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U.S. Department of Health & Human Services

Food and Drug Administration

SAVE REQUEST

USER:	(cwf)
FOLDER:	K972706 - 369 pages
COMPANY:	BAYER CORP. (BAYER)
PRODUCT:	TETRABROMO-M-CRESOLSULFONPHTHALEIN, ALBUMIN (CJG)
SUMMARY:	Product: CLINITEK MICROALBUMIN REAGENT STRIPS
DATE REQUESTED:	Jan 21, 2016
DATE PRINTED:	Jan 21, 2016
Note:	Printed

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

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-972706

SEP - 9 1997

510(k) SAFETY AND EFFECTIVENESS SUMMARY

Prepared: July 17, 1997

Submitter: Bayer Corporation, Business Group Diagnostics

Address: 1884 Miles Avenue, P.O. Box 70
Elkhart, IN 46515
(219) 262-6929

Contact: Rosanne M. Savol, R.A.C.
Manager, Regulatory Affairs

Device:
Trade/Proprietary Name: CLINITEK® Microalbumin Reagent Strips
Common/Usual Name: Test for microalbumin in urine
Test for creatinine in urine
Document Control Number: K97_____

Classification: Division of Clinical Laboratory Devices
Panel - Clinical Chemistry and Toxicology
Classification Code - 75 JIR (Urinary Protein or Albumin)
75 CGX (Alkaline Picrate, Colorimetry, Creatinine)

Predicate Devices: Micral-Test® strips (Boehringer Mannheim Corporation); Microalbumin Assay/Array® Analyzer (Beckman Instruments Inc.); SPQII™Reagent(INCSTARCorp.)/Roche COBAS-FARA® II Analyzer/Ciba-Corning Express Plus; Microprotein Reagent (Sigma Diagnostics)/Roche COBAS MIRA Analyzer/Paramax® Analytical System/DuPont XL System; Quantimetrics BGR Total Protein (Quantimetrics)/TECHNICON RA® 1000 Random Access Analyzer; CX3 Creatinine Reagent (Beckman)/ Beckman CX3 SYNCHRON® Analyzer; Paramax® Creatinine Reagent (Dade Diagnostics)/Paramax Analytical System; Miles Creatinine Reagent (Bayer)/TECHNICON RA 1000 Random Access Analyzer; Dade® Creatinine Reagent/DuPont XL System; DCA 2000+ Microalbumin/Creatinine Assay (Bayer)

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

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Device Description:

CLINITEK® Microalbumin Reagent Strips are firm plastic strips that contain two reagent areas to test for microalbumin (low concentration of albumin) and creatinine in urine. CLINITEK Microalbumin Reagent Strips are dipped into a urine specimen and "read" instrumentally by the CLINITEK® 50 or CLINITEK® 100 Urine Chemistry Analyzer. In addition to providing an albumin and a creatinine result, an albumin-to-creatinine ratio is also determined. Semi-quantitative results are available within one minute.

Intended Use:

CLINITEK® Microalbumin Reagent Strips are for screening urine specimens for microalbuminuria as an aid in the detection of patients at risk for developing kidney damage. CLINITEK Microalbumin Reagent Strips are for professional use in point-of-care testing locations such as physician office laboratories, clinics, and hospitals.

Technological Characteristics:

The CLINITEK® Microalbumin assay is a dip-and-read reagent strip allowing detection of urinary albumin at 20 to 40 mg/L, and the albumin-to-creatinine ratio of 30 to 300 mg/g. The albumin test is based on dye binding using a high affinity sulfonephthalein dye. At a constant pH, the development of a blue color is due to the presence of albumin. The creatinine test is based on the peroxidase-like activity of a copper creatinine complex that catalyzes the reaction of diisopropylbenzene dihydroperoxide and 3,3',5,5'-tetramethylbenzidine. The color of the reagent areas are read by the CLINITEK® 50 and CLINITEK® 100 instrument at specified times and the results are displayed or printed in clinically meaningful units.

Assessment of Performance:

The performance of CLINITEK® Microalbumin Reagent Strips was studied in clinical settings by typical users of the system and results compared to currently used tests for microalbumin and creatinine in urine. The studies demonstrated that typical users in decentralized, point-of-care laboratories can obtain clinical test results that are substantially equivalent to current methods.

Conclusion:

CLINITEK® Microalbumin Reagent Strips for use with the CLINITEK® 50 and CLINITEK® 100 Urine Chemistry Analyzers provide a convenient method for screening for microalbumin and creatinine in urine. Studies show that the system can be used in decentralized and point-of-care laboratories and provide clinical results comparable to other test methods in current clinical laboratory practice.

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

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DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP - 9 1997

Rosanne M. Savol, R.A.C.
Manager, Regulatory Affairs
Bayer Corporation
1884 Miles Avenue
P.O. Box 70
Elkhart, Indiana 46514-0070

Re: K972706
CLINITEK® Microalbumin Reagent Strips
Regulatory Class: II
Product Code: CJG, JFY
Dated: July 17, 1997
Received: July 21, 1997

Dear Ms. Savol:

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 Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS 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 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.

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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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) 594-4588. 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,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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

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510(k) Number (if known): _____

Device Name: **CLINITEK® Microalbumin Reagent Strips**

Indications for Use: **CLINITEK Microalbumin Reagent Strips are firm plastic strips that contain two reagent areas to test for small amounts of albumin in urine (microalbuminuria), creatinine in urine, and also determine the albumin-to-creatinine ratio in urine. The strips are read instrumentally using the CLINITEK® 50 or CLINITEK® 100 Urine Chemistry Analyzer and provide semi-quantitative results. CLINITEK Microalbumin Reagent Strips can be used for screening urine specimens for microalbuminuria as an aid in the detection of patients at risk for developing kidney damage. CLINITEK Microalbumin Reagent Strips are for professional use.**

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

_____ _____ _____ _____ _____ _____

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Clinical Laboratory Devices

510(k) Number K972726

Prescription Use ✓ **OR** **Over-The-Counter Use**_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

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

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Services
Food and Drug Administration

Memorandum

Date: 4/25/08

From: DMC (HFZ-401)

Subject: Premarket Notification Number(s): K972706/A1

To: Division Director: CH/DCTD

The attached information has been received by the 510(k) DMC on the above referenced 510(k) submission(s). Since a final decision has been rendered, this record is officially closed.

Please review the attached document and return it to the DMC, with one of the statements checked below.

_____ Information does not change the status of the 510(k); no other action required by the DMC; please add to image file. (Prepare K-25) THIS DOES NOT APPLY TO TRANSFER OF OWNERSHIP. PLEASE BRING ANY TRANSFER OF OWNERSHIP TO POS.

_____ Additional information requires a new 510(k); however, the information submitted is incomplete; (Notify company to submit a new 510(k); [Prepare the K30 Letter on the LAN]

X No response necessary (e.g., hard copy of fax for the truthful and accuracy statement, 510(k) statement, change of address, phone number, or fax number).

CLIA CATEGORIZATION refers to laboratory test system devices reviewed by the Division of Clinical Laboratory Devices (HFZ-440

NR

_____ Information requires a **CLIA CATEGORIZATION**; the complexity may remain the same as the original 510(k) or may change as a result of the additional information (Prepare a CAT letter)

_____ Additional information requires a **CLIA CATEGORIZATION**; however, the information submitted is incomplete; (call or fax firm)

X No response necessary

This information should be returned to the DMC within 10 working days from the date of this Memorandum.

Reviewed by: [signature]

Date: 8/18/08

4.19 pm

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

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MEMO TO FILE

DATE: Aug 15, 2008
TO: To File
RE: k972706/A001
FROM: Christine King, Scientific Reviewer, CDRH/OIVD/DCTD

I received an Add-to-File (AtF) from Bayer for k972706/A001 Clinitek Microalbumin. The AtF was for a labeling change for the device. The sponsor was updating several sections of the labeling which reflected the change in corporation name from Bayer to Siemens Healthcare Diagnostics. They also updated the disposal instructions to comply with current regulations and they updated the symbology on the package labeling. The AtF also included changes to the Summary and Explanation/Intended Use. I had concerns regarding the proposed changes to the Summary and Explanation/Intended Use. The sponsor wanted to expand the original Intended Use from the original 510k to include using the test to assess cardiovascular risk, based on more literature. On 6/18 I discussed my concerns with Carol Benson, Associate Director DCTD/OIVD. It was decided that if the sponsor wanted to change the Intended Use they would have to submit a new 510k and perform clinical studies. The proposed labeling also did not accurately reflect the literature studies' target populations, nor accurately reflect the authors' conclusions.

On 6/18/08 I called Noor Malki, the contact for the AtF, and discussed the FDA's concerns. We followed it with another phone call on 7/2/08 to work out the final details. The sponsor agreed to the following changes in their labeling: a) the Intended Use statement would appear as a separate section from the Summary and Explanation. It would be same statement as what appeared in the original 510k, b) more recent literature citing studies using microalbumin in patients with cardiovascular disease would be more accurately depicted in the Summary and Explanation section and footnoted with references in the Bibliography section of the labeling.

7/14 Having received the sponsor's revised labeling and another reference article, I discussed the matter again with Carol Benson. We felt the language was still attempting to change the indications for use however she suggested getting a consult from our medical officer, Dr. Tan Nguyen. I submitted a consult to Dr. Nguyen.

8/4 I discussed the AtF with Dr. Nguyen. He confirmed that the sponsor was using inappropriate references to substantiate their labeling changes for an AtF and that he felt they should submit a new 510k for changes in intended use.

8/15 I sent sponsor an email (see attachments) outlining our concerns about their labeling and requested new labeling with the updated symbols, company name and disposal instructions, excluding the proposed changes to the Summary and Explanation section referring to using the device as a marker for cardiovascular risk. If they wanted to

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include cardiovascular risk, a new 510k would be needed. The sponsor decided to withdraw the Add-to-File and submit all changes in a new 510k.

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King, Christine

From: Malki, Noor (MED US) [noor.malki@siemens.com]
Sent: Friday, August 15, 2008 4:01 PM
To: King, Christine
Subject: RE: k972706/A001 CLINITEK Microalbumin

Hi Chris,

I believe for now we will hold-off updating the IFU with the other changes. It makes more sense for us to introduce those changes as part of the 510(k). It is preferred to minimize updates to IFUs. So you can go ahead and close out the proposed Add-to-File as not to be implemented.

Let me know if this will work.
Thanks,
Noor

From: King, Christine [mailto:Chris.king@fda.hhs.gov]
Sent: Friday, August 15, 2008 3:46 PM
To: Malki, Noor (MED US)
Subject: RE: k972706/A001 CLINITEK Microalbumin

Hello Noor,
Will you be able to send the revised labeling for k972706/A001 soon so we can close out that Add-to-File? I'm sure you are anxious to complete that process.

Regarding the new 510k, I would suggest that you need to work out with your internal team what information you will need for your new submission. You may want to look at the 510k database http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm to see what other sponsors have done. Unfortunately, I am not able to do individual literature reviews because of our staffing and other submissions requiring my attention.

Best Regards,
Chris

From: Malki, Noor (MED US) [mailto:noor.malki@siemens.com]
Sent: Friday, August 15, 2008 1:56 PM
To: King, Christine
Subject: RE: k972706/A001 CLINITEK Microalbumin

Dear Chris,

Thank you for taking the time to review our Add-to-File. The information you have provided so far is very helpful. I have reviewed your input with the internal team. We are very interested in proceeding with a new 510(k) and changing the device intended use. Just recently, the internal team was able to identify an independent paper that used our product (CT Microalbumin) in a study that discussed Microalbuminuria as a predictor of cardiovascular morbidity and mortality. I would like to understand from you if this paper would be a more suitable approach in order to add this reference in our device intended use and proceed with a 510(k).

I would like to discuss this further with you. Is there a particular time that would work for you early next week? I look forward to hearing from you.
Hope you have a nice weekend.
Thanks,
Noor

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

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Noor Malki, MS
Head, POC Regulatory Affairs

ns Healthcare Diagnostics Inc.
f Care (POC) Products
ugewater Drive, Norwood, MA 02062
PHONE 781 269 3401
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From: King, Christine [mailto:Chris.king@fda.hhs.gov]
Sent: Friday, August 15, 2008 11:19 AM
To: Malki, Noor (MED US)
Subject: k972706/A001 CLINITEK Microalbumin

Hello Noor,

I have had a chance to discuss your Add-to-File k972706/A001 with our Medical Officer and one of our Associate Directors. The changes you have submitted for company name, updates to the symbols in the package insert, and disposal instructions are noted and we can proceed with the Add-to-File request on those items. We continue to have concerns regarding the Summary and Explanation section of the labeling and your references to microalbuminuria and cardiovascular risk.

e had discussed previously, the purpose, clinical history, demographics, and outcomes of the NHANES III study, HOPE study and LIFE study were not appropriate for your original proposed labeling changes. Although microalbumin was one of the tests included in the evaluation of patients in all three studies, your device was not the method of choice, nor was it the only factor used to determine increased cardiac risk.

We have also reviewed the revised Summary and Explanation which includes your changes to the statements referring to the NHANES III, HOPE, and LIFE studies. We are still concerned that including them in the Summary and Explanation implies to the consumer that your device was used in the studies and that you are trying to expand the Indications for Use to include use of the CLINITEK Microalbumin for evaluating cardiovascular risk without performing the appropriate studies. After consultation with our Medical Officer, who reviewed the papers you provided, he concurred that the studies were not appropriate for your proposed labeling. Please refer to our website http://www.fda.gov/cdrh/devadvice/314.html for additional information on when to submit a 510k.

The changes you have proposed for the Summary and Explanation section of your labeling implies a change in Intended Use for the CLINITEK Microalbumin to be used as a marker for cardiovascular risk. In order to change the Intended Use of a device, a new 510k is needed. We recommend that if you are citing literature, more appropriate studies be chosen.

Please provide new labeling for the Add-to-File that includes the updated company name, updates to the symbols, and disposal instructions. You may send the new labeling electronically.

Best Regards,
Chris

Christine King, MS, CLS(NCA)
Scientific Reviewer
FDA/CDRH/OIVD/DCTD

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

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2098 Gaither Road HFZ-440
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king@fda.hhs.gov

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King, Christine

From: King, Christine
Sent: Thursday, August 14, 2008 4:18 PM
To: Benson, Carol
Subject: RE: Response to Siemens re: microalbumin add to file
Importance: High

Yes, they did have that indication under the Summary and Explaination when they received clearance. Here is their IFU from the 510k template:

Indication(s) for use:

The HemoCue Albumin is a quantitative rapid turbidimetric immunoassay of albumin in human urine using a specially designed analyzer, the HemoCue Albumin 201 System. The system is designed to be used for the quantitative determination of low levels of albumin in urine at the point of care for the purpose of screening for, diagnosing, monitoring and to supplement the clinical evidence in the treatment of microalbuminuria. The system is designed for testing using spot samples or timed collections. A quantitative result is obtained within 90 seconds. HemoCue Urine Albumin Microcuvettes are for in vitro diagnostic use only. The HemoCue Albumin 201 Analyzer is only to be used with the HemoCue Urine Albumin Microcuvettes.

The statements about cardiac risk were on the original package insert in the 510k under the Summary & Explanation.

Are you able to telecon about the Pre-IDE at 2:00? I saw you were " tentatively busy" on your calendar.

Chris

From: Benson, Carol
Sent: Thursday, August 14, 2008 3:32 PM
To: King, Christine
Cc: Chesler, Ruth A
Subject: FW: Response to Siemens re: microalbumin add to file

I had some suggestions. Did Hemocue already have that indications when they received their clearance? What is on the indications for use page for hemocue? If yes, then Siemens can send a new 510(k) with supporting literature to claim the same. Thanks, Carol

---

From: King, Christine
Sent: Thursday, August 14, 2008 1:59 PM
To: Benson, Carol
Subject: Response to Siemens re: microalbumin add to file

Carol,
Attached is my response to Siemens regarding their add-to-file for microalbumin. They want to add cardiovascular risk to the Summary and Explaination. I have attached my response, their proposed labeling and a package insert from Hemocue. Hemocue was waived in 2005 for microalbumin.

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

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My concern is lack of consistency compared to the Hemocue. We already have a waived device out there with claims similar to what Siemens wants to do. (Ruth has also looked at my response). Please advise.

tine King, MS, CLS(NCA)
Scientific Reviewer
FDA/CDRH/OIVD/DCTD
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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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[redacted]

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King, Christine

From: King, Christine
Sent: Tuesday, July 29, 2008 2:08 PM
To: 'Malki, Noor (MED US)'
Subject: RE: Microalbumin k972706/A001

Hello Noor,
I have not gotten the report back yet from our Medical Officer. I will be sure to let you know as soon as I have it.

Thank you for your patience.

Chris

From: Malki, Noor (MED US) [mailto:noor.malki@siemens.com]
Sent: Monday, July 28, 2008 2:47 PM
To: King, Christine
Subject: RE: Microalbumin k972706/A001

Hi Chris,
Please let me know if you have heard back from medical affairs related to the status of the review below.

Thanks,
Noor

From: King, Christine [mailto:Chris.king@fda.hhs.gov]
Sent: Wednesday, July 16, 2008 7:49 AM
To: Malki, Noor (MED US)
Subject: Microalbumin k972706/A001

Hello Noor,
Thank you for sending me your revisions. I have asked our Medical Officer to look at your proposed revisions and the articles you cited to get his input on your revisions. Your Add-to-File is in his queue. He indicated he could get back to me next week. Thank you for your paitience.

Best Regards,
Chris

Christine King, MS, CLS(NCA)
Scientific Reviewer
FDA/CDRH/OIVD/DCTD
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Original Report: Laboratory Investigation

American Journal of Nephrology

Am J Nephrol 2008;28:324–329
DOI: 10.1159/000111825

Received: September 4, 2007
Accepted: October 16, 2007
Published online: November 29, 2007

A Comparative Evaluation of Various Methods for Microalbuminuria Screening

Pantelis A. Sarafidis[a, c] Jessica Riehle[a] Zvezdana Bogojevic[a] Emad Basta[a] Atul Chugh[b] George L. Bakris[b]

[a]Hypertension/Clinical Research Center, Department of Preventive Medicine, Rush University Medical Center, and [b]Hypertensive Diseases Unit, Section of Endocrinology, Diabetes and Metabolism, University of Chicago-Pritzker School of Medicine, Chicago, Ill., USA; [c]Section of Nephrology and Hypertension, 1st Department of Medicine, AHEPA University Hospital, Aristotle University of Thesaloniki, Thessaloniki, Greece

Key Words
Urinary albumin excretion · Hypertension · Diabetes · Kidney disease

Abstract
Background/Aims: Microalbuminuria is a marker of abnormal vascular response and a predictor of cardiovascular morbidity and mortality. We evaluated a new quantitative office-based method to assess urinary albumin excretion (UAE) and compared it to other established methods. ***Methods:*** Spot urine samples from 165 patients were analyzed at a single study site using the HemoCue system, Clinitek Microalbumin, and Chemstrip Micral test, as well as at a central laboratory, where UAE and creatinine levels were measured. The central laboratory UAE values were used as reference. We evaluated the validity of the HemoCue results and compared them to the respective data for the laboratory albumin-to-creatinine ratio (ACR). Additionally, we assessed, diagnostic sensitivity, specificity, and positive and negative predictive values of all four methods, as well as the reproducibility of the HemoCue measurements. ***Results:*** Linear regression analysis demonstrated a good correlation for the HemoCue system ($y = 0.9978x - 1.0217$, $R^2 = 0.904$) and ACR ($y = 0.0815x + 0.3373$, $R^2 = 0.784$). Sensitivity and specificity for microalbuminuria diagnosis were 92 and 98% for HemoCue, 73 and 96% for ACR, 100 and 81% for Clinitek Microalbumin, and 70 and 83% for Chemstrip Micral dipstick, respectively. The correlation coefficient of duplicate HemoCue measurements was $r = 0.98$ ($p < 0.001$). ***Conclusions:*** The HemoCue system for microalbuminuria detection was as accurate and precise as laboratory ACR estimations. Its diagnostic performance was much better than that of widely used dipstick methods. Copyright © 2007 S. Karger AG, Basel

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King, Christine

From: King, Christine
Sent: Wednesday, July 16, 2008 1:42 PM
To: 'Malki, Noor (MED US)'
Subject: RE: Microalbumin k972706/A001

Thank you Noor. I'll have to look at the paper first.

Chris

From: Malki, Noor (MED US) [mailto:noor.malki@siemens.com]
Sent: Wednesday, July 16, 2008 12:40 PM
To: King, Christine
Subject: RE: Microalbumin k972706/A001

Hi Chris,

Thank you for your prompt response. I certainly appreciate your efforts on this Add-to-File. I look forward to Medical Affairs input.

I just want to run by you a paper that the technical Marketing team just passed on to me. This paper included the Siemens Clinitek Microalbumin product as well as other products. It mentions the connection to vascular function and risk of cardiovascular mortality. The patients tested had risk factors for both cardiovascular and kidney disease. The Clinitek Microalbumin performance was actually included and the paper states 100% sensitivity and 81% specificity.

Do you think this paper could move us toward being able to change the indications for use and support a 510k in that direction? revising the indications for use is the long term objective and I would greatly appreciate your thoughts.

Kind Regards,
Noor

Noor Malki, MS
Head, POC Regulatory Affairs

Siemens Healthcare Diagnostics Inc.
Point of Care (POC) Products
2 Edgewater Drive, Norwood, MA 02062
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From: King, Christine [mailto:Chris.king@fda.hhs.gov]
Sent: Wednesday, July 16, 2008 7:49 AM
To: Malki, Noor (MED US)

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Subject: Microalbumin k972706/A001

Hello Noor,
Thank you for sending me your revisions. I have asked our Medical Officer to look at your proposed revisions and the articles cited to get his input on your revisions. Your Add-to-File is in his queue. He indicated he could get back to me next week. Thank you for your paitience.

Best Regards,
Chris

Christine King, MS, CLS(NCA)
Scientific Reviewer
FDA/CDRH/OIVD/DCTD
2098 Gaither Road HFZ-440
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From: Malki, Noor (MED US) [noor.malki@siemens.com]
Sent: Thursday, July 10, 2008 4:30 PM
To: King, Christine
Subject: Siemens Clinitek Microalbumin Add-to-File / revised verbiage

Attachments: SUMMARY AND EXPLANATION-revised20080710.doc

Dear Chris,

I am following up on the phone conversation we had few days ago. I passed on your input to my internal team and we have revised the proposed verbiage. Following the points we discussed, I have implemented the following changes:

1. Split out Intended Use from Explanation & Summary section
2. Revised proposed verbiage to balance the linkage between microalbuminuria and cardiovascular disease. Also, the new sentences better state the population discussed in the scientific papers

Please review the attached file and let me know your thoughts. The file only shows the first 2 sections of the IFU (Intended Use then Explanation and Summary). Upon your review, if the revised verbiage is approved I will then add to the full IFU.

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

Kind Regards,
Noor

Noor Malki, MS
Head, POC Regulatory Affairs

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CLINITEK® Microalbumin

Reagent Strips for Determining Albumin and Creatinine in Urine
For instrumental use only

INTENDED USE:

CLINITEK® Microalbumin Reagent Strips are firm plastic strips that contain two reagent areas to test for small amounts of albumin in urine (microalbuminuria), creatinine in urine, and also determine the albumin-to-creatinine ration in urine. The strips are read instrumentally using the CLINITEK® 50, CLINITEK® 100, or CLINITEK® Status Urine Chemistry Analyzers and provide semi-quantitative results. CLINITEK Microalbumin Reagent Strips can be used for screening urine specimens for microalbuminuria as an aid in the detection of patients at risk for developing kidney damage. CLINITEK Microalbumin reagent Strips are for professional use.

SUMMARY AND EXPLANATION:

An albumin-to-creatinine ratio is determined, which allows for the use of single-void specimens in testing. The ratio is given in milligrams albumin per gram or millimole creatinine (mg/g or mg/mmol). This product provides semi-quantitative results; positive results should be confirmed with quantitative methods for albumin.

Test results may aid clinicians in the detection of patients at risk of developing kidney damage. Microalbuminuria has been reported to be an early predictor of the development of glomerular damage in the absence of overt nephropathy.[1-3] Patients with diabetes and hypertension are the primary risk groups. Patients who have been exposed to nephrotoxins or who suffer from immune disorders form the secondary risk groups; micro-albuminuria has also been reported as an early predictor of the development of preeclampsia during pregnancy.[4]

According to the NHANES III study, microalbuminuria is highly associated with the metabolic syndrome.[5]

According to the HOPE study, in patients with and without diabetes and at high risk for cardiovascular disease, urine albumin is an easily measured sign of underlying vascular disease and future cardiovascular events.[6]

According to the LIFE study, microalbuminuria assessment in hypertensive patients improves cardiovascular risk stratification. Detecting microalbuminuria might also help the clinician decide when to initiate hypertensive therapy. Results of the LIFE study show that for every 10-fold increase in urine albumin:creatinine ratio (UACR), hazard ratios in non-diabetic patients increased by 97.7%.[7]

The reagent test areas on CLINITEK Microalbumin Reagent Strips are ready to use upon removal from the bottle and the entire reagent strip is disposable. The strips are read instrumentally, using the CLINITEK STATUS®, CLINITEK® 50, or CLINITEK® 100 Urine Chemistry Analyzer and the appropriate software (version 4.00 and higher with the CLINITEK 50 Analyzer and version 6.00 and higher with the CLINITEK 100 Analyzer). The instrument automatically identifies the strip being tested, using the colored bands near the handle of the strip.

The directions must be followed exactly. The reagent strips must be kept in the bottle with the cap tightly closed to maintain reagent reactivity. To obtain optimal results, testing should be done on FRESH urine.

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K972706/A1

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(b)(4) proposed labeling

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FDA CDRH DMC

APR 25 2008

Received

External Memorandum

Date: April 23, 2008

From: Noor Malki, Head POC Regulatory Affairs

To: FDA Reviewer / Document Mail Center (HFZ-401)

Subject: FDA records of k972706 Add-to-File

Dear FDA reviewer,

This package is an Add-to-File to k972706 explaining proposed labeling changes.

(b)(4) proposed labeling

[redacted]

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SIEMENS

(b)(4) proposed labeling

[redacted]

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(b)(4) proposed labeling

(b)(4) proposed labeling

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(b)(4) proposed labeling

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AJH 2003; 16:952–958

Association Between Microalbuminuria and the Metabolic Syndrome: NHANES III

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Scand J Clin Lab Inves 2005;65 (Suppl 240): 143-156

The HOPE (Heart Outcomes Prevention Evaluation) Study and its Consequences

M. J. MCQUEEN[1,2,3], E. LONN[2,3], H. C. GERSTEIN[2,3], J. BOSCH[2,3], S. YUSUF[2,3]

[1]*Department of Pathology and Molecular Medicine, McMaster University, Hamilton, Ontario, Canada* [2]*Department of Medicine, McMaster University, Hamilton, Ontario, Canada* [3]*Population Health Research Institute, Hamilton General Hospital, Hamilton Health Sciences, Hamilton, Ontario, Canada*

Abstract

The HOPE study was a 19 country, prospective randomized trial in which the ACE-inhibitor Ramipril but not Vitamin E significantly reduced the risk of future cardiovascular events in a high-risk population of men and women, including many with diabetes. The benefits were present in all sub-groups, independent of the presence or absence of diabetes, hypertension, evidence of cardiovascular disease, microalbuminuria, blood pressure lowering, the use of aspirin, lipid-lowering or antihypertensive medication. It provided clear evidence that Ramipril should safely and cost-effectively be used in individuals not known to have low ventricular ejection fraction or heart failure but at high-risk of cardiovascular events. It was also beneficial in patients with renal insufficiency, reducing progression of proteinuria and development of new microalbuminuria. It provided micro- and macrovascular benefits in people with diabetes, reduced the development of new cases of diabetes and showed a positive and graded association between the waist-to-hip ratio and the risk of developing diabetes. Sub-studies completed and on-going into the predictive role of natriuretic peptides, infectious and inflammatory markers, provide insight into possible mechanisms of action of Ramipril.

Background

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Cost Effectiveness (CE) of Ramipril Treatment in High-Risk Patients

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Albuminuria and Cardiovascular Risk in Hypertensive Patients with Left Ventricular Hypertrophy: The LIFE Study

Kristian Wachtell, MD, PhD; Hans Ibsen, MD; Michael H. Olsen, MD, PhD; Knut Borch-Johnsen, MD; Lars H. Lindholm, MD; Carl Erik Mogensen, MD; Björn Dahlöf, MD, PhD; Richard B. Devereux, MD; Gareth Beevers, MD; Ulf de Faire, MD; Frej Fyhrquist, MD; Stevo Julius, MD; Sverre E. Kjeldsen, MD; Krister Kristianson, PhD; Ole Lederballe-Pedersen, MD; Markku S. Nieminen, MD; Peter M. Okin, MD; Per Omvik, MD; Suzanne Oparil, MD; Hans Wedel, PhD; Steven M. Snapinn, PhD; and Peter Aurup, MD

Background: Several studies have shown that albuminuria is associated with increased risk for fatal and nonfatal cardiovascular events, independent of conventional risk factors. The partition values for urine albumin–creatinine ratio (UACR) used to identify microalbuminuria have been based on studies that predicted risk in diabetic patients.

Objective: To determine whether the relation between albuminuria and cardiovascular risk can be used to predict cardiovascular morbidity and mortality in hypertensive patients.

Design: Multicenter cohort study derived from a randomized, controlled trial.

Patients: 8206 patients with stage II or III hypertension randomly assigned to double-blind therapy with losartan or atenolol. Follow-up was 39 122 patient-years.

Measurements: Renal glomerular permeability evaluated by UACR.

Results: In nondiabetic hypertensive patients with left ventricular hypertrophy, the risk for the composite cardiovascular end point increased continuously as albuminuria increased ($P < 0.001$ for trend). There was no specific threshold for increased risk. For every 10-fold increase in UACR, hazard ratios in nondiabetic patients increased as follows: composite end point, by 57% (95% CI, 40.6% to 75.0%); cardiovascular mortality, by 97.7% (CI, 66.5% to 235%); all-cause mortality, by 75.2% (CI, 54.0% to 99.4%); stroke, by 51.0% (CI, 28.8% to 76.9%); and myocardial infarction, by 45% (CI, 19.9% to 75.4%) ($P < 0.001$ for all comparisons). Values were similar in diabetic patients, although for myocardial infarction the trend was weaker and not significant.

Conclusion: Increased UACR resulted in increasing risk for cardiovascular morbidity and mortality among hypertensive patients with left ventricular hypertrophy. We found no thresholds or plateaus. Risk increases at much lower UACR values than has been reported among diabetic patients.

Ann Intern Med. 2003;139:901-906. www.annals.org

For author affiliations, see end of text.

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DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP - 9 1997

Rosanne M. Savol, R.A.C.
Manager, Regulatory Affairs
Bayer Corporation
1884 Miles Avenue
P.O. Box 70
Elkhart, Indiana 46514-0070

Re: K972706
CLINITEK® Microalbumin Reagent Strips
Regulatory Class: II
Product Code: CJG, JFY
Dated: July 17, 1997
Received: July 21, 1997

Dear Ms. Savol:

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 Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS 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 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.

