9
250	13	8.1	8.7	9.4
250	14	8.6	9.2	10.0
250	15	9.1	9.7	10.4
250	20	11.4	12.0	12.9
250	25	13.7	14.4	15.3
250	30	15.9	16.7	17.6
250	35	18.1	18.9	19.9
250	40	20.2	21.1	22.2
250	45	22.4	23.4	24.3
250	50	24.6	25.5	26.6

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TABLES OF EXPECTED PROBABILITY OF FAILURE

Sample size	Failure	Expected Probability Of Failure		
		upper 5%	upper 2.5%	upper 1%
300	0	1.0	1.2	1.5
300	1	1.6	1.8	2.2
300	2	2.1	2.4	2.8
300	3	2.6	2.9	3.3
300	4	3.0	3.4	3.8
300	5	3.5	3.8	4.3
300	6	3.9	4.3	4.8
300	7	4.3	4.7	5.2
300	8	4.8	5.2	5.7
300	9	5.2	5.6	6.2
300	10	5.6	6.1	6.6
300	11	6.0	6.4	7.0
300	12	6.4	6.9	7.5
300	13	6.8	7.3	7.9
300	14	7.2	7.7	8.3
300	15	7.6	8.1	8.7
300	20	9.6	10.1	10.8
300	30	13.3	13.9	14.8
300	40	17.0	17.7	18.5
300	50	20.6	21.3	22.2
300	60	24.1	25.0	26.0
400	0	0.8	0.9	1.1
400	1	1.2	1.4	1.6
400	2	1.6	1.8	2.1
400	3	1.9	2.2	2.5
400	4	2.3	2.5	2.9
400	5	2.6	2.9	3.2
400	6	2.9	3.2	3.6
400	7	3.3	3.6	4.0
400	8	3.6	3.9	4.3
400	9	3.9	4.2	4.6
400	10	4.2	4.6	5.0
400	11	4.5	4.9	5.3
400	12	4.8	5.2	5.6
400	13	5.1	5.5	6.0
400	14	5.4	5.8	6.3
400	15	5.7	6.1	6.6
400	20	7.2	7.6	8.1
400	30	10.0	10.5	11.1
400	40	12.8	13.3	14.0
400	50	15.5	16.1	16.8
400	60	18.2	18.9	19.6
400	70	20.9	21.6	22.4
400	80	23.6	24.2	25.0

(continued)

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TABLES OF EXPECTED PROBABILITY OF FAILURE

Sample size	Failure	Expected Probability Of Failure		
		upper 5%	upper 2.5%	upper 1%
500	0	0.6	0.7	0.9
500	1	0.9	1.1	1.3
500	2	1.3	1.4	1.7
500	3	1.6	1.7	2.0
500	4	1.8	2.0	2.3
500	5	2.1	2.3	2.6
500	6	2.4	2.6	2.9
500	7	2.6	2.9	3.2
500	8	2.9	3.1	3.4
500	9	3.1	3.4	3.7
500	10	3.4	3.7	4.0
500	11	3.6	3.9	4.2
500	12	3.9	4.2	4.5
500	13	4.1	4.4	4.8
500	14	4.3	4.6	5.0
500	15	4.6	4.9	5.3
500	25	6.9	7.3	7.7
500	50	12.5	13.0	13.5
500	75	17.9	18.4	19.1
500	100	23.1	23.8	24.4
600	0	0.5	0.6	0.8
600	1	0.8	0.9	1.1
600	2	1.0	1.2	1.4
600	3	1.3	1.4	1.7
600	4	1.5	1.7	1.9
600	5	1.7	1.9	2.2
600	6	2.0	2.2	2.4
600	7	2.2	2.4	2.6
600	8	2.4	2.6	2.9
600	9	2.6	2.8	3.1
600	10	2.8	3.0	3.3
600	11	3.0	3.2	3.6
600	12	3.2	3.5	3.8
600	13	3.4	3.7	4.0
600	14	3.6	3.9	4.2
600	15	3.8	4.1	4.4
600	25	5.8	6.1	6.5
600	50	10.5	10.8	11.3
600	75	14.9	15.4	15.9
600	100	19.4	19.9	20.5
600	125	23.7	24.3	24.9

(continued)

TABLES OF EXPECTED PROBABILITY OF FAILURE

Sample size	Failure	Expected Probability Of Failure		
		upper 5%	upper 2.5%	upper 1%
800	0	0.4	0.5	0.6
800	1	0.6	0.7	0.8
→ 800	2	0.8	0.9	1.0
800	3	1.0	1.1	1.2
800	4	1.1	1.3	1.4
800	5	1.3	1.4	1.6
800	6	1.5	1.6	1.8
800	7	1.6	1.8	2.0
800	8	1.8	2.0	2.2
800	9	2.0	2.1	2.3
800	10	2.1	2.3	2.5
800	11	2.3	2.4	2.7
800	12	2.4	2.6	2.8
800	13	2.6	2.8	3.0
800	14	2.7	2.9	3.2
800	15	2.9	3.1	3.3
800	25	4.3	4.6	4.8
800	50	7.8	8.2	8.5
800	75	11.3	11.6	12.0
800	100	14.6	15.0	15.5
800	125	17.9	18.3	18.8
800	160	22.4	22.9	23.5

TABLES OF EXPECTED PROBABILITY OF FAILURE

Table 2. Sample sizes of n=1000 or greater.

Sample size	Failure	Expected Probability Of Failure		
		upper 5%	upper 2.5%	upper 1%
1000	0	0.30	0.37	0.46
1000	1	0.47	0.56	0.66
1000	2	0.63	0.72	0.84
1000	3	0.77	0.87	1.00
1000	4	0.92	1.02	1.16
1000	5	1.05	1.16	1.30
1000	6	1.18	1.30	1.45
1000	7	1.31	1.44	1.59
1000	8	1.44	1.57	1.73
1000	9	1.57	1.71	1.87
1000	10	1.69	1.83	2.00
1000	11	1.81	1.96	2.14
1000	12	1.94	2.09	2.26
1000	13	2.06	2.22	2.40
1000	14	2.17	2.33	2.54
1000	15	2.30	2.46	2.66
1000	25	3.47	3.67	3.90
1000	50	6.29	6.52	6.85
1000	75	8.97	9.31	9.65
1000	100	11.69	12.04	12.39
1000	125	14.31	14.73	15.15
1000	150	16.96	17.33	17.81
1000	175	19.56	19.97	20.52
1000	200	22.27	22.57	23.17
2500	0	0.12	0.15	0.18
2500	1	0.19	0.22	0.27
2500	2	0.25	0.29	0.34
2500	3	0.31	0.35	0.40
2500	4	0.37	0.41	0.46
2500	5	0.42	0.47	0.52
2500	10	0.68	0.73	0.81
2500	15	0.92	0.99	1.07
2500	25	1.39	1.47	1.57
2500	50	2.52	2.63	2.75
2500	75	3.62	3.74	3.89
2500	100	4.69	4.85	5.00
2500	125	5.80	5.94	6.13
2500	150	6.83	6.99	7.21
2500	175	7.88	8.07	8.26
2500	200	8.92	9.13	9.35
2500	250	11.02	11.28	11.46
2500	300	13.08	13.29	13.60
2500	400	17.23	17.49	17.75
2500	500	21.29	21.60	21.91

(continued)

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

October 08, 1999

SERIM RESEARCH CORP.
23565 REEDY DRIVE
P.O. BOX 4002
ELKHART, IN 46514
ATTN: JAMES E. CHRISTNER

510(k) Number: K992341
Product: CIDEX OPA
SOLUTION TEST
STRIP

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. Because of equipment and personnel limitations, we cannot accept telefax material as part of your official premarket notification submission unless specifically requested of you by an FDA official.

If after 30 days the requested information, 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. 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 Assistance at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

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

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Memorandum

From: Reviewer(s) - Name(s) October 8, 1999
Elaine Mayhall

Subject: 510(k) Number K992341

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

- Refused to accept.
- Requires additional information (other than refuse to accept).
- Accepted for review _____.
- Is substantially equivalent to marketed devices.
- NOT substantially equivalent to marketed devices.

*Phone Hold
see memo dated
10/8/99*

- De Novo Classification Candidate? YES NO
- Other (e.g., exempt by regulation, not a device, duplicate, etc.)

- Is this device subject to 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 YES NO

This 510(k) contains:

- Truthful and Accurate Statement Requested Enclosed
(required for originals received 3-14-95 and after)
- A 510(k) summary OR A 510(k) statement
- The required certification and summary for class III devices
- The indication for use form (required for originals received 1-1-96 and after)
- 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 *[Signature]* *JWC3* *10-8-99*
 (Branch Chief) (Branch Code) (Date)

Final Review: _____

MEMORANDUM

DATE: October 8, 1999

FROM: Elaine Schalk Mayhall, Ph.D., Chemist, Infection Control Devices Branch,
DDIGD, HFZ-480

SUBJECT: K992341
SERIM RESEARCH CORP.
CIDEX™ OPA SOLUTION TEST STRIP

CONTACT: James Christner
219-264-3440 (IN)
219-266-6222 fax

TO: The Record

Intended Use

The Cidex™ OPA Solution Test Strips are semi-quantitative chemical indicators used to determine whether the concentration of ortho-phthalaldehyde in Cidex™ OPA Solution is above or below the minimum effective concentration of 0.3%.

Background

Serim Research previously has submitted the following three 510(k)s for this product:

- K972739 - withdrawn by the firm in a letter dated 9/4/97 because the 510(k) for Cidex™ OPA Solution had been deleted.
- K983290 - withdrawn and deleted from the system by FDA because the submission for Cidex™ OPA Solution had significant deficiencies that could not be resolved within 30 days (letter dated 10/98).
- K983806 – withdrawn and deleted from the system by FDA because the submission for Cidex OPA Solution was deleted (letter dated /98); A list of our concerns about the indicator was sent to the firm via fax on 12/8/98.

Device Description

The Cidex™ OPA Solution Test Strips are chemical indicators used for determining whether the concentration of OPA in Cidex™ OPA Solution is above or below the minimum effective concentration of 0.3%. The indicator pad measures 0.2 inches x 0.2 inches and is attached to a 0.2 inch x 3.25 inch polystyrene handle. The strips are packaged in groups of 60 strips with a desiccant pack in containers made of HDPE. One 12x75 mm glass test tube is supplied with each bottle. The cap is made of HDPE with a cap liner consisting of pulpboard backing covered with vinyl coated aluminum foil. The formula is shown in Table 1. The firm did not identify

K992341

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"Gantrez" any further.

Table 1. Formulation of the Strips

Ingredients	% by Weight
Sodium sulfite	(b)(4)
Ammonium citrate	(b)(4)
Gantrez	(b)(4)
TOTAL	100%

Chemical principle: The OPA reacts with sodium sulfite to form an addition compound. The excess OPA then reacts with ammonium ions to form colored polymers. When the OPA concentration is 0.3% or less, it is entirely consumed with the sodium sulfite to produce colorless product. When its concentration is sufficient to overwhelm the sodium sulfite, the excess reacts with ammonium ions to produce colored polymers (brown/black). If the solution contains 0.3% OPA or less, the pad will be lighter than the color block on the package and should indicate FAIL. If the solution contains 0.45% OPA or more, the pad color will be equal to or darker than the color block and should indicate PASS. At intermediate concentrations of OPA, the test strip may indicate either PASS or FAIL.

A 12x75 glass test tube is provided with the strips for use in testing samples of Cidex™ OPA solutions. About 1 ml of Cidex™ OPA solution is placed in the glass test tube. After immersing the strip in the Cidex™ OPA solution for exactly 30 seconds, the test strip is removed by touching the side edge of the pad against the inside of the tube and is drawn upward for 2-3 seconds against the entire length of the test tube. The handle end of the strip is laid on a paper towel so that the indicator pad hangs over the edge to prevent further absorption. After 2.5 minutes following removal of the strip from the solution, the color of the indicator pad is compared to the color block on the container.

Comparison Products

The firm noted that the Cidex™ OPA Solution Test Strip is similar in design, composition and function to the Cidex™ Solution Test Strips (K915170; a.k.a., PyMah Sterilog Indicator Strips). The firm has provided a table comparing the indicator strips.

Labeling

The firm has provided the proposed labeling for the Cidex™ OPA strips. The label includes the intended use, warnings and precautions, directions for use, information on how to interpret the results, a reference color chart, the chemical principle, performance characteristics, quality control procedures, and a statement indicating that the strips should not be used as a means of validating a sterilization process. The storage instructions indicate that the strips should be stored in a dry place at 16-32°C and used within 90 days after opening the bottle and not used after the expiration date.

In the package insert, the firm provides the following information to the user:

K992341

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- Leaving the strip in the Cidex™ OPA solution for longer than 30 seconds or swirling the strip vigorously could cause excess color development and lead to a false PASS result when the OPA concentration is truly below the MEC.
- A false pass may result if the indicator pad is not drawn up the tube slowly (2-3 seconds); the use of the provided test tube is important to the performance of the strip.
- Reading the strip after a total of 3 minutes may also result in a false PASS result.
- Fresh solution should be used for each strip.

These aspects of the strips are addressed with performance testing.