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

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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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) 594-4588. 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,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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

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510(k) Number (if known): _____

Device Name: **CLINITEK® Microalbumin Reagent Strips**

Indications for Use: **CLINITEK Microalbumin Reagent Strips are firm plastic strips that contain two reagent areas to test for small amounts of albumin in urine (microalbuminuria), creatinine in urine, and also determine the albumin-to-creatinine ratio in urine. The strips are read instrumentally using the CLINITEK® 50 or CLINITEK® 100 Urine Chemistry Analyzer and provide semi-quantitative results. CLINITEK Microalbumin Reagent Strips can be used for screening urine specimens for microalbuminuria as an aid in the detection of patients at risk for developing kidney damage. CLINITEK Microalbumin Reagent Strips are for professional use.**

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

_____ _____ _____ _____ _____ _____

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Signature)
Division of Clinical Laboratory Devices
510(k) Number K972726

Prescription Use ✓ **OR** **Over-The-Counter Use**_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

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

3

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food And Drug Administration

Memorandum

9/2/97

From: Reviewer(s) - Name(s) RETFORD BERKO

Subject: 510(k) Number K972706

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 7/28/97.
- ☑ Is substantially equivalent to marketed devices.
- ☐ NOT substantially equivalent to marketed devices.
- ☐ Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Is this device subject to 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

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 N/A

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

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 panel and class: Additional Product Code(s) with panel (optional):

(1) 75 CJG, II; Tetrabromo-M-cresolsulfonphthalein, Albumin
(2) 75 JFY, II; Enzymatic method, creatinine,

Review: (Branch Chief) (Branch Code) DMB 9-3-97 (Date)

Final Review: (Division Director) 9-8-97 (Date)

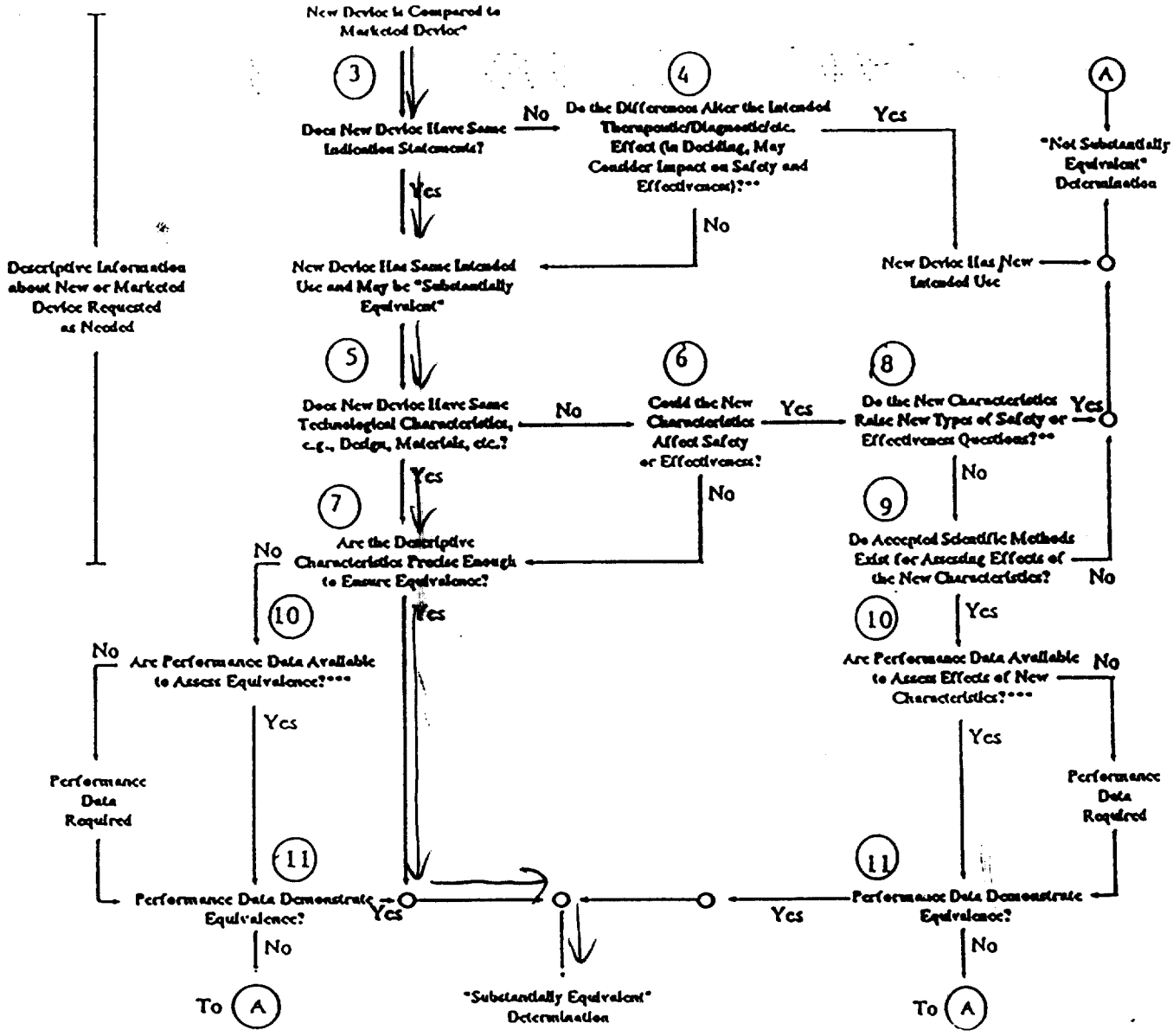
Rec'd 9/8/97

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-6118

Revised:11-20-96

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

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



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

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

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

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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 972706

Reviewer: RETFORD BERKO

Division/Branch: DCLD / TOX

Device Name: Clinitek Microalbumin Reagent Strips for Albumin and Creatinine (Bayer Corpn.)

Product To Which Compared (510(K) Number If Known): Micral-Test Strips by Boehringer Mannheim Corp. (Albumin/creatinine)

	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.

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

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August 21, 1997

Substantial Equivalence (SE) Decision-Making Documentation:

Intended Use:

Clinitek Microalbumin Reagent Strips (Bayer Corp.) are intended for use in the semi-quantitative determination of albumin and creatinine in human urine. The strips are also intended for use in this screening assay in conjunction with the Clinitek 150 or Clinitek 100 clinical analyzer. Sponsor promotes the device for use at point-of-care setting (POL, clinics and hospitals).

Summary:

The reagent test strips assay for albumin and creatinine in urine based on colorimetry. It is stated in the application file that urinary albumin is detected in the range of 20-40 mg/L and albumin-to-creatinine ration of 30-300 mg/g. Several predicate devices are identified for the device, e.g. the Micral-Test strips commercially distributed by Bohringer Mannheim Corp. The analyzers use software modifications for which the sponsor has established release criteria (see Part 3 of the file). The analyzers are pre-calibrated and automatically identifies the test strip being tested. Results are displayed automatically. User manuals for the analyzers are enclosed in the application file.

Performance characteristics are provided supporting the claim that the Microalbumin Reagent test trips are substantially equivalent to the predicate device. The sponsor provides two types of studies from which clinical performance evaluations were obtained.

(a) Part 1 of the file describes the protocol used in the "in-house" testing and the ensuing data for precision and interference studies. Comparative data for the predicate device is also provided (Part 1, pp 5/10).
(b) Part 2 of the file describes the point-of-care clinical evaluations conducted at three clinical laboratories with a summary provided (Part 2, pp 13/29)
(c) Physician lab evaluation (POL) and relevant information with survey data is provided (Part 2, pp 15/29). The qualifications of point-of care users (who can be representative of users of device at POL's) are also described briefly in the section.
(d) The labeling has provided a summary version of the evaluation data showing accuracy, sensitivity and specificity which for a test stip used for urinalysis is found comparable to what was shown for the predicate device (see predicate devices tab).

Recommendation:

Based upon the data submitted, Clinitek miroalbumin reagent strips are found to be substantially equivalent to marketed predicate devices for the same intended use.

Reginald Burks

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

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PREMARKET NOTIFICATION (510(K)) CHECKLIST FOR ACCEPTANCE DECISION

K 1942706 Device Name CLINITEK Microalbumin Reagent Strips

Division/Branch DCD/CLCB

Administrative Reviewer Signature Damian Jackson Date 4/28/97

Supervisory Signature [illegible] Date 5-3-97

Did the firm request expedited review? _____Yes ✓ No

Did we grant expedited review? _____Yes ✓ No

Truthful and accurate statement enclosed? ✓ Yes _____No
(If Not Enclosed, Must Be A Refuse To Accept Letter)
Required For Originals Received 3/14/95 And After

Is the Indication for Use Form enclosed? ✓ YES _____No
(Required for Original 510(k)s received 1/1/96 and after -- must be submitted on a separate sheet of paper)

Without reviewing this 510(k), do you believe this device type may be a preamendments class III device? _____Yes _____No (IF YES, NOTIFY POS IMMEDIATELY IF THE OUTSIDE OF THE 510(k) HAS NOT BEEN STAMPED CLASS III SO THAT THE GMP INSPECTION CAN BE SCHEDULED AS SOON AS POSSIBLE). Class III devices can not receive a determination of substantial uivalence until the GMP inspection process has been completed.

Is this a file that was determined to be substantially equivalent by ODE, but placed on hold due to GMP violations and deleted after 12 months on hold? If so, a new ODE review is not required, please forward to POS.

_____Yes ✓ No

_____ Accepted

_____ Refuse To Accept

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

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I. CRITICAL ELEMENTS:	YES PRESENT OMISSION JUSTIFIED	NO INADEQUATE OMITTED
A. Is The Product A Device?	☑	☐
B. Is The Device Exempt From 510(k) By Regulation Or Policy?	☐	☑
C. Is Device Subject To Review By CDRH?	☑	☐
D. (i) Are You Aware That This Device Has Been The Subject Of A Previous NSE Decision?	☐	☑
(ii) If Yes, Does This New 510(k) Address The NSE Issue(s) (E.G., Performance Data)?	☐	☐
E. (i) Are You Aware Of The Submitter Being The Subject Of An Integrity Investigation? If Yes, Consult The ODE Integrity Officer.	☐	☑
(ii) Has The ODE Integrity Officer Given Permission To Proceed With The Review? (Blue Book Memo #I91-2 And Federal Register 90N-0332, September 10, 1991.)	☐	☐
F. Does The Submission Contain The Information Required Under Sections 510(k), 513(f), And 513(i) Of The Federal Food, Drug, and Cosmetic Act (Act) And Subpart E Of Part 807 In Title 21 Of The Code Of Federal Regulations?:	☐	☐
1. Device Trade Or Proprietary Name	☑	☐
2. Device Common Or Usual Name Or Classification Name	☑	☐
3. Establishment Registration Number (Only Applies If Establishment Is Registered)	☑	☐
4. Class Into Which The Device Is Classified Under (21 CFR Parts 862 to 892)	☑	☐
5. Classification Panel	☑	☐
6. Action Taken To Comply With Section 514 Of The Act	☐	☐
7. Proposed Labels, Labeling And Advertisements (If Available) That Describe The Device, Its Intended Use, And Directions For Use (Blue Book Memo #G91-1)	☑	☐

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

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8. A 510(k) Summary Of Safety And Effectiveness Or A 510(k) Statement That Safety And Effectiveness Information Will Be Made Available To Any Person Upon Request	☑	☐
9. For Class III Devices Only, A Class III Certification And A Class III Summary	☐ n/a	☐
10. Photographs Of The Device	☑	☐
11. Engineering Drawings For The Device With Dimensions And Tolerances	☑	☐
12. The Marketed Device(s) To Which Equivalence Is Claimed Including Labeling And Description Of The Device	☑	☐
13. Statement Of Similarities And/Or Differences With Marketed Device(s)	☑	☐
14. Data To Show Consequences And Effects Of A Modified Device(s)	☑	☐
15. Truthful And Accurate Statement	☑	☐
II. Additional Information That Is Necessary Under 21 CFR 807.87(h):	☐	☐
A. Submitter's Name And Address	☑	☐
B. Contact Person, Telephone Number And Fax Number	☑	☐
C. Representative/Consultant If Applicable	☐ n/a	☐
D. Table Of Contents With Pagination	☑	☐
E. Address Of Manufacturing Facility/Facilities And, If Appropriate, Sterilization Site(s)	☑	☐
III. Additional Information That May Be Necessary Under 21 CFR 807.87(h):	☐	☐
A. Comparison Table Of The New Device To The Marketed Device(s)	☑	☐
B. Action Taken To Comply With Voluntary Standards	☐	☐
C. Performance Data	☐	☐
MARKETED DEVICE:	☐	☐
Bench Testing	☐	☐
Animal Testing	☐	☐
Clinical Data	☐	☐
NEW DEVICE:	☐	☐
Bench Testing	☐	☐
Animal Testing	☐	☐

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Clinical Data	☐	☐
D. Sterilization Information	☐ n/a	☐
E. Software Information	☑	☐
F. Hardware Information	☐ n/a	☐
G. If This 510(k) Is For A Kit, Has The Kit Certification Statement Been Provided?	☐	☐
H. Is This Device Subject To Issues That Have Been Addressed In Specific Guidance Document(s)?	☐	☐
If Yes, Continue Review With Checklist From Any Appropriate Guidance Documents.	☐	☐
If No, Is 510(k) Sufficiently Complete To Allow Substantive Review?	☑	☐
I. Other (Specify)	☐	☐

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

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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 ar 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

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

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 21, 1997

BAYER CORP.
DIAGNOSTICS DIV.
1884 MILES AVE.
ELKHART, IN 46515
ATTN: ROSANNE M. SAVOL

510(k) Number: K972706
Received: 21-JUL-97
Product: CLINITEK MICROALBUMIN REAGENT STRIPS

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 at the number below for more information.

With regard to the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88) which became effective September 1, 1992, the Center for Disease Control (CDC) and Prevention is currently handling complexity category/assignments concurrent with FDA's 510(k) review. To determine if your device requires a CLIA complexity categorization, contact CDC at (770)488-7655.

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).

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

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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

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

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Bayer

Business Group Diagnostics

Bayer Corporation
1884 Miles Avenue
P.O. Box 70
Elkhart, IN 46515-0070

RECEIVED
21 JUL 97 09 46
FDA/CDRH/ODE/DMC

July 17, 1997

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

SUBJECT: 510(k) Premarket Notification
Bayer Corporation, Business Group Diagnostics
CLINITEK® Microalbumin Reagent Strips

ODE Division: Division of Clinical Laboratory Devices
Panel - Clinical Chemistry and Toxicology
Classification Code - 75 JIR (Urinary Protein or Albumin)
75 CGX (Alkaline Picrate, Colorimetry, Creatinine)

Dear Sir or Madam:

Bayer Corporation, Business Group Diagnostics, hereby advises you that upon satisfactory completion of the review of this 510(k) Premarket Notification, Bayer Corporation intends to begin the introduction into interstate commerce for commercial distribution of CLINITEK® Microalbumin Reagent Strips.

Pursuant to 21 *CFR* §807.87, we are providing the following information pertaining to CLINITEK Microalbumin Reagent Strips:

Common Name of the Device [§807.87 (a)]

Test for microalbumin in urine
Test for creatinine in urine

CH II

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

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Trade Name of the Device [§807.87 (a)]

CLINITEK® Microalbumin Reagent Strips

Establishment Registration Number [§807.87 (b)]

The establishment registration number for Bayer Corporation, Business Group Diagnostics, Elkhart, Indiana, is 1810909.

Classification of the Device [§807.87 (c)]

In 21 *CFR* §862.1645, a Urinary Protein or Albumin Test System is classified as a **Class** I medical device. In 21 *CFR* §862.1215, a Creatinine Test System is classified as a **Class** II medical device.

Actions Taken to Comply With Section 514 of the *FD&C Act* [§807.87 (d)]

Class I medical devices are not subject to Section 514 of the *Federal Food, Drug and Cosmetic Act.* As of this date there are no requirements for Creatinine Test Systems pursuant to Section 514 of the *Federal Food, Drug and Cosmetic Act.*

Representative Labels, Labeling and Advertisements [§807.87 (e)]

Attached in the Appendix to this submission (LABELING) is a draft copy of the labeling for CLINITEK Microalbumin Reagent Strips.

Substantial Equivalence of CLINITEK Microalbumin Reagent Strips to a Predicate Device(s) [§807.87 (f)]

CLINITEK Microalbumin Reagent Strips are firm plastic strips that contain two reagent areas to test for microalbumin (low concentration of albumin) and creatinine in urine. CLINITEK Microalbumin Reagent Strips are manually dipped into a urine specimen and "read" instrumentally by the CLINITEK® 50 or CLINITEK® 100 Urine Chemistry Analyzer and the appropriate software. In addition to providing an albumin and a creatinine result, an albumin-to-creatinine ratio is also determined. The device is designed for use with random, overnight, or timed specimens. Semi-quantitative results are available within one minute. CLINITEK Microalbumin Reagent Strips are for professional use in point-of-care testing locations such as physician office laboratories, clinics, and hospitals.

The CLINITEK 50 and CLINITEK 100 Urine Chemistry Analyzers are semi-automated urinalysis instruments.[①] They are benchtop reflectance photometers suitable for use in

[①] Code: 75 KQO Classification; 21*CFR* §862.2900; Class I.

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point-of-care locations. The CLINITEK® family of automated urinalysis reagents and instruments has been the subject of several 510(k) Premarket Notifications.[2] To accommodate the CLINITEK Microalbumin Reagent Strip, the software of the CLINITEK 50 and CLINITEK 100 instruments has been updated and will be made available to users of CLINITEK Microalbumin Reagent Strips.

Indication Statement:

Microalbuminuria, i.e., albumin excretion > 30 mg/24h, identifies persons at risk for developing kidney disease, and is an early predictor of glomerular damage in the absence of overt nephropathy and albuminuria. Persons at greatest risk for end-stage renal disease are those with diabetes and hypertension, especially those with long-standing disease. Persons who have been exposed to nephrotoxins or who have immune disorders form the secondary risk groups. Microalbuminuria has also been reported as an early predictor of pre-eclampsia during pregnancy.[3]

Albumin is normally present in urine at concentrations of < 30 mg/L. Microalbuminuria is indicated with results of 30 mg/L or greater. Results of 150 mg/L or greater indicate overt albuminuria. The albumin-to-creatinine ratio in a random urine specimen is used to estimate the 24-h albumin excretion. Albumin is normally present in urine at concentrations of less than 30 mg albumin/g creatinine. Microalbuminuria is indicated at a ratio result of ≥ 30 mg/g and overt albuminuria at a ratio of ≥ 300 mg/g.[4]

The CLINITEK Microalbumin assay is a convenient dip-and-read reagent strip allowing rapid detection of urinary albumin at 20 to 40 mg/L, and the albumin-to-creatinine ratio of 30 to 300 mg/g. The product provides semi-quantitative results of 0, 30, 80, and 150 mg/L albumin, and 30, 100, 200, and 300 mg/dL creatinine. The albumin-to-creatinine ratio is displayed as "< 30 mg/g (Normal)", "30-300 mg/g (Abnormal)", and "> 300 mg/g (High Abnormal)". CLINITEK Microalbumin Reagent Strips can be used for screening samples for microalbuminuria. Positive results should be confirmed with quantitative methods for albumin.

Technological Characteristics:

The CLINITEK assay for albumin is based on dye binding using a high affinity sulfonephthalein dye. At a constant pH, the development of a blue color is due to the presence of albumin. The intensity of the color, which ranges from pale green to aqua blue,

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[2] K971209; K960546, K946183; K932674; K926359; K862134; K841041; K842238; K842237; K821738; K760472.

[3] References to the medical literature are provided in the Appendix to this Premarket Notification (STUDIES Part I - Pages 9-10).

[4] STUDIES Part I - Page 1.

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

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is proportional to the albumin concentration in the specimen. The CLINITEK assay for creatinine is based on the peroxidase-like activity of copper creatinine complexes that catalyze the reaction of diisopropylbenzene dihydroperoxide and 3,3',5,5'-tetramethyl-benzidine. The resulting color ranges from orange through green to blue.

Both albumin and creatinine reagent areas are attached to one reagent strip. The color of the reagent areas are read by the CLINITEK 50 and CLINITEK 100 reflectance photometers at specified times and the results are displayed or printed in clinically meaningful units. The displayed values represent nominal values. Actual values will vary around the nominal values.

Predicate Devices:

CLINITEK Microalbumin Reagent Strips are substantially equivalent for purposes of Section 510(k) of the *Federal Food, Drug and Cosmetic Act* to many products for the determination of albumin (microalbumin) or creatinine in urine including the following predicate devices which were used in the performance studies reported in the Appendix to this Premarket Notification (STUDIES):

- Micral-Test® strips (Boehringer Mannheim Corporation). An immunochromatographic, semi-quantitative visual method. The color chart gives values as 0, 10, 20, 50 and 100 mg/L albumin.
- The microalbumin reagent on the Array® Analyzer (Beckman Instruments Inc.). An immunonephelometric method.
- The SPQII™ Reagent (INCSTAR Corp.). An immunonephelometric method. on the Roche COBAS-FARA® II Analyzer and the Ciba-Corning Express Plus.
- The Microprotein reagent (Sigma Diagnostics). A pyrogallol red dye-binding method for total protein used on the Roche COBAS MIRA Analyzer, Paramax® Analytical System and the DuPont XL System.
- Quantimetrics BGR Total Protein (Quantimetrics). A pyrogallol red dye-binding method used on the TECHNICON RA® 1000 Random Access Analyzer
- The CX3 Creatinine Reagent (Beckman). A Jaffe kinetic method used on a Beckman CX3 SYNCHRON® Analyzer.
- Paramax® Creatinine Reagent (Dade Diagnostics). A Jaffe kinetic method used on the Paramax Analytical System.
- Miles Creatinine Reagent (Bayer). A Jaffe kinetic method used on the TECHNICON RA 1000 Random Access Analyzer.
- Dade® Creatinine Reagent. A Jaffe kinetic method used on the DuPont XL System.

CLINITEK Microalbumin Reagent Strips are similar to the Micral Test strips in that both are convenient point-of-care tests that provide semi-quantitative results for microalbumin. The two devices differ in that the CLINITEK albumin test is not a visually read

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immunochemical test for albumin. The Micral Test strip does not contain a creatinine test and therefore, does not report the albumin-to-creatinine ratio. CLINITEK Microalbumin Reagent Strips primarily differ from the other predicate devices for the determination of albumin and creatinine in that the CLINITEK assays provide semi-quantitative results. Furthermore, the CLINITEK 50 and CLINITEK 100 Urine Chemistry Analyzers are designed for point-of-care testing locations rather than the high volume, traditional clinical laboratory.

CLINITEK Microalbumin Reagent Strips are also substantially equivalent to the Bayer DCA 2000+® Microalbumin/Creatinine Assay. The two devices are similar in that both are point-of-care systems that determine urine albumin and creatinine and automatically calculate the albumin-to-creatinine ratio. The DCA 2000+ Microalbumin/Creatinine Assay, however, employs a quantitative immunoassay for albumin and a quantitative colorimetric test for creatinine.

Further information representative of the predicate devices is provided in the Appendix to this premarket notification (PREDICATE DEVICES).

Performance and Validation:

The performance of CLINITEK Microalbumin Reagent Strips was evaluated to show substantial equivalence to the predicate devices. A report on the CLINITEK Microalbumin Reagent Strips performance studies and instrument software validation is provided in the Appendix to this Premarket Notification (STUDIES).

Summary of Safety and Effectiveness [§807.87 (h)]

In accordance with the requirements of 21 *CFR* §807.92 a "510(k) Summary" for CLINITEK Microalbumin Reagent Strips is provided in the Appendix to this Premarket Notification [510(k) SUMMARY].

"Truthful and Accurate" Statement [§807.87 (j)]

A statement of truth and accuracy is attached.

Additional Information [§807.87 (k)]

An "Indications for Use" statement is attached.

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

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Accordingly, it is respectfully submitted that CLINITEK® Microalbumin Reagent Strips are substantially equivalent for purposes of Section 510(k) of the *Federal Food, Drug and Cosmetic Act* to a predicate device(s) which is in commercial distribution in interstate commerce.

I would appreciate hearing from you regarding this Premarket Notification at your earliest convenience.

Very truly yours,

BAYER CORPORATION, BUSINESS GROUP DIAGNOSTICS

Rosanne M. Savol, R.A.C.
Manager, Regulatory Affairs
1884 Miles Avenue, P.O. Box 70
Elkhart, IN 46514-0070
phone: 219-262-6929
FAX: 219-262-6945

attachment

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

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PREMARKET NOTIFICATION

CLINITEK® Microalbumin Reagent Strips

Section 807.87(j) Statement

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

Rosanne M. Savol

Rosanne M. Savol, R.A.C.

July 17, 1997

Date

Premarket Notification [510(k)] Number K_____

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510(k) Number (if known): _____

Device Name: **CLINITEK® Microalbumin Reagent Strips**

Indications for Use: **CLINITEK Microalbumin Reagent Strips are firm plastic strips that contain two reagent areas to test for small amounts of albumin in urine (microalbuminuria), creatinine in urine, and also determine the albumin-to-creatinine ratio in urine. The strips are read instrumentally using the CLINITEK® 50 or CLINITEK® 100 Urine Chemistry Analyzer and provide semi-quantitative results. CLINITEK Microalbumin Reagent Strips can be used for screening urine specimens for microalbuminuria as an aid in the detection of patients at risk for developing kidney damage. CLINITEK Microalbumin Reagent Strips are for professional use.**

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

_____ _____ _____ _____ _____

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Clinical Laboratory Devices

510(k) Number K972706

Prescription Use ✓ **OR** **Over-The-Counter Use**____

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

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

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Bayer Corporation, Business Group Diagnostics
CLINITEK® Microalbumin Reagent Strips
510(k) Premarket Notification
July 17, 1997

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Data Demonstrating Substantial Equivalence to the Predicate Device(s)	APPENDIX - STUDIES Part I pp 2-6 APPENDIX - STUDIES Part II pp 3-14
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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Label:29

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

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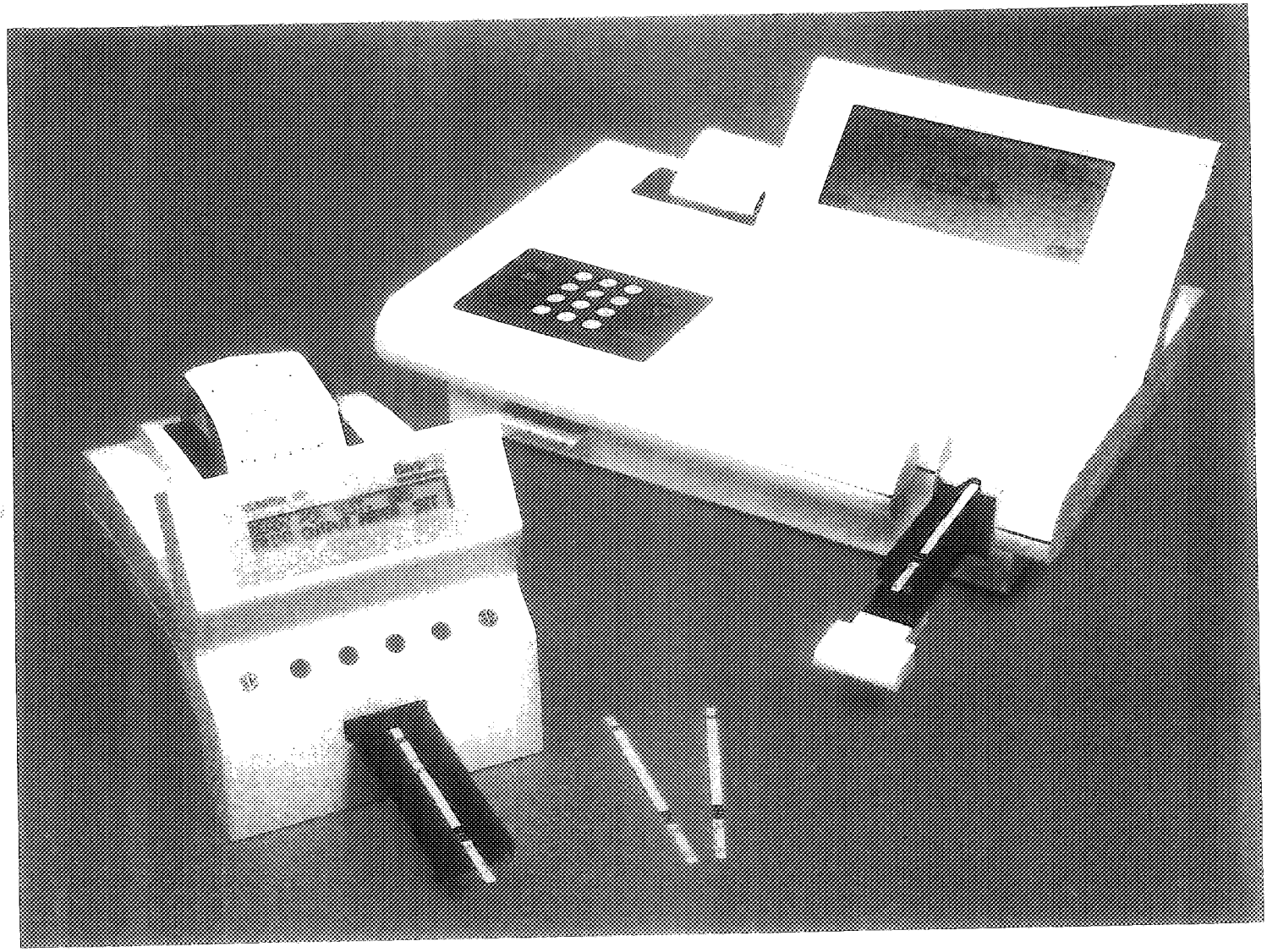

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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CLINITEK® Microalbumin

Reagent Strips for Determining Albumin and Creatinine in Urine

For instrumental use only

SUMMARY AND EXPLANATION/INTENDED USE: CLINITEK® Microalbumin Reagent Strips are firm plastic strips that contain two reagent areas that test for albumin and creatinine in urine. An albumin-to-creatinine ratio is also determined, which allows for the use of single-void specimens in testing. The ratio is given in milligrams albumin per gram creatinine (mg/g). This product provides semi-quantitative results and can be used for screening samples for microalbuminuria; positive results should be confirmed with quantitative methods for albumin.

Test results may aid clinicians in the detection of patients at risk of developing kidney damage. Microalbuminuria has been reported to be an early predictor of the development of glomerular damage in the absence of overt nephropathy.[1-4] Patients with diabetes and hypertension are the primary risk groups.[5,6] Patients who have been exposed to nephrotoxins or who suffer from immune disorders form the secondary risk groups; microalbuminuria has also been reported as an early predictor of the development of preeclampsia during pregnancy.[7]

The reagent test areas on CLINITEK Microalbumin Reagent Strips are ready to use upon removal from the bottle and the entire reagent strip is disposable. The strips are read instrumentally, using the CLINITEK® 50 or CLINITEK® 100 Urine Chemistry Analyzer and the appropriate software (contact your Bayer representative for further information). The instrument automatically identifies the strip being tested, using the colored bands near the handle of the strip.

The directions must be followed exactly. The reagent strips must be kept in the bottle with the cap tightly closed to maintain reagent reactivity. To obtain optimal results, testing should be done on FRESH urine.

CHEMICAL PRINCIPLES OF PROCEDURES:

Albumin: This test is based on dye binding using a high affinity sulfonephthalein dye. At a constant pH, the development of any blue color is due to the presence of albumin. The resulting color ranges from pale green to aqua blue.

Creatinine: This test is based on the peroxidase-like activity of a copper creatinine complex that catalyzes the reaction of diisopropylbenzene dihydroperoxide and 3,3',5,5'-tetramethylbenzidine. The resulting color ranges from orange through green to blue.

REAGENTS: (based on dry weight at time of impregnation)

Albumin: 1.9% w/w 5',5-dinitro-3,3"-diiodo, 3,4,5,6-tetrabromophenol sulfonephthalein dye; 94.2% w/w buffer; 3.9% w/w nonreactive ingredients.

Creatinine: 3.0% w/w copper sulfate; 4.6% w/w diisopropylbenzene dihydroperoxide; 2.2% w/w 3,3',5,5'-tetramethylbenzidine; 69.5% w/w buffer; 20.7% w/w nonreactive ingredients.

WARNINGS AND PRECAUTIONS: CLINITEK Microalbumin Reagent Strips are for *in vitro* diagnostic use. They have been determined to be nonhazardous under the guidelines issued by OSHA in 29 CFR 1910.1200(d).

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.

PROCEDURES FOR HANDLING CLINITEK Microalbumin: 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 packet(s) from bottle. **Remove each strip from the bottle 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.

IMPORTANT: PROTECTION AGAINST AMBIENT MOISTURE, LIGHT AND HEAT IS ESSENTIAL TO GUARD AGAINST ALTERED REAGENT REACTIVITY. Discoloration or darkening of reagent areas may indicate deterioration. If this is evident, or if test results are questionable or inconsistent with expected findings, the following steps are recommended: (1) confirm that the product is within the expiration date shown on the label; (2) check performance against known positive and negative control materials; (3) retest with fresh product. If proper results are not obtained, consult your local Bayer representative, or contact the Customer Service Department by calling toll free 1-800-348-8100, for advice on testing technique and results.

SPECIMEN COLLECTION AND PREPARATION: Test the urine specimen as soon as possible. Boric acid, at a concentration of 1.0 g/L, is the only urine preservative that can be used. If testing cannot be done within two hours after voiding, refrigerate the specimen immediately and let it return to room temperature before testing. Prolonged exposure of unpreserved urine to room temperature may result in microbial proliferation with resultant loss of albumin. Specimens may be stored at 0° to 8°C for one week or at -20°C for one month without significant effect on results with this test.

Any single-void urine specimen, when evaluated in conjunction with the albumin-to-creatinine ratio, can be used to discriminate between normal and abnormal levels of microalbuminuria.[8-10] First-morning specimens are recommended; specimens obtained following strenuous physical activity should *not* be used. Urinary albumin fluctuates day-to-day; therefore, testing three urine samples over a three-to-six month period may increase the predictive value, where two positive samples are predictive of incipient nephropathy.[10,11] Twenty-four hour or timed collections may also be used with this test to determine the albumin excretion rate (AER). Additional information on screening guidelines is available from the American Diabetes Association Position Statement.[10]

It is suggested that you screen the urine for protein and occult blood, using a Bayer Reagent Strip such as MULTISTIX® 10 SG. Urines showing a result of 30 mg/dL or greater for protein or a "Large" result for occult blood should not be tested using CLINITEK Microalbumin Reagent Strips.

Contamination of the urine specimen with soaps, detergents, antiseptics, or skin cleansers may affect test results. The user should determine whether the use of such products is warranted.

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

1. **Collect** a FRESH urine specimen in a clean, dry container.
2. **Remove** one strip from bottle and replace the cap tightly.
3. **Dip** the test pads into the urine, making sure both pads are wetted. (Do not dip the colored bands near the handle.)
4. **Immediately remove** the strip, dragging the edge of the strip against the rim of the urine container as to remove excess urine.
5. **Press** the green ◇ key (START) on the CLINITEK 50 or CLINITEK 100 Analyzer **at the same time** as the strip is removed from the urine.
6. **Blot** the strip by **touching the edge only** to a paper towel.
7. **Place** the reagent strip, **with the reagent pads facing up**, onto the instrument's test/feed table. Slide the strip along the table until it touches the **end** of the table.
8. The table is automatically pulled into the instrument, where the strip is identified and read. Results are displayed or printed as soon as they are available.
9. **Record** the results you obtain, then discard the strip into a suitable trash container.

   NOTE: Wipe the test table with a damp, lint-free tissue as often as needed to prevent urine from building up.

QUALITY CONTROL: For best results, performance of reagent strips should be confirmed whenever a new bottle is first opened by testing with commercially-available negative and positive controls that include values for microalbumin and creatinine. These control specimens may also be randomly hidden in each batch of specimens

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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.

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

The presence of hemoglobin or myoglobin (≥5 mg/dL or an occult blood result of "Large" using a Bayer Reagent Strip) may cause falsely elevated results with both the albumin and creatinine tests. Contamination of the urine specimen with soaps, detergents, antiseptics, or skin cleansers, or the use of urine preservatives other than boric acid (1.0 g/L), may also affect test results.

Substances that cause abnormal urine color, such as drugs containing azo dyes (e.g., Pyridium®*, Azo Gantrisin®*, Azo Gantanol®*), nitrofurantoin (Macrodantin®*, 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 as a false positive.

TABLE OF RESULTS:

The following table shows the results, in both conventional and SI units, that can be obtained when using the CLINITEK 100 or CLINITEK 50 Analyzer:

Test	Abbreviation	Printed/Displayed Results			
		Conventional		S.I. Units	
Albumin	ALB	0 mg/L	80 mg/L	0 mg/L	80 mg/L
		30 mg/L	150 mg/L	30 mg/L	150 mg/L
Creatinine	CRE	30 mg/dL	200 mg/dL	2.7 mmol/L	17.7 mmol/L
		100 mg/dL	300 mg/dL	8.8 mmol/L	26.5 mmol/L
Albumin-to-Creatinine Ratio	A:C	<30 mg/g (Normal)		<3.4 mg/mmol (Normal)	
		30–300 mg/g (Abnormal)		3.4-33.9 mg/mmol (Abnormal)	
		>300 mg/g (High Abnormal)		>33.9 mg/mmol (High Abnormal)	

Shaded areas = abnormal results

EXPECTED VALUES:

Albumin: Albumin is normally present in urine at concentrations of less than 30 mg/L. Microalbuminuria is indicated with results of 30 mg/L or greater; results of 150 mg/L or greater indicate overt albuminuria.[10] Children may have higher levels of albumin without the presence of kidney disease.

Creatinine: Creatinine is normally present in urine at concentrations of 10 to 300 mg/dL.

Albumin-to-Creatinine Ratio: Albumin is normally present in urine at concentrations of less than 30 mg albumin/g creatinine. Microalbuminuria is indicated at a ratio result of ≥30 mg/g and overt albuminuria at a ratio result of ≥300 mg/g.[10]

SPECIFIC PERFORMANCE CHARACTERISTICS:

Specific performance characteristics are based on clinical and analytical studies. In clinical specimens, the sensitivity of the reagent tests and their respective reference assays depends upon the presence or absence of inhibitory factors typically found in urine (see LIMITATIONS OF PROCEDURES section).

Each instrumental result represents a range of values. Because of specimen variability, specimens with analyte concentrations that fall between nominal levels may give results at either level.

The performance characteristics of the CLINITEK Microalbumin test on the CLINITEK 50 and CLINITEK 100 Analyzers was determined at three hospital clinical laboratories with urine specimens from patients presenting for routine urinalysis. CLINITEK instrument albumin results were compared to the results obtained with a commercially-available immunoassay test; the creatinine results were compared to a kinetic Jaffe creatinine assay. An SDS-polyacrylamide gel electrophoresis method was used to resolve any discrepant albumin results.

The following table shows the results of the testing. Accuracy is defined as the agreement between the CLINITEK instrument/reagent system and the comparative methods. Sensitivity is defined as the percentage of positive results obtained by the instrument/reagent system relative to those obtained by the comparative methods, while specificity refers to the percentage of negative results.

Albumin Test Pad with:	Accuracy	Sensitivity	Specificity
CLINITEK 50	93% n=847	92% n=412	93% n=435
CLINITEK 100	91% n=844	92% n=417	91% n=427

Albumin-to-Creatinine Ratio with:	Accuracy	Sensitivity	Specificity
CLINITEK 50	90% n=847	89% n=372	91% n=475
CLINITEK 100	89% n=844	88% n=364	90% n=480

Albumin: In contrived urine, the albumin test generally detects albumin at a concentration of 20-40 mg/L; because of the inherent variability of clinical urines, lesser concentrations may be detected under certain conditions. The test is specific for albumin and is not affected by the following proteins when tested at concentrations at least 9 times greater than the excretion rate considered to be abnormal (data is available from Bayer Corporation, Elkhart, IN):

lysozyme	β-2-microglobulin
prealbumin	β-2-glycoprotein
immunoglobulins	α-1-acid glycoprotein
haptoglobin	α-1-microglobulin
transferrin	α-2-macroglobulin
Bence-Jones proteins	retinol binding protein
Tamm Horsfall glycoprotein	

Creatinine: This test area detects urinary creatinine in concentrations as low as 30 mg/dL; the absence of creatinine in a specimen cannot be determined. Levels of albumin, bilirubin, citrate, creatine, and ascorbic acid normally found in urine do not interfere with this test.

Albumin-to-Creatinine Ratio: In contrived urines, the ratio generally detects 30–300 mg/g albumin-to-creatinine.

AVAILABILITY: CLINITEK Microalbumin Reagent Strips for Urinalysis are available in bottles of 25 strips (Product #2085) and 100 strips (Product #2086).

PATENTS: U.S. Patent Nos. 5,187,104; 5,279,790; 5,374,561; 5,424,215; other patents pending.

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11. Mogensen, C.E. *et al.*: Prevention of Diabetic Renal Disease with Special Reference to Microalbuminuria. *Lancet 346:*1080-1085; 1995.

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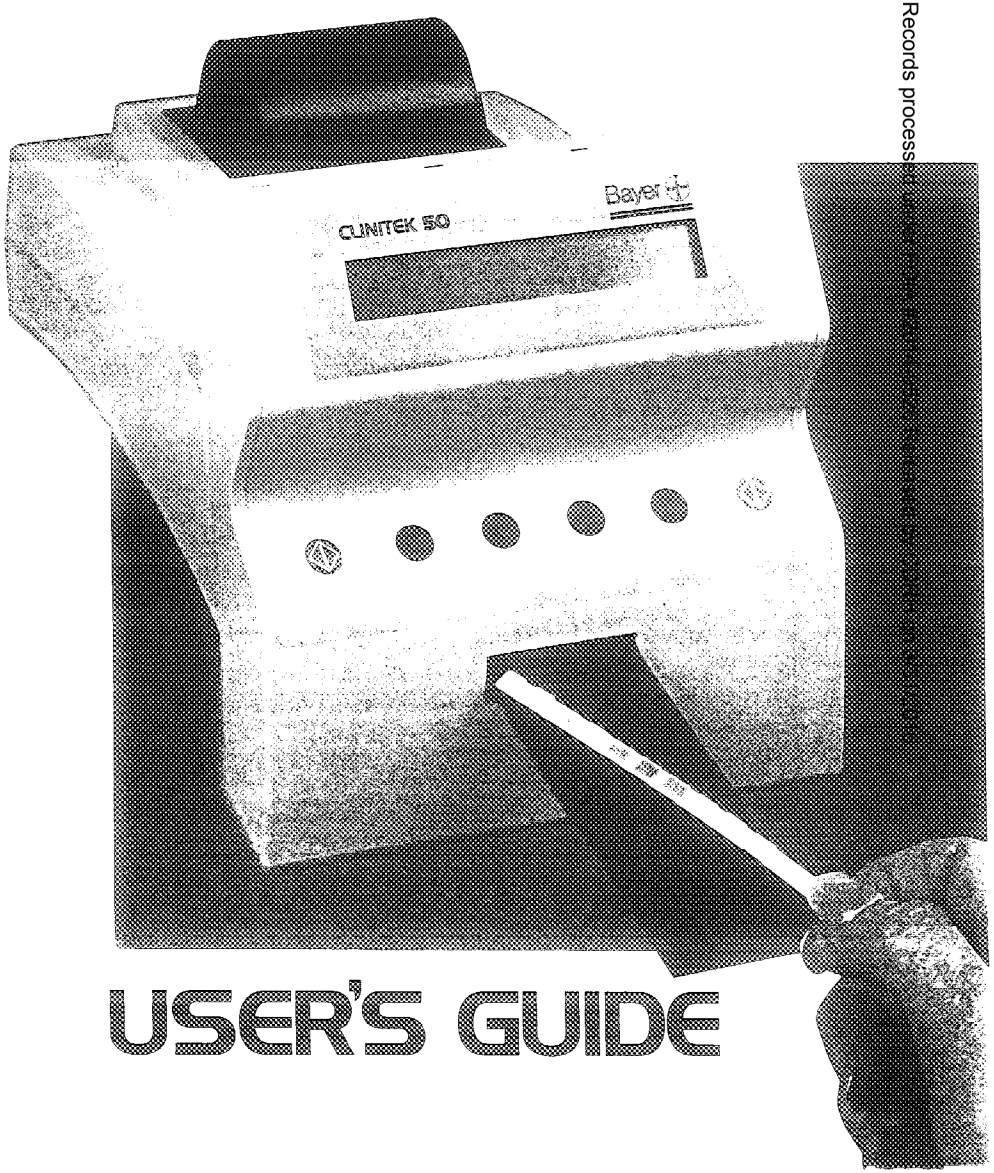
Guides you do not use.

CLINITEK® 50



USER'S GUIDE

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Elkhart, IN 46515 USA

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A Brief Description

What does this instrument do?

Your CLINITEK® 50 Urine Chemistry Analyzer is a portable instrument for reading Bayer Reagent Strips for Urinalysis. Depending on which type of Bayer Reagent Strips is used, the CLINITEK 50 Analyzer can give results for glucose, bilirubin, ketone (acetoacetic acid), specific gravity, occult blood, pH, protein, urobilinogen, nitrite, and leukocytes. It can also report the color of the urine sample.

The Analyzer can be plugged into an electrical outlet for use on the benchtop, or it can be powered by batteries and freely moved from one testing site to another. The battery pack, which is purchased separately, fits into an opening on the bottom side of the instrument.

Do I have to calibrate?

You do not have to do anything extra to calibrate. The instrument performs a "self-test" and calibration each time it is turned *on*. Then, each time a test is run, the instrument calibrates again, using the white plastic bar located on the end of the test strip table.

How does it work?

Testing starts when either of the two Start keys (labeled "◇") is pressed. You have 10 seconds after the ◇ key is pressed to blot the edge of the wet reagent test strip and place it on the test strip table. The table is then pulled into the instrument, where the test strip is read. The instrument measures the color and amount of light that is reflected from the test pads on the strip. It then changes these measurements into meaningful results.

How do I get results?

Results can be either printed or displayed. The results can also be transferred to a computer using a special cable that is plugged into the computer port on the back of the instrument.

What about this User's Guide?

The User's Guide contains the directions you need to unpack the instrument, use it for your daily urine testing, and keep it in good working condition. The User's Guide is provided in several languages; please recycle the Guides you will not be using.

As you read through the User's Guide, you will find these symbols:

✎ **NOTES** contain useful tips on using your instrument. *They appear in italicized type.*

☞ **CAUTIONS** should be followed carefully to ensure your instrument operates correctly and is not damaged. **Cautions appear in bold type like this.**

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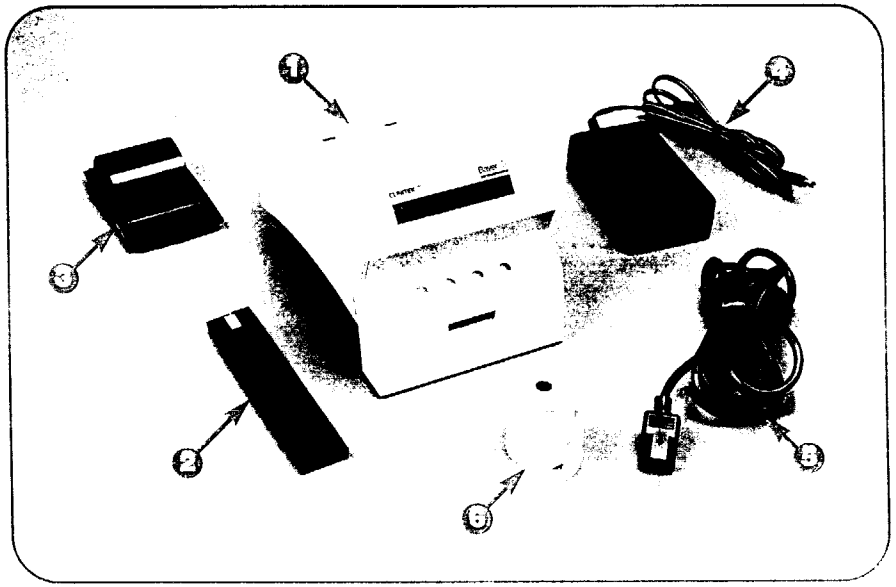
Unpacking and Setup

Unpacking

1 Carefully remove the contents of the shipping carton. Check the carton and instrument for visible signs of damage; if seen, immediately contact the carrier.

2 Remove each of the wrappings and check for the following items:



1. CLINITEK 50® Analyzer
2. Test strip table
   (Do not touch the white bar!)
   If you will be using a Reagent Strip that has four or fewer test pads, you must use a short test strip table, which must be ordered separately (see page 26).
3. Printer cover
4. Power transformer
5. Power cord
   If the power cord is not the style you need, contact your Bayer office (see page 26).
6. Paper roll

Depending on the model you have received, there may also be a Warranty Registration Card, Customer Information Card, Unpacking Guide, and/or Quick Reference Guide included.

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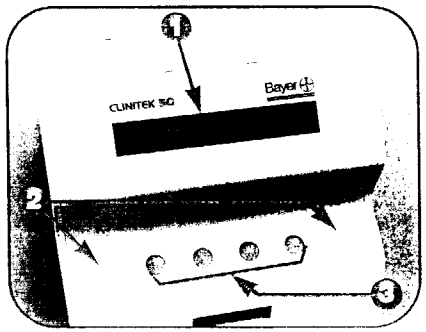
3 Place the instrument on a level work surface where the temperature and humidity are fairly constant.

☞ **The best temperature for using the instrument is between 22°C and 26°C (72°F to 79°F). Do not place the instrument near such things as an outside window, oven, hot plate, or radiator.**

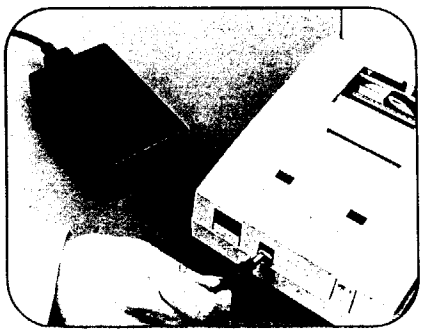
4 Locate the following:

1. Display
2. ◇ (START) Keys
   Either key can be pressed to start a test.
3. Option Keys
   Each key corresponds to one of four words that may be shown on the bottom line of the display; press the key beneath the word to select that choice.

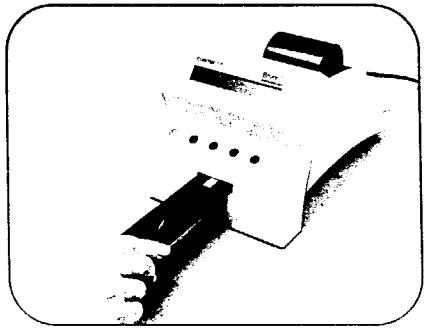


✎ *If you will be using the optional battery pack instead of the power cord and transformer, skip Step 5.*

5 Plug the power cord into the transformer, then plug the transformer cord into the instrument. Plug the power cord into an AC electrical wall outlet.



6 Insert the test strip table into the instrument, holding it by the end opposite the white bar and with the flat side facing up. **Do not touch the white bar.** Push the table in about halfway.



7 If you will be sending results to a computer, you must obtain a special Computer Cable/ Connector Kit (see page 25 to order). The kit includes all the information you need to connect and use the cable.

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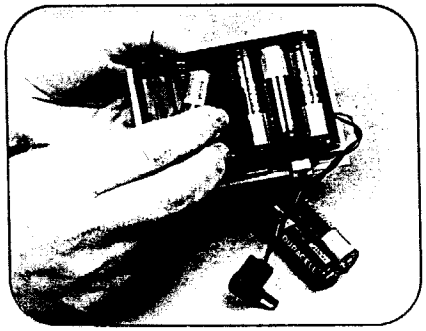
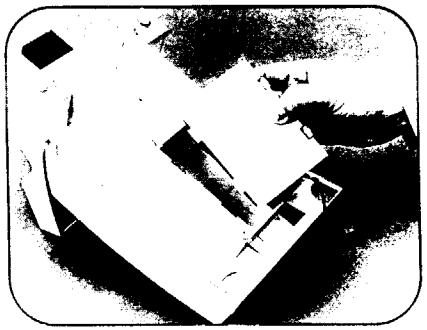
Installing the Battery Pack

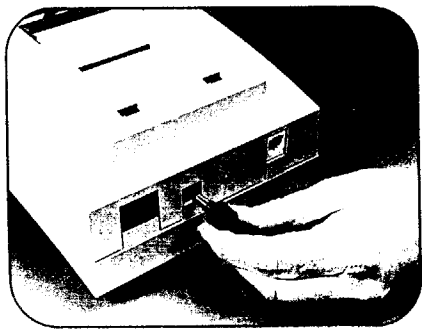
1. If you will be using the optional battery pack, place six AA-size batteries into the battery compartment.



2. Turn the instrument over and snap the battery pack into the opening.



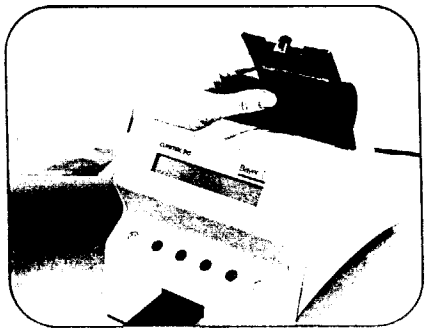
3. Plug the cord into the power inlet.



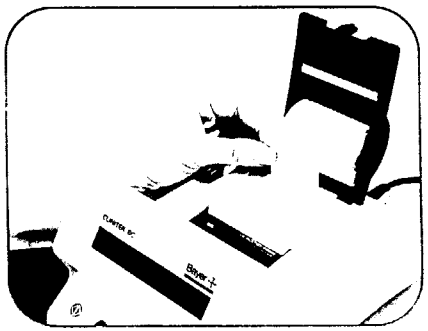
Loading the Paper Roll

1. Insert the two tabs on the printer cover into the two openings on the instrument. Rest the cover on its back edge.

If changing the paper, leave the cover down and pull out the remaining paper. Then raise the cover and remove the empty core to continue.



2. Trim the end of the paper so it has a large "V" shape at least 2 inches (5 cm) long. With the paper unrolling from underneath, insert the paper under the printer roller until the tip comes through the other side of the roller.



3. ***Pulling toward the back,*** gently pull the end of the paper until the full width of the paper is completely exposed.

Do not pull the paper straight up or toward the front, as this will damage the printer.

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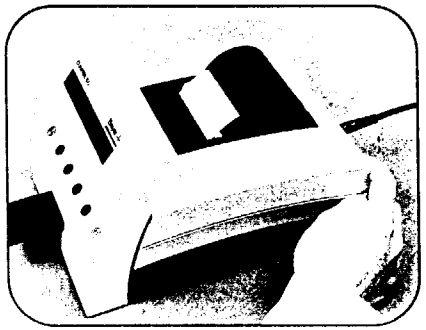
4 Feed the paper through the printer cover opening and snap the cover into position.

*If you have Model Number 6510A, the cover **must** be latched in order for the instrument to function.*

To prevent damage to the printer, do not tear the paper without the cover in place.

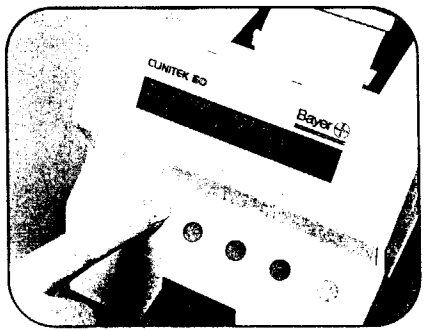
Powering Up

1 Press the power switch on the back of the instrument to the "—" (ON) position.



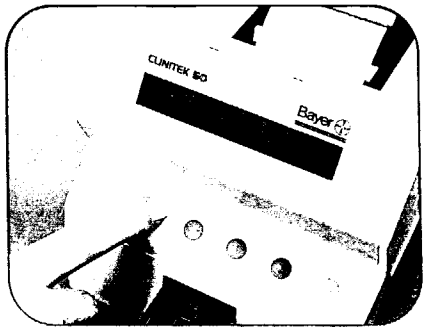
2 If you want to use the language and units shown on the screen, press the key under the word **YES.** If you want another language and/or units, press the key under the word **NO.**

Refer to pages 28 to 30 for the test abbreviations and results that are used with each of the three options for English.



3 Press the key under the word **NORMAL** if you want the results to appear in clinical units. Press the key under **+/–** if you prefer plus and minus signs.

The screens shown in Steps 2 and 3 appear the first three times the instrument is turned on or three times after a change is made to either screen.



4 The instrument briefly displays two screens while it does an internal check. When the check is complete, the READY screen appears. Look for the name of the Reagent Strip – it is shown after the words "READY FOR TEST."

Do not use any Reagent Strip product other than what is shown on the display. Using the wrong Reagent Strip will give you incorrect results.

Final Paper Work

1 Find the bar-coded serial number label on the bottom of the instrument. Write this number and today's date on the Problem Checklist on page 23.

2 Fill out and mail the Warranty Registration Card and Customer Information Card if these are included with your instrument.

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Selecting Your Options

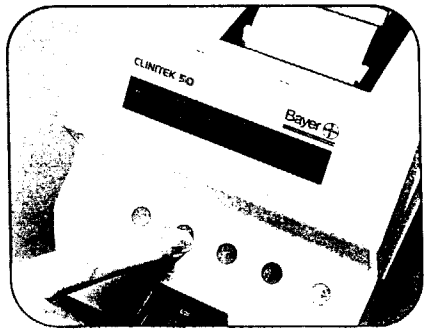
Location of Results and Number of Copies

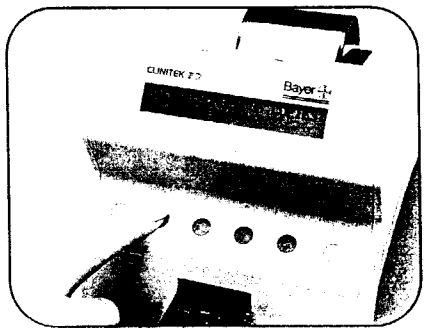
1. If you want more than one printed copy or if you prefer results to be displayed on the screen, press the key under the word **OUTPUT.**

2. Press the key under your choice.

3. If you pressed **PRINTER,** you can choose to have more than one copy of the results. Press the key under your choice.

One copy of each set of results will be printed if you do not change this option.





Setting the Time

1. Press the key under the word **SET.**

2. Press the key under **TIME** and select the 12 hour (AM/PM) format or the 24 hour (military) format.

3. Press the ↑ key to adjust the hour.

If you press and hold the ↑ key, the numbers will advance more quickly.

4. Press the → key, then press ↑ to adjust the minutes.

5. Press **EXIT.**

Setting the Date

1. Press the key under the word **SET.**

2. Press the key under **DATE** and select a date format:

MDY	Month-Day-Year
DMY	Day-Month-Year
YMD	Year-Month-Day

3. Press the ↑ key to adjust the first number.

4. Press the → key, then press ↑ to adjust the second number.

5. Press the → key, then press ↑ to adjust the third number.

6. Press **EXIT.**

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Reporting the Urine Color

1. Press the key under the word **SET.**

2. Press **MORE,** then press **COLOR.** Press the **YES** or **NO** key to make your selection.

3. Press **EXIT** as needed.

*Color will be reported automatically if this option is set to **YES.***

Color results reported by the instrument may be different from the color seen visually. This is because of the inherent differences between the human eye and the optical system of the instrument.

Setting the Sequence Number

1. If you want to have the sequence number appear, press the key under the word **SET.**

2. Press **MORE,** then press **SEQ#.**

3. Press **YES** to use sequence numbers (or press **NO** if you don't want them displayed).

4. Press **EXIT** as needed.

The sequence number will not be displayed or printed unless you change this option.

If you are already using sequence numbers and the number is greater than 001, you will first be given the option of setting it to 001.

Clearing the Memory and Marking Positives

1. If you want to clear the instrument's memory of all test results, or to turn off the asterisk, press the key under the word **SET.**

2. Press **MORE,** then press **CMPTR.**

3. Press **YES** to clear the memory and reset the sequence number to 001.

4. Then select whether positives will be marked with an asterisk (*).

5. Press **EXIT** as needed.

You can connect the instrument to a computer to transfer results. Fifty sets of results are stored (for transfer only) if the memory is not cleared.

*Check whether your software program can accept the asterisk that marks positive results. Press **NO** if it cannot.*

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3 Testing Controls

Positive and negative control solutions should be tested on a regular basis. This provides a check to ensure that the Bayer Reagent Strips are reacting properly and the instrument is reading the strips properly. Testing controls also helps detect errors caused by incorrect user technique.

You may want to test controls:

- at the start of the day;
- when you open a new bottle of Reagent Strips;
- when changing instrument operators;
- whenever test results are in doubt.

CHEK-STIX® Positive and Negative Control Strips are available for use in your quality control program (see page 25 for product numbers). Prepare the control solutions as instructed in the package insert that comes with the control product. Then test the control solution using the same procedure as you use when testing patient urines.

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Testing Routine Urines 4

Procedure

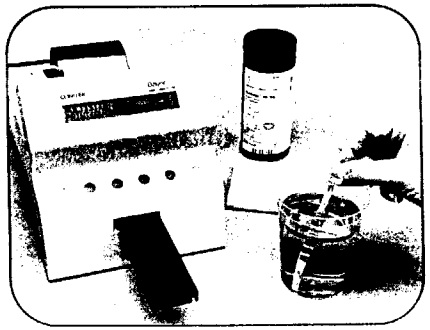
Before beginning the day's testing, check the test strip table to make sure it is clean. If it looks dirty, remove the table and clean it, as described on page 17.

The urine specimen should be fresh, well-mixed, and uncentrifuged. If the urine depth is less than about 3 inches (7.6 cm), pour the specimen into a narrow tube, such as a URIN-TEK® Specimen Tube.

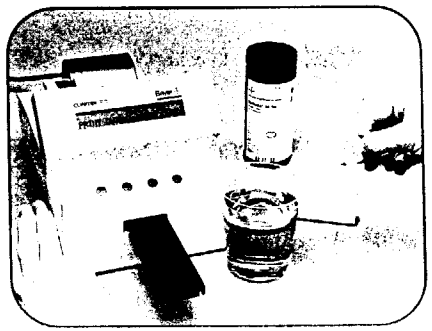
Testing can be started only from the READY FOR TEST screen. Be sure the Reagent Strip name agrees with the strip being used.

1 Dip a Bayer Reagent Strip into the urine. Be sure *all* the test pads are wet.

Refer to the direction insert included with your Reagent Strips for complete information on using the strips.



2 Immediately remove the Reagent Strip from the urine, dragging the edge of the strip against the side of the container as you remove the strip. At the same time, press the ◇ (START) key. You now have 10 seconds to complete Steps 3 and 4.



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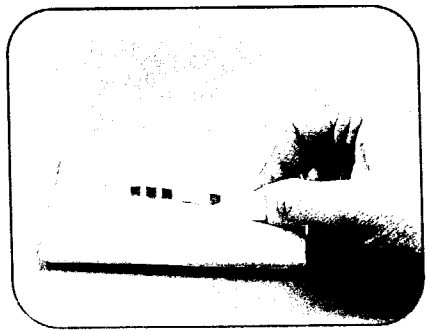
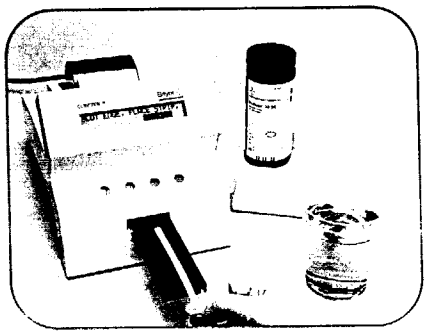
4 Blot the strip by ***touching the edge*** to a paper towel. Do not drag the strip across the towel; touch the edge only.

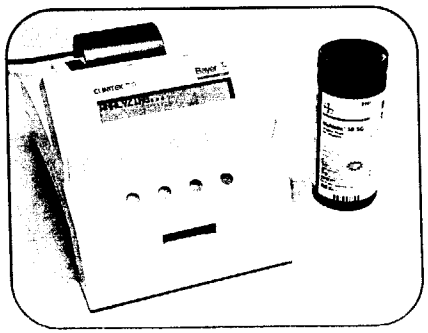


5 Place the Reagent Strip, **with the test pads facing up,** into the trough of the test strip table. Slide the strip along the table until it touches the end of the trough.

☞ **You must place the test strip while the message BLOT EDGE, PLACE STRIP is on the screen. It will appear for 10 seconds.**



6 The table is pulled into the instrument for reading. Results are available in one minute.



7 Remove the used Reagent Strip and discard it in the proper container.

If results are printed:
The test results are automatically printed. Press the **PRINT** key to reprint the last set of test results. Press **PAPER,** if desired, to add blank lines after the results.

If results are displayed:
To view results, press the ↓ key repeatedly. When all results have been displayed and recorded, press **EXIT.** To display the results again, press **DISPL.**

✎ *Wipe the test strip table with a damp, lint-free tissue as often as needed to prevent urine from building up. Also, wipe the table after testing a urine that is visibly bloody or that gives a very high result on any test pad.*

☞ **Thermal print will fade with time. Also, do not cover thermally printed results with transparent tape.**

Summary of Steps

1 **Dip** a new Reagent Strip into the urine sample.