Performance Data

(b) (4)



K992341

Page 4

(b) (4)

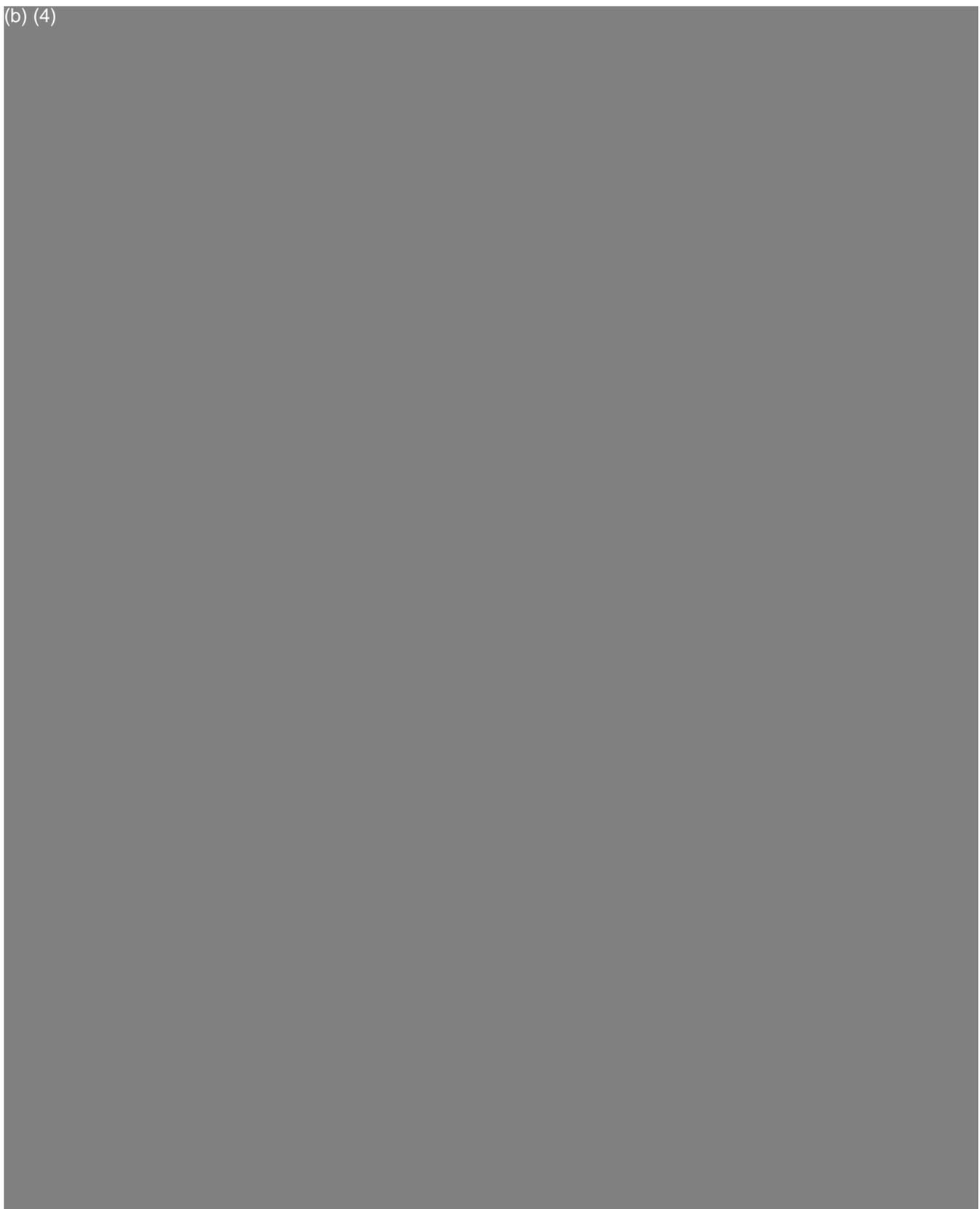


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(b) (4)



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Page 6

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Stability

(b) (4)



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CONCLUSION:

(b) (4)



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(b) (4)



(b) (4)



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(b) (4)



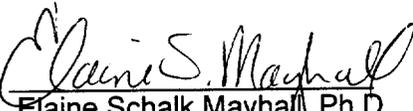
Conclusion

(b) (4)

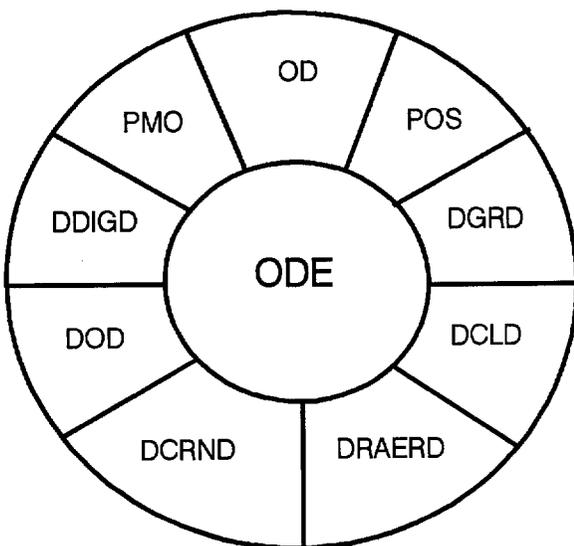


RECOMMENDATION: I recommend that the document, K992341 be placed on PHONE HOLD until the labeling issues have been resolved for the Cidex OPA Solution Test Strip.

Reviewed by:


Elaine Schalk Mayhall, Ph.D.

**DHHS/PHS/FDA/CDRH/ODE
DIVISION OF DENTAL, INFECTION CONTROL, AND
GENERAL HOSPITAL DEVICES
9200 CORPORATE BOULEVARD, HFZ-480
ROCKVILLE, MARYLAND 20850**



FROM: Elaine S. Mayhall, Ph.D.

DATE: 9/14/99

NO. OF PAGES: 2

PHONE NO: (301) 443-8913

FAX NO: (301) 480-3002

TO: Dr. James Christner, Serim Research Corp.

FAX NO: 219-266-6222

SUBJECT: K992341 Questions

ADDITIONAL COMMENTS: Please contact me at the above number if you have any questions. Thank you. Elaine S. Mayhall

THIS DOCUMENT 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 APPLICABLE 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 or other action based on the content of the communication is not authorized. If you have received this document in error, please immediately notify us by telephone and return it to us at the above address by mail. Thank you.

September 14, 1999

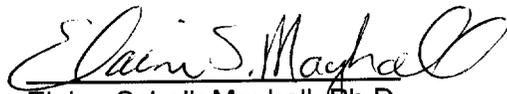
Dr. Christner:

Please provide the following additional information regarding the Cidex™ OPA Solution Test Strips:

(b)(4)



Thank you.


Elaine Schalk Mayhall, Ph.D.

CONFIDENTIAL

Re: K992341
Page 1 of 3



P.O. Box 4002, Elkhart, IN 46514-0002 • (219) 264-3440 • FAX (219) 266-6222

September 16, 1999

Elaine S. Mayhall, Ph.D.
Chemist, Infection Control Devices Branch
Division of Dental, Infection Control and General Hospital Devices
Office of Device Evaluation
Center for Devices and Radiological Health
Fax: (301) 480-3002

Dear Dr. Mayhall:

Your fax of 9/14/99 lists three questions/comments about the 510(k) submission for the Cidex OPA Solution Test Strips (K992341) to which I am replying.

(b) (4)

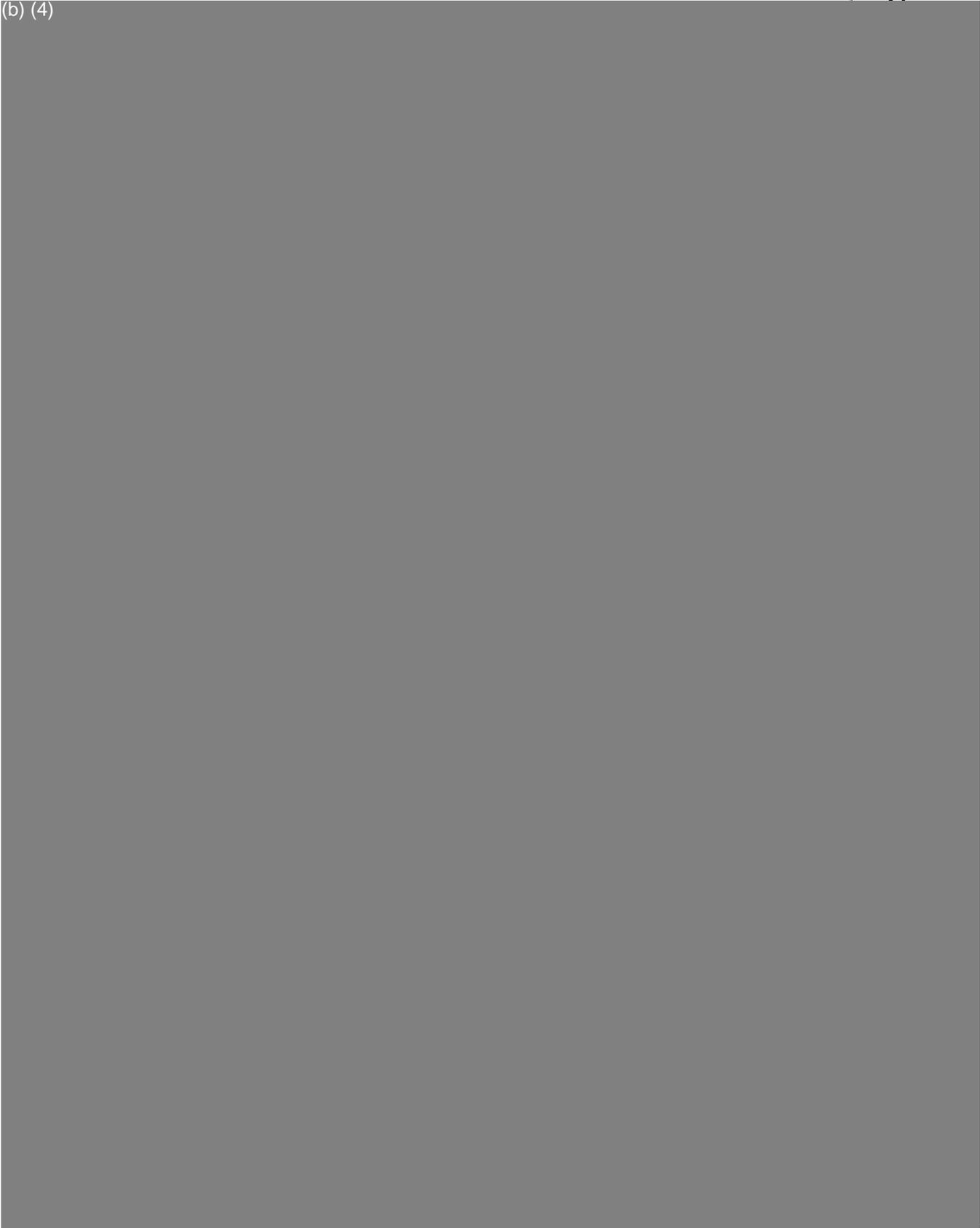


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Re: K992341
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Re: K992941

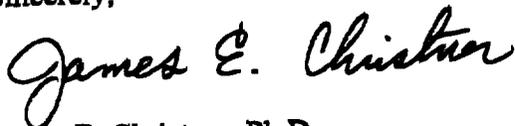
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(b) (4)



If you have any further questions or need further clarification, please feel free to contact me by phone, fax or e-mail.

Sincerely,



James E. Christner, Ph.D.

Phone: 219-264-3440

Fax: 219-266-6222

Email: jchristner@serim.com

SERIM RESEARCH CORPORATION

PO BOX 4002

ELKHART, IN 46514-0002

(219) 264-3440

Fax: (219) 266-6222

Fax Transmittal

To: E. S. Mayhall

Fax#: 301/480-3002

From: J. E. Christner

Date: 9/20/99

Subject:

Total Pages: 9, including cover sheet

Message: The product insert we discussed
this date rel K992341 follows.

CHEMICAL PRINCIPLES OF THE PROCEDURE:

Glucose: This test is based on a double sequential enzyme reaction. One enzyme, glucose oxidase, catalyzes the formation of gluconic acid and hydrogen peroxide from the oxidation of glucose. A second enzyme, peroxidase, catalyzes the reaction of hydrogen peroxide with a potassium iodide chromogen to oxidize the chromogen to colors ranging from green to brown.

Bilirubin: This test is based on the coupling of bilirubin with diazotized dichloroaniline in a strongly acid medium. The color changes through various shades of tan.

Ketone: This test is based on the development of colors ranging from buff-pink, for a negative reading, to purple when acetoacetic acid reacts with nitroprusside.

Specific Gravity: This test is based on the apparent pKa change of certain pretreated polyelectrolytes in relation to ionic concentration. In the presence of an indicator, colors range from deep blue-green in urine of low ionic concentration through green and yellow-green in urines of increasing ionic concentration.

Blood: This test is based on the peroxidase-like activity of hemoglobin, which catalyzes the reaction of diisopropylbenzene dihydroperoxide and 3,3',5,5'-tetramethylbenzidine. The resulting color ranges from orange through green; very high levels of blood may cause the color development to continue to blue.

pH: The test is based on the double indicator principle that gives a broad range of colors covering the entire urinary pH range. Colors range from orange through yellow and green to blue.

Protein: This test is based on the protein-error-of-indicators principle. At a constant pH, the development of any green color is due to the presence of protein. Colors range from yellow for "Negative" through yellow-green and green to green-blue for "Positive" reactions.

Urobilinogen: This test is based on a modified Ehrlich reaction, in which p-diethylaminobenzaldehyde in conjunction with a color enhancer reacts with urobilinogen in a strongly acid medium to produce a pink-red color.