2 **Press** ◇ as the strip is removed from the urine; at the same time, drag the strip edge against the side of the container.

3 **Blot** by touching the edge of the strip to a paper towel;

4 **Place** it on the test strip table within 10 seconds.

5 **Discard** the strip when the test is finished.

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When You Are Finished Testing

1. Clean the test strip table and check the white bar at the end of each day or after testing 50 strips, whichever is more often. Follow the directions for "Daily Cleaning," given on page 17.

2. Be sure there is no Reagent Strip on the test strip table. Then gently push the table about halfway into the instrument.

3. The instrument can be left *on* when it is not being used. However, if you are using the battery pack, turn the instrument *off* to save battery power.

*You will be prompted to clean the table after every 50 strips. Press **CONT** to return to the READY FOR TEST screen.*

If the battery pack is installed, a unique tone will sound after 15 minutes of nonuse to remind you to turn the instrument off. It will repeat in 5 minutes, then again every minute.

Operating Notes

- The instrument does not detect when the internal printer is out of paper. However, a pink edge will appear on the last several feet of paper. Change the roll shortly after you see this.

- If you never erase the memory or reset the sequence number, the number will continue to increase until 999 is reached. The next number will then be 001.

Cleaning the Instrument 5

Daily Cleaning

The test strip table must be kept clean if the instrument is to provide accurate test results and operate correctly. Clean the table and check the white bar at the end of every day.

1. Remove the test strip table by pulling it straight out of the instrument.

2. Wet a cotton-tipped stick with distilled water. Thoroughly scrub the trough and surrounding areas. Rinse the entire table (both top and bottom) with distilled water.

3. Dry the table thoroughly (except for the white bar) with a soft cloth or lint-free tissue.

4. Check the white bar for dust, marks, or scratches. If it is dirty, wet a new cotton-tipped stick and gently wipe the bar. Allow the white bar to air dry and check it again. If it is scratched or scuffed, or if it cannot be cleaned, replace the table (see page 26).

5. If you want to disinfect the table, do that now. Or insert the table into the instrument.

Do not touch the white bar.

Do not use anything that will scratch the white bar. Do not use solvents of any kind to clean the bar.

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

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Disinfecting the Table

1. Remove, clean, and dry the table.

2. Several solutions are safe to use on the table when they are used for no longer than 10 minutes once a day. Prepare one of the following solutions:

▲ **Cidex,™* Theracide,*** and **Amphyl®*** — these products (or their equivalent) can be purchased for use in general disinfection. Prepare and use the solution according to the directions that come with the product.

▲ **Household Bleach** (5% sodium hypochlorite) — can be used either full strength or diluted to as much as a 1:20 dilution. To make a 1:20 dilution, add 5 mL of bleach to a container and add 95 mL of water, for a total volume of 100 mL. (To make a 1:10 dilution, combine 10 mL of bleach and 90 mL of water.)

▲ **Isopropyl Alcohol** (70% to 85%) — can be used full strength.

☞ **Use of any other solution may damage the table.**

* **Cidex** (trademark of Surgikos, Inc., Arlington, TX) is a 3.2% glutaraldehyde solution.
Theracide (distributed by T Prime Technologies, Inc., Houston, TX) is a quaternary ammonium solution.
Amphyl (registered trademark of National Laboratories, L&F Products, Montvale, NJ) is a phenol solution.

3. Fill a tall, narrow container to a depth of about 4 inches (10 cm) with the solution you have prepared.

4. Place the table into the solution, making sure the white bar remains above the liquid level.

☞ **Be sure the solution does not come in contact with the white bar! Do not cover the container while the table is soaking.**

5. Soak the table for no longer than 10 minutes, then rinse it thoroughly with water.

6. Dry the table with a soft cloth or tissue and insert it into the instrument.

Removing Heavy Buildup

If the table is cleaned each day, heavy buildup should not occur. However, if the urine has dried on the table for many days, you may need to use a stronger solution to clean the table completely.

1. Obtain a small volume of 0.1N sodium hydroxide (NaOH).

2. Remove the table from the instrument and clean it.

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3 Wet a cotton-tipped stick with the NaOH. Thoroughly clean the trough and side areas of the table until all urine is removed.

4 Rinse the table **thoroughly** with water to remove the NaOH.

5 Wipe the surface of the table and the grooves on the under side of the table with a damp cloth. Then dry the table with a soft cloth or tissue and insert it into the instrument.

☞ **Do not touch the white bar with the NaOH!**

General Cleaning

Always keep the outside of the CLINITEK® 50 instrument clean and free of dust. You can wipe the outside with a *damp* (not wet) cloth and a mild detergent.

Wipe the display screen with a soft, nonabrasive cloth that has been dampened with a mild glass cleaner. Do not spray the glass cleaner directly onto the screen. Do not use laboratory wipes, such as Kimwipes,® since they may scratch the screen.

☞ **Do not use any type of solvent, oil, grease, silicone spray, or lubrication on the instrument.**

The keypad and display may be disinfected using the same solutions as for the test strip table (see page 18). Wipe the solution on and allow to remain for 10 minutes. Rinse using a clean cloth dampened with water, then dry.

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

Appendix

Solving Problems

Your CLINITEK® 50 Analyzer will give you trouble-free operation if you follow the directions for using and cleaning the instrument. If a problem occurs, however, an error message will be displayed. Follow the steps on the next page to help solve the problem.

If the Bayer Reagent Strips seem to be causing the problem, carefully read the direction insert that comes with the Reagent Strips for information that might help solve the problem.

If the Display is Blank

If there are no words on the display after the instrument has been turned *on*, check for each of these possible causes:

- **The printer cover is not latched:** This might occur only if the serial number of your instrument begins with "6510A." If the cover is unlatched, the instrument turns itself *off;* it turns *on* again when the cover is snapped shut. *If a strip was being read or results being printed when the cover was raised, the results will be lost and the specimen must be retested.*

- **The power cord is not plugged in:** Check the connections at the instrument, transformer, and wall outlet.

- **The batteries in the battery pack are dead:** Place fresh batteries into the pack.

- **The instrument is broken:** Contact Customer Service (see page 24).

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Error Message	Possible Cause and Remedy
REPLACE BATTERIES	The batteries do not have enough power to test any more strips. Turn the power *off* and replace the batteries.
READING PROBLEM-RETEST HELP CONT	The test strip is either upside down or was not fully dipped. Discard the strip, press **CONT**, and retest with a new test strip.
STRIP PROBLEM-RETEST HELP CONT	A test strip is either not present or not positioned properly, or the short table is being used when the long table is required. Discard the strip, then press **CONT** and retest using a new test strip and the correct table.
TABLE PROBLEM-RETEST HELP CONT	The test strip table is not in its correct position. The instrument or table may have been moved or bumped during testing, or the bottom of the table may be dirty. Discard the strip. Remove and clean the table, then reinsert. Press **CONT** and retest with a new test strip.
INSTRUMENT ERROR #X HELP CONT	Error #5: The long table is being used when the short table is required. Insert the proper table and retest with a new test strip. All other Error #'s: Discard the strip. Turn the instrument *off*, wait several seconds, then turn it back *on*. If the error occurs again, contact Customer Service (see page 24).

If you need additional help with an instrument or Reagent Strip problem, our Customer Service Department is here to assist you. Before you call, please fill out this checklist (you may want to make a photocopy of the page first). Then call the nearest Bayer office using the list on the next page.

CLINITEK® 50 Problem Checklist

Serial Number _ _ _ _ _ _ _ _ _ _ _ _

Installation Date _____

	YES	NO
1. Have you reviewed the error messages on page 22?	☐	☐
2. Does the test strip table move out to the "load" position when the Analyzer is first turned *on?*	☐	☐
3. If Step 2 is NO —		
• Is the power cord plugged into a live electrical outlet, into the transformer, and then into the Analyzer?	☐	☐
• If using the battery pack, are the batteries fully charged and correctly placed in the pack and the cord plugged into the Analyzer?	☐	☐
4. Does the display show the expected messages? (If the display is blank, see page 21 for possible causes.)	☐	☐
5. Does the test strip table move into the Analyzer shortly after the ◇ key is pressed?	☐	☐
6. Does a Bayer Reagent Strip dipped into a negative control provide correct results?	☐	☐
• Has a second Reagent Strip been tried?	☐	☐
7. Is the name of the Reagent Strip shown on the display the same as the product being used?	☐	☐
8. Does the display or printout show the correct test names and reasonable results?	☐	☐
9. Is the test strip table or the white bar dirty, scratched, or damaged?	☐	☐
10. Does the test strip table operate correctly?	☐	☐

If not, describe: _____

_____

11. Please record any error messages that have been displayed:

_____

_____

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

Where to Call for Service

If you are located in the United States, contact the Customer Service Department of Bayer Corporation by calling toll free:

1-800-348-8100

The office is open from 8:00 AM to 8:00 PM Eastern Time.

If you are located in a country other than the United States, call the Bayer office that is nearest you:

Canada
Bayer Inc. Healthcare Division
77 Belfield Road
Etobicoke, Ontario M9W 1G6
Telephone: 416-248-0771

U.K.
Bayer Diagnostics
Bayer Plc, Evans House
Hamilton Close
Basingstoke, Hampshire RG21 6YE
Telephone: 01 256 29 181

Australia
Bayer Australia Ltd.
Healthcare Division
875 Pacific Highway
Pymble NSW 2073
Telephone: 61 2 391-6400
1-800-028-251

East Asia, Pakistan, Sri Lanka, Bangladesh
Bayer (Singapore) Pte, Ltd.
Regional Headquarters BG-DS
9 Benoi Sector
Singapore 629844
Telephone: 65 261-3389
Fax: 65 266-3376

Ordering Accessories

Product No.	Description
6511	Battery Pack and Batteries
5773	Thermal Printer Paper (5 rolls)
1364	CHEK-STIX® Combo Pak Control Strips (1 bottle each — Positive and Negative Control Strips)
1360	CHEK-STIX® Positive Control Strips for Urinalysis (1 bottle of 25 strips)
1365	CHEK-STIX® Negative Control Strips for Urinalysis (1 bottle of 25 strips) (not available in the U.S.A.)
6517	Computer Cable/Connector Kit

Where to Order:

In the United States, you can order these accessory items directly from your authorized CLINITEK distributor.

In countries other than the United States, you can order these accessory items through your nearest Bayer office. You can find the address and phone number on page 24.

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

Ordering Replacement Parts

Part No.	Description
95001874	Test Strip Table — Long (labeled "L") (for use with Reagent Strips with five or more tests)
95001875	Test Strip Table — Short (labeled "S") (for use with Reagent Strips with four or fewer tests)
50062316	Printer Cover

Where to Order:

In the United States, you can order these replacement parts directly from:

Instrument Service
Bayer Corporation
P.O. Box 2004
Mishawaka, IN 46546

or by calling toll free:
1-800-348-8100

In countries other than the United States, you can order these replacement parts through your nearest Bayer office. You can find the address and phone number on page 24.

Specifications

Power Required:

Power Transformer:
Input: 100-250 V~, 50/60 Hz, 0.5-0.3 A
Output: +9 V ⎓, 2.78 A

Optional Battery Pack —
Holds 6 "AA" standard alkaline or rechargeable NiCad batteries

Up to 200 tests can be run when using new alkaline batteries, fewer with rechargeable batteries.

Instrument Fuse:
4A, 63V, Quick-Acting
(not replaceable by the user)

Line Leakage Current:

<0.5 milliamperes in normal condition
<3.5 milliamperes in single fault condition
(Testing protocol and allowable limits as specified by the safety standards for laboratory equipment outlined in UL 3101-1, CSA 22.2, No. 1010.1, and IEC 1010-1.)

Computer Interface:

Customized RJ11 Cable
(For use in connecting to a computer only)

Dimensions:

Depth — 23.5 cm (9.2 in.)
Width — 15.2 cm (6.0 in.)
Height — 15.5 cm (6.1 in.)

Weight:

Instrument only — 1.25 kg (2.8 lbs.)
Instrument with Battery Pack — 1.42 kg (3.1 lbs.)

Ambient Operating Temperature Range:

18°C to 30°C (64°F to 86°F)

Optimum Operating Temperature Range:

22°C to 26°C (72°F to 79°F)

Ambient Operating Humidity Range:

20% to 85% Relative Humidity

Safety Standards:

The CLINITEK® 50 Urine Chemistry Analyzer (Models 6510 and 6510A) conforms to the Low Voltage Safety Directive 73/23/EEC. The instrument is listed by the Underwriters' Laboratories, Inc. (UL) and the Canadian Standards Association (CSA) as certified and complies with the safety standards specified in UL 3101 and CSA-C22.2, No. 1010.1

Model 6510A conforms to EMC Directive 89/336 Amendment 92/31/EEC.

Warning:

This instrument must be used in the manner specified in this User's Guide in order to provide the safety and performance standards specified.

Symbols:

⚠ Refer to User's Guide for complete information.

⎓ DC Voltage Power Input

10101 Computer Interface

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Test	Abbre-viation	Units	Printed/Displayed Results	
			Normal System	+ / – System
Glucose	GLU	mg/dL	NEGATIVE 500 100 > = 1000 250	NEGATIVE 2+ TRACE 3+ 1+
Bilirubin	BIL		NEGATIVE MODERATE SMALL LARGE	NEGATIVE 2+ 1+ 3+
Ketone	KET	mg/dL	NEGATIVE 40 TRACE > = 80 15	NEGATIVE 2+ TRACE 3+ 1+
Specific Gravity	SG		< = 1.005 1.020 1.010 1.025 1.015 > = 1.030	No Difference
pH	pH		5.0 6.5 8.0 5.5 7.0 8.5 6.0 7.5 > = 9.0	No Difference
Protein	PRO	mg/dL	NEGATIVE 100 TRACE 300 30	NEGATIVE 2+ TRACE 3+ 1+
Urobilinogen	URO	E.U./dL	0.2 4.0 1.0 > = 8.0 2.0	No Difference
Nitrite	NIT		NEGATIVE POSITIVE	No Difference
Occult Blood	BLO		NEGATIVE SMALL TRACE-LYSED MODERATE TRACE-INTACT LARGE	NEGATIVE 1+ TRACE-LYSED 2+ TRACE-INTACT 3+
Leukocytes	LEU		NEGATIVE MODERATE TRACE LARGE SMALL	NEGATIVE 2+ TRACE 3+ 1+
Color*			YELLOW GREEN ORANGE BLUE RED BROWN	No Difference

*Color may be preceded with "LT." or "DK."

Table 1

ENGLISH — CONV.
Units — Conventional

Test	Abbre-viation	Units	Printed/Displayed Results	
			Normal System	+ / – System
Glucose	GLU	mmol/L	NEGATIVE 28 5.5 > = 55 14	NEGATIVE 2+ TRACE 3+ 1+
Bilirubin	BIL		NEGATIVE MODERATE SMALL LARGE	NEGATIVE 2+ 1+ 3+
Ketone	KET	mmol/L	NEGATIVE 3.9 TRACE > = 7.8 1.5	NEGATIVE 2+ TRACE 3+ 1+
Specific Gravity	SG		< = 1.005 1.020 1.010 1.025 1.015 > = 1.030	No Difference
pH	pH		5.0 6.5 8.0 5.5 7.0 8.5 6.0 7.5 > = 9.0	No Difference
Protein	PRO	g/L	NEGATIVE 1.0 TRACE > = 3.0 0.3	NEGATIVE 2+ TRACE 3+ 1+
Urobilinogen	UBG	µmol/L	3.2 66 16 > = 131 33	No Difference
Nitrite	NIT		NEGATIVE POSITIVE	No Difference
Occult Blood	BLD	Ery/µL	NEGATIVE Ca 25 TRACE-LYSED Ca 80 TRACE-INTACT Ca 200	NEGATIVE 1+ TRACE-LYSED 2+ TRACE-INTACT 3+
Leukocytes	LEU	Leu/µL	NEGATIVE Ca 125 Ca 15 Ca 500 Ca 70	NEGATIVE 2+ TRACE 3+ 1+
Color*			YELLOW GREEN ORANGE BLUE RED BROWN	No Difference

*Color may be preceded with "LT." or "DK."

Table 2

ENGLISH — S.I.
Units — International (S.I.)

Test	Abbre-viation	Units	Printed/Displayed Results	
			Normal System	+ / – System
Glucose	GLU		NEGATIVE 3+ 1+ 4+ 2+	NEGATIVE 2+ TRACE 3+ 1+
Bilirubin	BIL		NEGATIVE 2+ 1+ 3+	No Difference
Ketone	KET		NEGATIVE 3+ 1+ 4+ 2+	NEGATIVE 2+ TRACE 3+ 1+
Specific Gravity	SG		< = 1.005 1.020 1.010 1.025 1.015 > = 1.030	No Difference
pH	pH		5.0 6.5 8.0 5.5 7.0 8.5 6.0 7.5 > = 9.0	No Difference
Protein	PRO		NEGATIVE 2+ +/ 3+ 1+	NEGATIVE 2+ TRACE 3+ 1+
Urobilinogen	URO	µmol/L	3.2 66 16 > = 131 33	No Difference
Nitrite	NIT		NEGATIVE POSITIVE	No Difference
Occult Blood	BLD		NEGATIVE 1+ + / – 2+ + / – INTACT 3+	No Difference
Leukocytes	LEU		NEGATIVE 3+ 1+ 4+ 2+	NEGATIVE 2+ TRACE 3+ 1+
Color*			YELLOW GREEN ORANGE BLUE RED BROWN	No Difference

*Color may be preceded with "LT." or "DK."

Table 3

ENGLISH — NORDIC
Units — Nordic Plus System

Addendum

Technical Information for Professional Users

Description of Optical System

The optical system consists of an incandescent lamp and a photodiode pack that contains four filters, one each at 400-510 nm (blue), 510-586 nm (green), 586-660 nm (red), and 825-855 nm (IR).

The lamp illuminates a fixed "read area" that is specially situated to reflect light back into the photodiode pack. The feed table moves the calibration chip and Reagent Strip test areas into the read area for instrument reading.

Light reflected from the surface of the reagent test area is detected by the photodiode pack, where it is converted into electrical impulses. The impulses are processed by the instrument's microprocessor and converted into clinically meaningful results that are shown on the display screen or printed by the internal printer.

Description of Internal Checks

When the CLINITEK® 50 Analyzer is first turned *on,* the instrument does a series of electronic, signal, and memory checks, as well as ensuring there is sufficient battery voltage to operate the instrument (if the optional battery pack is being used).

Each time a Reagent Strip is read, the instrument positions the table correctly and checks the electronics and signals. It then takes reference readings of the white plastic bar on the test strip table. The readings are taken at each of the four wavelengths and are then used as part of the ratio and calculation to determine the sample readings. When all readings have been taken, the position of the table is again checked to ensure that all pads were read in their proper location.

Differences Between the Human Eye and Instrumental Optics

There are inherent differences between the colors that are perceived by the human eye and that are detected by any instrumental optical system. The human eye is capable of detecting minute differences in shade and very small areas of color; artificial optical systems are less sensitive to such small changes. Conversely, instrumental optics are capable of detecting certain colors that are masked by or blended with other colors to the human eye.

For this reason, exact agreement between visual results and instrumental results might not be found. However, agreement is generally within one visual color block or reported level and is equal to or better than the agreement between two visual readers. Agreement of urine color is generally within one step along the chromatic scale.

New Information
CLINITEK® 50 User's Guide

General Information

The software in your CLINITEK® 50 Analyzer now supports a new line of products from Bayer. When one of the new tests is placed onto the feed table and pulled into the instrument for reading, the instrument automatically determines its identity. If the test is recognized, the instrument reads it at the appropriate time(s) without any user intervention. (A message is displayed if the new test is not recognized.)

This sheet describes the changes you will see with the new software; place the sheet into your CLINITEK® 50 User's Guide. **Refer to the direction insert included with each new product for information on using the test with the instrument.**

Refer to Sections 1 and 2 in the User's Guide to unpack and set up the instrument and to select your options. A new option of **LIST** (described next) is shown on the READY FOR TEST screen.

Listing the Tests

You can print or display a list of the selected Bayer Reagent Strip and the new CLINITEK® Tests that can be used with your instrument through the **LIST** option on the READY screen.

1. Press the key under the word **LIST**.
2. If PRINTER has been selected as the output, the list is printed. If DISPLAY was selected, press the ↓ key to display each test name, then press **EXIT**.

If the CLINITEK® Test you want to use is not listed, the software in your Analyzer must be updated before using the product. Refer to "Ordering Accessories" in your User's Guide for information on where to order the Software Update Kit (Product No. 6521).

Error Message

If the test being used cannot be identified by the software, the following error message is displayed:

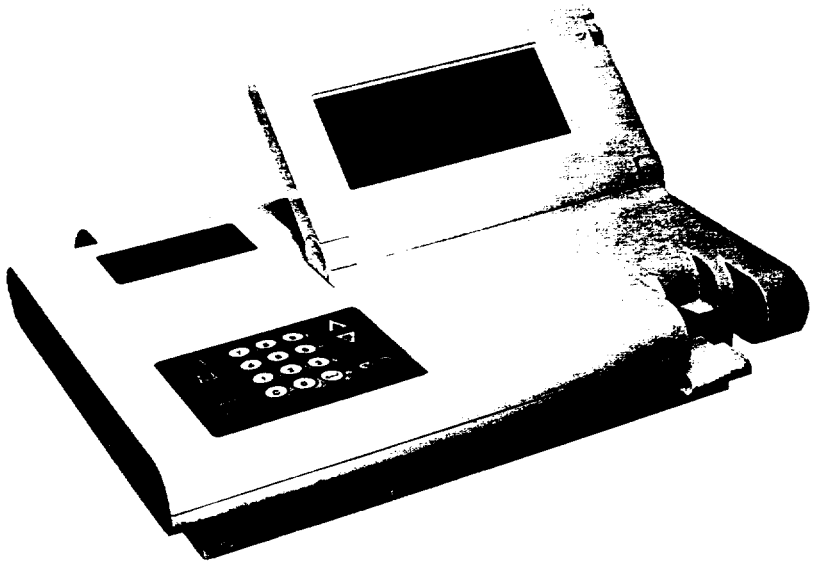
```
STRIP PROBLEM-RETEST
HELP                CONT
```

(This message is also displayed if a test strip is either not present or not positioned properly.) Discard the strip, press **CONT**, and press **LIST** to see if your test can be used.

Bayer
Bayer Corporation
Elkhart, IN 46515 USA
Rev. 7/97

CLINITEK® 100

Urine Chemistry Analyzer



Operating Manual

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Elkhart, IN 46515 USA

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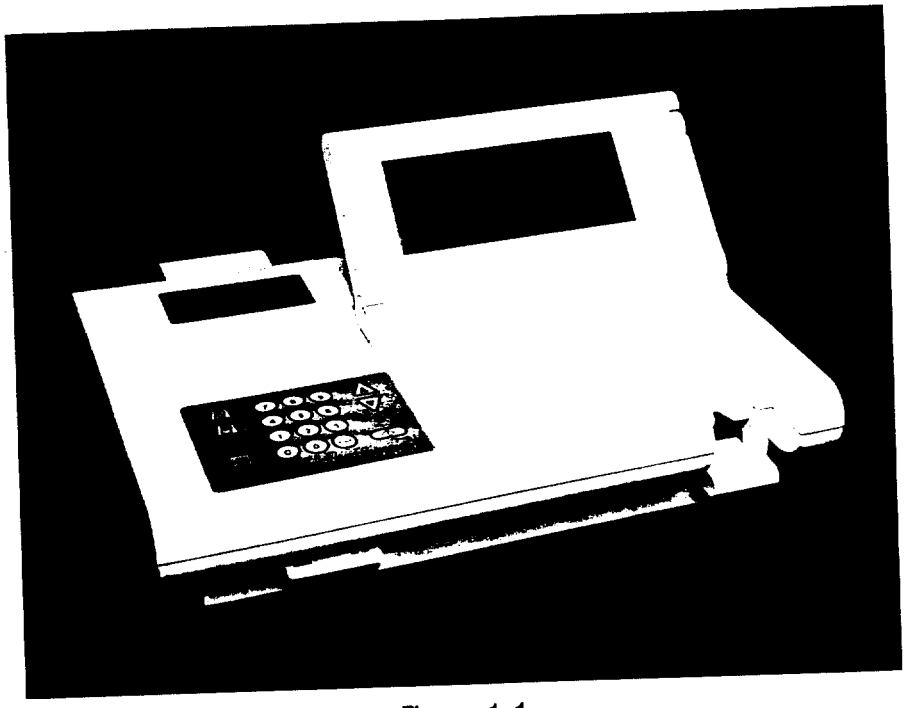

Figure 1-1
CLINITEK® 100 Urine Chemistry Analyzer

Figure 1-2
Front of the Instrument

Section 1

INTRODUCTION

General Description

The CLINITEK® 100 Urine Chemistry Analyzer (Figure 1-1) is a semiautomated, benchtop instrument designed to "read" Bayer Diagnostics Reagent Strips for Urinalysis. The instrument system includes a Program Card that contains the programming necessary for the CLINITEK 100 instrument to read these Reagent Strips. The instrument is initially configured to read MULTISTIX® 10 SG Reagent Strips; in the United States, MULTISTIX® 9 and URISTIX® 4 Reagent Strips are also qualified for use. Outside of the United States, contact your Bayer Diagnostics representative or office for the products that can be used in your country.

Depending on the product being used, Bayer Diagnostics Reagent Strips contain reagent areas for testing glucose, bilirubin, ketone (acetoacetic acid), specific gravity, occult blood, pH, protein, urobilinogen, nitrite, and leukocytes. The CLINITEK 100 instrument is a reflectance photometer that analyzes the color and intensity of the light reflected from the reagent area and displays the results in clinically meaningful units (see Tables 1-1 through 1-8). No calculations are required.

Components and Mechanical Operation

Figures 1-2 through 1-4 show the major components of the CLINITEK 100 instrument. Reagent Strips are loaded onto the reagent strip feed table (1), which will automatically move out to the "load" position when the instrument is first turned *on*. Test results are printed by the internal thermal printer (2) (unless this option is deselected by the user). All communications between the operator and the instrument are made through the keyboard (3) and the display screen (4). The keyboard consists of 10 numeric keys (0 to 9), plus several special function keys. The display screen is an 8-line, 40-character liquid crystal display (LCD). Test results are displayed on the screen, in addition to multiple choice menus for selecting various modes and functions of the instrument. Selections from the menus and requested information are entered directly from the keyboard.

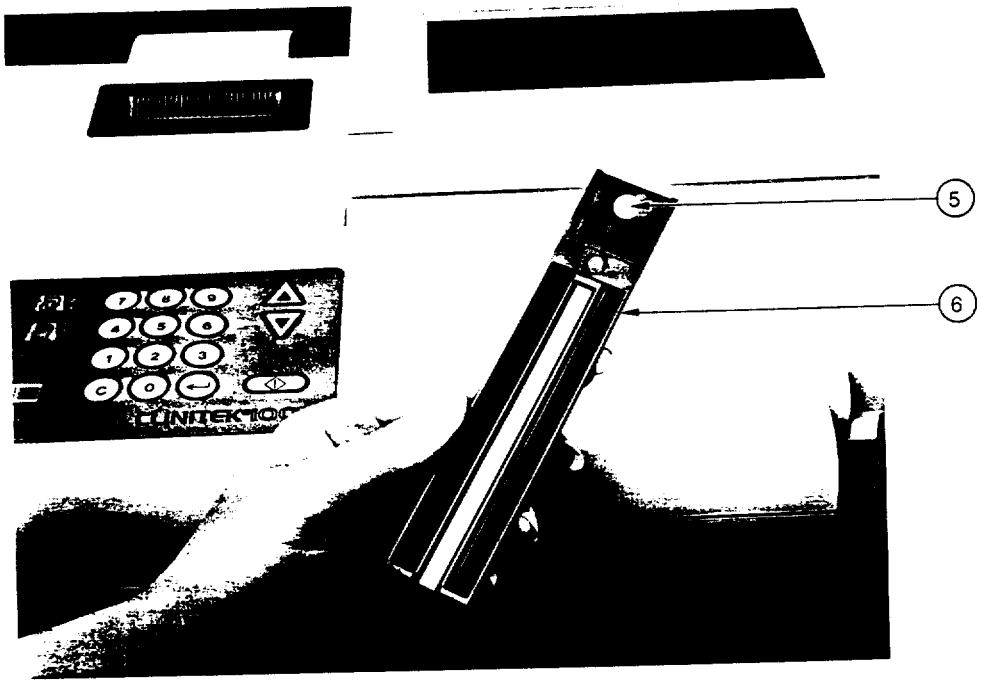

Figure 1-3
Reagent Strip Insert

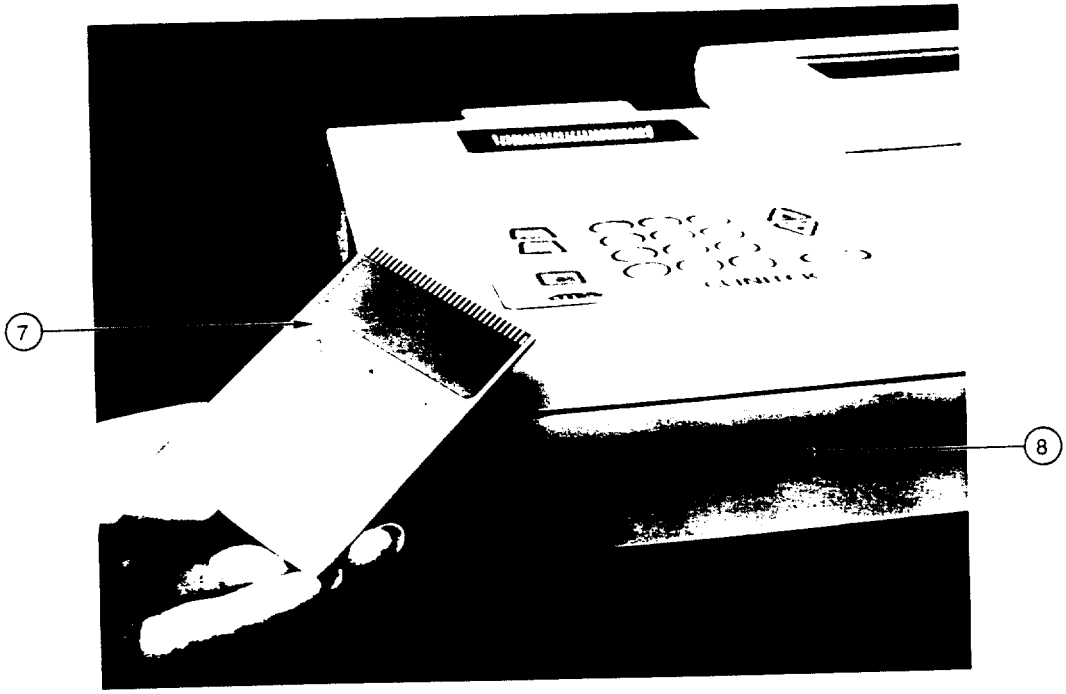

Figure 1-4
Program Card and Receptacle

When the CLINITEK 100 instrument is first turned *on,* an optical calibration and self-test procedure is performed, during which the position of the feed table is checked and the light intensity of the optical system is checked and calibrated. Each time a Reagent Strip is read, another calibration procedure is performed, using a white plastic chip (5) that is located on the feed table insert (6). This calibration chip provides a reference reflectance surface for the internal calibration of the instrument's optical system. Calibration is accomplished automatically by the measurement of reflected light from the calibration chip surface. The calibration chip must be kept clean for proper instrument calibration.

All programming for the instrument is contained in a replaceable Program Card (7). The program card is programmed with such information as wavelengths, error messages, operating sequence, and the algorithms needed to convert reflectance into clinically meaningful results. The program card is inserted into the card receptacle (8).

Figure 1-5 shows the rear view of the CLINITEK 100 instrument. The line cord connects into the line cord receptacle (9), which is located on the power module (10). The power switch (11) is also located on the power module, as is the fuse holder (12), which protects against serious electrical overload. The interface connectors (13) are the points at which a computer and/or a form or 80-column printer may be interfaced with the instrument.

The instrument stores the operating parameters and up to 100 sets of patient results in a battery-backed RAM memory. This memory is saved in the instrument regardless of whether the power is *on* or *off.*

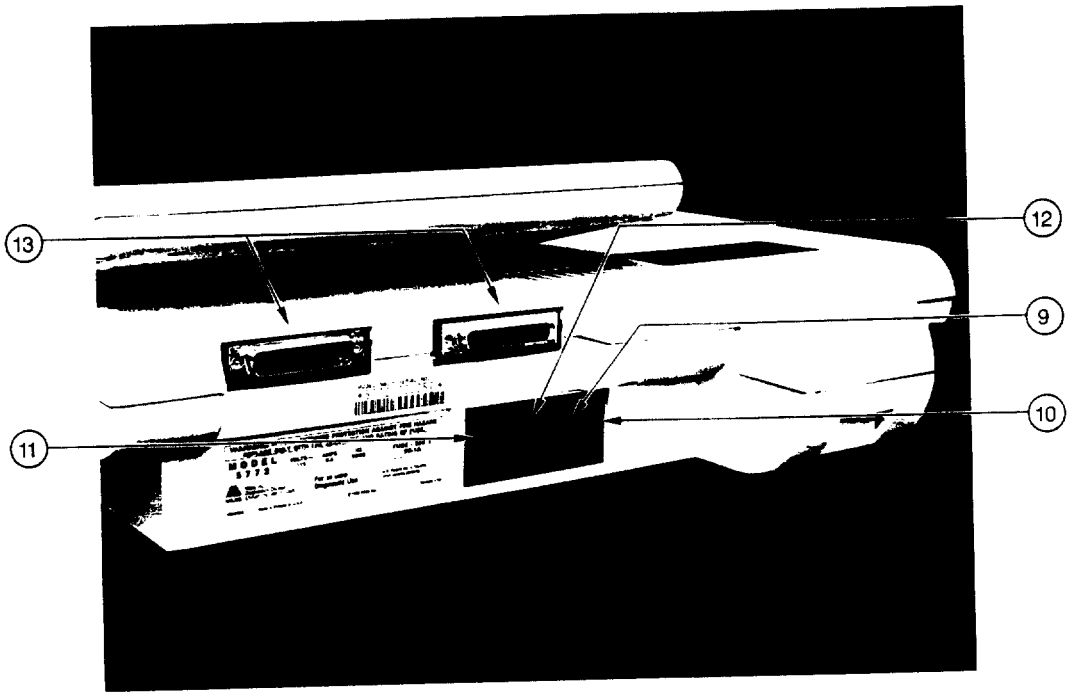

Figure 1-5
Rear of the Instrument

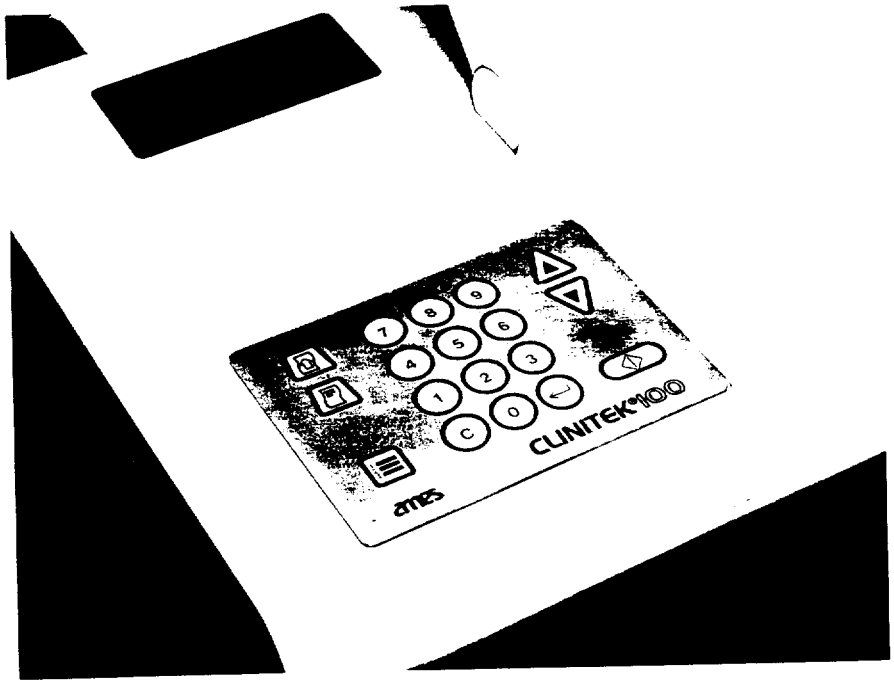

Figure 1-6
Keyboard

Keyboard

The keyboard (Figure 1-6) consists of a 10-digit numeric keypad (0 to 9) and 8 additional function keypads. A small green light is also located on the keyboard, directly above the [◇] key; this light illuminates when the power is turned *on.*

[0] to [9]	These keys are used to enter numerical information requested in the various displays.
[◇] (START)	When this key is pressed, the instrument begins a timed analysis sequence that includes mechanical operation of the feed table. Pressing the [◇] key (START) when the instrument is in the **Analyze** Mode has no effect on instrument operation, as the key is inoperable during this mode. Movement of the feed table is delayed 10 seconds after pressing [◇]. The delay allows for placement of the Reagent Strip onto the feed table and for reactions of the reagent test areas.
[≡] (MENU)	Pressing this key causes the display to return to the most previous menu screen (or in certain cases, directly back to the Main Menu). If a numeric entry is requested on a display, any changes made will be retained *only* if the [↵] key is pressed prior to pressing [≡]. The display can be returned to the Main Menu by pressing this key one or more times.

↵ (ENTER)	Pressing this key ends the input for the current field for which data is being entered or accepts the information that is currently highlighted or displayed.
C (CLEAR)	If an error is made in entering numerical information, this key can be pressed prior to pressing ↵ to erase any previously entered digits, allowing for them to be entered again. Once ↵ has been pressed, the C (CLEAR) key has no effect.
▲ (UP ARROW) ▼ (DOWN ARROW)	These two keys move the highlighting on a multiple choice menu to the next or previous line item. The movement of the arrow keys is circular; that is, if the first menu item is highlighted, pressing ▲ will cause the last item to be highlighted, and vice versa for the ▼ key. When the desired menu item is highlighted, pressing ↵ will cause that item to be selected.
(PRINT)	This key is used to print the results that are displayed when data files are recalled from memory (Data Recall Routine) or to reprint the displayed results while in the **Analyze** Mode (the instrument automatically prints each set of test results as soon as all results are available if either the internal or external printer has been selected).
(FEED PAPER)	Each time this key is pressed, the paper in the internal printer will be moved up 2 lines.

Reagent Strip Feed Table

The reagent strip feed table is a two-piece assembly designed to correctly hold and transport a Bayer Diagnostics Reagent Strip through the testing cycle. A Reagent Strip that has been dipped into a urine specimen and had excess urine removed must be correctly positioned in the strip holding channel, with the end of the strip positioned against the rear barrier of the feed table insert. **CAUTION: Avoid placing objects in the path of or onto the feed table at any time during instrument operation. Never push or pull the feed table during instrument operation.**

The feed table insert can be removed for cleaning and must always be correctly repositioned on the feed table. The insert is held in position by two rails and four plastic contact points, located under the insert (Figure 1-7). If a contact point becomes damaged, the feed table insert will not be properly held in place on the feed table and the Reagent Strips will not be properly positioned on the feed table insert. **Therefore, a defective feed table insert should always be replaced.**

The feed table insert contains the white plastic calibration chip that is used for instrument calibration. This calibration chip must be kept clean for proper instrument calibration (see Section 6, "Daily Cleaning"). The chip should be inspected periodically for scratches and scuffs; if damaged, the feed table insert should be replaced.

The feed table has two rest positions—out or "load" position, and in or "storage" position. The feed table will automatically move out to the "load" position when the instrument is turned *on.* To place the feed table in the "storage" position, gently push the table in to the end stop. **When the instrument is not in use, the feed table should be placed in the "storage" position.**

Figure 1-7
Underside of Reagent Strip Feed Table

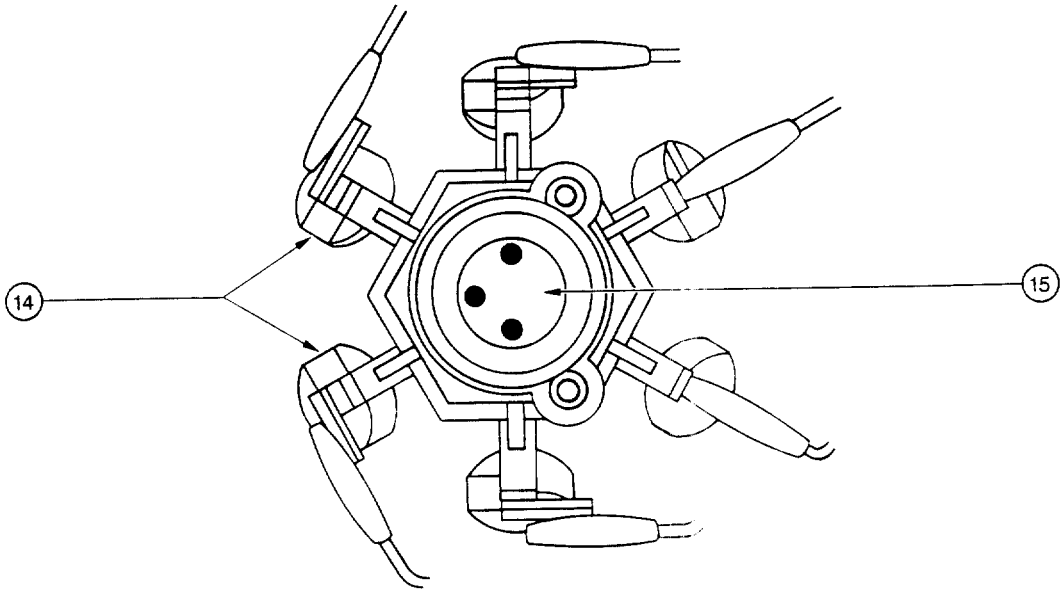

Figure 1-8
Optical System

Optical System

The optical system (Figure 1-8) consists of six LEDs (Light Emitting Diodes) and a photodiode. There are three pairs of LEDs (14), two each at 557 nm (green), 610 nm (amber), and 660 nm (red). The LEDs are situated in a circle around the photodiode (15), with each member of the matched pairs located directly across from one another.

The LEDs illuminate a fixed "read area" that is specially situated to reflect light back into the photodiode. The feed table moves the calibration chip and Reagent Strip test areas into the read area for instrument reading. The LEDs are automatically switched on and off for each strip reading cycle, and are electronically regulated to maintain a constant light output during each reading cycle. The illumination of the LEDs may be seen against the dark background of the feed table about an inch inside the instrument.

Light reflected from the surface of the reagent test area is detected by the photodiode where it is converted into electrical impulses. The impulses are processed by the instrument's microprocessor and converted into clinically meaningful results that are shown on the display screen and printed by the internal printer.

Specifications

Power Required:
115 VAC +10% / −15% 50/60 Hz
Optional—
100 VAC +10% / −15% 50/60 Hz
220 VAC +10% / −15% 50/60 Hz
240 VAC +10% / −15% 50/60 Hz

NOTE: The CLINITEK 100 instrument has been manufactured and inspected as a 115 VAC instrument. Before being used at any voltage other than 115 VAC, the instrument line cord, fuse, and/or rating label must be changed in order to comply with the specific requirements of each country.

***Line Leakage Current:**
<5 milliamperes

Dimensions:
Depth—32.0 cm (12.6 in.)
Width—39.4 cm (15.5 in.)
Height—11.2 cm (4.4 in.)
With display screen up:
21.6 cm (8.5 in.)

Weight: 3.86 kg (8.5 lbs.)

Ambient Operating Temperature Range:
18°C to 30°C (64°F to 86°F)

Ambient Operating Humidity Range:
20% to 85% Relative Humidity

Optimum Operating Conditions:
22°C to 26°C (72°F to 79°F) / 30% to 60% Relative Humidity
NOTE: Because of the nature of the urobilinogen and leukocytes reagent areas found on Bayer Diagnostics Reagent Strips, results for these two tests may be decreased at temperatures or humidity below the optimum conditions and vice versa.

The CLINITEK® 100 Urine Chemistry Analyzer (Models 5772 and 5772C) is listed by the Underwriters' Laboratories (UL) and the Canadian Standards Association (CSA) as certified. Model 5772C conforms to EMC Directive 89/336 Amendment 92/31/EEC and to the Low Voltage Safety Directive 73/23/EEC.

*Testing protocol and allowable limits as specified by the safety standards for laboratory equipment outlined in UL1262 and CSA 22.2 No. 151.

Test	Printed Abbre-viation	Units	Measured Values	
			Standard (Default) System	PLUS System
Glucose	GLU	mg/dL	Negative 500 Trace >=1000 250	Negative 2+ Trace 3+ 1+
Bilirubin	BIL		Negative Moderate Small Large	Negative 2+ 1+ 3+
Ketone	KET	mg/dL	Negative 40 Trace >=80 15	Negative 2+ Trace 3+ 1+
Specific Gravity	SG		<=1.005 1.020 1.010 1.025 1.015 >=1.030	No Difference
pH	PH		5.0 7.5 5.5 8.0 6.0 8.5 6.5 >=9.0 7.0	No Difference
Protein	PRO	mg/dL	Negative 100 Trace >=300 30	Negative 2+ Trace 3+ 1+
Urobilinogen	URO	EU/dL	0.2 4.0 1.0 >=8.0 2.0	No Difference
Nitrite	NIT		Negative Positive	No Difference
Occult Blood	BLO		Negative Moderate Trace Large Small	Negative 2+ Trace 3+ 1+
Leukocytes	LEU		Negative Moderate Trace Large Small	Negative 2+ Trace 3+ 1+

Table 1-1
Displayed/Printed Results

ENGLISH CONV.
Units—Conventional

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Test	Printed Abbre-viation	Units	Measured Values	
			Standard (Default) System	PLUS System
Glucose	GLU	g/dL	– 0.1 0.25 0.5 >=1.0	– +/– 1+ 2+ 3+
Bilirubin	BIL		– 1+ 2+ 3+	No Difference
Ketone	KET		– +/– 1+ 2+ 3+	No Difference
Specific Gravity	SG		<=1.005 1.010 1.015 1.020 1.025 >=1.030	No Difference
pH	PH		5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 >=9.0	No Difference
Protein	PRO	mg/dL	– +/– 30 100 >=300	– +/– 1+ 2+ 3+
Urobilinogen	URO	EU/dL	0.1 1.0 2.0 4.0 >=8.0	No Difference
Nitrite	NIT		– +	No Difference
Occult Blood	OB		– +/– 1+ 2+ 3+	No Difference
Leukocytes	WBC		– +/– 1+ 2+ 3+	No Difference

Table 1-2
Displayed/Printed Results

ENGLISH +/–
Units—Conventional, +/– System

Revised 2/92

Test	Printed Abbre-viation	Units	Measured Values	
			Standard (Default) System	PLUS System
Glucose	GLU	mmol/L	Negative 28 5.5 >=55 14	Negative 2+ Trace 3+ 1+
Bilirubin	BIL		Negative Moderate Small Large	Negative 2+ 1+ 3+
Ketone	KET	mmol/L	Negative 3.9 0.5 >=7.8 1.5	Negative 2+ Trace 3+ 1+
Specific Gravity	SG		<=1.005 1.020 1.010 1.025 1.015 >=1.030	No Difference
pH	PH		5.0 7.5 5.5 8.0 6.0 8.5 6.5 >=9.0 7.0	No Difference
Protein	PRO	g/L	Negative 1.0 Trace >=3.0 0.3	Negative 2+ Trace 3+ 1+
Urobilinogen	UBG	µmol/L	3.2 66 16 >=131 33	No Difference
Nitrite	NIT		Negative Positive	No Difference
Occult Blood	BLD	Ery/µL	Negative Ca80 Ca10 Ca200 Ca25	Negative 2+ Trace 3+ 1+
Leukocytes	LEU	Leu/µL	Negative Ca125 Ca15 Ca500 Ca70	Negative 2+ Trace 3+ 1+

Table 1-3
Displayed/Printed Results

ENGLISH S.I.
Units—International (S.I.)

Test	Printed Abbre-viation	Units	Measured Values	
			Standard (Default) System	PLUS System
Glucose	GLU	g/L	NEGATIF 5.0 TRACES >=10 2.5	NEGATIF 2+ TRACES 3+ 1+
Bilirubin	BIL		NEGATIF MOYEN FAIBLE FORT	NEGATIF 2+ 1+ 3+
Ketone	CET	g/L	NEGATIF 0.4 TRACES >=0.8 0.15	NEGATIF 2+ TRACES 3+ 1+
Specific Gravity	DEN		<=1.005 1.020 1.010 1.025 1.015 >=1.030	No Difference
pH	PH		5.0 7.5 5.5 8.0 6.0 8.5 6.5 >=9.0 7.0	No Difference
Protein	PRO	g/L	NEGATIF 1.0 TRACES >=3.0 0.3	NEGATIF 2+ TRACES 3+ 1+
Urobilinogen	URO	mg/dL	0.2 4.0 1.0 >=8.0 2.0	No Difference
Nitrite	NIT		NEGATIF POSITIF	No Difference
Occult Blood	SNG	GR/µL	NEGATIF env80 env10 env200 env25	NEGATIF 2+ TRACES 3+ 1+
Leukocytes	LEU	GB/µL	NEGATIF env125 env15 env500 env70	NEGATIF 2+ TRACES 3+ 1+

Table 1-4
Displayed/Printed Results

FRENCH CONV.
Units—Conventional

Test	Printed Abbre-viation	Units	Measured Values	
			Standard (Default) System	PLUS System
Glucose	GLU	mmol/L	NEGATIF 28 TRACE >=55 14	NEGATIF 2+ TRACE 3+ 1+
Bilirubin	BIL		NEGATIF MOYEN FAIBLE FORT	NEGATIF 2+ 1+ 3+
Ketone	CET	mmol/L	NEGATIF 3.9 TRACE >=7.8 1.5	NEGATIF 2+ TRACE 3+ 1+
Specific Gravity	DEN		<=1.005 1.020 1.010 1.025 1.015 >=1.030	No Difference
pH	PH		5.0 7.5 5.5 8.0 6.0 8.5 6.5 >=9.0 7.0	No Difference
Protein	PRO	g/L	NEGATIF 1.0 TRACE >=3.0 0.3	NEGATIF 2+ TRACE 3+ 1+
Urobilinogen	URO	µmol/L	3.2 66 16 >=131 33	No Difference
Nitrite	NIT		NEGATIF POSITIF	No Difference
Occult Blood	SNG		NEGATIF MOYEN TRACE FORT FAIBLE	NEGATIF 2+ TRACE 3+ 1+
Leukocytes	LEU		NEGATIF MOYEN TRACE FORT FAIBLE	NEGATIF 2+ TRACE 3+ 1+

Table 1-5
Displayed/Printed Results

FRENCH S.I.
Units—International (S.I.)

Test	Printed Abbre-viation	Units	Measured Values	
			Standard (Default) System	PLUS System
Glucose	GLU	mg/dL	Negativ 500 Spur >=1000 250	Negativ 2+ Spur 3+ 1+
Bilirubin	BIL		Negativ Maessig Schwach Stark	Negativ 2+ 1+ 3+
Ketone	KET	mg/dL	Negativ 40 Spur >=80 15	Negativ 2+ Spur 3+ 1+
Specific Gravity	SG		<=1.005 1.020 1.010 1.025 1.015 >=1.030	No Difference
pH	PH		5.0 7.5 5.5 8.0 6.0 8.5 6.5 >=9.0 7.0	No Difference
Protein	PRO	mg/dL	Negativ 100 Spur >=300 30	Negativ 2+ Spur 3+ 1+
Urobilinogen	UBG	mg/dL	0.2 4.0 1.0 >=8.0 2.0	No Difference
Nitrite	NIT		Negativ Positiv	No Difference
Occult Blood	OBL	Ery/µL	0 Ca80 Ca10 Ca200 Ca25	Negativ 2+ Spur 3+ 1+
Leukocytes	LEU	Leu/µL	0 Ca125 Ca15 Ca500 Ca70	Negativ 2+ Spur 3+ 1+

Table 1-6
Displayed/Printed Results

GERMAN CONV.
Units—Conventional

Test	Printed Abbre-viation	Units	Measured Values	
			Standard (Default) System	PLUS System
Glucose	GLU	mg/dL	Negativo 500 Indicio >=1000 250	Negativo 2+ Indicio 3+ 1+
Bilirubin	BIL		Negativo Moderado Bajo Alto	Negativo 2+ 1+ 3+
Ketone	CET	mg/dL	Negativo 40 Indicio >=80 15	Negativo 2+ Indicio 3+ 1+
Specific Gravity	DEN		<=1.005 1.020 1.010 1.025 1.015 >=1.030	No Difference
pH	PH		5.0 7.5 5.5 8.0 6.0 8.5 6.5 >=9.0 7.0	No Difference
Protein	PRO	mg/dL	Negativo 100 Indicio >=300 30	Negativo 2+ Indicio 3+ 1+
Urobilinogen	URO	EU/dL	0.2 4.0 1.0 >=8.0 2.0	No Difference
Nitrite	NIT		Negativo Positivo	No Difference
Occult Blood	SAN	eri/µL	Negativo Ap 80 Ap 10 Ap 200 Ap 25	Negativo 2+ Indicio 3+ 1+
Leukocytes	LEU	cel/µL	Negativo Ap 125 Ap 15 Ap 500 Ap 70	Negativo 2+ Indicio 3+ 1+

Table 1-7
Displayed/Printed Results

SPANISH CONV.
Units—Conventional

68

Test	Printed Abbre-viation	Units	Measured Values	
			Standard (Default) System	PLUS System
Glucose	GLU	g/dL	Negativo Tracce 0.25 0.5 >=1.0	Negativo Tracce 1+ 2+ 3+
Bilirubin	BIL		Negativo Leggero Medio Forte	Negativo 1+ 2+ 3+
Ketone	KET	mg/dL	Negativo Tracce 15 40 >=80	Negativo Tracce 1+ 2+ 3+
Specific Gravity	PS		<=1.005 1.010 1.015 1.020 1.025 >=1.030	No Difference
pH	PH		5.0 5.5 6.0 6.5 7.0 7.5 8.0 8.5 >=9.0	No Difference
Protein	PRO	mg/dL	Negativo Tracce 30 100 >=300	Negativo Tracce 1+ 2+ 3+
Urobilinogen	URO	EU/dL	0.2 1.0 2.0 4.0 >=8.0	No Difference
Nitrite	NIT		Negativo Positivo	No Difference
Occult Blood	SAN		Negativo Tracce Leggero Medio Forte	Negativo Tracce 1+ 2+ 3+
Leukocytes	LEU	Cel/µL	Negativo Ca15 Ca70 Ca125 Ca500	Negativo Tracce 1+ 2+ 3+

Table 1-8
Displayed/Printed Results

ITALIAN CONV.
Units—Conventional

EXPLANATION OF SOFTWARE AND ROUTINES

When the CLINITEK® 100 Urine Chemistry Analyzer is first turned *on*, the display will show the message "Instrument Calibrating–Please Wait." Once the calibration/self-test has been completed, the display will show the time and date, the name of the Bayer Diagnostics Reagent Strip that is programmed to be read, the software version, and the key prompts of MENU and START. For example:

```
Multistix 10 SG                    10-22-91
                                   03:08 pm

                Clinitek 100
                Version F3.00

MENU                                   START
```

Press the key (MENU) to display the Main Menu, from which all user-selectable options can be accessed.

A. Main Menu

The Main Menu displays the time and date. the Reagent Strip name, and the sequence number assigned to the next specimen to be tested. It also lists a menu of options that can be selected by the user. For example:

```
Multistix 10 SG      0-001         10-22-91
                                   03:08 pm

Set Sequence No.
STAT Sample
Control Sample
Data Recall
Set Up Instrument
Print Load List                        START
```

One option in the list will be highlighted; that is, the type will be reversed out of a dark block. The ▼ and ▲ keys move the highlighting up and down the list. When the desired option is being highlighted. press ↵ to select that option.

10

1. **Set Sequence No.**
   The sequence number that will be assigned to the next test is displayed in the center of the top line of the display. The number consists of two parts, a prefix number and a sequential sample identification number. A different prefix number, from 0 to 9, can be assigned to distinguish between different instruments, work shifts, or operators. This number will precede the sequential ID number printed with each set of results. The sequential ID number increments with each test and may be set to any number from 001 to 999.
   a. If the sequence number being displayed is correct and does not need to be changed, do nothing; move the highlighting to the next desired option or begin testing samples, as instructed in Part C below, "ANALYZE MODE."
   b. If the sequence number needs to be changed from that being displayed, use the ▲ or ▼ keys as necessary to highlight the option "Set Sequence No.", then press ↵ to select the option. The next display will show, for example:

```
Set Sequence Number

  Sequence Number    0-001



                                          MENU
```

   The blinking cursor will be located on the first digit of the existing number. Press the appropriate numeric keys on the keypad to enter the desired number. The blinking cursor will move one position to the right with each entry. Both the prefix number and all three digits of the sequential ID number must be entered, including any leading zeros.

When the correct number has been entered, press [↵] ; if an error is made, press [C] (CLEAR) and enter the correct number, pressing [↵] when it has been entered. The display will return to the Main Menu, with the newly entered sequence number displayed.

NOTE: If only the prefix number needs to be changed, with the rest of the sequence number remaining as it is currently displayed, the new prefix can be entered, immediately followed by [↵] ; the sequential ID number will not be changed. (Pressing either [↵] or [≡] prior to making *any* changes will return the display to the previous menu *without* changing the existing number.)

2. **STAT Sample**

   The prefix number of the sequence number can be changed to a prefix of "S" to denote a STAT sample by highlighting the "STAT Sample" option on the menu, then pressing [↵] . The sequence number shown on the top line of the display will then show "S-xxx," with the sequential ID portion of the number remaining unchanged. If a load list is in memory, use of the STAT sample option interrupts the display of loadlisted ID numbers and allows the ID number of the STAT sample to be entered. After a single test has been run, the prefix will return to the assigned number and the loadlisted ID numbers (if being used) will return to the point at which the run was interrupted. The "S" prefix can be removed without running a test by merely pressing [↵] a second time. The sequence number that is printed on the report will also reflect the "S" prefix.

3. **Control Sample**

   In the same manner as for "STAT Sample" above, the prefix can be changed to a "C" to denote a control specimen by highlighting the "Control Sample" option on the menu and pressing [↵] . The sequence number shown on the display will show "C-xxx," with the sequential ID portion of the number remaining unchanged. As with a STAT sample, use of the control sample option interrupts the display of loadlisted ID numbers if a load list is in memory. After a

single test has been run, the prefix will return to the assigned number and the use of loadlisted ID numbers (if being used) returns to the point at which the run was interrupted. The "C" prefix can be removed without running a test by merely pressing [↵] a second time. The sequence number that is printed on the report will also reflect the "C" prefix.

4. **Data Recall**
   Up to 100 sets of test results are stored in the memory of the CLINITEK 100 instrument. Each of these data files can be recalled by highlighting "Data Recall" on the Main Menu and pressing [↵]. The most recently-run test will be displayed first. Pressing the ▼ key will recall the next earlier file and vice versa. The arrow keys are circular: if the most recent file is being displayed, pressing ▲ will recall the earliest file in memory (up to 100 samples); if the earliest file is being displayed, pressing ▼ will recall the most recent file. The displayed file can be reprinted by any active printer (external and/or internal) by pressing [🖨] (PRINT). When all desired files have been recalled, press [☰] to return to the Main Menu or [◇] to test a new sample.
   NOTE: After a data file is transmitted to a computer, it is no longer retained in memory and is not available for recall through the "Data Recall" option.

5. **Set Up Instrument**
   When "Set Up Instrument" is highlighted and [↵] is pressed, the Setup Menu will be displayed. This menu lists numerous options by which changes can be made to the time and date, data output can be designated, and several data management capabilities selected. Each of these options are explained in Part B, Instrument Setup.

6. **Print Load List**
   If a load list is present in the memory of the instrument, it can be printed by highlighting "Print Load List" and pressing [↵].
   NOTE: A load list can be downloaded from a host computer anytime the CLINITEK 100 screen is displaying the "START" prompt (e.g., from the Main Menu, after testing

of a Reagent Strip has been completed and printed, or from a "Data Recall" screen). As soon as the transmission is complete, the load list will be printed by the CLINITEK 100 printer. The load list can then be reprinted at any time through the "Print Load List" prompt.

B. Instrument Setup

When "Set Up Instrument" is selected from the Main Menu, the Setup Menu will be displayed as:

```
Setup Menu

  Set Time and Date     Use ID Numbers
  Clear Memory          Use Color/Clarity
  Printer               Select Tone
  Computer Port         Use Plus System
  Time & Date Format    Status
  Identify Abnormals                    MENU
```

1. **Set Time and Date**
   When "Set Time and Date" is highlighted and ↵ is pressed, a new menu will display two options: "Set Time" (which will be highlighted) and "Set Date."
   a. To change the **time,** press ↵ . The display will show the current time, along with an indication of the format in which the time is being displayed; the cursor will be located on the first digit of the time. For example:

```
        Format:  24 Hour

      Set Current Time to:  15:09


                                    MENU
```

or for example:

```
Format:  12 Hour

Set Current Time to:  03:09 pm


                                MENU
```

i. Enter the correct time in the format shown by pressing the appropriate numeric keys, then press ↵ . Be sure to enter leading zeros for any numbers lower than 10.
NOTE: If ↵ is pressed before all digits have been entered, only those digits to the left of the cursor will be changed; all others will remain unchanged. Therefore, if only the hour needs to be changed, the correct digits for the hour can be entered, followed by ↵ ; the minutes already being displayed will remain unchanged.

ii. If the clock is in the 12 Hour Mode, the display will show the options for "am" and "pm," with the current designation highlighted. Use the ▲ or ▼ key to move the cursor to the appropriate designation, if necessary, and press ↵ .

iii. The display will return to the Setup Menu.

b. To change the **date,** move the cursor until "Set Date" is highlighted, then press ↵ . The display will show the current date, along with the format in which the date is being displayed; the cursor will be located on the first digit of the date. For example:

```
Set Current Date to:   10-22-91
                       MM-DD-YY


                                MENU
```

i. Enter the correct date **in the format shown** by pressing the appropriate numeric keys, then press ↵ . Be sure to enter leading zeros for any numbers lower than 10. The display will return to the Setup Menu.
NOTE: If ↵ is pressed before all digits have been entered, only those digits to the left of the cursor will be changed: all others will remain unchanged.

NOTE: If the **format** of the time or date is incorrect (that is, 12 Hour vs. 24 Hour time; month/day/year vs. day/month/year vs. year/month/day for the date), it can be changed through the "Time & Date Format" prompt (see Step B-5 below).

2. **Clear Memory**
If you wish to clear the instrument's memory, move the cursor until "Clear Memory" is highlighted, then press ↵ . The following screen will display the number of records in memory and confirm whether you wish to clear the memory; for example:

```
059 Records In Memory
Clear Memory?

  No
  Yes

                                    MENU
```

If you are certain you wish to clear the memory, move the cursor to highlight "Yes" ("No" will always be highlighted initially to help prevent accidental clearing of the memory) and press ↵. The display will return to the Setup Menu.

3. **Printer**
Results can be printed by the internal printer and/or one of two styles of external printers. The CLINITEK® Form Printer can be used, by which results are printed on 3-copy

forms (see Section 5, ACCESSORIES); in addition, most 80-column, continuous feed, parallel printers are acceptable. Use of the internal instrument printer and/or an external printer can be selected through this prompt. Highlight this prompt to select the desired printing configuration and press ↵. The Printer Menu will be displayed as:

```
Select Printer

  Internal Printer
  External Printer
  Both
  None
                                        MENU
```

a. Use of the internal printer is selected by default; this printer can be turned *off* by selecting either "None" or "External Printer." Select the desired printer configuration by using the ▲ and ▼ keys to highlight the desired selection, then press ↵.
b. If "External Printer" or "Both" was selected, the next screen will request selection of the type of external printer:

```
Select External Printer Type

  80-Column
  Form Printer

                                        MENU
```

Highlight the desired printer and press ↵.
c. The display will return to the Setup Menu.