Nitrite: This test depends upon the conversion of nitrate (derived from the diet) to nitrite by the action of Gram negative bacteria in the urine. At the acid pH of the reagent area, nitrite in the urine reacts with p-arsanilic acid to form a diazonium compound. This diazonium compound in turn couples with 1,2,3,4-tetrahydrobenzo(h)quinolin-3-ol to produce a pink color.

area. Urine containing glucose may decrease in pH as organisms metabolize the glucose. Bacterial growth from contaminating organisms may cause false positive blood reactions from the peroxidases produced. In random urine specimens from females, a positive result for leukocytes may be due to a source external to the urinary tract.

Contamination of the urine specimen with skin cleansers containing chlorhexidine may affect protein (and to a lesser extent specific gravity and bilirubin) test results. The user should determine whether the use of such skin cleansers is warranted.

PROCEDURE: MUST BE FOLLOWED EXACTLY TO ACHIEVE RELIABLE TEST RESULTS:

RELIABLE TEST RESULTS:

1. Collect FRESH urine specimen in a clean, dry container. Mix well immediately before testing.
2. Remove one strip from bottle and replace cap. Completely immerse reagent areas of the strip in FRESH urine and remove immediately to avoid dissolving out reagents.
3. While removing, run the edge of the strip against the rim of the urine container to remove excess urine. Hold the strip in a horizontal position to prevent possible mixing of chemicals from adjacent reagent areas and/or contaminating the hands with urine.
4. a. If reading visually, compare reagent areas to corresponding Color Chart on the bottle label at the time specified. **HOLD STRIP CLOSE TO COLOR BLOCKS AND MATCH CAREFULLY.** Avoid laying the strip directly on the Color Chart, as this will result in the urine soiling the chart.
- b. If reading instrumentally, carefully follow the directions given in the appropriate instrument operating manual.

Proper read time is critical for optimal results. If using strips visually, read the glucose and bilirubin test at 30 seconds after dipping. Read the ketone test at 40 seconds; the specific gravity test at 45 seconds; pH, protein, urobilinogen, blood, and nitrite at 60 seconds; and leukocytes at 2 minutes. The pH and protein areas may also be read immediately or at any time up to 2 minutes after dipping.

After dipping the strip, check the pH area. If the color on the pad is not uniform, read the reagent area immediately, comparing the

Leukocytes: Granulocytic leukocytes contain esterases that catalyze the hydrolysis of the derivatized pyrrole amino acid ester to liberate 3-hydroxy-5-phenyl pyrrole. This pyrrole then reacts with a diazonium salt to produce a purple product.

REAGENTS:

(Based on dry weight at time of impregnation):

Glucose: 2.2% w/w glucose oxidase (microbial, 1.3 IU); 1.0% w/w peroxidase (horse radish, 3300 IU); 8.1% w/w potassium iodide; 69.8% w/w buffer; 18.9% w/w nonreactive ingredients.

Bilirubin: 0.4% w/w 2,4-dichloroaniline diazonium salt; 37.3% w/w buffer; 62.3% w/w nonreactive ingredients.

Ketone: 7.1% w/w sodium nitroprusside; 92.9% w/w buffer.

Specific Gravity: 2.8% w/w bromthymol blue; 68.8% w/w poly (methyl vinyl ether/maleic anhydride); 28.4% w/w sodium hydroxide.

Blood: 6.8% w/w disopropylbenzene dihydroperoxide; 4.0% w/w 3,3',5,5'-tetramethylbenzidine; 48.0% w/w buffer; 41.2% w/w nonreactive ingredients.

pH: 0.2% w/w methyl red; 2.8% w/w bromthymol blue; 97.0% w/w nonreactive ingredients.

Protein: 0.3% w/w tetrabromophenol blue; 97.3% w/w buffer; 2.4% w/w nonreactive ingredients.

Urobilinogen: 0.2% w/w p-diethylaminobenzaldehyde; 99.8% w/w nonreactive ingredients.

Nitrite: 1.4% w/w p-arsanilic acid; 1.3% w/w 1,2,3,4-tetrahydrobenzo(h)-quinolin-3-ol; 10.8% w/w buffer; 86.5% w/w nonreactive ingredients.

Leukocytes: 0.4% w/w derivatized pyrrole amino acid ester; 0.2% w/w diazonium salt; 40.9% w/w buffer; 58.5% w/w nonreactive ingredients.

WARNINGS AND PRECAUTIONS:

Bayer Diagnostics Reagent Strips are for *in vitro* diagnostic use. They have been determined to be nonhazardous under the guidelines issued by OSHA in 29CFR 1910.1200(d).

darkest color to the appropriate Color Chart. All reagent areas except leukocytes may be read between 1 and 2 minutes for identifying negative specimens and for determination of the pH and SG. A positive reaction (Small or greater) at less than 2 minutes on the leukocyte test may be regarded as a positive indication of leukocytes in urine. Color changes that occur after 2 minutes are of no diagnostic value. If using strips instrumentally, the instrument will automatically read each reagent area at a specified time.

QUALITY CONTROL:

For best results, performance of reagent strips should be confirmed by testing known negative and positive specimens or controls whenever a new bottle is first opened. Negative and positive specimens or controls may also be randomly hidden in each batch of specimens tested. Each laboratory should establish its own goals for adequate standards of performance, and should question handling and testing procedures if these standards are not met. CHEK-STIX® Positive and Negative Control Strips, with positive, negative or defined results, provide a convenient basis for a urinalysis quality control program.

Because of the various constituents that are added to commercial controls other than CHEK-STIX Control Strips, or the way in which they are processed, specific gravity values determined using Bayer Diagnostics Reagent Strips may not always correspond with values given in the product inserts for these controls.

Due to its specificity for acetoacetic acid, the ketone reagent area may not react with commercial controls other than CHEK-STIX Positive Control Strips. If questionable results are obtained with the ketone reagent area, strip reactivity should be checked with CHEK-STIX Positive Control Strips or by testing negative and positive clinical specimens that have been identified as positive or negative with a reference test method, such as ACETEST® Reagent Tablets.

STORAGE:
Store at room temperature between 15°-30°C (59°-86°F). Do not use product after expiration date. Do not store the bottle in direct sunlight.

RECOMMENDED PROCEDURES FOR HANDLING BAYER DIAGNOSTICS REAGENT STRIPS:

All unused strips must remain in the original bottle. Transfer to any other container may cause reagent strips to deteriorate and become unreactive. Do not remove desiccant(s) from bottle. **Do not remove strip from the bottle until immediately before it is to be used for testing. Replace cap immediately and tightly after removing reagent strip.** Do not touch test areas of the reagent strip. Work areas and specimen containers should be free of detergents and other contaminating substances.

Dip test areas in urine completely, but briefly, to avoid dissolving out the reagents. If using strips visually, read test results carefully at the times specified, in a good light (such as fluorescent) and with the test area held near the appropriate Color Chart on the bottle label. Do not read the strips in direct sunlight. If the strips are used instrumentally, carefully follow the directions given in the appropriate instrument operating manual.

IMPORTANT: PROTECTION AGAINST AMBIENT MOISTURE, LIGHT AND HEAT IS ESSENTIAL TO GUARD AGAINST ALTERED REAGENT REACTIVITY. Discoloration or darkening of

RESULTS:

Results with Bayer Diagnostics Reagent Strips are obtained in clinically meaningful units directly from the Color Chart comparison when using strips visually. With instrumental use, the reagent pads are "read" by the instrument and the results are displayed or printed. The color blocks and instrumental display values represent nominal values; actual values will vary around the nominal values.

LIMITATIONS OF PROCEDURES:

As with all laboratory tests, definitive diagnostic or therapeutic decisions should not be based on any single result or method.

Substances that cause abnormal urine color, such as drugs containing azo dyes (e.g., Pyridium[®], Azo Gantrisin[®], Azo Gantranol[®]), nitrofurantoin (Macrodanit[®], Furadantin[®]), and riboflavin, may affect the readability of the reagent areas on urinalysis reagent strips. The color development on the reagent pad may be masked, or a color reaction may be produced on the pad that could be interpreted visually and/or instrumentally as a false positive.

Glucose: Ascorbic acid concentrations of 50 mg/dL or greater may cause false negatives for specimens containing small

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amounts of glucose (75-125 mg/dL). Ketone bodies reduce the sensitivity of the test; moderately high ketone levels (40 mg/dL) may cause false negatives for specimens containing small amounts of glucose (75-125 mg/dL) but the combination of such ketone levels and low glucose levels is metabolically improbable in screening. The reactivity of the glucose test decreases as the SG of the urine increases. Reactivity may also vary with temperature.

Bilirubin: Indican (indoxyl sulfate) can produce a yellow-orange to red color response that may interfere with the interpretation of a negative or a positive bilirubin reading. Metabolites of Iodine[®] (Ictodolac) may cause false positive or atypical results; ascorbic acid concentrations of 25 mg/dL or greater may cause false negatives. Since very small amounts of bilirubin may be found in the earliest phases of liver disease, the user must consider whether the sensitivity of Bayer Diagnostics Reagent Strips to bilirubin is sufficient for the intended use. When very small amounts of bilirubin in urine are sought (e.g., earliest phase of viral hepatitis), ICTOTEST[®] Reagent Tablets should be the method of choice.

Ketone: False positive results (Trace or less) may occur with highly pigmented urine specimens or those containing large amounts of levodopa metabolites. Compounds such as mesna (2-mercaptoethane sulfonic acid) that contain sulphydryl groups may cause false positive results or an atypical color reaction.

Specific Gravity: The chemical nature of the Bayer Diagnostics SG test may cause slightly different results from those obtained with other specific gravity methods when elevated amounts of certain urine constituents are present. Highly buffered alkaline urines may cause low readings relative to other methods. Elevated specific gravity readings may be obtained in the presence of moderate quantities (100-750 mg/dL) of protein.

Blood: Elevated specific gravity may reduce the reactivity of the blood test. Capoten[®] (Captopril) may also cause decreased reactivity. Certain oxidizing contaminants, such as hypochlorite, may produce false positive results. Microbial peroxidase associated with urinary tract infection may cause a false positive reaction. Levels of ascorbic acid normally found in urine do not interfere with this test.

how long the urine specimens were retained in the bladder prior to collection. Identification of known positive cases with the nitrite test ranges from as low as 40%, when little bladder incubation occurred, to as high as approximately 80%, when a minimum of four hours of bladder incubation occurred.

Leukocytes: Normal urine specimens generally yield negative results; positive results (Small or greater) are clinically significant. Individually observed Trace results may be of questionable clinical significance; however, Trace results observed repeatedly may be clinically significant. Positive and repeated Trace results indicate the need for further testing of the patient and/or urine specimen, according to medically accepted procedures for pyuria. Positive results may occasionally be found with random specimens from females due to contamination of the specimen by vaginal discharge.

SPECIFIC PERFORMANCE CHARACTERISTICS:

Specific performance characteristics are based on clinical and analytical studies. In clinical specimens, the sensitivity depends upon several factors: the variability of color perception; the presence or absence of inhibitory factors typically found in urine, the specific gravity, and the pH (see LIMITATIONS OF PROCEDURES section); and the lighting conditions when the product is read visually. Because the color of each reagent area changes as the analyte concentration increases, the percentage of specimens detected as positive will increase with the analyte concentration.

Each color block or instrumental display value represents a range of values. Because of specimen and reading variability, specimens with analyte concentrations that fall between nominal levels may give results at either level. Results at levels greater than the second positive level for the glucose, ketone, protein, and urobilinogen tests will usually be within one level of the true concentration. Exact agreement between visual results and instrumental results might not be found because of the inherent differences between the perception of the human eye and the optical system of the instruments.

The following table lists the generally detectable levels of analytes

Records processed under FOIA Request # 2013-7845; Released by CDRH

pH: If proper procedure is not followed and excess urine remains on the strip, a phenomenon known as "runover" may occur, in which the acid buffer from the protein reagent will run onto the pH area, causing a false lowering of the pH result.

Protein: False positive results may be obtained with highly buffered or alkaline urines. Contamination of the urine specimen with quaternary ammonium compounds (e.g., from some antiseptics and detergents) or with skin cleansers containing Ethoxthexidine may also produce false positive results.

Urobilinogen: The reagent area may react with substances known to interfere with Ehrlich's reagent, such as p-aminosalicylic acid and sulfonamides. Atypical color reactions may be obtained in the presence of high concentrations of p-aminobenzoic acid. False negative results may be obtained if formalin is present. Strip reactivity increases with temperature; the optimum temperature is 22°-26°C. The test is not a reliable method for the detection of porphobilinogen. The absence of urobilinogen cannot be determined with this test.

Nitrite: Pink spots or pink edges should not be interpreted as a positive result. Any degree of uniform pink color development should be interpreted as a positive nitrite test suggesting the presence of 10⁵ or more organisms per mL, but color development is not proportional to the number of bacteria present. A negative result does not in itself prove that there is no significant bacteriuria. Negative results may occur when urinary tract infections are caused by organisms that do not contain reductase to convert nitrate to nitrite; when urine has not been retained in the bladder long enough (four hours or more) for reduction of nitrate to nitrite to occur; or when dietary nitrate is absent, even if organisms containing reductase are present and bladder incubation is ample. Sensitivity of the nitrite test is reduced for urines with high specific gravity. Ascorbic acid concentrations of 25 mg/dL or greater may cause false negative

in centrifuged urine; however, because of the inherent variability of clinical urines, lesser concentrations may be detected under certain conditions.