4. **Computer Port**
If you wish to interface the CLINITEK 100 to a computer, press ↵ after highlighting the prompt "Computer Port." The following screen will be displayed:

```
Computer Port

  ON
  OFF
  Baud Rate

                                    MENU
```

a. If a computer interface is not desired, highlight the menu option "OFF" and press ↵ ; the display will return to the Setup Menu.
b. If the CLINITEK 100 instrument will be interfaced to a computer, the appropriate Baud rate must be selected; in doing so, the computer port will be automatically turned *on*. Highlight the menu option for "Baud Rate" and press ↵ . The next screen will display the various Baud rates from which to select:

```
Select Baud Rate

  300
  600
  1200
  2400
  4800
  9600                              MENU
```

Use the ▲ and ▼ keys to highlight the Baud rate that is appropriate for the computer to which the CLINITEK 100 will be interfaced, then press ↵ . *(Failure to select the appropriate Baud rate may result in lost data.)* The display will return to the Setup Menu. When the ▲ and ▼ keys are used to highlight the desired Baud

rate, followed by pressing ↵, the computer port is automatically turned *on.* If the default Baud rate of 4800 is the desired option, the ▲ and ▼ keys must still be used to highlight this option before pressing ↵ in order to automatically turn the computer port *on.*

NOTE: The computer port can be turned *off* or *on* without changing the Baud rate by highlighting the desired status in the Computer Port Menu and pressing ↵.

CAUTION: Turning the computer port *on* or *off,* or changing the Baud rate, automatically clears the memory. Therefore, be sure all patient results that have been previously run have been printed before making any changes to these screens.

NOTE: If the computer port is *on* and results have not been transmitted to a computer, the instrument will display a message of "MEMORY FULL" when the memory contains 100 sets of results. Some or all of the results must then be transferred to the computer or the memory must be cleared before additional samples can be tested. If the computer port is *off* and the memory contains 100 sets of results, testing can continue; however, each new set of test results will overwrite the earliest set of results (that is, the results for specimen #101 will replace the file for specimen #1, #102 will overwrite #2, and so on). When a file has been overwritten, it is no longer stored nor available for recall.

5. **Time & Date Format**
   Several formats for displaying the time and date are available and can be selected by the user through this prompt. The time can be displayed as 12 hour (am/pm) or as 24 hour (military) time; the date can be displayed as month-day-year (MM-DD-YY), day-month-year (DD-MM-YY), or year-month-day (YY-MM-DD). Upon selecting this prompt from the Setup Menu, the following will be displayed:

```
Set Time & Date Format

  Set Date Format
  Set Time Format


                                        MENU
```

a. To change the date format, highlight "Set Date Format" and press ↵ . The next screen will allow you to select the desired date format:

```
Set Date Format

  YY-MM-DD
  MM-DD-YY
  DD-MM-YY


                                        MENU
```

The format currently selected will be highlighted. Use the ▼ and ▲ keys to move the highlighting to the desired format, then press ↵ . The display will then return to the Setup Menu; the date that is displayed in the Main Menu will immediately reflect the new format. **NOTE:** If the date format is changed, any records that were stored in memory prior to the change will reflect the new format if they are subsequently printed. That is, regardless of what date format was used when a record was stored, the current format will be reflected if a record is printed through the "Data Recall" prompt in the Main Menu.

b. To change the **time** format, highlight "Set Time Format" and press ↵ . The next screen will allow you to select the desired time format:

```
Set Time Format

  24 hour
  12 hour


                                        MENU
```

The format currently selected will be highlighted. Use the ▼ and ▲ keys to move the highlighting to the desired format, then press ↵ . The display will then return to the Setup Menu; the time that is displayed in the Main Menu will immediately reflect the new format.

6. **Identify Abnormals**
   Results greater than negative can be flagged on the display of results and on the printed report, if desired. Abnormal results are highlighted on the display and an asterisk is printed beside the test name on the printed report. The status of this option can be changed by selecting the prompt "Identify Abnormals" from the Setup Menu:

```
Identify Abnormals?

  No
  Yes


                                        MENU
```

   a. The current status will be highlighted. Move the cursor to highlight the other option, if needed, then press ↵ . If "No" is selected, the display will return immediately to the Setup Menu. If "Yes" is selected, the screens will continue as shown below:

```
Identify First Abnormal Level

  Protein                    Leukocyte/WBC
  Glucose                    Use Defaults
  Ketone
  Bilirubin
  Occult Blood
  Urobilinogen                            MENU
```

b. The first level at which results will be flagged can be selected separately for each of the reagent tests listed, or default levels can be used. The following list shows the values that will be flagged as abnormal if the default levels are used:

Protein Glucose Ketone Bilirubin Occult Blood Nitrite Leukocyte	All values greater than Negative
Urobilinogen	≥2.0 EU(mg)/dL (≥33 μmol/L)

If the default values are not desired for one or more tests, each test for which a change is desired can be selected from the menu being displayed. Upon selecting a specific test, all possible results greater than negative will be displayed; for example, if protein is selected:

```
Protein Levels

    Trace
    30 mg/dL
    100 mg/dL
    >=300 mg/dL

                                          MENU
```

The currently selected level will be highlighted. Move the cursor to highlight the level at which you desire flagging to occur (the selected level will also be flagged) and press ↵. The display will return to the previous menu (Identify First Abnormal Level) for additional changes. Refer to Tables 1-1 to 1-8 for the designations of positive results for your particular Reagent Strip and language.

NOTE: If you wish to use the default values for all tests except one (for example, Protein), select "Use Defaults" first, then select the test for which a change is to be made (in this example, Protein), and select the desired level at which flagging will occur.

c. When all selections have been made, press ☰ to return to the Setup Menu.

7. **Use ID Numbers**

If desired, an identification (ID) number can be entered for each specimen. This number is in addition to the sequential number assigned to each specimen by the instrument. The ID number (up to 10 digits) can be an accession number or patient identification number (such as social security number). If you desire to download ID numbers from a host computer to create a load list, this option *must* be used ("Yes" must be pressed). Highlight the prompt "Use ID Numbers" and press ↵ to select this option:

```
Use ID Numbers?

  No
  Yes

                                    MENU
```

The current status of the option will be highlighted. Move the cursor to highlight the desired response, then press ↵. The display will return to the Setup Menu.

NOTE: Turning the ID option *off*, then back *on*, will clear the load list that is currently in memory.

8. **Use Color/Clarity**
The color and clarity of each specimen can be entered into each record by choosing from a rotating set of options that are displayed as each patient sample is being tested. There are eight descriptions for color (Yellow, Dk Yellow, Straw, Amber, Green, Orange, Red, and Other) and five descriptions for clarity (Clear, Sl Cloudy, Cloudy, Turbid, and Other). Highlight the "Use Color/Clarity" prompt and press ↵ to select this option:

```
Use Color/Clarity?

  No
  Yes

                                    MENU
```

The current status of the option will be highlighted. Move the cursor to highlight the desired response, then press ↵ . The display will return to the Setup Menu.

9. **Select Tone**
A tone will sound on the CLINITEK 100 after the instrument calibration and Self Test have been completed and after all tests on each Reagent Strip have been read and displayed during the **Analyze** Mode. The *pitch* (as opposed to volume) of this tone can be selected, or the tone turned *off* completely, through this prompt.

```
Select Tone Level

  LOW
  MED
  HIGH
  OFF

                                    MENU
```

The current status will be highlighted. Use the ▼ and ▲ keys to highlight the desired pitch of the tone, or to "OFF" to eliminate the tone completely, then press ↵. The display will then return to the Setup Menu.

NOTE: A different tone will sound whenever there is an error condition. This error tone *cannot* be changed or turned *off.*

10. **Use Plus System**

Results for several of the tests can be displayed in the Plus System, rather than as semi-quantitative descriptions or units, through this prompt. Tables 1-1 through 1-8 in Section 1 show the relationship between the semi-quantitative units and the Plus System. Upon selection of this prompt, the following screen is displayed:

```
Use Plus System?

  No
  Yes


                                        MENU
```

The current status will be highlighted. Move the cursor to the desired response and press ↵. The display will then return to the Setup Menu.

NOTE: A change in status (either selecting or deselecting the Plus System) will change the format in which all results in memory are displayed and printed accordingly; the designations for identifying abnormals will also change accordingly.

11. **Status**
Upon selecting this prompt, the display will show the status of all previously-made selections, plus show the name of the Bayer Diagnostics Reagent Strip being used, the number of records in memory, and the Seq # that will be assigned to the next test. For example:

```
Instrument Status

Multistix 10 SG            Color/Clarity    ON
Internal Printer  ON       Sequence No. 1-115
External Printer  ON       Memory Used     052
   Form Printer            Plus System     OFF
Computer 9600     ON       Abnormals        ON
ID Numbers        ON
```

Press [≡] to return to the Setup Menu and again to return to the Main Menu.

C. ANALYZE MODE

The **Analyze** Mode is the normal operating mode of the CLINITEK 100, in which all urine testing is performed. The mode is initiated upon pressing the [◇] key. This is done immediately after the Bayer Diagnostics Reagent Strip has been dipped into and removed from the patient urine or control specimen. *To run a STAT specimen, especially if a load list is present, the "STAT Sample" option must be selected from the Main Menu* ***before*** *pressing* [◇]. The following events occur after pressing [◇]:

1. The display changes to the Test Screen, which shows the sequence number (Seq. No.) of the strip being tested and the message "Place Strip on Table." Fields for entering the ID number, color, and clarity will also be shown if these options were selected through the Instrument Setup Routine.

2. Approximately 10 seconds after [◇] was pressed, the reagent strip feed table will move into the instrument for reading of the reagent tests. As each test is read, the result is displayed on the screen. Abnormal results will be highlighted on the screen, if this option was selected through the Instrument Setup Routine. The display for the occult blood test will be blank until the result is available. If the strip contains a reagent area for leukocytes, the display will show a series of

dashes (---) in place of the result for "LEU" until the leukocytes result is obtained. It will be displayed as soon as it is available. (The SG result may also briefly show a series of dashes while waiting for the pH test result; this allows the instrument to automatically adjust the SG result according to the pH reading [refer to the package insert for your Bayer Diagnostics Reagent Strips for further information on this adjustment].)

3. If the options for using specimen ID and/or color/clarity have been selected, the information can be entered or confirmed at the user's convenience during and after the testing cycle. The easiest times to enter data are:
   - immediately after the strip is placed onto the feed table,
   - while waiting for the leukocyte result, and
   - after all results have been displayed.

   Data can also be entered at almost any time during the testing cycle; however, the keyboard will lock when the instrument is actually taking a reading, so any key that is pressed during this time will not respond immediately. (Several keystrokes can be held in memory and will be displayed after the reading has been taken.) Enter the requested information as instructed in Steps 4-6 below.

4. a. **If ID numbers have been loadlisted,** the first number in the list will be displayed in the ID number field. If the number being displayed agrees exactly with the specimen being tested, press [↵] . If it does not agree, either:
      i. Enter the correct ID number using the numeric keyboard, directly replacing the number being displayed, or
      ii. Press [C] (CLEAR) to erase the number. If the [C] key is used, the ID number that was initially displayed will be lost and will be replaced by the next number in the load list. Repeat Step 4-a to enter the correct ID number.

   NOTE: As long as a load list is present in the instrument's memory, the abbreviation "LDLST" (for "Loadlist") will appear on the display screen. When the final ID number has been removed from the load list, "LDLST" will no longer be displayed.

b. **If there are no numbers in a load list,** either because they have all been tested or because a load list was not present initially, enter the ID number using the numeric keyboard. Up to 10 digits can be entered. When the number has been correctly entered, press [↵]. If an error is made, press [C] (CLEAR) and enter the number again.

5. The cursor will move to the Color field, where the default color of "Yellow" will be displayed. To change the displayed description, press the ▼ or ▲ keys until the desired description is being displayed, then press [↵].

6. The cursor will move to the Clarity field, where the default value of "Clear" will be displayed. Change the displayed description, if necessary, by pressing ▼ or ▲ until the desired description is being displayed, then press [↵].

7. As soon as all results have been displayed and the ID number, color, and clarity have been entered (if these fields were displayed), the results will be printed by the internal printer and/or external printer (depending upon which printer option was selected through the Instrument Setup Routine). While results are being printed, the keyboard is locked. Once printing is complete, however, the display of results will also list the active keys of "MENU" and "START." **NOTE:** If using a Form Printer, insert the form into the printer while the Reagent Strip is being read. The results will then be printed onto the form when they are available. If a form is not present in the printer when the results are transmitted, a "Printer Error" message will be displayed; after returning to the Main Menu, ensure that a form is in place and press the [⎙] key to resend the last set of results.

8. Remove and discard the used Reagent Strip.

9. a. To run another test, dip a fresh strip into the next specimen, and press [◇] as soon as the strip is removed from the specimen; or
   b. press [1 2 3] to return to the Main Menu.

D. STAT MODE

If it is necessary to run a STAT specimen during a run, the normal routine using loadlisted specimens can be interrupted and the sequence number can be altered to reflect an "S" prefix.

1. To enter the STAT Mode, return the display to the Main Menu (by pressing the key) *before* beginning the testing sequence for the STAT specimen.
2. Use the and keys to highlight the "STAT Sample" option and press . The sequence number will be changed to reflect a prefix of "S."
3. The STAT specimen can now be analyzed in the normal manner. After pressing and placing the Reagent Strip on the feed table, the ID number and/or color/clarity can be entered, if these options have been selected. If a load list is present in the instrument's memory, display of the loadlisted ID numbers will be interrupted for the STAT specimen, allowing the STAT ID number to be entered.
4. After the STAT specimen has been analyzed and the result printed, the prefix will return to the assigned number and the loadlisted ID numbers (if being used) will return to the point at which the run was interrupted.

Section 3

INSTALLATION

General

This section provides detailed installation instructions for the CLINITEK® 100 Urine Chemistry Analyzer. The installation steps must be followed correctly to ensure proper installation, operation, and service. Read this Operating Manual carefully before attempting to operate the CLINITEK 100 instrument. Follow all instructions carefully.

The CLINITEK 100 is a precision instrument and must be handled accordingly. Rough handling or dropping of the instrument will disturb internal calibrated optics and electronics and/or cause other damage. Always handle the instrument with care.

Environmental Factors

As with all sensitive electronic instruments, prolonged exposure to excessive humidity and temperature should be avoided. Temperature should be held relatively constant to obtain the highest degree of operating stability. The ambient temperature range for instrument operation is 18°C to 30°C (64°F to 86°F); the ambient operating humidity range is 20% to 85% relative humidity. The *optimum* operating conditions are 22°C to 26°C (72°F to 79°F) and 30% to 60% relative humidity. Before operating, allow the instrument to equilibrate to the environmental conditions.

Place the instrument where it will not be subjected to extreme temperature variations. Avoid proximity to open windows, ovens, hot plates, open burners, radiators, dry ice baths, and in particular. to direct sunlight. The CLINITEK 100 should not be used in an explosive atmosphere.

Unpacking

1. Carefully remove the CLINITEK 100 instrument and accessory package from the shipping carton. Inspect the carton and instrument for visible signs of damage. If damage to the instrument exists. immediately file a complaint with the carrier.

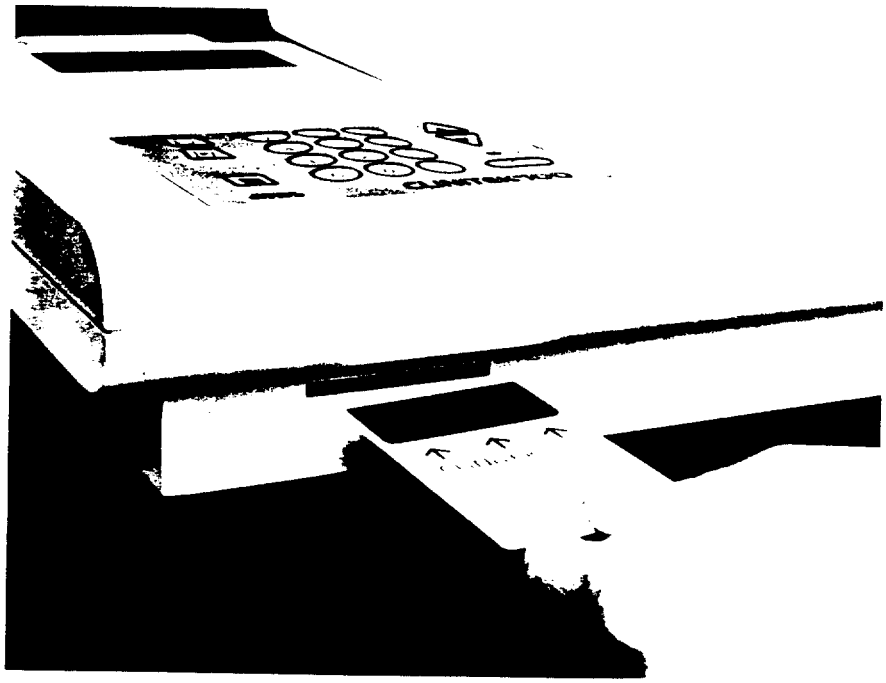

Figure 3-1
Inserting the Program Card

2. The following parts and accessories should be included with the instrument:
   - Operating Manual (1)
   - Program Card (1)
   - Line Cord (1)
   - Feed Table Insert – 4¼" (1)
   - Paper Rolls (2)
   - Warranty Card (1)
   - Replacement Fuse (1)

   Depending on the specific country, the following items may be included:
   - System Information Card (1)
   - Multi-language sheet of labels (1 each):
     - feed table insert labels
     - rating labels

   Make sure all these items have been included with your instrument, and keep them for future use.

3. After the instrument has been unpacked, place it on a firm work surface in the designated work area. Make sure there is nothing in front of the instrument that will obstruct the reagent strip feed table when it moves out to the "load" position.
   NOTE: Retain the CLINITEK 100 shipping carton for future use. If the instrument ever needs to be shipped, the shipping carton will afford the best protection.

Instrument Setup

1. Plug the Program Card into the instrument by inserting it into the card receptacle and pressing it in firmly until it "snaps" into place (Figure 3-1). The side containing the metal ridges is inserted into the instrument, with the label side up and the arrows facing into the instrument.
2. Plug the instrument line cord into the instrument and into an appropriate grounded AC electrical outlet.
3. Install the roll of printer paper (refer to Section 6, "Periodic Maintenance").

4. Install the feed table insert (refer to Section 6, "Daily Maintenance," Step 5).
   NOTE: If you will be using a configuration of Bayer Diagnostics Reagent Strips that contains four tests or fewer, you must use a different feed table insert than the one supplied with the instrument. The *only* exception to this is with LIFESTIX™ Reagent Strips (not available in all countries). Most Reagent Strip configurations use the 4¼ inch insert, which can be identified by a circle (○) that is engraved on the end of the insert, near the calibration chip. Reagent Strips with four tests or fewer (except LIFESTIX) require a 3¼ inch insert, identified by a triangle (△). Refer to Section 9, SERVICE AND REPLACEMENT PARTS, to order the 3¼ inch insert.
5. Position the display screen for convenient viewing by raising it to the fully upright position, then lowering it to the desired position. (The screen must also be raised to prevent blocking of the ventilation openings on the instrument top.)

Interfacing To A Printer

The CLINITEK 100 can be interfaced to the CLINITEK® Form Printer or to most commercially available 80-column, continuous feed printers, via the printer port that is found on the rear of the instrument.

1. If interfacing to the Form Printer (Product No. 5255), obtain the interface cable that is supplied with the printer. Plug the appropriate end of the cable into the printer (parallel) port (labeled as [◎]) on the CLINITEK 100 instrument; plug the other end of the cable into the printer.
2. If interfacing to an 80-column printer, the interface cable must be obtained separately. Refer to Addendum I, "COMPUTER AND PRINTER INTERFACE," for the pin specifications for the female connector. The other end of the cable will be dependent upon the particular printer. Appropriate cables are available at most retail computer stores. Plug

the appropriate end of the interface cable into the printer (parallel) port (labeled as [◎]) on the CLINITEK 100; plug the other end into the printer.

3. Carefully read the operating manual that accompanies the printer and become familiar with its operation before using.

Interfacing To A Computer

The CLINITEK 100 can also be interfaced to a host computer via the EIA-232-D (serial) port. The specifications for interfacing to a computer are found in Appendix I, "COMPUTER AND PRINTER INTERFACE." Plug the appropriate end of the interface cable into the EIA-232-D port on the CLINITEK 100; plug the other end into the appropriate port on the computer, following the instructions given with the computer.

Initial Instrument Check

After the CLINITEK 100 has been properly installed, perform the following Initial Instrument Check. The actions that should occur during instrument operation are described in this check. If problems occur during this procedure or if an error is displayed, refer to Section 7, TROUBLESHOOTING.

1. Turn the instrument power *on* by placing the power switch (on the back of the instrument) to the ON position. Be sure the display screen has been raised to an upright position; adjust the contrast, if necessary, using the dial found on the right side of the screen. The reagent strip feed table will automatically move out to the "load" position and the display will show:

```
CLINITEK 100

CALIBRATING INSTRUMENT - PLEASE WAIT
```

The instrument will then perform a calibration and self-test procedure, which consists of checking the position of the feed table, checking the light intensity of the LEDs, and calibrating the LEDs. Once the procedure is complete, the display will change to, for example:

```
Multistix 10 SG                    10-22-91
                                   03:30 pm


              CLINITEK 100
              Version F3.00

MENU                                  START
```

NOTE: The name of the Reagent Strip being displayed must correspond to the name of the Bayer Diagnostics Reagent Strip to be used. Use of any other strip will cause erroneous results. If the name being displayed is not correct for the strip being used, contact your Bayer Diagnostics representative or office.

2. Inspect the feed table insert. The insert must be fully inserted into the feed table. The strip holding channel must be free of dust and foreign matter. For detailed information, see Section 6, "Daily Cleaning."
3. Press the [◇] (START) key. The display will change to the Test Screen:

```
Seq No: 1-001        Color:    Yellow
I.D.                 Clarity:  Clear




          Place Strip on Table
```

After approximately 10 seconds, the feed table will move inward and stop in the "storage" position. With no Reagent Strip on the table, the feed table will return to the "load" position and the display will show the message "Caution: INSTRUMENT WARNING . . . STRIP MISSING Press Any Key to Continue . . ."

4. Once any key is pressed, the display will return to the Main Menu (described in Section 2).
5. Carefully immerse a fresh Bayer Diagnostics Reagent Strip into a negative control urine, such as CHEK-STIX® Negative Control Strips solution. Remove the strip immediately; while removing, run the edge of the entire length of the Reagent Strip against the side of the tube to remove excess urine. Press ◇ at the same time the strip is removed; the display will again change to the Test Screen (shown in Step 3 above).
6. With the reagent areas to one side, touch the edge of the strip on a paper towel (Figure 3-2). *Do not draw the strip across the towel: touch the edge only.*
7. Place the Reagent Strip, **with reagent areas up,** in position on the reagent strip feed table within 10 seconds after pressing ◇ (Figure 3-3). Place the tip of the Reagent Strip near the center of the feed table and slide the strip onto the table until it is touching the end stop. Following a brief delay, the feed table will move into the instrument to allow the Reagent Strip to be read.
   NOTE: Be sure the tip of the strip lies flat against the table and is touching the end stop of the feed table insert. **If the strip does not lie flat, retest with a fresh strip.**
8. Press the ← key 3 times to bypass the displays for I.D., color, and clarity.
9. The test results will be shown on the display as each test is read. If the strip contains a reagent area for leukocytes, the display will show a series of dashes (---) in place of the result for "LEU" until the leukocyte test is read (approximately 10-20 seconds later, depending on which Reagent Strip is being used); the display for the blood test will be blank. As soon as the results are available, they will be displayed. (The SG result may also briefly show a series of dashes; refer to Section 2, Step C-2 for full information.)
   NOTE: The leukocytes reagent area, located at the tip of the Reagent Strip, is read later than the other reagent areas. Therefore the feed table will remain almost fully out until after the leukocytes area is read. **Be very careful not to bump the feed table during this waiting period.**

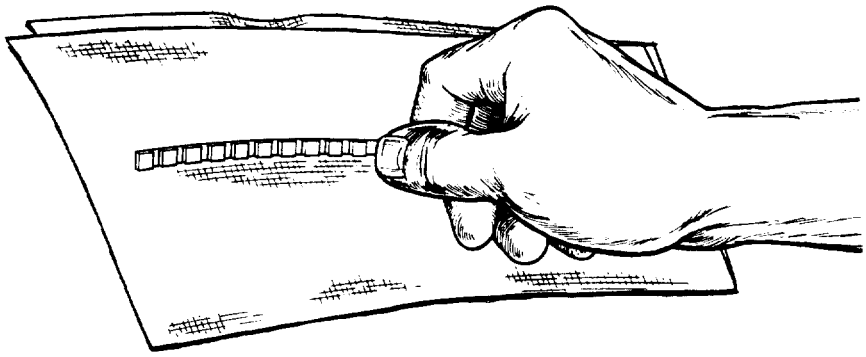

Figure 3-2
Blotting the Reagent Strip

Figure 3-3
Placing Reagent Strip on Feed Table

10. Once all results are displayed, they will be printed by the internal printer.

11. The instrument should produce a result for each reagent area that is within the limits given in the package insert for the control urine, as shown on the following example:

```
Seq No: 0-001          Color:    Yellow
I.D.                   Clarity:  Clear

GLU Negative         PRO Negative
BIL Negative         URO 0.2 EU/dL
KET Negative         NIT Negative
SG  1.010            BLO Negative          MENU
pH  6.0              LEU Negative         START
```

12. If the instrument does not display the expected values for the reagent areas selected, refer to Section 7, TROUBLE-SHOOTING, for customer service information.

13. Remove and discard the used Reagent Strip.

14. Press the [≡] key (MENU) to return the display to the Main Menu. If necessary, set the desired beginning sequence number, as described in Section 2, EXPLANATION OF SOFTWARE AND ROUTINES, Part A, Step 1. Then enter the "Instrument Setup Routine" and select the desired operating parameters, as described in Part B of the same section. After all parameters have been set, highlight "Status" on the Setup Menu and press [↵] to display the instrument setup parameters. Record and save a copy of these parameters, in case a replacement instrument must be set up.

15. With satisfactory completion of the Initial Instrument Check and selection of the desired operating parameters, the CLINITEK 100 instrument is ready for routine testing.

16. Before beginning normal instrument use, carefully review the following sections to become familiar with operating techniques and instrument cleaning requirements:
    Section 4—OPERATING INSTRUCTIONS
    Section 6—CARE OF THE INSTRUMENT

17. Locate the serial number on the back of the instrument. Write the installation date and the instrument serial number on the Warranty Registration Card packed with the instrument. Also write the installation date and serial number on the Manufacturer's Warranty page at the end of this manual and in the "Preservice Checklist" in Section 9. Completely fill out the Warranty Registration Card and mail.

Section 4

OPERATING INSTRUCTIONS

Following initial installation (Section 3), the CLINITEK® 100 Urine Chemistry Analyzer can be operated on a day-to-day basis by the following procedures. Carefully read Section 2 (EXPLANATION OF SOFTWARE AND ROUTINES) for a complete description of the displays, prompts, and operating sequences before beginning any testing.

Activating the CLINITEK 100 Instrument

Ensure that the Program Card is firmly in place. Turn the CLINITEK 100 instrument *on*, if necessary. Be sure the display screen is in an upright position; adjust the contrast, if necessary, using the dial on the right side of the screen.

The feed table will automatically move out to the "load" position and the display will show the message "Calibrating Instrument Please Wait." The instrument will automatically perform a calibration and self-test procedure; upon successful completion of the procedure, the display will change to the Main Menu; for example:

```
Multistix 10 SG                    10-22-91
                                   09:30 am

              CLINITEK 100
              Version F3.00

MENU                                  START
```

IMPORTANT: The name of the Reagent Strip being displayed must correspond to the name of the Bayer Diagnostics Reagent Strip for Urinalysis that is to be used. Use of any other strip will cause erroneous results. If the names do not agree, contact your Bayer Diagnostics representative or office to select the correct Reagent Strip.

NOTE: The CLINITEK 100 may be used immediately after it is turned *on* and the self-test is complete. No warm-up time is required.

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Inspection of Reagent Strip Feed Table

Inspect the feed table and feed table insert for cleanliness and correct positioning. If either appears dirty, remove the feed table insert and clean as described in Section 6, "Daily Cleaning."

CLINITEK 100 Instrument/Reagent Strip Performance Check

The following procedure provides a check on Reagent Strip performance and instrument operation. This procedure is intended to provide confidence that Reagent Strips are reacting and being read properly. Errors resulting from user techniques can also be detected. It is suggested that Performance Checks be made under the following conditions:

a. At the start of the day's run;
b. When using a new bottle of Reagent Strips;
c. When changing instrument operators;
d. Whenever test results are in doubt.

CHEK-STIX® Positive and Negative Control Strips for Urinalysis are available for CLINITEK 100 Instrument/Reagent Strip Performance Checks. These Control Strips provide positive, negative, or defined reactions when used with Bayer Diagnostics Reagent Strips for Urinalysis. Alternatively, a urine specimen from a normal, healthy individual can be used as a negative specimen. Additional information on CHEK-STIX Positive and Negative Control Strips can be found in Section 5 of this manual and in the package insert.

To perform the CLINITEK 100 Instrument/Reagent Strip Performance Check procedure, proceed as follows:

1. Prepare the appropriate CHEK-STIX solution by following the directions found in the package insert or on the bottle label.
   NOTE: Use freshly prepared CHEK-STIX solution only. See package insert or bottle label for stability information.
2. Set the appropriate sequence number, if needed, through the Main Menu ("Set Sequence No."). If desired, use the "C" prefix for the test by selecting the "Control Sample" prompt in the Main Menu.

3. Completely immerse all reagent areas of a Bayer Diagnostics Reagent Strip in the CHEK-STIX solution. Remove the Reagent Strip immediately; while removing, run the edge of the entire length of the Reagent Strip against the side of the container to remove excess CHEK-STIX solution. Press [◇] (START) at the same time the strip is removed; the display will change to the Test Screen, with the prompt "Place Strip on Table."

4. With the reagent areas to one side, touch the edge of the strip on a paper towel (Figure 4-1). Do not draw the strip across the towel; touch the edge only.

5. Place the Reagent Strip, **with reagent areas up,** in position on the reagent strip feed table within 10 seconds after pressing [◇] (Figure 4-2). Place the tip of the Reagent Strip near the center of the feed table and slide the strip onto the table until it is touching the end stop. Be sure the tip of the strip lies flat against the table and is touching the end stop of the feed table insert. **If the strip does not lie flat, retest with a fresh strip.**

6. After a brief delay, the feed table will move into the instrument. The test results will be displayed as each reagent area is read. If the strip contains a reagent area for leukocytes, the display will show a series of dashes (---) in place of the result for "LEU" until the leukocyte result is obtained; the display for the blood test will be blank. As soon as the results are available, they will be displayed. (The SG result may also briefly show a series of dashes; refer to Section 2, Step C-2 for full information.)
   NOTE: The leukocytes reagent area, located at the tip of the Reagent Strip, is read later than the other reagent areas. Therefore the feed table will remain almost fully out until after the leukocytes area is read. **Be very careful not to bump the feed table during this waiting period.**

7. Press [↵] up to 3 times to bypass the I.D., Color, and Clarity prompts if they are being displayed. Once all results are displayed, they will be printed by the internal and/or external printer (depending upon the parameters selected in the Instrument Setup Routine).