Reagent Area	Sensitivity
Glucose	75-125 mg/dL glucose
Bilirubin	0.4-0.8 mg/dL bilirubin
Ketone	5-10 mg/dL acetoacetic acid
Blood	0.015-0.062 mg/dL hemoglobin
Protein	15-30 mg/dL albumin
Nitrite	0.06-0.1 mg/dL nitrite ion
Leukocytes	5-15 cells/hpf in clinical urine

Glucose: The test is specific for glucose; no substance excreted in urine other than glucose is known to give a positive result. The reagent area does not react with lactose, galactose, fructose nor reducing metabolites of drugs (e.g., salicylates and nalidixic acid). This test may be used to determine whether the reducing substance found in urine is glucose. Reactivity may be influenced by urine specific gravity and temperature. In dilute urines containing less than 5 mg/dL ascorbic acid, as little as 40 mg/dL glucose may produce a color change that might be interpreted as positive. The test is more sensitive than the copper reduction test (e.g., CLINITEST® Reagent Tablets). If the color appears somewhat mottled at the higher glucose concentrations, match the darkest color to the color blocks.

Bilirubin: The test is less sensitive than ICTOTEST Reagent Tablets.

Ketone: The test reacts with acetoacetic acid in urine. It does not react with acetone or B-hydroxybutyric acid. Some high specific gravity/low pH urines may give reactions up to and including Trace. Clinical judgment is needed to determine the significance of reactions up to and including Trace.

Specific Gravity: The specific gravity test permits determination of urine specific gravity between 1.000 and 1.030. In general, it

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6.

results with specimens containing small amounts of nitrite ion (0.06 mg/dL or less).

Leukocytes: Elevated glucose concentrations (≥ 3 g/dL) or high specific gravity may cause decreased test results. The presence of cephalixin (Kelfex[®]), cephalothin (Keflin[®]), or high concentrations of oxalic acid may also cause decreased test results. Tetracycline may cause decreased reactivity, and high levels of the drug may cause a false negative reaction.

EXPECTED VALUES:

Expected values for the typical "normal" healthy population and the abnormal population are listed below for each reagent. Exact agreement between visual results and instrumental results might not be found because of the inherent differences between the perception of the human eye and the optical system of the instruments.

Glucose: Small amounts of glucose are normally excreted by the kidney³. These amounts are usually below the sensitivity of this test but on occasion may produce a color between the Negative and the 100 mg/dL color blocks and that is interpreted by the instrument as a positive. Results at the first positive level may be significantly abnormal if found consistently.

Bilirubin: Normally no bilirubin is detectable in urine by even the most sensitive methods. Even trace amounts of bilirubin are sufficiently abnormal to require further investigation. Atypical colors (colors that are unlike the negative or positive color blocks shown on the Color Chart) may indicate that bilirubin-derived bile pigments are present in the urine sample and may be masking the bilirubin reaction. These colors may indicate bile pigment abnormalities and the urine specimen should be tested further (e.g., ICTOTEST Reagent Tablets).

Ketone: Normal urine specimens ordinarily yield negative results with this reagent. Detectable levels of ketone may occur in urine during physiological stress conditions such as fasting, pregnancy and frequent strenuous exercise.⁴ In ketoacidosis, starvation or with other abnormalities of carbohydrate or lipid metabolism, ketones may appear in urine in large amounts before serum ketone is elevated.⁷

correlates within 0.005 with values obtained with the refractive index method. For increased accuracy, 0.005 may be added to readings from urines with pH equal to or greater than 6.5. Strips read instrumentally are automatically adjusted for pH by the instrument. The Bayer Diagnostics SG test is not affected by certain nonionic urine constituents such as glucose nor by the presence of radiopaque dye.

Blood: The sensitivity of this test may be reduced in urines with high specific gravity. The test is equally sensitive to myoglobin as to hemoglobin. The appearance of green spots on the reacted reagent area indicates the presence of intact erythrocytes in the urine. The color chart includes examples of trace and moderate nonhemolyzed color blocks. Reactions ranging from trace to large, with proportionately more numerous spots, may be observed. (Hemoglobin concentration of 0.015-0.062 mg/dL is approximately equivalent to 5-20 intact red blood cells per microliter.) Because of the optical systems of urine chemistry instruments, the sensitivity to intact erythrocytes is lower than that perceived visually.

pH: The pH test area measures pH values generally to within 1 unit in the range of 5-8.5 visually and 5-9 instrumentally. pH readings are not affected by variations in the urinary buffer concentration.

Protein: The reagent area is more sensitive to albumin than to globulins, hemoglobin, Bence-Jones Protein and mucoprotein; a negative result does not rule out the presence of these other proteins.

Urobilinogen: This test area will detect urobilinogen in concentrations as low as 0.2 mg/dL (approximately 0.2 EU/dL) in urine. The absence of urobilinogen in the specimen being tested cannot be determined.

Nitrite: Comparison of the reacted reagent area against a white background may aid in the detection of low levels of nitrite ion, which may otherwise be missed. The test is specific for nitrite and will not react with any other substance normally excreted in urine.

Leukocytes: The sensitivity claim has been verified by clinical evaluations at a number of clinical sites.

Specific Gravity: Random urines may vary in specific gravity from 1.001-1.035. Twenty-four hour urines from normal adults with normal diets and normal fluid intake will have a specific gravity of 1.016-1.022.

Blood: The significance of the Trace reaction may vary among patients, and clinical judgment is required for assessment in an individual case. Development of green spots (intact erythrocytes) or green color (free hemoglobin/myoglobin) on the reagent area within 60 seconds indicates the need for further investigation. Blood is often, but not always, found in the urine of menstruating females. This test is highly sensitive to hemoglobin and thus complements the microscopic examination.

pH: Both the normal and abnormal urinary pH range is from 5 to 9.

Protein: Normally no protein is detectable in urine, although a minute amount is excreted by the normal kidney. A color matching any block greater than Trace indicates significant proteinuria. For urine of high specific gravity, the test area may most closely match the Trace color block even though only normal concentrations of protein are present. Clinical judgment is needed to evaluate the significance of Trace results.

Urobilinogen: The normal urobilinogen range obtained with this test is 0.2 to 1.0 mg/dL (1 mg/dL is approximately equal to 1 Ethich Unit/dL). A result of 2.0 mg/dL represents the transition from normal to abnormal, and the patient and/or urine specimen should be evaluated further.

Nitrite: Normally no nitrite is detectable in urine. The proportion of positive nitrite tests in cases of significant infection depends on

AVAILABILITY: Bayer Diagnostics Reagent Strips for Urinalysis are available in bottles of 100 strips: MULTISTIX® 10 SG (#2161); MULTISTIX® 9 (#2162); MULTISTIX® 9 SG (#2163); MULTISTIX® 8 SG (#2164); MULTISTIX® 7 (#2165); N-MULTISTIX® SG (#2176); MULTISTIX® SG (#2177); N-MULTISTIX® (#2178); MULTISTIX® (#2179); and BILL-LABSTIX® (#2180).

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Bayer Corporation
Diagnostics Division
Elihart, IN 46515 USA

Chemical reagent manufactured in the U.S., cut and assembled in the U.K.

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Screening Checklist For all Premarket Notification 510(k) Submissions

Device Name: <u>Adexo OPA Solution Test Strip</u>						K992341						
Submitter (Company):												
Items which should be included (circle missing & needed information)						S P E C I A L	A B B R E V I A T E D		T R A D I T I O N A L		✓ IF ITEM IS NEEDED AND IS MISSING	
						YES	NO	YES		NO	YES	NO
1. Cover Letter clearly identifies Submission as:												
a) "Special 510(k): Device Modification"										✓		
b) "Abbreviated 510(k)"												
c) Traditional 510(k)						GO TO # 2,3		GO TO # 2,4,5			GO TO # 4,5	
2. GENERAL INFORMATION: REQUIRED IN ALL 510(K) SUBMISSIONS											✓ IF ITEM IS NEEDED	
Financial Certification or Disclosure Statement for 510(k)s with a Clinical Study 807.87(i)						NA		YES		NO		AND IS MISSING
						SPECIALS		ABBREVIATED		TRADITIONAL		
						YES	NO	YES	NO	YES	NO	
a) trade name, classification name, establishment registration number, device class										✓		
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				✓		
d) compliance with Section 514 - performance standards						NA				✓		
e) address of manufacturer										✓		
f) Truthful and Accurate Statement										✓		
g) Indications for Use enclosure										✓		
h) SMDA Summary or Statement (FOR ALL DEVICE CLASSES)										✓		
i) Class III Certification & Summary (FOR ALL CLASS III DEVICES)										✓		
j) Description of device (or modification) including diagrams, engineering drawings, photographs, service manuals										✓		
k) Proposed Labeling:										✓		
i) package labeling (user info)										✓		
ii) statement of intended use										✓		
iii) advertisements or promotional materials										✓		
i) MRI compatibility (if claimed)										✓		
l) Comparison Information (similarities and differences) to named legally marketed equivalent device (table preferred) should include:										✓		
i) Labeling										✓		
ii) intended use										✓		
iii) physical characteristics										✓		
iv) anatomical sites of use										✓		
v) performance (bench, animal, clinical) testing						NA						
vi) safety characteristics						NA						
m) If kit, kit certification												
3. "SPECIALS" - ONLY FOR MODIFICATIONS TO MANUFACTURER'S OWN CLASS II, III OR RESERVED CLASS I DEVICE												
a) Name & 510(k) number of legally marketed (unmodified) predicate device												
b) STATEMENT - INTENDED USE AND INDICATIONS FOR												* If no - STOP not a special

USE OF MODIFIED DEVICE AS DESCRIBED IN ITS LABELING HAVE NOT CHANGED*				
c) STATEMENT - FUNDAMENTAL SCIENTIFIC TECHNOLOGY OF THE MODIFIED DEVICE HAS NOT CHANGED*			* If no - STOP not a special	
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:				
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(s) and the results demonstrated that the predetermined acceptance criteria were met				
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.				

	SPECIALS		ABBREVIATED		TRADITIONAL		✓ IF ITEM IS NEEDED AND IS MISSING
	YES	NO	YES	NO	YES	NO	
4. ABBREVIATED 510(K): SPECIAL CONTROLS/CONFORMANCE TO RECOGNIZED STANDARDS - PLEASE FILL OUT THE STANDARDS ABBREVIATED FORM ON THE H DRIVE							
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 use 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			

5. Additional Considerations: (may be covered by Design Controls)									
a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation:									
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) ETO residues									
vi) radiation dose									
c) Software validation & verification:									
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: 11/6/2009

Concurrence by Review Branch: _____

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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	
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 for home use 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

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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.		✓

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

July 13, 1999

SERIM RESEARCH CORP.
23565 REEDY DRIVE
P.O. BOX 4002
ELKHART, IN 46514
ATTN: JAMES E. CHRISTNER

510(k) Number: K992341
Received: 13-JUL-1999
Product: CIDEX OPA SOLUTION
TEST STRIP

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 January 1, 1996, FDA began requiring that all 510(k) submitters provide on a separate page and clearly marked "Indication For Use" the indication for use of their device. If you have not included this information on a separate page in your submission, please complete the attached and amend your 510(k) as soon as possible. Also if you have not included your 510(k) Summary or 510(k) Statement, or your Truthful and Accurate Statement, please do so as soon as possible. There may be other regulations or requirements affecting your device such as Postmarket Surveillance (Section 522(a)(1) of the Act) and the Device Tracking regulation (21 CFR Part 821). Please contact the Division of Small Manufacturers Assistance (DSMA) at the telephone or web site below for more information.

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 Document Mail Center will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations, we cannot accept telefaxed material as part of your official premarket notification submission, unless specifically requested of you by an FDA official. Any telefaxed material must be followed by a hard copy to the Document Mail Center (HFZ-401).

You should be familiar with the manual entitled, "Premarket Notification 510(k) Regulatory Requirements for Medical Devices" available from DSMA. If you have other procedural or policy questions, or want information on how to check on the status of your submission (after 90 days from the receipt date), please contact DSMA 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
Consumer Safety Officer
Premarket Notification Staff
Office of Device Evaluation

K992341



P.O. Box 4002, Elkhart, IN 46514-0002 • (219) 264-3440 • FAX (219) 266-6222

July 8, 1999

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

Re: 510(k) Submission for Cidex® OPA Solution Test Strips

To Whom it May Concern:

Germicides that are labeled for reuse can be used safely and effectively only if the user has a chemical indicator available to measure the level of active ingredients in the germicide solution¹. The Cidex® OPA Solution Test Strips (the subject of this submission) are semi-quantitative chemical indicators used to determine whether the concentration of active ingredient in Cidex® OPA Solution is above or below the minimum effective concentration (MEC).

The Premarket Notification [510(k)] for the germicide, Cidex® OPA Solution, has been submitted separately (K991487) by Advanced Sterilization Products, a Johnson & Johnson company, Division of Ethicon, Inc., Irvine, CA.

James E. Christner
Vice President, Research & Development
Serim Research Corporation
P.O. Box 4002
Elkhart, IN 46514

RECEIVED
JUL 13 11 42 AM '99
FDA/CDRH/OCE/DID

® Advanced Sterilization Products, a Johnson & Johnson company, Division of Ethicon, Inc., Irvine, CA.
¹ December 6, 1996 draft document, "Guidance on the Content and Format of Premarket Notification [510(k)] Submissions for Liquid Chemical Germicides".

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Premarket Submission Cover Sheet

Date of Submission: July 8, 1999

FDA Document Number:

Section A Type of Submission

- | | | | |
|---|---|--|---|
| <input checked="" type="checkbox"/> 510(k) | <input type="checkbox"/> IDE | <input type="checkbox"/> PMA | <input type="checkbox"/> PMA Supplement - Regular |
| <input type="checkbox"/> 510(k) Add'l information | <input type="checkbox"/> IDE Amendment | <input type="checkbox"/> PMA Amendment | <input type="checkbox"/> PMA Supplement - Special |
| | <input type="checkbox"/> IDE Supplement | <input type="checkbox"/> PMA Report | <input type="checkbox"/> PMA Supplement - 30 day |
| | <input type="checkbox"/> IDE Report | | <input type="checkbox"/> PMA Supplement - Panel Track |

Section B1 Reason for Submission — 510(k)s Only

- | | | |
|--|---|--|
| <input checked="" type="checkbox"/> New device | <input type="checkbox"/> Additional or expanded indications | <input type="checkbox"/> Change in technology, design, materials, or manufacturing process |
| <input type="checkbox"/> Other reason (specify): | | |

Section B2 Reason for Submission — PMAs Only

- | | | |
|---|---|--|
| <input type="checkbox"/> New device | <input type="checkbox"/> Change in design, component, or specification: | <input type="checkbox"/> Location change: |
| <input type="checkbox"/> Withdrawal | <input type="checkbox"/> Software | <input type="checkbox"/> Manufacturer |
| <input type="checkbox"/> Additional or expanded indications | <input type="checkbox"/> Color Additive | <input type="checkbox"/> Sterilizer |
| <input type="checkbox"/> Licensing agreement | <input type="checkbox"/> Other (specify below) | <input type="checkbox"/> Packager |
| <input type="checkbox"/> Labeling change: | <input type="checkbox"/> Process change: | <input type="checkbox"/> Report submission: |
| <input type="checkbox"/> Indications | <input type="checkbox"/> Manufacturer | <input type="checkbox"/> Annual or periodic |
| <input type="checkbox"/> Instructions | <input type="checkbox"/> Sterilizer | <input type="checkbox"/> Post-approval study |
| <input type="checkbox"/> Performance Characteristics | <input type="checkbox"/> Packager | <input type="checkbox"/> Adverse reaction |
| <input type="checkbox"/> Shelf life | | <input type="checkbox"/> Device defect |
| <input type="checkbox"/> Trade name | <input type="checkbox"/> Response to FDA correspondence (specify below) | <input type="checkbox"/> Amendment |
| <input type="checkbox"/> Other (specify below) | <input type="checkbox"/> Request for applicant hold | |
| <input type="checkbox"/> Change in ownership | <input type="checkbox"/> Request for removal of applicant hold | |
| <input type="checkbox"/> Change in correspondent | <input type="checkbox"/> Request for extension | |
| <input type="checkbox"/> Other reason (specify): | <input type="checkbox"/> Request to remove or add manufacturing site | |

Section B3 Reason for Submission — IDEs Only

- | | | |
|---|--|--|
| <input type="checkbox"/> New device | <input type="checkbox"/> Change in: | <input type="checkbox"/> Response to FDA letter concerning: |
| <input type="checkbox"/> Addition of institution | <input type="checkbox"/> Correspondent | <input type="checkbox"/> Conditional approval |
| <input type="checkbox"/> Expansion / extension of study | <input type="checkbox"/> Design | <input type="checkbox"/> Deemed approved |
| <input type="checkbox"/> IRB certification | <input type="checkbox"/> Informed consent | <input type="checkbox"/> Deficient final report |
| <input type="checkbox"/> Request hearing | <input type="checkbox"/> Manufacturer | <input type="checkbox"/> Deficient progress report |
| <input type="checkbox"/> Request waiver | <input type="checkbox"/> Manufacturing | <input type="checkbox"/> Deficient investigator report |
| <input type="checkbox"/> Termination of study | <input type="checkbox"/> Protocol - feasibility | <input type="checkbox"/> Disapproval |
| <input type="checkbox"/> Withdrawal of application | <input type="checkbox"/> Protocol- other | <input type="checkbox"/> Request extension of time to respond to FDA |
| <input type="checkbox"/> Unanticipated adverse effect | <input type="checkbox"/> Sponsor | <input type="checkbox"/> Request meeting |
| <input type="checkbox"/> Emergency use: | <input type="checkbox"/> Report submission: | <input type="checkbox"/> IOL submissions only: |
| <input type="checkbox"/> Notification of emergency use | <input type="checkbox"/> Current investigator | <input type="checkbox"/> Change in IOL style |
| <input type="checkbox"/> Additional information | <input type="checkbox"/> Annual progress | <input type="checkbox"/> Request for protocol waiver |
| <input type="checkbox"/> Other reason (specify): | <input type="checkbox"/> Site waiver limit reached | |
| | <input type="checkbox"/> Final | |

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Section C Product Classification

Product code: 79J0J	C.F.R. Section: 21CFR 880.2800	Device class: <input type="checkbox"/> Class I <input type="checkbox"/> Class III	<input checked="" type="checkbox"/> Class II <input type="checkbox"/> Unclassified
Classification panel:			

Section D Information on 510(k) Submissions

Product codes of devices to which substantial equivalence is claimed:				Summary of, or statement concerning, safety and effectiveness data:	
1 79J0J	2	3	4	<input checked="" type="checkbox"/> 510(k) summary attached	
5	6	7	8	<input type="checkbox"/> 510(k) statement	

Information on devices to which substantial equivalence is claimed:

510(k) Number	Trade or proprietary or model name	Manufacturer
1 K915170	1 Cidex* Solution Test Strips	1 Pymah
2	2	2
3	3	3
4	4	4
5	5	5
6	6	6

Section E Product Information — Applicable to All Applications

Common or usual name or classification name:

Chemical Sterilization Process Indicator

Trade or proprietary or model name	Model number
1 Cidex* OPA Solution Test Strip	1 N/A
2	2
3	3
4	4
5	5
6	6

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

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

Data included in submission: Laboratory testing Animal trials Human trials

Indications (from labeling): CIDEX* OPA Solution Test Strips are semi-quantitative chemical indicators used to determine whether the concentration of active ingredient in CIDEX* OPA Solution is above or below the minimum effective concentration (MEC). **CIDEX* OPA Solution Test Strips cannot be used to validate the disinfection process.**

Section F Manufacturing / Packaging / Sterilization Sites

<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	FDA establishment registration number: 1833387	<input checked="" type="checkbox"/> Manufacturer <input type="checkbox"/> Contract manufacturer	<input type="checkbox"/> Contract sterilizer <input type="checkbox"/> Repackager / relabeler
--	---	--	---

Company / Institution name: Serim Research Corporation

Division name (if applicable):	Phone number (include area code): (219) 264-3440
--------------------------------	---

Street address: 23565 Reedy Drive Mail address: P.O. Box 4002	FAX number (include area code): (219) 266-6222
--	---

City: Elkhart	State / Province: IN	Country: U.S.	ZIP / Postal Code: 46514-0002
---------------	----------------------	---------------	-------------------------------

Contact name: Robert C. Boguslaski, Ph.D.

Contact title: President

<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:

Division name (if applicable):	Phone number (include area code): ()
--------------------------------	--

Street address:	FAX number (include area code): ()
-----------------	--

City:	State / Province:	Country:	ZIP / Postal Code:
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Contact name:

Contact title:

<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:

Division name (if applicable):	Phone number (include area code): ()
--------------------------------	--

Street address:	FAX number (include area code): ()
-----------------	--

City:	State / Province:	Country:	ZIP / Postal Code:
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Contact name:

Contact title:

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Records processed under FOIA Request # 2013-7845		FDA Document Number: 7845		Released by CDRH on 08-17-2015	
Section G Applicant or Sponsor					
Company / Institution name: Serim Research Corporation			FDA establishment registration number: 1833387		
Division name (if applicable):			Phone number (include area code): (219) 264-3440		
Street address: 23565 Reedy Drive Mail address: P.O. Box 4002			FAX number (include area code): (219) 266-6222		
City: Elkhart	State / Province: IN	Country: U.S.	ZIP / Postal Code: 46514-0002		
Signature:  7/8/99					
Name: James E. Christner, Ph.D.					
Title: Vice President of Research and Development					
Section H Submission correspondent (if different from above)					
Company / Institution name:					
Division name (if applicable):			Phone number (include area code): ()		
Street address:			FAX number (include area code): ()		
City:	State / Province:	Country:	ZIP / Postal Code:		
Contact name:					
Contact title:					

Your voluntary completion of this Premarket Submission Cover Sheet will not affect any FDA decision concerning your submission, but will help FDA's Center for Devices and Radiological Health process your submission more efficiently. The information you provide should apply *only* to a single accompanying submission. Please do not send cover sheets for any previous submissions. See the instructions for additional information on completing the cover sheet. If you have a question concerning completion of the cover sheet, please contact the Division of Small Manufacturers Assistance at (800) 638-2041 or (301) 443-6597.

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510(k) Number (if known): _____

Device Name: CIDEX* OPA Solution Test Strips

Indications For Use:

CIDEX* OPA Solution Test Strips are semi-quantitative chemical indicators used to determine whether the concentration of active ingredient in CIDEX* OPA Solution is above or below the minimum effective concentration. **CIDEX* OPA Solution Test Strips cannot be used to validate the sterilization or disinfection process.**

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

_____ Concurrence of CDRH, Office of Device Evaluation (ODE) _____

Prescription Use _____
(Per 21 CFR 201.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)

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TABLE OF CONTENTS

510(k) for Cidex® OPA Solution Test Strips

<u>Enclosure</u>	<u>Pages</u>	<u>Description</u>
		510(k) Summary
		Truthful and Accurate Statement for 510(k) Premarket Notification.
A	1 - 6	Draft Product Insert for the Cidex* OPA Solution Test Strips.
B	7	Draft Test Strips Bottle Label for the Cidex* OPA Solution Test Strips.
C	8 - 9	Product Insert for the Cidex* Family of Solutions Test Strips (Device to which substantial equivalence is being claimed).
D	10	Photograph of Unreacted and Reacted Cidex* OPA Solution Test Strips.
E	11	Engineering Drawing of Cidex* OPA Solution Test Strip.
F	12	Chemical Composition of Cidex* OPA Solution Test Strip
G	13	Comparison Table of Features of the Cidex* OPA Solution Test Strips and the Cidex* Family of Solutions Test Strips.
H	14	Bottle and Cap Specifications
I		Supporting Data
	15 - 16	Background Information
	17 - 29	Summary
	21 - 53	Experimental Methods and Results Generated in Support of the Substantial Equivalence of the Subject Device.



P.O. Box 4002, Elkhart, IN 46514-0002 • (219) 264-3440 • FAX (219) 266-6222

510(k) SUMMARY

CIDEX®¹ OPA Solution Test Strips

SUBMITTED BY

James E. Christner
Serim Research Corporation
P.O. Box 4002
23565 Reedy Dr.
Elkhart, IN 46514

Phone: (219) 264-3440
Fax: (219) 266-6222
E-mail: jchristner@serim.com
Contact Person: James E. Christner
Date Prepared: July 7, 1999

DEVICE NAME

Trade Name: CIDEX® OPA Solution Test Strips
Common Name: Test Strips for *ortho*-Phthalaldehyde (OPA) in CIDEX® OPA Solution
Classification Name: Chemical Sterilization Process Indicator

PREDICATE DEVICE

Cidex® Solution Test Strips (K915170)

DESCRIPTION OF THE CIDEX® OPA SOLUTION TEST STRIP

The CIDEX® OPA Solution Test Strips consist of a 0.2 x 0.2-inch reagent-containing pad attached to one end of a 0.2 x 3.25-inch polystyrene handle. The indicator pad contains a color-forming reagent. It also contains an inhibiting compound that prevents visible reaction when the OPA concentration is at or below the MEC. When the OPA level is in sufficient excess of the MEC, the surplus reacts with the color-forming reagent.

The sample is placed in a 12 x 75-mm glass test tube. The indicator pad is immersed in the sample for 30 seconds, removed and allowed to react for an additional two and one-half

¹ ® Advanced Sterilization Products, a Johnson & Johnson company, Division of Ethicon, Inc., Irvine, CA.

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minutes at which time it is compared to a color standard. If the color of the entire pad is equal to or darker than the color standard, the concentration of *ortho*-phthalaldehyde (OPA) in CIDEX® OPA Solution is above the minimum effective concentration (MEC). If any part of the pad is lighter than the color standard, the CIDEX® OPA Solution should not be used.

INTENDED USE

CIDEX® OPA Solution Test Strips are semi-quantitative chemical indicators used to determine whether the concentration of OPA in CIDEX® OPA Solution is above or below the MEC. CIDEX® OPA Solution Test Strips cannot be used to validate the disinfection process.

TECHNOLOGICAL COMPARISON TO THE PREDICATE DEVICE

CIDEX® OPA Solution Test Strips are used for determining OPA in CIDEX® OPA Solution whereas the CIDEX® Solution Test Strips are used for determining glutaraldehyde levels in CIDEX® Activated Dialdehyde Solution. Both tests have dry, reagent-containing paper indicator pads attached to plastic handles. Both pads contain an inhibitor that prevents reaction with an indicator at ineffective active ingredient concentrations.

The reaction pad of the CIDEX® OPA Solution Test Strips is observed three minutes after the strip is immersed in the solution while that of CIDEX® Solution Test Strips is read between five and eight minutes after immersion. For interpretation of the result, the indicator pad of the CIDEX® OPA Solution Test Strip is compared with a standard color block. The CIDEX® Solution Test Strips use a visual standard for interpretation of the result.