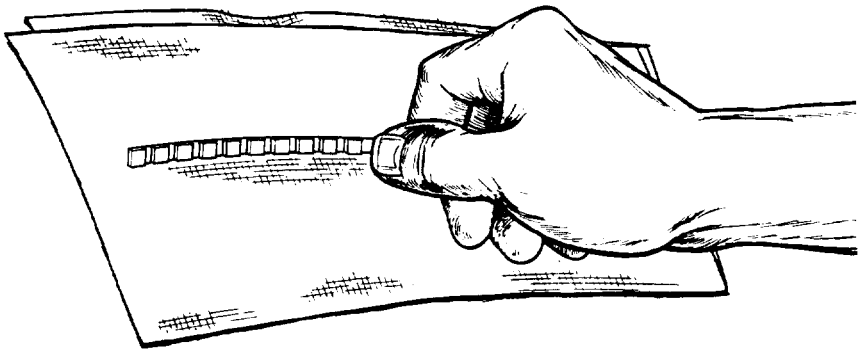

Figure 4-1
Blotting the Reagent Strip

Figure 4-2
Placing Reagent Strip on Feed Table

8. Remove and discard the used Reagent Strip.
9. The CHEK-STIX solution should produce the values stated in the CHEK-STIX package insert.

If a CLINITEK 100/Reagent Strip Performance Check falls outside the stated values, the following sources of error may have occurred:

a. Improper technique or instrument setup. Check that the Reagent Strip being used corresponds to the Reagent Strip name given on the Main Menu display. Carefully repeat the Instrument/Reagent Strip Performance Check procedure as described above.
b. Deterioration of the Reagent Strip test areas due to exposure to light, ambient moisture or heat. Obtain a fresh bottle of the Bayer Diagnostics Reagent Strips being used and repeat the Instrument/Reagent Strip Performance Check procedure. If fresh Reagent Strips fail to give results within the expected values, proceed to Step c.
c. Deterioration of the CHEK-STIX solution. Prepare a fresh CHEK-STIX solution and repeat the Instrument/ Reagent Strip Performance Check procedure. If fresh solution fails to give results within the expected values, proceed to Step d.
d. Deterioration of the CHEK-STIX Control Strips. Obtain a fresh bottle of CHEK-STIX Control Strips and prepare a fresh CHEK-STIX solution. Repeat the Instrument/ Reagent Strip Performance Check procedure. If the solution from the fresh Control Strip fails to give results within the expected values, proceed to Step e.
e. CLINITEK 100 instrument malfunction. Perform an Initial Instrument Check procedure (see Section 3). If the Initial Instrument Check or the Instrument/Reagent Strip Performance Check procedures cannot be successfully completed and an instrument malfunction or Reagent Strip problem is suspected, see Section 7, TROUBLE-SHOOTING, or contact the Customer Service Department for assistance (see Section 9 for further customer service information).

Procedure for Urine Analysis

Using the CLINITEK 100 Instrument/Reagent Strip System

1. Set the appropriate sequence number, if needed, through the Main Menu ("Set Sequence No."). To run a STAT specimen, highlight the "STAT Sample" option in the Main Menu and press [←].
2. Completely immerse all reagent areas of a Bayer Diagnostics Reagent Strip in *fresh,* well-mixed, uncentrifuged urine. Remove the Reagent Strip *immediately;* while removing, run the edge of the entire length of the Reagent Strip against the side of the urine container to remove excess urine. Press the [◇] key on the instrument at the same time the strip is removed. The display will change to the Test Screen, showing the sequence number (Seq No.) of the strip being tested, as well as the fields for entry of the identification number (I.D.), color, and clarity, if these options were selected through the Instrument Setup Routine.
3. With the reagent areas to one side, touch the edge of the strip on a paper towel (Figure 4-1). Do not draw the strip across the towel: touch the edge only.
4. Place the Reagent Strip, **with reagent areas up,** in position on the reagent strip feed table within 10 seconds after pressing [◇] (Figure 4-2). Place the tip of the Reagent Strip near the center of the feed table and slide the strip onto the table until it is touching the end stop. Be sure the tip of the strip lies flat against the table and is touching the end stop of the feed table insert. **If the strip does not lie flat, retest with a fresh strip.** After a brief delay, the feed table will move into the instrument.

5. If the options for using ID numbers and/or color/clarity have been selected, there are several opportunities to enter or confirm the requested information. The easiest times to enter data are:
   - immediately after the strip is placed onto the feed table,
   - while waiting for the leukocyte result; and
   - after all results have been displayed.

   Data can also be entered at almost any time during the testing cycle; however, the keyboard will lock when the instrument is actually taking a reading, so any key that is pressed during this time will not respond immediately. Enter the requested information as instructed in Steps 6-8 below.

6. a. **If ID numbers have been loadlisted,** the first number in the list will be displayed in the ID number field. If the number being displayed agrees exactly with the specimen being tested, press [↵]. If it does not agree, either:
      i. Enter the correct ID number using the numeric keyboard, directly replacing the number being displayed, or
      ii. Press [C] (CLEAR) to erase the number. If the [C] key is used, the ID number that was initially displayed will be lost and will be replaced by the next number in the load list. Repeat Step 6-a to enter the correct ID number.

      NOTE: As long as a load list is present in the instrument's memory, the abbreviation "LDLST" (for "Load-list") will appear on the display screen. When the final ID number has been removed from the load list, "LDLST" will no longer be displayed.

   b. **If there are no ID numbers in a load list,** either because they have all been tested or because a load list was not present initially, enter the ID number using the numeric keyboard. Up to 10 digits can be entered. When the number has been correctly entered, press [↵]. If an error is made, press [C] (CLEAR) and enter the number again.

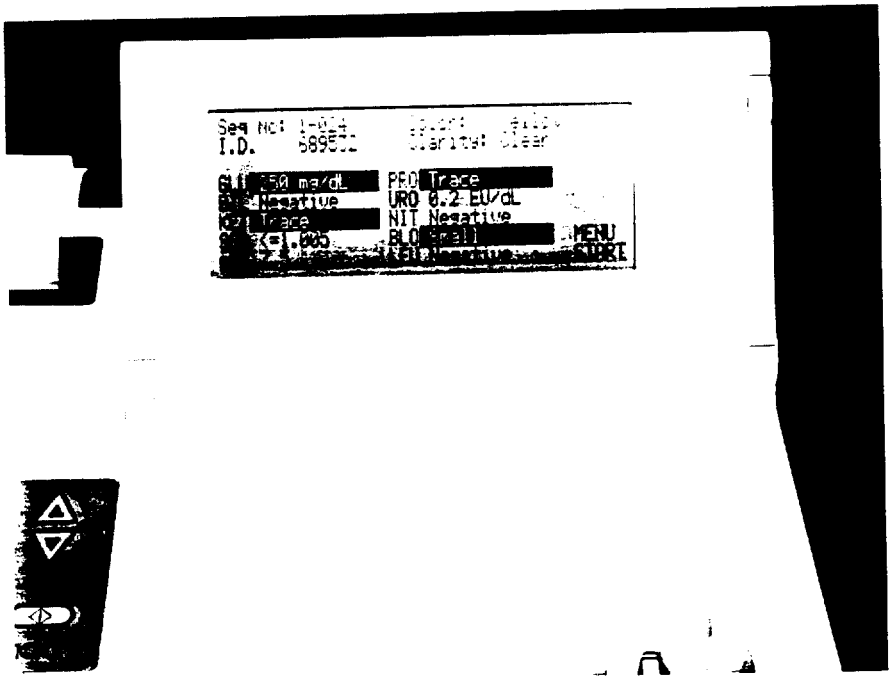

Figure 4-3
Display of Results

```
#1-024      01-19-92
I.D. 689532
Color:    Yellow
Clarity: Clear

*GLU 250 mg/dL
 BIL Negative
*KET Trace
 SG  <=1.005
 pH  7.5
*PRO Trace
 URO 0.2 EU/dL
 NIT Negative
*BLO Small
 LEU Negative
```

Figure 4-4
Printout of Results

7. The cursor will move to the Color field, where the default color of "Yellow" will be displayed. To change the displayed value, press the ▼ or ▲ keys until the desired description is being displayed, then press ↵ . There are eight descriptions for Color: Yellow, Dk Yellow, Straw, Amber, Green, Orange, Red, and Other.

8. The cursor will move to the Clarity field, where the default value of "Clear" will be displayed. Change the displayed value, if necessary, by pressing ▼ or ▲ until the desired description is being displayed, then press ↵ . There are five descriptions for Clarity: Clear, Sl Cloudy, Cloudy, Turbid, and Other.

9. The test results will be displayed as each reagent area is read. If the strip contains a reagent area for leukocytes, the display will show a series of dashes (---) in place of the result for "LEU" until the leukocyte result is obtained; the display for the blood test will be blank. As soon as the results are available, they will be displayed. (The SG result may also briefly show a series of dashes; refer to Section 2, Step C-2 for full information.)
NOTE: The leukocytes reagent area, located at the tip of the Reagent Strip, is read later than the other reagent areas. Therefore, the feed table will remain almost fully out until after the leukocytes area is read. **Be very careful not to bump the feed table during this waiting period.**

10. Once all results are displayed, including entry of the specimen ID, color, and clarity if these options were selected, they will be printed by the internal and/or external printer (depending upon the parameters selected in the Instrument Setup Routine). While results are being printed, the keyboard is locked. Once printing is complete, however, the display of results will also list the active keys of "MENU" and "START" (Figure 4-3). Refer to Figure 4-4 for an example of the internal printout with abnormal results flagged.

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NOTE: If the ID and/or color/clarity fields are being displayed, this information *must* be entered before the test results will be printed and before another strip can be run. The [◇] key will not respond until *all* results for the current test (including ID, color, and clarity) have been entered and printed.

11. Remove and discard the used Reagent Strip.

12. a. To run another test, dip a fresh strip into the next specimen and press [◇] as soon as the strip is removed from the specimen; or
    b. Press [≡] to return to the Main Menu.

    IMPORTANT: Do not attempt to test a new specimen until "START" is being displayed.

13. **To run a STAT sample,** return to the Main Menu (by pressing [≡]) *before* beginning the testing sequence for the STAT sample. Highlight "STAT Sample" in the Main Menu and press [↵] to change the prefix of the sequence number to "S." Analyze the STAT sample in the normal manner. The operating sequence is identical to that previously described; however, if a load list is present in the instrument's memory, display of the loadlisted ID numbers will be interrupted for the STAT sample, allowing the STAT ID number to be entered. After the results have been printed, the prefix will return to the assigned number and the loadlisted ID numbers (if being used) will return to the point at which the run was interrupted.

14. If an error is detected by the instrument, an appropriate error message will be displayed. Should this occur, refer to Section 7, TROUBLESHOOTING, for the probable cause and remedy of the error condition.

Operating Notes

1. To keep the feed table insert and its strip holding channel clean, wipe the channel with a damp, absorbent tissue as frequently as necessary to prevent excessive accumulation of urine. Also, wipe the insert after each batch is completed. To prevent the insert from misaligning, press against it with the thumb while wiping. See Section 6, CARE OF THE INSTRUMENT, for complete information on cleaning the feed table and feed table insert.
2. The instrument does not detect when the internal printer is out of paper and therefore will continue printing results even if there is no paper. However, the last several feet of paper on the roll contains a pink edge; the roll should be changed when this appears. Should any results be lost, they can be reprinted by entering the "Data Recall" routine from the Main Menu and pressing the key to print the desired files as each is displayed.
3. When the sequential ID number reaches "999," the next number assigned will be "001"; the prefix number will not change. For example, sequence number 1-999 will become 1-001 with the next specimen.
4. If you wish to clear a load list (partial or full) from the instrument memory, enter the **Instrument Setup** Routine and turn *off,* then back *on,* the option to use ID numbers. The load list will be erased to allow entry of a new list.

When Testing is Complete

1. When all testing has been completed, clean the feed table and feed table insert and inspect the white calibration chip, as described under "Daily Cleaning" in Section 6, CARE OF THE INSTRUMENT. If the insert is excessively dirty, clean as described under "Periodic Cleaning" in Section 6.
2. Gently push the table in to the "storage" position.
   NOTE: No Reagent Strip should be on the feed table when the instrument is not in use.
3. The instrument may be left *on* when it is not in use.

Figure 5-1
CHEK-STIX® Control Strips for Urinalysis

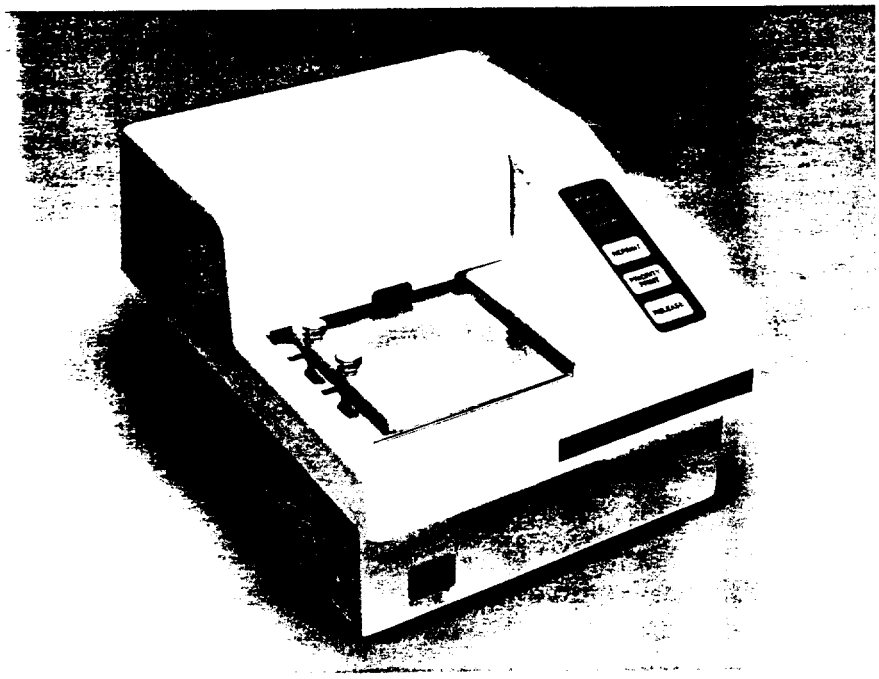


Figure 5-2
CLINITEK® Form Printer

Section 5

ACCESSORIES

CHEK-STIX® Positive and Negative Control Strips for Urinalysis

Combo Pak (Product Code No. 1364)
Positive Control Strips (Product Code No. 1360)
Negative Control Strips (Product Code No. 1365)

CHEK-STIX® Positive and Negative Control Strips for Urinalysis (Figure 5-1) provide a performance check for the CLINITEK® 100 Instrument/Reagent Strip System. CHEK-STIX Control Strips provide confidence that the Reagent Strips are reacting and being read properly. Errors resulting from user technique can also be detected.

CHEK-STIX Control Strips are reconstituted in distilled water to make up a CHEK-STIX control solution. Instructions are included in the package insert and on the bottle label, and test results that should be obtained are listed in the package insert. The Control Strips are available as a Combo Pak, which contains one bottle each of the Positive Control Strips and Negative Control Strips (25 strips/bottle). The Positive Control Strips and Negative Control Strips are also each available as separate products (one bottle of 25 strips).

CLINITEK® Form Printer

(Product Code No. 5255)

The CLINITEK® Form Printer (Figure 5-2) is available from Bayer Diagnostics for use with the CLINITEK 100 instrument. It can be interfaced to the instrument and all results then printed onto multi-copy forms. Three-copy forms (Product Code No. 5163) and replacement ribbon cartridges (Product Code No. 5256) are available from Bayer Diagnostics for use with the printer. The printer includes an interface cable for use with the CLINITEK 100 instrument.

Figure 6-1
Removing the Feed Table Insert

Figure 6-2
Cleaning the Feed Table Insert

Section 6

CARE OF THE INSTRUMENT

General Cleaning

Keep the exterior of the instrument free of dust at all times. If needed, the exterior may be cleaned using a damp cloth and a mild detergent. Do not use any type of solvent on any part of the instrument. Do not use any type of lubrication on the instrument; use of oil, grease, silicon spray, or any other lubrication may damage the instrument.

The display screen may be cleaned as needed by wiping with a soft, nonabrasive cloth that has been dampened with glass cleaner. Do not spray the glass cleaner directly on the screen. Do not use laboratory wipes, such as Kimwipes®, as they may scratch the screen.

Daily Cleaning

The feed table and feed table insert must be kept clean to obtain the best results with the CLINITEK® 100 Instrument/ Reagent Strip system. At the end of each day's use, the instrument's white plastic calibration chip, located on the feed table insert, and the reagent strip holding channel should be cleaned. To clean the feed table insert, perform the following:

1. Turn the CLINITEK 100 instrument *on.* The feed table will move out from the "storage" position to the "load" position. (If the instrument is already *on* but the feed table is in the "storage" position, it can be gently pulled out to the "load" position.)
2. **To remove the feed table insert from the feed table:** Grasp the front end of the insert on each side with the thumb and one finger. Apply a counter pressure with the palm of the hand against the feed table and gently pull the insert outward (Figure 6-1). After the insert is completely exposed, lift the front end of the insert up and off the table.
3. Clean the insert using a cotton-tipped applicator stick or other suitable absorbent material wetted with distilled water. Thoroughly swab the strip holding channel area until it is clean (Figure 6-2). Inspect the surface of the white plastic calibration chip for dust, foreign material, scratches, or scuffs. If necessary, gently wipe the calibration chip with

Figure 6-3
Replacing the Feed Table Insert

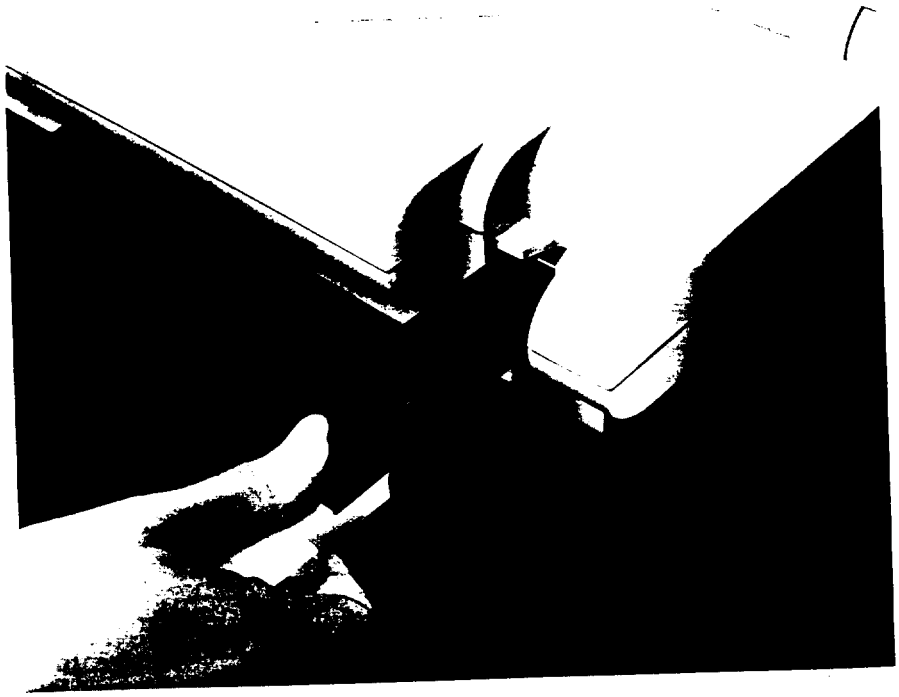


Figure 6-4
Replacing the Feed Table Insert

a cotton-tipped applicator stick wetted with distilled water. Allow the calibration chip to air dry before using. Make sure no foreign particles remain on its surface. If the calibration chip cannot be cleaned or is scratched or scuffed, replace the feed table insert (see Section 9, "Replacement Parts"). **CAUTION: Do not use any material that will scratch the feed table insert or the plastic calibration chip. Do not use solvents of any kind to clean the calibration chip.**

4. Wipe the feed table surface and feed table mounting groove with a damp cloth. Wipe the feed table dry with an absorbent tissue.

5. **To replace the feed table insert in the feed table:** Hold the feed table insert in the same manner as when it was removed (holding it by the end opposite the calibration chip). With the front end angled upwards, insert the calibration chip end about midway onto the feed table (Figure 6-3). Slide the insert in while lowering the front end until the insert is laying flat against the table and resistance is felt. Then place the thumb against the front edge of the insert and two fingers against the underside of the feed table. Apply a counter-pressure to the feed table while pressing the insert firmly inward (Figure 6-4). The insert is properly positioned in the feed table when the front edge is flush with the retaining rails of the feed table.

6. After replacing the feed table insert, the LEDs must be recalibrated. To ensure this occurs, turn the instrument *off,* wait several seconds, then turn it *on* again before testing additional samples.

CAUTION: If the calibration chip or a contact point becomes damaged, the feed table insert should be replaced.

Disinfection

The only part of the CLINITEK 100 instrument that comes into contact with the urine specimen is the feed table insert. To disinfect the insert, perform the following procedure:

1. Remove, clean, and dry the feed table insert as directed in "Daily Cleaning," Steps 1 to 4.
2. Prepare one of the following solutions for use in disinfection:
   a. 2% glutaraldehyde solution–Cidex™ * (used full strength) is a commercially available product that is acceptable for use. Refer to the labeling accompanying this disinfection product for complete instructions on its use.
   b. 0.25% sodium hypochlorite solution–dilute 5 mL of 5% sodium hypochlorite (e.g., Clorox®** Bleach) into 95 mL of water for a 1:20 dilution.
   c. Isopropyl alcohol (70%–85%), undiluted.
3. Fill a tall, narrow container to a depth of 4 inches (10 cm) with the disinfection solution.
4. Immerse the feed table insert into the disinfection solution **so the white plastic calibration chip remains above the liquid level.**
   CAUTION: Do not allow the disinfection solution to come in contact with the white plastic calibration chip, located on the feed table insert, or with any other portion of the feed table or instrument.

*Cidex™ is a trademark of Surgikos, Inc., Arlington, Texas.
**Clorox® is a registered trademark of The Clorox Company, Oakland, California.

5. Allow the feed table insert to remain in the solution for 10 minutes.
6. Remove the feed table insert and rinse thoroughly with distilled water to remove any residual solution.
7. Wipe the feed table insert dry with an absorbent tissue.
8. Replace the feed table insert in the feed table, as instructed in Steps 5 and 6 of the "Daily Cleaning" procedure.

Periodic Maintenance

Changing the Paper:

1. Lift the cover on the internal printer by pressing in on the lever on the back of the printer cover and lifting up on the cover (Figure 6-5). Remove the cover by pulling it towards the back of the instrument.
2. Remove the used paper roll core.
3. Place a new roll of paper into the printer, with the paper unrolling from beneath.
4. Feed the paper under the roller, as shown in the diagram in the printer, and advance the paper through the printer by rotating the knob on the right side of the printer (Figure 6-6). If the paper does not catch immediately, gently feed the paper into the roller while continuing to rotate the knob. To make insertion easier, be sure the leading edge is a clean, straight cut; trimming the paper to a point may also assist in easier insertion.
5. Allow 2-3 inches of paper to advance through the roller, then feed the paper through the opening on the printer cover. Place the lip of the cover under the ledge on the instrument opening and close the cover. Press down firmly on the back of the cover until it snaps into place.

Figure 6-5
Removing the Printer Cover

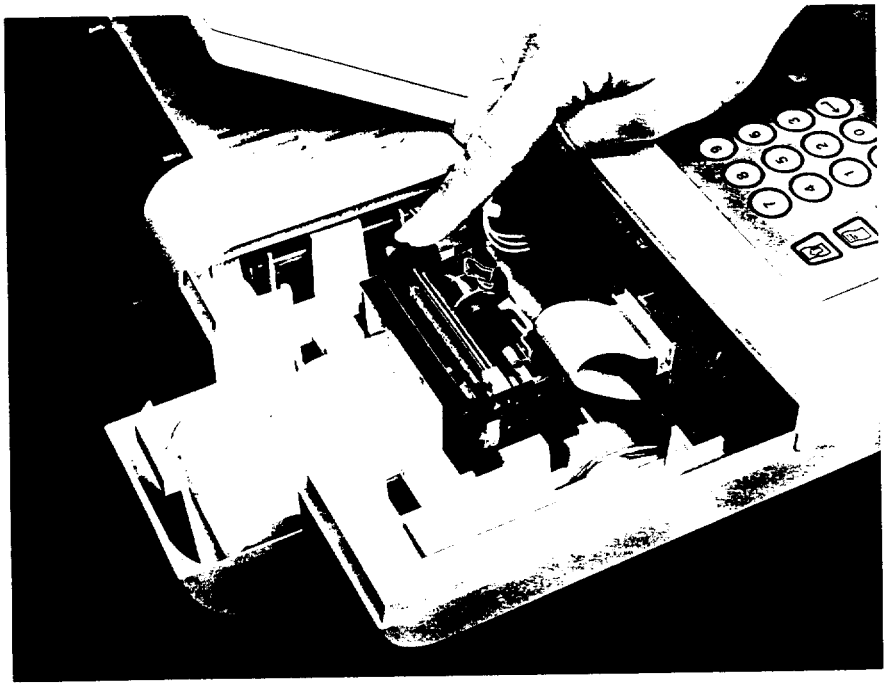


Figure 6-6
Installing the Paper

Periodic Cleaning:

If the feed table insert becomes excessively dirty and cannot be adequately cleaned as described in the "Daily Cleaning" procedure, the following procedure should be used:

1. Remove the feed table insert from the feed table, as described in Step 2 of the "Daily Cleaning" procedure.
2. Wipe the strip holding channel of the feed table insert with 0.1 N sodium hydroxide (NaOH) using a cotton-tipped applicator stick or other suitable absorbent material. Thoroughly swab the channel area until it is clean. **Do not wipe the white calibration chip with the NaOH.**
   CAUTION: Do not use any material that will scratch the feed table insert. Do not allow the NaOH to come in contact with the white plastic calibration chip or with any other portion of the feed table or instrument.
3. Rinse the feed table insert channel thoroughly with water to remove any residual NaOH.
4. Wipe the feed table surface and feed table mounting groove with a damp cloth. Wipe the feed table dry with an absorbent tissue.
5. Replace the feed table insert in the feed table. as instructed in Steps 5 and 6 of the "Daily Cleaning" procedure.

TROUBLESHOOTING

General Information

Error messages may be shown on the display of the CLINITEK® 100 Urine Chemistry Analyzer to alert the operator of an operational or instrument problem. This section of the manual lists the various errors that may be displayed, along with probable causes and recommended remedies, so that many isolated problems can be quickly corrected.

If additional assistance is required concerning an instrument problem, complete the "Preservice Checklist" in Section 9, SERVICE AND REPLACEMENT PARTS, then contact the Customer Service Department of Bayer Corporation, Diagnostics Division, by calling toll free 1-800-348-8100.

For problems concerning the Bayer Diagnostics Reagent Strips for Urinalysis or CHEK-STIX® Control Strips for Urinalysis, refer to the appropriate package insert for information that may help solve the problem, or contact the Customer Service Department.

For Customer Service outside the United States, contact the nearest Bayer Diagnostics office for information and assistance.

TROUBLESHOOTING CHART

Error/Message	Probable Cause	Remedy
Cal Chip Read Error (HIGH) or (LOW)	The reading taken on the calibration chip was above or below the specified limits because:	
	1. The calibration chip is dirty.	1. Clean the feed table insert and calibration chip, as directed in Section 6, "Daily Cleaning."
	2. The feed table insert is not properly positioned on the feed table.	2. Reinstall the insert so it is properly positioned; recalibrate the instrument (turn the power *off*, wait several seconds, then turn it back *on*).
	3. The ambient room temperature has changed significantly since the instrument was turned *on*.	3. Recalibrate the instrument (turn the power *off*, wait several seconds, then turn it back *on*).
Calibration Edge Error	Error in calibration because:	
	1. Feed table was bumped during the calibration procedure.	1. Be sure not to bump or jar the feed table during calibration. Turn the instrument *off*, wait several seconds, then turn it back *on* to recalibrate the instrument.
	2. Feed table insert is not properly positioned on the feed table.	2. Reinstall the insert so it is properly positioned; recalibrate the instrument (turn the power *off*, wait several seconds, then turn it back *on*).
	3. Instrument malfunction.	3. Recalibrate the instrument (turn the power *off*, wait several seconds, then turn it back *on*). If error repeats, contact Customer Service.

Calibration Error (HIGH) or (LOW)	The reading taken during calibration was above or below the specified limit.	Recalibrate the instrument (turn the power *off*, wait several seconds, then turn it back *on*). If error message repeats, contact Customer Service.
HARDWARE ERROR	Instrument malfunction	Contact Customer Service.
MEMORY FULL	The internal memory of 100 records is full (occurs only when computer port is *on*).	Transmit some or all of the records to the host computer to empty the memory (the computer must be turned *on* and request transmission); alternatively, clear the memory or turn *off* the computer port through the **Instrument Setup** Routine.
NO Computer Port Response	The computer port is not responding when requested to transmit data.	Check the computer interface cables; check the Baud rate selected through the **Instrument Setup** Routine. Request retransmission of the record. **CAUTION: Turning the computer port *on* or *off*, or changing the Baud rate, will clear the memory.**
NO DATA in Memory	There are no records stored in memory.	No strips have been run since either the memory was cleared or all records were transmitted to a host computer. **CAUTION: Turning the computer port *on* or *off*, or changing the Baud rate, will clear the memory.**

TROUBLESHOOTING CHART

Error/Message	Probable Cause	Remedy
No LOAD LIST in Memory	There are no ID numbers stored in the load list.	No ID numbers have been downloaded from a host computer or all numbers in the load list have been run. **CAUTION: Turning the "Use ID Numbers" option *off* or *on* will clear the load list memory.**
Printer Error	1. Internal printer: a. Printer is not properly connected to either the power or interface cables. (This should occur *only* if the module has just been replaced.) b. Printer malfunction.	1. Internal printer: a. Remove the printer module and reconnect the cables, making sure both are securely connected (see Section 8). b. Turn printer *off* through **Instrument Setup** Routine and contact Customer Service for replacement and repair information.
	2. External printer: a. A form was not present in the Form Printer. b. Printer is not turned *on* or is not "On-Line."	2. External printer: a. Be sure a form is in place in the Form Printer before the results are transmitted. Resend the last record by pressing the key after returning to the Main Menu. b. Be sure the printer is turned *on* and is "On-Line," ready to receive data, before transmitting records. Resend the last record by pressing the key after returning to the Main Menu.

	c. Interface cable is not properly connected.	c. Be sure the cable is plugged into the printer port on the CLINITEK 100 instrument and into the appropriate port on the printer. Resend the last record by pressing the key after returning to the Main Menu.
RAM Chip Failure	All memory within the RAM chip has been lost, either because the battery backup for the chip has failed or because the chip is faulty.	Turn the instrument *off*, wait several seconds, then turn it back *on*. Reset all instrument parameters to the correct strip configuration, time and date, etc. (all memory is lost with this error). If error repeats continuously, contact Customer Service.
STRAY LIGHT Warning	1. Excess ambient light was detected by the instrument during the reading cycle. 2. Instrument malfunction.	1. Do not place instrument where it is exposed to bright light (i.e., direct sun or a bright desk lamp). Rerun the specimen using a fresh Reagent Strip. 2. If error repeats continuously and the instrument is properly located away from sources of bright light, contact Customer Service.
STRIP MISSING	There is no Reagent Strip detected on the feed table; strip is missing or has not been properly positioned on the table.	Be sure the Reagent Strip is in place on the feed table before the table moves into the instrument for reading; be sure the tip of the strip is positioned against the end stop of the feed table.

TROUBLESHOOTING CHART

Error/Message	Probable Cause	Remedy
Strip Placement Error	1. Reagent Strip is dry, upside down, or incorrectly positioned on the feed table. 2. A configuration of Reagent Strips other than what is programmed to be read is being used (this error cannot always be detected).	1. Be sure the strip is properly positioned on the feed table, has been dipped in the urine or control solution, and is placed with the pads facing up. 2. Be sure the strip being used corresponds to the name of the Reagent Strip shown on the Main Menu. Use of any other strip may give erroneous results.
Table Position Error (IN) or (OUT)	1. The table was bumped or otherwise mispositioned while reading a Reagent Strip. 2. Instrument malfunction.	1. Retest the urine or control sample using a fresh Reagent Strip. Be sure not to bump or jar the feed table during the entire testing procedure. 2. If error repeats continuously, contact Customer Service.
Table SENSOR Failure	Instrument malfunction.	Retest the urine or control sample using a fresh Reagent Strip. If error repeats, contact Customer Service.