STATEMENT OF SUBSTANTIAL EQUIVALENCE

Eight individuals used CIDEX® OPA Solution Test Strips from three trial production lots in blind studies to test CIDEX® OPA Solution standards. Three of the readers were inexperienced in laboratory techniques. A total of 324 results were obtained with each standard.

At the MEC (0.30% OPA), 324 results were FAIL giving a specificity (lack of false PASS results) of 1.00. At 0.40% and 0.45% OPA, 322 and 324 results, respectively, were PASS. These results show that the CIDEX® OPA Solution Test Strips effectively indicate when the OPA concentration in CIDEX® OPA Solution is at the MEC of 0.3%.



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PREMARKET NOTIFICATION
TRUTHFUL AND ACCURATE STATEMENT
(As Required by 21 CFR 807.87(j))

I certify that, in my capacity as Vice President of Research and Development of Serim Research Corporation, I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.



James E. Christner, Ph.D.

07/08/99

Date

[Premarket Notification 510(k) Number]

CONFIDENTIAL

MASTER DRAFT
510K Re-submission

CIDEX[®] OPA Solution Test Strips

Enclosure A-Package Insert

A. INTENDED USE

CIDEX[®] OPA Solution Test Strips are semi-quantitative chemical indicators used to indicate whether the concentration of *ortho*-phthalaldehyde (OPA), the active ingredient in CIDEX[®] OPA Solution, is above the minimum effective concentration (MEC) of 0.3% OPA. It is recommended that CIDEX[®] OPA Solutions be tested before each usage with CIDEX[®] OPA Solution Test Strips.

WARNING - CIDEX[®] OPA Solution Test Strips cannot be used to validate the disinfection process. Do not use CIDEX[®] OPA Solutions beyond the 14-day maximum use life even if the test strip shows the solution is above the MEC.

B. PRINCIPLE OF THE TEST PROCEDURE

The filter paper square (indicator pad) mounted on the end of plastic strip comprises the reactive portion of the CIDEX[®] OPA Solution Test Strip. The indicator pad contains an inhibitor and a color-forming reagent. If the concentration of OPA is at or below the MEC, the inhibitor will prevent any color formation. If the concentration of OPA is present in excess of the inhibitor, it reacts with the color-forming reagent to form colored pigments.

C. STORAGE

Proper storage and handling of test strips is important to maintain proper product performance. Store CIDEX[®] OPA Solution Test Strips in the original bottle with the cap tightly closed. Store in a dry place at controlled room temperature; 16°-32° C (61°-90° F).

The expiration date for unopened bottles of CIDEX[®] OPA Solution Test Strips is printed on each bottle label.

Open Bottle Shelf Life

When opening a bottle of CIDEX[®] OPA Solution Test Strips for the first time, record the date opened in the space provided on the bottle label ("Date Opened _____"). Strips may be used up to 90 days after first opening the bottle if the cap is promptly replaced and tightened after removal of each strip. Do not use test strips (from an opened or unopened bottle) after the expiration date.

Each kit contains two bottles of strips and two test tubes. For optimal results, use a new test tube with each new bottle of strips.

D. SAMPLE COLLECTION and PREPARATION

Pipette or dispense approximately 1 mL of room temperature CIDEX[®] OPA Solution into the 12x75-mm glass test tube provided. (The tube should be approximately 1/5 full, allowing the indicator pad on the test strip to be fully immersed in the sample.) Caution: Use only the test tube provided.

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Enclosure A-Package Insert

E. DIRECTIONS FOR USE

NOTE: Prior to starting routine use of the CIDEX® OPA Solution Test Strips, practicing the testing technique with control solutions (the preparation of which is described in Section H., "QUALITY CONTROL") will familiarize the user with proper testing technique and interpretation of results.

Test Procedure:

1. Dispense approximately 1-mL of CIDEX® OPA Solution into the 12x75-mm glass test tube. The test tube should be approximately 1/5 full.
2. Dip the test strip into the sample for exactly 30 seconds making sure that the indicator pad is fully immersed.
3. At 30 seconds, remove the test strip by touching the side edge of the indicator pad against the inside of the test tube and draw upward (for approximately 2-3 seconds) against the entire length of the test tube, gradually removing excess sample. (See Figure 1.)

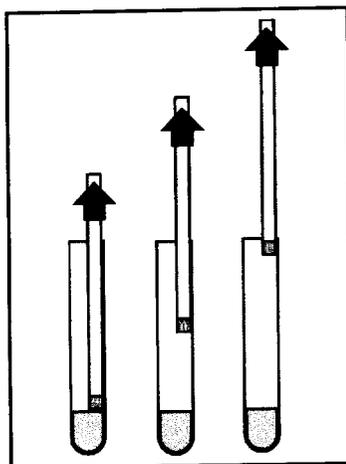


Figure 1

4. Lay the handle end of the test strip on a paper towel so that the indicator pad hangs over the edge of the towel to prevent absorption of the sample solution.
5. Compare the color of the indicator pad to the color block on the bottle label at exactly 3 minutes after the test was started (2½ minutes after removing the strip from the test tube.)
6. Use the logbook in CIDEX® Solutions Information Station (Reorder No. 20251) to record results.
7. Discard the test strip and CIDEX® OPA Solution test sample in accordance with federal, state, local and institution guidelines. Rinse the test tube with Enzol® or equivalent detergent, then rinse the test tube thoroughly with distilled water. Dry completely prior to next use.

*Note: For optimal results, use a new test tube with each new bottle of strips.

Enclosure A-Package Insert**F. TEST RESULTS INTERPRETATION**

The color developed on the CIDEX® OPA Solution Test Strip Indicator Pad is used to determine whether the concentration of OPA in the sample is above or below the MEC of 0.3%.

- For a "PASS", the entire indicator pad should be equal to or darker than the gray color block on the bottle label.
- If the entire indicator pad is lighter than the color block on the label or distinct areas of lighter color are observed, the result is a "FAIL". The CIDEX® OPA Solution is at or below the MEC and must be discarded.

At concentrations slightly above the MEC the indicator pad may have a mottled appearance. However, if any portion of the indicator pad is lighter than the color block, the results should be considered a "FAIL".

NOTE: False "FAILS" may occur as the MEC is approached. This is due in part to a safety margin provided by the test strip ensuring that solutions at or below the MEC will "FAIL" virtually 100% of the time.

G. MATERIAL REQUIRED - NOT SUPPLIED

- Watch or Timer

H. QUALITY CONTROL PROCEDURES**Testing Frequency:**

It is recommended that the testing of positive and negative controls be performed periodically. Each facility should determine the frequency of control testing for its own QC program. Regular testing of the control solutions will increase user proficiency, minimize procedural errors and protect against the inadvertent use of outdated product or product that has deteriorated due to improper storage or handling.

Preparation and Testing of Control Solutions:

Verify that the CIDEX® OPA Solution has an acceptable expiration date. Label two tubes, one for the positive control and one for the negative control. To prepare a positive control use fresh, full strength solution. To prepare a negative control, dilute one part of full strength solution with one part of distilled water. Following the "Directions for Use" (Section F), dip one test strip in the positive control and one in the negative control.

Results for Control Solutions:

Refer to the color block on the test strip bottle for interpretation of results.

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Enclosure A-Package Insert

At 3 minutes, the test strip dipped in the full strength positive control solution should exhibit a completely gray/black color on the indicator pad equal to or darker than the color block on the bottle label.

The test strip dipped in the negative control should show a color lighter than the color block on the bottle label when read at 3 minutes.

If the results obtained from using the positive and negative controls indicate the test strip is not performing as expected, do not use the remaining strips, but retain them for possible return to Product Quality Services. For technical product information and support, contact Advanced Sterilization Products at 1-888-783-7723.

I. PERFORMANCE CHARACTERISTICS

The performance characteristics of CIDEX® OPA Solution Test Strips are based on testing samples of CIDEX® OPA Solution of known *ortho*-phthalaldehyde concentrations that are at and above the MEC. The analytical method used to determine the *ortho*-phthalaldehyde concentration in these samples is High Pressure Liquid Chromatography with UV detection. The CIDEX® OPA Solution Test Strips have been designed to indicate "FAIL" virtually 100% of the time at and below the MEC of 0.3% *ortho*-phthalaldehyde (OPA).

J. WARNINGS and PRECAUTIONS

- Replace and tighten cap immediately after removing strip.
- Do not touch indicator pad.
- Protect strips from chemicals or contaminated surfaces.
- Use strips within 90 days after opening bottle.
- Protect strips from exposure to extremes of heat, light and moisture.
- Do not ingest the strip or allow the indicator pad to come in contact with the eye.
- Do not remove desiccant pack from bottle. Keep desiccant out of reach of children.
- For optimal results, use a new test tube when opening a new bottle of strips.
- Discard used or expired CIDEX® OPA Solution Test Strips in an appropriate waste receptacle in accordance with federal, state and local laws and your facility's regulations.
- CIDEX® OPA Solution Test Strips cannot be used as a means of validating the disinfection process.

CIDEX® OPA Solution Test Strips are designed specifically to detect *ortho*-phthalaldehyde. They cannot be used to measure other disinfectants and should only be used to test CIDEX® OPA Solution.

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Enclosure A-Package Insert

K. HOW SUPPLIED

<u>Product Code</u>	<u>Description</u>	<u>Package</u>
<u>Information</u> 20392	CIDEX® OPA Solution Test Strips	60 strips/bottle (2
bottles/shipper)	Glass test tubes (12x75 mm)	(2/shipper)

DISTRIBUTED BY:

Advanced Sterilization Products a Johnson & Johnson Company Irvine, CA 92618. For technical information and/or information regarding safety and effectiveness, call 1-888-783-7723.

Printed in the U.S.A.

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CONFIDENTIAL**Enclosure A-Package Insert****UNDERSTANDING THE TESTING TECHNIQUE:**

It is important that the "DIRECTIONS FOR USE" be followed closely to achieve optimal test results. Outlined below is an explanation of the significance of the technique for each step in the Test Procedure. This information may be useful for training and troubleshooting.

- Leaving the test strip in the sample of CIDEX® OPA Solution for longer than 30 seconds or swirling the strip vigorously could cause excess color development. This could lead to a false "PASS" result, i.e., the concentration of OPA in the solution is truly below the MEC, but due to improper technique the test strip gives a "PASS" result.
- Removing the test strip too soon from the solution or blotting the indicator pad with an absorbent material such as a paper towel could cause insufficient color development. This could cause a false "FAIL" result when the solution would normally pass.
- It is important to use the 12x75-mm glass test tube provided. The procedure and timing were optimized using this specific test tube
- Failure to draw the side edge of the indicator pad slowly (for 2-3 seconds) up the inside of the test tube could lead to a false "PASS" due to retention of excess sample.
- Thoroughly clean, rinse and dry the test tube between each use. For optimal results, use a new test tube with each new bottle of strips.
- Although excess sample solution must be allowed to drain from the indicator pad, it is important not to remove too much solution. Therefore it is recommended that once the test strip is removed from the test tube, the indicator pad should not come in contact with an absorbent surface. The test tube wall removes the proper amount of sample as opposed to paper towels, which have a tendency to absorb an excessive amount of solution from the indicator pad.

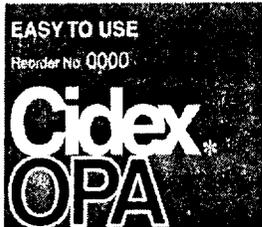
Note: The use of this test tube/sample removal technique provides significantly improved and consistent results when compared to alternate sample removal methods used with other tests (i.e., blotting or shaking excess liquid from the indicator pad).

- It is important to interpret the results of the test strip exactly 3 minutes after starting the test (dip for 30 seconds, then allow reaction to develop for an additional 2½ minutes).
- If the test is read in less than 3 minutes, the color change may be incomplete and a solution could give a false "FAIL" result. If the test is read after 3 minutes, excess color may develop and the solution could yield a false "PASS" result.
- The test strip may take on a mottled appearance as it approaches the MEC. Appearance of distinct areas of color lighter than the color block is considered a "FAIL" result.
- Only one test strip per one mL of sample may be dipped. If the test is repeated, 1 mL of fresh sample is required.

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Enclosure B - Bottle Label

Developed exclusively for testing
CIDEX, OPA Solution



Test Strips
60 STRIPS

ADVANCED STERILIZATION
PRODUCTS

Reorder No. 0000

Lot No _____

Expiration Date _____

Composition: CIDEX® OPA Solution
Test Strips consist of an inhibitor and
a color-forming reagent impregnated
and dried on filter paper.

STORAGE

IMPORTANT: Keep cap tightly closed.
Store bottle at controlled room
temperature 18°- 32°C (61°- 90°F)
and in a dry place. Do not remove
desiccant. **CAUTION:** Do not use
after 90 days of opening the bottle.

Date Opened _____

Do Not Use After _____

Distributed by:
ADVANCED STERILIZATION
PRODUCTS
a Johnson & Johnson company
Division of Ethicon Inc., Irvine, CA 92618
For technical information and/or information
regarding safety and effectiveness,
call 1-866-733-1723
*TRADEMARK © ASP 1987

DIRECTIONS FOR USE:

1. Dispense at least a 1 ml. sample of
CIDEX OPA Solution into a 12x75mm
glass test tube.
2. Dip the Test Strip into the sample for exactly
30 seconds making sure that the Indicator
Pad is fully immersed.
3. At 30 seconds, remove the Test Strip from
the sample and draw the side edge of the
Indicator Pad upward (for 2-3 seconds)
against the entire length of the test tube
to gradually remove excess sample.
4. Lay the handle end of the Test Strip on a
paper towel so that the Indicator Pad hangs
over the edge to prevent further absorption
of the sample solution.
5. Compare the color of the Indicator Pad to
the color block on the bottle label at exactly
3 minutes after the test was started (2-1/2
minutes after removing the strip from the test
tube.) If the Indicator Pad is equal in color
or darker than the color block on the bottle
label, the result is "PASS" (the CIDEX OPA
Solution is above the MEC).
If the Indicator Pad is lighter
than the color block ("FAIL"),
the CIDEX OPA Solution
should be discarded.



PASS
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Enclosure C - Package Insert for Cidex® Family Solutions Test Strips

CIDEX* Family of Solutions Test Strips

A. Intended Use

The CIDEX* Family of Solutions Test Strips are semi-quantitative chemical indicators for use in determining whether the concentration of glutaraldehyde, the active ingredient in CIDEX Disinfecting and Sterilizing Solutions, is above or below the minimum effective concentration (MEC) established for each of the CIDEX Solutions. **CIDEX Solutions Test Strips cannot be used to validate the sterilization or disinfection process.**

B. Explanation of the Test

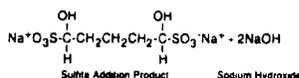
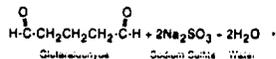
CIDEX Solutions Test Strips are developed exclusively for monitoring the effectiveness of CIDEX Solutions. Each CIDEX Solution formulation has its own test strip (i.e., CIDEX Solution Test Strip, CIDEX FORMULA 7* Solution Test Strip, CIDEX PLUS* Solution Test Strip), specifically designed for its MEC and accurate results. It is recommended that CIDEX Solutions be tested before each usage with the appropriate CIDEX Solutions Test Strip in order to guard against dilution, which may lower the glutaraldehyde level of the solution below its MEC.

WARNING: Do not use CIDEX Solutions beyond the 14 or 28 day maximum use life of the solution.

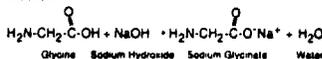
C. Chemical Principle of the Test Procedure

Glutaraldehyde reacts with sodium sulfite in the test strip to form a sulfite addition product and an equivalent amount of base. If sufficient glutaraldehyde is present, it further reacts with sodium glycinate in the test strip to form yellow colored addition products in the following manner:

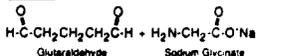
STEP 1



STEP 2



STEP 3



yellow colored addition products

When the concentration of glutaraldehyde is sufficient, a color change from white to yellow occurs on the reagent pad at the end of the strip.

D. Reagents

The reagent pad at the end of the test strips is composed of paper impregnated with two reactive ingredients, glycine and sodium sulfite, in a ratio of 9.5:90.5.

Store CIDEX Solutions Test Strips in the original bottle with the cap tightly closed. Store at controlled room temperature, 15°C-30°C (59°-86°F), and in a dry place. Do not remove the silica gel desiccant from the bottle.

CIDEX Solutions Test Strips have a two-year shelf-life from date of manufacture in the unopened bottle. The expiration date for the unopened bottle will be stamped on the immediate container label. When opening the bottle for the first time, record the date opened in the space provided on the immediate container label ("Do not use after").

CAUTION:

- Do not use any remaining strips 90 days after opening the bottle.
- Do not freeze.
- Protect strips from exposure to light, heat, and moisture.
- Do not remove desiccant from container.

E. Specimen Collection and Preparation

CIDEX Solutions Test Strips can be used to test activated CIDEX Solutions directly in the tray, bucket or other container holding the solution. When this is not feasible, remove approximately 5 ml of the activated CIDEX Solution from its container and place the solution into a clean plastic container (polyethylene or polypropylene).

F. Directions for Use

1. Dip the indicating pad at the end of the test strip into the container of the CIDEX Solution being tested for **one second and remove**. Do not leave the strip in the test solution for longer than one second or "stir" the test strip in the solution. Incorrect dipping technique, such as dipping much longer than the specified 1 second and/or swirling the test strip vigorously in the solution, will wash off the reagents in the test strip pad; this can cause a lack of yellow color formation (FAIL) when testing a solution that will normally test as PASS.
2. **Remove excess solution** from the indicating pad by touching the long edge of the indicating pad to a paper towel. Do not shake the strip after removal. When removing excess solution, incorrect technique, such as violently shaking the test

strip and/or blotting the test strip with the pad face down against a paper towel, can remove the reagents and solution, which can again cause FAIL results for solutions that will normally test as PASS.

3. **Read the results** of the color reaction present on the indicating pad between 5 and 8 minutes after the test strip is removed from the solution. If read in less than 5 minutes, the color change may be incomplete and may be interpreted incorrectly. (NOTE: Positive results may be obtained in as early as 3 minutes when CIDEX Solutions are tested immediately after activation, or one or two days after activation when the solution has been reused less than three cycles per day). Do not read the pad after 8 minutes, as the color will gradually fade making interpretation difficult. The pad will be completely yellow to indicate an effective solution. Any shade of yellow is acceptable; the intensity will vary due to concentration variation. If any white remains on the indicating pad, the CIDEX Solution is ineffective (below the MEC) and should be discarded. Refer to the visual standard on the test strip bottle for interpretation of test results. Use log book in CIDEX Solution Information Station (Reorder No. 20251) to record results. See Section I, Test Strip Interpretation, for additional important information.

G. Materials Required

The following materials are not provided with the CIDEX Solutions Test Strips but will be needed for the test:

- watch or timer
- paper towel
- If the solution cannot be tested directly in the tray, bucket or container in which it is being held, a clean polyethylene or polypropylene container will be required to hold the CIDEX Solution sample.

H. Quality Control Procedures

1. **Preparation of Control Solutions**
To prepare positive and negative control solutions for testing, first verify that the labeled expiration date for the unactivated solution is appropriate. Activate the CIDEX Solution according to labeling instructions. This freshly activated, full strength solution may be used as a positive control. To prepare a negative control, dilute one part of full strength solution with one part of water. Label each control solution appropriately.

CONFIDENTIAL**Enclosure C - Package Insert for Cidex® Family Solutions Test Strips****2. Testing Procedure**

Following the Directions for Use, dip three test strips in each of the above freshly prepared solutions. The three strips dipped in the full strength positive control solution should exhibit a completely yellow color on the indicating pad within 5 to 8 minutes. The three strips dipped in the diluted negative control should either remain completely white or exhibit an incomplete color change to yellow when read at 5 to 8 minutes. Refer to the visual standard on the test strip bottle for interpretation of results.

3. Testing Frequency

It is recommended that the testing of positive and negative controls be performed on a newly opened test strip bottle from each case of CIDEX Solutions Test Strips that is received. After this initial testing, it is recommended that testing of freshly prepared positive and negative controls be performed on a regular basis as established by your own quality control procedures and program. This testing program will serve to minimize errors between different users, use of outdated materials or product that has been improperly stored or handled.

4. Unsatisfactory QC Test Performance

If the results obtained from using the positive and negative controls indicate the test strip is not functioning properly, discard the remaining strips. **Do Not Use.** For technical product information, contact Johnson & Johnson Medical, Inc., Product Quality Services, 1-800-423-5850 or contact your local JJMI sales representative.

5. Storage

Keep the cap on bottles of CIDEX Solutions Test Strips tightly closed. Store at controlled room temperature, 15°-30°C (59°-86°F) and in a dry place. Do not remove desiccant from bottle. Do not store in a refrigerator or freezer.

CAUTION: Do not use remaining CIDEX Solutions Test Strips 90 days after opening the bottle.

1. Test Results Interpretation

Following the one second dip in the CIDEX Solution being tested and removal of excess solution from the pad by touching the long edge to a paper towel, the CIDEX Solutions Test Strip should be compared to the color chart provided on the test strip bottle after 5 to 8 minutes. The entire indicating pad must be completely yellow to pass the test indicating an effective solution. If any white remains on the indicating pad this is a failure, verifying the solution is ineffective and should be discarded. As the minimum effective concentration (MEC) of CIDEX Solutions is approached during

the maximum use life after activation, the test strip will give some PASSES and some FAILS. This is due to the inherent variability of the test strip and is part of the large safety margin provided by the test strip for 100% TB kill. FAIL indications based on reading the test strips, especially when read after less than 5 minutes, are not unusual after less than the maximum number of days for reuse for the CIDEX Solution, especially if the usage by the customer is greater than 3 cycles per day or dilution by the customer is heavy. As the CIDEX Solution is being reused, read the strip at between 5 and 8 minutes, but not more than 8 minutes, to get consistent results after the solution has undergone more than a few days of reuse.

J. Limitations

Although CIDEX Solutions Test Strips may give a color reaction with glutaraldehyde-based disinfectants from other manufacturers, their use is limited to the specific CIDEX Solution indicated. Disinfectants from other manufacturers may claim different MECs which will lead to inaccurate test results using CIDEX Solutions Test Strips.

It is also important to point out that CIDEX Solutions Test Strips will not detect failure to add the activator to the CIDEX Solutions.

K. Performance Characteristics

The performance characteristics of CIDEX Solutions Test Strips are based on testing strips on samples of CIDEX Solutions with known concentrations of glutaraldehyde at the minimum effective concentration (MEC) and above the MEC for each individual CIDEX Solution (CIDEX Activated Dialdehyde Solution, CIDEX FORMULA 7 Long-Life Activated Dialdehyde Solution and CIDEX PLUS 28 Day Solution). The analytical method used to determine the glutaraldehyde concentrations in these samples is based on the reaction of glutaraldehyde with hydroxylamine hydrochloride followed by the titration of released hydrochloric acid with a standardized solution of sodium hydroxide.¹

The performance of CIDEX Solutions Test Strips has been designed to indicate FAIL 100% of the time at the MEC of glutaraldehyde for each CIDEX Product as shown below:

TEST STRIP/SOLUTION	MEC (% GLUTARALDEHYDE)
CIDEX	1.5%
CIDEX FORMULA 7	1.8%
CIDEX PLUS	2.1%

Since the accuracy and sensitivity limit of CIDEX Solutions Test Strips is approximately $\pm 0.25\%$, at concentrations of 0.25% above the MEC shown above for each CIDEX Solution, the corresponding test strips will indicate FAIL about 50% of the time and PASS about 50% of the time.

This provides the user with a high margin of safety. An independent publication has confirmed that concentrations of greater than 1% glutaraldehyde are required for total kill of *Mycobacterium tuberculosis*.² The MEC for each CIDEX Solution is based on its ability to give 100% TB kill.

L. Warnings & Precautions

- Discard used or expired test strips in a trash receptacle in accordance with federal, state and local laws.
- Keep desiccant (silica gel) out of reach of children.
- Do not ingest the strip and/or expose to the eye.
- Chemical indicators such as CIDEX Solutions Test Strips cannot be relied upon as a means of validating the sterilization or disinfection process. Chemical indicators can only establish that a specific factor exists within the specified limits of performance of the indicator.

M. Bibliography

- Johnson & Johnson Medical, Inc.'s Standard Test Method Number 1198 (available upon request).
- Cole, E.C., Rutala, W.A., Nessen, L., Wannamaker, N.S., and Weber, D.J., "Effect of Methodology, Dilution and Exposure Time on the Tuberculocidal Activity of Glutaraldehyde-based Disinfectants", *Applied and Environmental Microbiology*, 56, 1813-1817 (1990).

N. How Supplied

PRODUCT CODES	DESCRIPTION	PACKAGE INFORMATION
2920	CIDEX® Solution Test Strips	60 Strips/Bottle 2 Bottles/Shipper
2921	CIDEX Solution Test Strips	60 Strips/Bottle 12 Bottles/Shipper
2927	CIDEX Solution Test Strips	15 Strips/Bottle 2 Bottles/Shipper
2924	CIDEX PLUS® Solution Test Strips	60 Strips/Bottle 2 Bottles/Shipper
2926	CIDEX PLUS Solution Test Strips	15 Strips/Bottle 2 Bottles/Shipper
2922	CIDEX FORMULA 7® Solution Test Strips	60 Strips/Bottle 2 Bottles/Shipper
2928	CIDEX FORMULA 7 Solution Test Strips	15 Strips/Bottle 2 Bottles/Shipper

MARKETED BY:

Johnson & Johnson
MEDICAL INC.

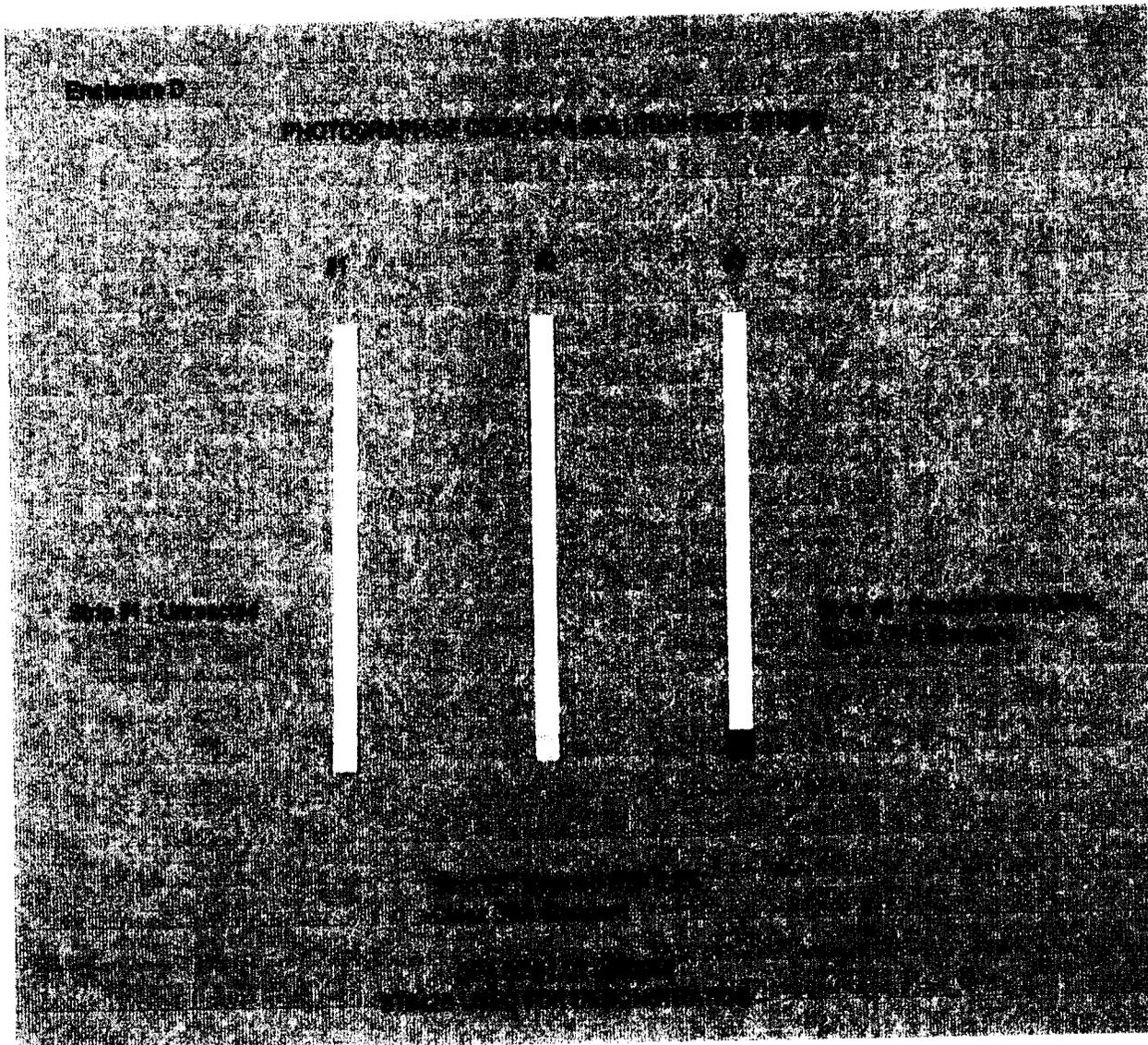
ARLINGTON, TEXAS 76004-3130

For technical information and/or information regarding safety and effectiveness, call 1-800-423-5850.

U.S. PAT. NOS. 4,521,376—4,643,980

*TRADEMARK © JJM, INC. 1994 2920 11-0

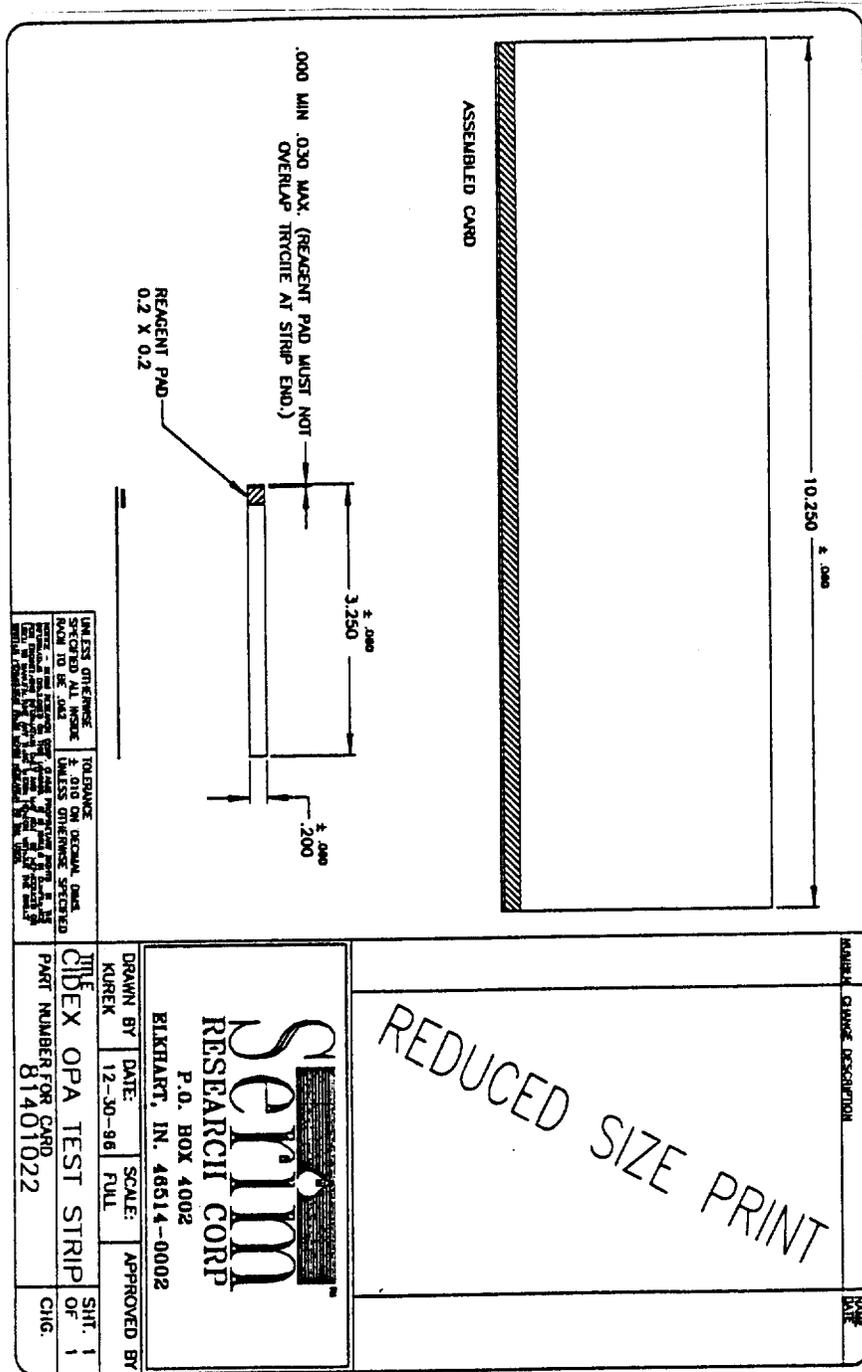
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Enclosure E - Engineering Drawing of the Cidex® OPA Solution Test Strip

(74% of original size).



UNLESS OTHERWISE SPECIFIED ALL DIMENSIONS SHALL BE IN INCHES. DIMENSIONS IN PARENTHESES ARE FOR INFORMATION ONLY. DIMENSIONS IN PARENTHESES ARE NOT TO BE USED FOR MANUFACTURING PURPOSES. DIMENSIONS IN PARENTHESES ARE NOT TO BE USED FOR MANUFACTURING PURPOSES.

<p>SEYMOUR RESEARCH CORP P.O. BOX 4002 ELKHART, IN. 46514-0002</p>	<p>ISSUED: CHANGE DESCRIPTION</p>
<p>DRAWN BY: KUREK DATE: 12-30-96 SCALE: FULL</p>	<p>DATE</p>
<p>CIDEX OPA TEST STRIP PART NUMBER FOR CARD: 81401022</p>	<p>APPROVED BY</p>
<p>SHT. 1 OF 1 CHG.</p>	

REDUCED SIZE PRINT

111

Enclosure F

Chemical Composition of Cidex® OPA Solution Test Strips

Active Ingredients

Per Cent by Weight

(b)(4)



TOTAL

100.0

112

CONFIDENTIAL**Enclosure G**

**COMPARISON TABLE OF FEATURES OF
THE CIDEX® OPA SOLUTION TEST STRIPS
AND THE CIDEX® FAMILY SOLUTION TEST STRIPS¹**

Parameter	Cidex® OPA Solution Test Strips	Cidex¹ Family Solution Test Strips
Analyte	>Ortho-phthalaldehyde in Cidex® OPA Solution	>Disinfecting and Sterilizing Solution containing Glutaraldehyde
Indicator Strip	>Paper Indicator pad attached to plastic strip	>Paper Indicator pad attached to plastic strip
Indicator Pad	>Contains ammonium ion with sulfite inhibitor	>Sodium glycinate with sulfite inhibitor
Test Method	>Strip is dipped into sample for 30 seconds and then removed	>Strip is dipped into sample for 1 second removed and side blotted for 1 second
Quality control	>Time for completion of test 3 minutes	>Time for completion of test 5-8 minutes
	>Uses freshly opened disinfectant. Full strength for positive control.	>Uses freshly opened disinfectant. Activated full strength for positive control.
Results	>1:1 strength for negative	>1:1 strength for negative
	>Obtained in 3 minutes	>Obtained in 5-8 minutes
	>Plus/Minus results	>Plus/Minus results

¹Device to which substantial equivalence is being claimed.

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Enclosure H

Specifications of Cidex® OPA Solution Test Strip Bottle and Cap

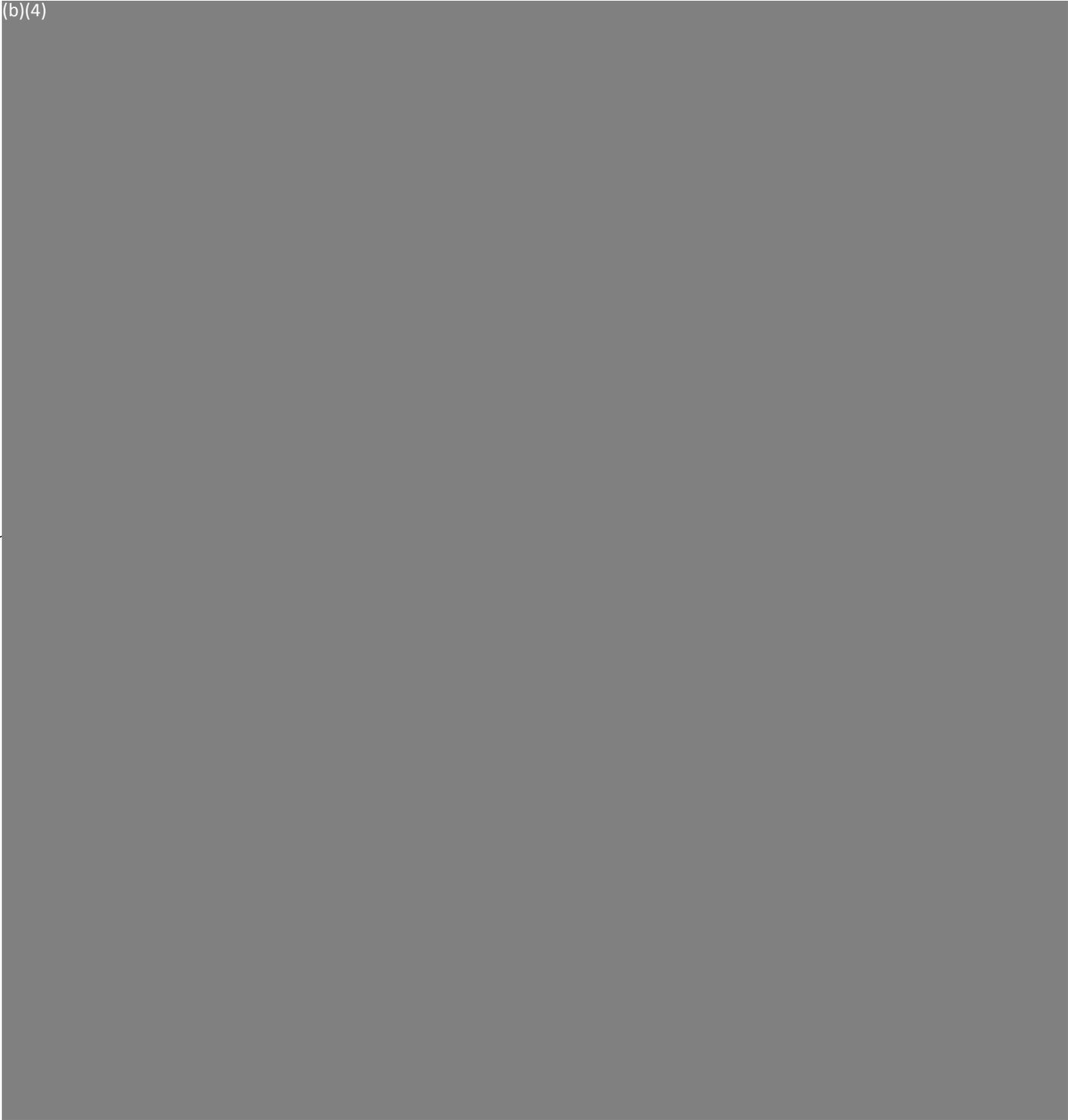
(b) (4)



Enclosure I - Supporting data

**PERFORMANCE STUDIES WITH
THE OPA SOLUTION CHEMICAL INDICATOR STRIP**

(b)(4)



Enclosure I - Supporting data

(b)(4)



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Records processed under FOIA Request # 2013-7845; Released by CDRH on 08-17-2015

Records processed under FOIA Request # 2013-7845; Released by CDRH on 08-17-2015

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