Section 8

MINOR REPAIR

The CLINITEK® 100 Urine Chemistry Analyzer is a self-contained instrument that is almost maintenance free. With proper care and use, the instrument should operate reliably with a minimum of operator attention. The only minor repairs that can be performed are the replacement of the feed table insert and replacement of the fuse. In addition, the modular printer can be removed from the instrument and replaced with a new printer. This section is provided as an aid in performing these minor repairs and functions. For any repairs other than those given in this section, refer to Section 9, SERVICE AND REPLACEMENT PARTS, for instructions on obtaining service for your instrument.

Replacement of Feed Table Insert

Tools Required:
None

Parts Required:
Feed Table Insert (4¼ inch—Part No. 95001086)

The feed table insert must be replaced if it has become damaged. Remove the insert that is in the instrument, as directed in Section 6, "Daily Cleaning," Step 2. Install the new insert, as directed in Steps 5 and 6 of the same section.

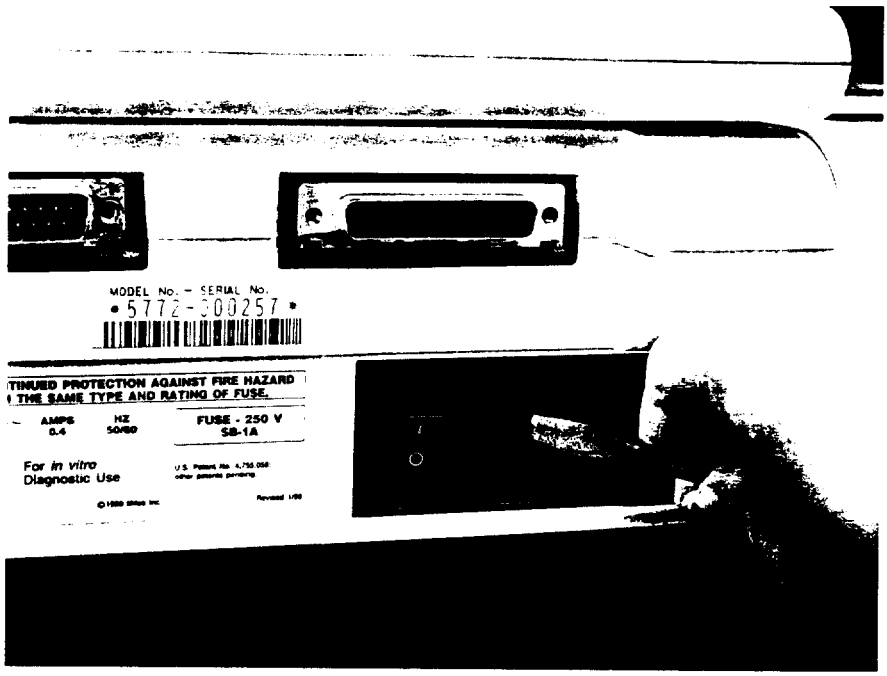


Figure 8-1
Opening the Fuse Cover

Figure 8-2
Replacing the Fuse

Fuse Replacement

Tools Required:
Screwdriver (narrow blade type, stubby)

Parts Required:
Instrument Line Fuse—
1.0 amp, Slo-Blo, 5x20mm (Part No. 40151108)
(for 115 VAC instruments)
*1.0 amp, Time Delay
(for 100 VAC instruments)
*2.0 amp, Time Delay
(for 220 or 240 VAC instruments)

Procedure:

1. **WARNING: TURN THE INSTRUMENT *OFF* AND REMOVE THE AC ELECTRICAL CORD FROM THE INSTRUMENT BEFORE REPLACING THE FUSE.**
2. Using a short, narrow-blade screwdriver (no more than about 2½ inches long), pry the fuse cover open (Figure 8-1). The entire fuse holder will now pull out of the instrument like a small drawer.
3. Pull the fuse out of the holder (Figure 8-2) and discard if blown.
4. Replace the defective fuse with an identical type fuse listed above.
   CAUTION: Use fuse of specified type and amperage rating only.
5. Replace the fuse cover into the instrument (with the closed side of the holder to the right). Press firmly on the cover until it snaps into place and is flush with the power module plate.

*For instruments located outside the United States, contact your local distributor for the appropriate fuse.

Figure 8-3
Removing the Printer Cover

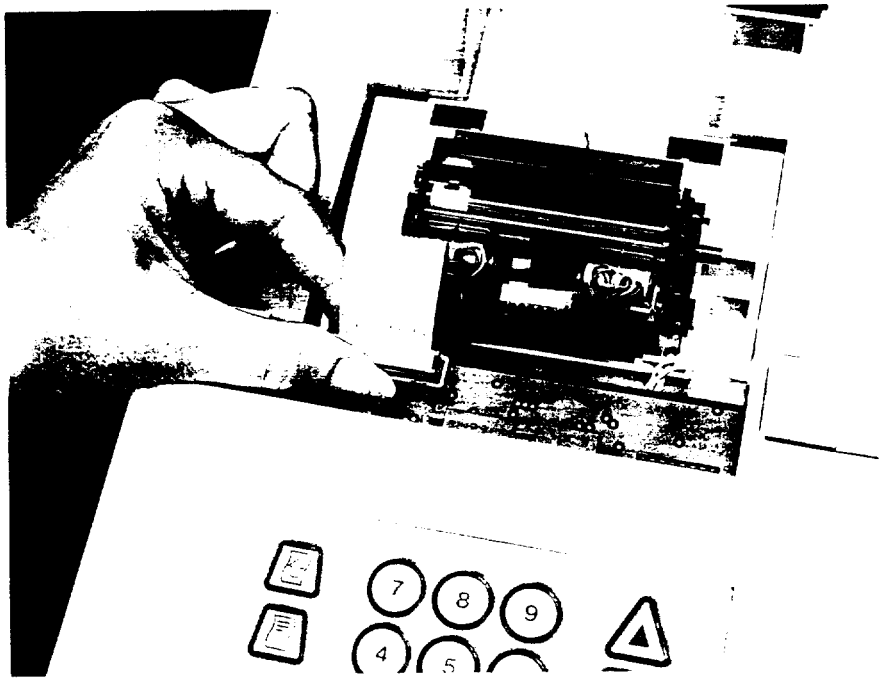


Figure 8-4
Printer Module Interface Cable

Removal and Replacement of Printer Module

Tools Required:
None

Parts Required:
Printer Module (Part No. 95001186)

Procedure:

CAUTION: When removing and replacing the printer module, do not touch the underside of the module; handle by the sides and top only. The lead pins underneath the module are sharp and may scratch, and static electricity from touching the pins may cause damage to the components.

1. **WARNING: TURN THE INSTRUMENT *OFF* AND REMOVE THE AC ELECTRICAL CORD FROM THE OUTLET.**
2. Lift the cover on the internal printer by pressing in on the lever on the back of the printer cover and lifting up on the cover (Figure 8-3). Remove the cover by pulling it towards the back of the instrument.
3. Remove the roll of paper from the printer by gently pulling the paper backwards from the print head (tear off any excess paper first), then lifting the roll out of the printer.
4. **To remove the printer module:**
   a. The printer is connected in the instrument by two different cables, a 14-pin interface cable for transferral of data (shown in Figure 8-4) and a 3-pin power cable that connects to a jumper cable via a keyed connector (shown in Figure 8-7). The jumper cable is tucked underneath the instrument cover and is most easily revealed *after* removing the printer module (Step 4-b). Disconnect the interface cable from the PC board by pulling straight up on the plug (Figure 8-4).

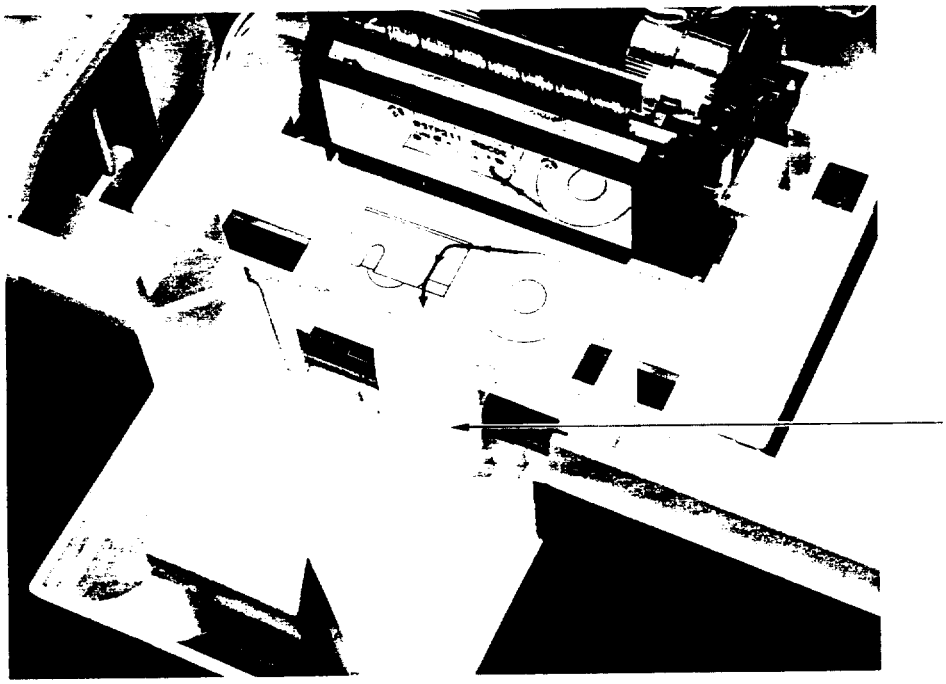


Figure 8-5
Printer Module Lever

Figure 8-6
Removing the Printer Module

b. The module hooks under a ledge at the front and snaps into position at the back with a small lever (Figure 8-5). Press in on the lever at the back and lift up on the printer (Figure 8-6). Raise the module partially out of its cavity by lifting up and back.
c. The module will still be connected to the instrument by the power cable. The keyed connector on this cable has a small lever on each side; press these together and pull apart the two sides of the plug to disconnect the power cable (Figure 8-7). Completely remove the module from the instrument.

5. **To replace the printer module:**
   a. Obtain the replacement printer module, to which is attached an interface cable and jumper cable. Be sure both cables are firmly attached to their appropriate receptacles on the module by pushing *straight down* on the connectors (the jumper cable connects into the board immediately to the left of the printhead).
   b. Carefully set the new module onto the edge of the CLINITEK 100 instrument or partially into the instrument cavity. Plug the power cable into the jumper cable by pressing together the two sides of the connector. Notice that the two sides fit together in only one direction.

Figure 8-7
Disconnecting the Power Cable

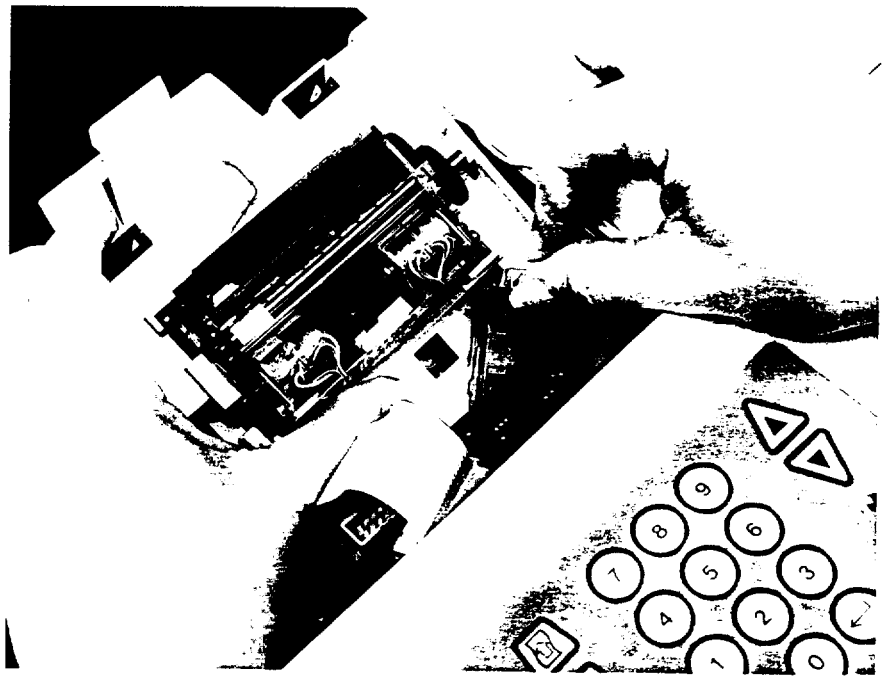


Figure 8-8
Reinstalling the Printer Module

c. Place the module into its proper position in the cavity of the instrument by lowering the front of the module down and forward under the ledge. At the same time, maneuver the connector so it slides under the ledge along with the module (Figure 8-8). Then lower the back of the module and press down firmly until it snaps into place.
d. Carefully plug the interface cable onto the rows of pins on the PC board. Press *straight down* on the pins until the cable is securely connected.
e. Replace the roll of paper, as instructed in Section 6, "Periodic Maintenance."
f. Plug in and turn *on* the CLINITEK 100 instrument. Test the new printer by printing out a record through the Data Recall prompt (in the Main Menu) or by performing several Reagent Strip tests. (If you had turned the internal printer *off* prior to replacement of the module, be sure to turn it back *on* through the Instrument Setup Routine.)
   NOTE: If "Printer Error" is displayed when attempting to print, check for a tight and proper connection of each of the two cables.

Section 9

SERVICE AND REPLACEMENT PARTS

Where To Call For Service

When problems arise during operation of the CLINITEK® 100 instrument, first refer to Section 7, TROUBLESHOOTING. Avoid erroneous instrument/Reagent Strip results by following proper instrument and Reagent Strip procedures. If the problem cannot be solved and an instrument defect is apparent, contact your nearest authorized Customer Service or Instrument Service Representative. In the United States, contact the Customer Service Department of Bayer Corporation, Diagnostics Division, by calling toll free 1-800-348-8100 for complete information regarding service for your CLINITEK 100 instrument. In countries other than the United States, contact the nearest Bayer Diagnostics office for service information.

If the problem centers on the Bayer Diagnostics Reagent Strips for Urinalysis, the CHEK-STIX® Control Strips for Urinalysis, or operator technique, contact the Customer Service Department (continental U.S. customers only). For Customer Service outside the United States, contact the nearest Bayer Diagnostics office.

Before calling for instrument service, collect the information requested in the following "Preservice Checklist." This information will help the Customer Service Representative to identify the probable cause of instrument malfunction.

CLINITEK® 100 Preservice Checklist

For reference, record the following information:

Instrument Serial Number_____

Installation Date_____

	YES	NO
1. Has Section 7, TROUBLESHOOTING, been reviewed?	☐	☐
2. Does the feed table move out to the "load" position when the instrument is first turned *on*?	☐	☐
3. If Step 2 is NO—		
• is the instrument plugged into a live AC electrical outlet?	☐	☐
• is the line fuse defective? (See Section 8.)	☐	☐
• is the Program Card firmly in place and properly oriented?	☐	☐
4. Does the display show the appropriate series of messages when the instrument is first turned *on*?	☐	☐
5. Do the three colored LEDs flash *on* and *off* when the instrument is performing its "Self-Test"? (See Section 1, "Optical System.")	☐	☐
6. Does the feed table move into the "storage" position shortly after [◇] is pressed?	☐	☐
7. Is the keyboard operating properly?	☐	☐
• Is the instrument taking a reading on a Reagent Strip?	☐	☐
8. Does a Bayer Diagnostics Reagent Strip dipped into a negative control urine provide correct readings?	☐	☐
• Has a second strip been tried?	☐	☐
9. Does the Reagent Strip name displayed correspond to the Bayer Diagnostics Reagent Strip being used?	☐	☐
10. Is the display area functioning properly?	☐	☐
11. Does the display show the appropriate test names and numbers? (See Tables 1-1 to 1-8.)	☐	☐
12. Is the feed table insert properly positioned on the feed table?	☐	☐
13. Is the feed table insert or calibration chip scratched or damaged?	☐	☐
14. Does the feed table operate properly?	☐	☐

If not, describe:_____

_____

15. Please record the software version being used (displayed below the instrument name when power is first turned *on*)._____

Replacement Accessory Items

Product No.	Description
1364	CHEK-STIX® Combo Pak Control Strips for Urinalysis
1360	CHEK-STIX® Positive Control Strips for Urinalysis
1365	CHEK-STIX® Negative Control Strips for Urinalysis
5773	Thermal Printer Paper (5 Rolls)
5371	Epson LX-series Printer
5255	CLINITEK® Form Printer
5256	CLINITEK® Form Printer Ribbon Cartridge
5163	CLINITEK® Report Forms

In the United States, the above Accessory Items are available from your authorized CLINITEK 100 distributor. Outside of the United States, contact the nearest Bayer Diagnostics office.

Replacement Parts

Part No.*	Description
95001474	Feed Table Insert—4¼ inch ( )
95001476	Feed Table Insert—3¼ inch ( )
40151108	Instrument Line Fuse—1.0 Amp, Slo-Blo, 5x20mm (for 115 VAC instruments)
*	Instrument Line Fuse—1.0 Amp, Time Delay (for 100 VAC instruments)
*	Instrument Line Fuse—2.0 Amp, Time Delay (for 220 or 240 VAC instruments)
6040	Program Card
95001186	Printer Module
40330028	AC Power Cord
99957728	CLINITEK 100 Service Manual

In the United States, the above Replacement Parts are available directly from Instrument Service, Bayer Corporation, Diagnostics Division, P.O. Box 2004, Mishawaka, IN 46546.

*Outside of the United States, contact the nearest Bayer Diagnostics office.

Appendix I

COMPUTER AND PRINTER INTERFACE

General Information

This appendix is written primarily to assist a software engineer in writing a program for interfacing the CLINITEK® 100 Urine Chemistry Analyzer to a host computer via the serial port on the instrument. It also contains information for interfacing a printer via the parallel port on the instrument.

Computer Interface–Data Transfer To/From a Computer

EIA-232D (Serial) Port

The EIA-232D (serial) port is the means by which Reagent Strip data or test information is transferred to a computer or data management system. In addition, specimen number "load lists" are downloaded to the instrument from a host computer via this port. The EIA-232D standard was accepted in 1986 by the Electronics Industries Association (E.I.A.) as the revised and upgraded standard of the earlier RS-232C version.

The interface connector for the serial port is found on the rear of the instrument and is labeled "EIA-232-D." The connector has the following characteristics: DCE Male, DB25, EIA-232D. The data interface operates using 7-bit ASCII in a serial asynchronous data transfer method. Each character is preceded by one start bit, followed by eight data bits/no parity, and ends with one stop bit.

CAUTION: The serial port can be interfaced *only* to an EIA-232D or RS-232C connector; use of any other configuration of serial port (e.g., RS-422, RS-423, RS-485) may result in instrument errors or damage. If a different serial configuration is required (for example, because the interface cable must be longer than is suggested for an EIA-232 or RS-232 cable), a converter box must be used between the serial port on the instrument and the alternate cable. (Depending upon your computer requirements, you may also need a second converter box on the computer end of the cable.)

The operating characteristics of the port may be defined by the operator in the **Setup** Routine, which is accessed through the **Menu** Function (refer to Section 2, Part B). The following settings may be configured:

Settings	Description
1. Computer Port	Enables output from EIA-232D port in the handshake mode: On Off
2. Baud Rate	Selects the transmission speed: 300 600 1200 2400 4800 9600
3. Date Format	Selects the format for the date: YY-MM-DD MM-DD-YY DD-MM-YY
4. Time Format	Selects the format for the time: 24 Hour 12 Hour
5. Identify Abnormals	Sends flag with abnormal results (see "Possible Clinical Results"): No Yes
6. Identify First Abnormal Level	Selects the first level at which the abnormal flag will be sent (option available only with Identify Abnormal set to "Yes"—see "Possible Clinical Results").
7. Specimen ID Entry	Sends ID number with data: No Yes
8. Color/Clarity Entry	Sends Color and Clarity with data: No Yes
9. Plus System	Sends results in "Plus" system (1+, 2+, 3+) rather than semiquantitative or qualitative results: No Yes

Software Handshaking

The computer protocol can be written to operate in either of two modes for sending and/or receiving data to and from the CLINITEK 100 instrument:

1) **Handshake ON:** The computer handshake mode allows a connected computer to "request" that a set of data be transmitted or that the last set of data be resent. Recovery of bad data is possible through the use of special control characters (defined below). If the computer port is turned ON, the handshake mode is automatically enabled.
2) **Handshake OFF:** If the computer port is turned OFF, the instrument will still transmit data to a host computer under the following three conditions:
   a) the host computer must be connected to the CLINITEK 100 instrument through the serial port;
   b) the host computer must be turned *on;* and
   c) all data is transmitted in a non-handshake mode.

   The data is transmitted to the connected computer as soon as it is available (that is, each time a strip is run on the instrument); the results are NOT stored in the instrument memory, regardless of whether a computer is connected to receive the data. No response is required from the computer; however, once data is sent, it is gone and cannot be recovered. The data format is such that a printer with a serial port could be connected if desired.

Data transmission from the CLINITEK 100 can be suspended by the connected computer by either of two methods:

1) The hardware handshake lines may be used to stop data transmission.
2) An XON/XOFF software protocol can be used to stop data transmission temporarily. Sending the XOFF control character to the CLINITEK 100 stops data flow; sending the XON control character starts data flow again. When the instrument is turned *on,* the XON condition is in effect. Before any character in a data set is transmitted, the input buffer is checked; if an XOFF (DC3; 13Hex) has been received, no transmission will occur until an XON (DC1; 11Hex) character is received.

The instrument sends its data in frames beginning with an STX (Start of Text; 02Hex) and ending with an ETX (End of Text; 03Hex). Each frame contains one full set of patient data.

The special control characters and functions are listed in Table App I-1 below:

ASCII	Hex	Function/Command
Data Control:		
CAN	18	Reset RS-232C port to default conditions.
DC1	11	XON–Enable transmission.
DC3	13	XOFF–Disable transmission.
Data Output Control (computer "handshake" operation)		
DC2	12	Prompt character; send one set of data. If an ENQ (05Hex) was the last control character received, send the instrument ID message instead.
ACK	06	Move to the next set of data for future data prompts.
NAK	15	Do not change to the next data set. (This control code is not required to be sent, since it is the default condition. Sending a DC2 will send the same data set again.)
Instrument ID Message (active only when *not* in Run Mode)		
ENQ	05	Send the instrument ID message when the next DC2 is received. This message includes information on the time and date, instrument identity and software revision, language and units, and Reagent Strip name.

Table App I-1

Cabling and Pin Specifications

The cable normally used to interface with the CLINITEK 100 instrument is a Null modem cable. This cable crosses pins 2 & 3, 4 & 5, and 6 & 20; pins 1 and 7 are straight through. Refer to Table App I-2 below for definitions of the pin assignments and hardware handshaking.

Pin Assignments:

Pin Number	Signal Name	Function	Type	Signal Source
1	CHAS GND	Protective Ground	Ground	N/A
2	TXD	Transmission Data	Data	CLINITEK 100
3	RXD	Received Data	Data	Computer
4	RTS	Request To Send	Control	CLINITEK 100
5	CTS	Clear to Send	Control	Computer
7	SIG GND	Signal Ground	Ground	N/A

(All other pins are unused.)

Hardware Handshaking:

RXD	Receive Data	This input receives control characters for software handshaking and data for ID#'s.
TXD	Transmit Data	This output sends test data, control characters, and instrument information.
RTS	Request To Send	This output line, when high, indicates to the computer that it may send data.

The following signal lines are NOT implemented:

DSR	Data Set Ready	Pin 6
DCD	Data Carrier Detect	Pin 8
DTR	Data Terminal Ready	Pin 20
RNG	Ring Indicator	Pin 22

Table App I-2

Computer Checksum

Computer checksum is provided to allow the computer system to detect transmission errors. Parity provides for character-by-character error checking, but it is only good for detecting single bit errors and does not detect double bit errors and missing characters. A checksum will detect these types of errors in transmission.

The checksum is a two-digit ASCII hexadecimal code transmitted immediately before the ETX character at the end of a data set. The checksum is calculated by adding all characters between the STX and ETX characters (not including the two checksum bytes), ignoring any carry. The result is an 8 bit number (0 to 255) that is converted into two hexadecimal ASCII codes ("0" - "9", "A" - "F"). For example, the binary code "01011010" equals "5A," and the two bytes "5" and "A" would be sent as the checksum. The least significant byte (in this example, "A") is sent first, followed by the most significant byte (in this example. "5").

Data Output Formats

Table App I-3 below shows the data format for each record sent by the CLINITEK 100 instrument.

CHARACTERS/COLUMNS

```
01 02 03 04 05 06 07 08 09 10 11 12 13 14 15 16 17 18 19 20 21 22
STX CR LF
 #  X  -  X  X  X SP SP SP SP SP  X  X  -  X  X  -  X  X CR LF     (Seq# and date)
 I  .  D  . SP  X  X  X  X  X  X  X  X  X  X CR LF                 (If ID#'s selected)
 C  o  l  o  r  : SP SP SP  X  X  X  X  X  X  X  X  X  X  X CR LF  (If Color selected)
 C  l  a  r  i  t  y  : SP  X  X  X  X  X  X  X  X  X  X  X CR LF  (If Clarity selected)
CR LF
 X  X  X SP SP SP  X  X  X  X  X  X  X  X  X  X  X  X CR LF       (Analyte mnemonic
                                                                   & result)
                                  .
                                  .
                                  .  (Up to 9 additional tests)
LSB MSB ETX
```

STX—Start of Text (02Hex)
CR —Carriage Return (0DHex)
LSB—Least Significant Byte of Checksum
SP —Space Character (20Hex)

ETX —End of Text (03Hex)
LF —Line Feed (0AHex)
MSB—Most Significant Byte of Checksum

Table App I-3

All analyte/result lines are 20 characters long, including the Carriage Return and Line Feed. There are three spaces between the mnemonic and the result field for each analyte except SG and pH, for which there are four; the number of spaces following the result field varies. Table App I-5 shows all possible results for each of the ten analytes plus color and clarity.

Depending upon the Bayer Diagnostics Reagent Strip being used, there are at most 10 lines of analytes/results. The order in which the analytes are output is the same order in which they are read by the instrument, as shown in Table App I-5; this order is the same for every configuration of Bayer Diagnostics Reagent Strips that can be used on the instrument.

Table App I-4 shows the data format of the instrument ID information that is sent by the CLINITEK 100 instrument when an ENQ and a DC2 are sent to it by the computer.

CHARACTERS/COLUMN

01	02	03	04	05	06	07	08	09	10	11	12	13	14	15	16	17	18	19	20	
STX	CR	LF																		
I	D	SP	0	9	:	5	1	0	5	-	2	2	-	9	2	CR	LF			(18 characters)
A	M	5	7	7	2	SP	SP	SP	F	3	.	0	2	CR	LF					(16 characters)
E	N	G	L	I	S	H	SP	C	O	N	V	.	CR	LF						(20 characters maximum)
M	U	L	T	I	S	T	I	X	SP	1	0	SP	S	G	CR	LF				(20 characters maximum)
LSB	MSB	ETX																		

Table App I-4

Line 1 identifies this as an ID message and gives the date and time programmed into the instrument. Line 2 identifies the instrument as a CLINITEK 100 and gives the software revision. Line 3 identifies the language and units, if applicable, that are selected. Line 4 identifies the Bayer Diagnostics Reagent Strip currently selected.

NOTE: The instrument will send an ID message only while in the **Standby** Mode; the message will not be sent while in the **Run** Mode.

After correctly receiving the instrument ID message, the host computer must respond by sending an ACK. Failure to do so will cause the instrument to continually send the instrument ID message for each DC2 prompt received.

Data Reception from a Host Computer (Downloading)
The CLINITEK 100 instrument can receive a "load list" of specimen identification numbers from a host computer. Each ID# must contain exactly 10 numeric digits. The load list (up to 50 specimen numbers) is stored in the load list buffer of the instrument and can be printed by the internal printer of the instrument. The host computer can transmit the specimen numbers whenever the instrument is in the **Standby** Mode and information is not being printed by the instrument's internal printer. Operation is as follows:

1. The computer sends an STX.
2. The instrument responds with an ACK.
3. The computer sends a specimen ID number as:

   01 02 03 04 05 06 07 08 09 10 11 12
   STX X X X X X X X X X X X ETX (10 numeric digits)

4. If the CLINITEK 100 instrument can accept the number, it is stored in the load list buffer and an ACK control character is sent to the computer. The remaining specimen ID numbers can then be sent. For each additional number, the computer sends an STX as in Step 1 (the instrument does not respond with an ACK) and then sends the ID number (Step 3).
5. If the instrument cannot accept the number, a NAK control character is sent to the computer. A NAK will be sent if the instrument is not in the **Standby** Mode or if the load list buffer is full.
6. The computer must send an EOT at the end of the transmission of ID numbers. When the EOT (04Hex) is received by the instrument, and if there are ID numbers in the buffer, the number(s) will be printed by the instrument's internal printer as a "load list."

   NOTE: If "Specimen ID Entry" was selected as "No" in the **Setup** Routine, the load list buffer will clear after printing the load list. This allows for another load list to be sent. If "Specimen ID Entry" was selected as "Yes," the load list will be retained in the buffer until recalled through the **Run** Mode.

NOTES:

a) The ACK or NAK will be returned within 25 ms. of reception of the ETX.

b) At Baud rates of 1200 or greater, a minimum delay of 5 ms. must be placed between each character, regardless of whether or not handshake is used.

Possible Results

Color	Yellow	Dk Yellow	Straw	Amber	Red	Orange	Green	Other	
Clarity	Clear	Sl Cloudy	Cloudy	Turbid	Other				
GLU	Negative	Trace	250 mg/dL	500 mg/dL	>=1000 mg/dL				
BIL	Negative	Small	Moderate	Large					
KET	Negative	Trace	15 mg/dL	40 mg/dL	>=80 mg/dL				
SG	<=1.005	1.010	1.015	1.020	1.025	>=1.030			
pH	5.0	5.5	6.0	6.5	7.0	7.5	8.0	8.5	>=9.0
PRO	Negative	Trace	30 mg/dL	100 mg/dL	>=300 mg/dL				
URO	0.2 EU/dL	1.0 EU/dL	2.0 EU/dL	4.0 EU/dL	>=8.0 EU/dL				
NIT	Negative	Positive							
BLO	Negative	Trace	Small	Moderate	Large				
LEU	Negative	Trace	Small	Moderate	Large				

Table App I-5

NOTES:

1. If the "Plus System" option is being used, the results are modified as follows:
   GLU, KET, PRO, BLO, LEU: Results greater than Trace are 1+, 2+, and 3+
   BIL: Results greater than Negative are 1+, 2+, and 3+

2. If "Identify Abnormals" is selected as "Yes," any result greater than Negative may be flagged for GLU, BIL, KET, PRO, NIT, BLO, and LEU; any result greater than 1.0 EU/dL for URO may also be flagged. The lowest level that is considered to be abnormal is determined through the Setup Routine. Abnormal results are flagged with an asterisk (*), immediately after the mnemonic abbreviation for the analyte. If not flagged, a SPACE character follows the mnemonic. In both cases, the line length remains the same.

Printer Interface–Data Transfer to a Printer

Printer (Parallel) Port

The printer (parallel data) port is of the "Centronics" style of interface with a DB-25 connector. It is provided for use with either of two types of printers:

1. CLINITEK® Form Printer–a special format of data is generated for this form printer when "Form Printer" is selected as "ON" in the **Setup** Routine. The Form Printer (Product No. 5255) includes an interface cable to connect the printer to the CLINITEK 100 instrument.
2. Any standard 80-column printer having a Centronics style of interface–"80 Column Printer" must be selected as "ON" in the **Setup** Routine. The interface cable that is used to connect the 80-column printer to the CLINITEK 100 must contain a DB-25 female connector (standard IBM configuration).

Pin Specifications for Printer Interface (DB-25 Female Connector)

Pin Number	Signal Name	Function	Note	Signal Source
1	STROBE-L	Data Strobe	1	CLINITEK 100
2	Data 1	Parallel Data Line		CLINITEK 100
3	Data 2	Parallel Data Line		CLINITEK 100
4	Data 3	Parallel Data Line		CLINITEK 100
5	Data 4	Parallel Data Line		CLINITEK 100
6	Data 5	Parallel Data Line		CLINITEK 100
7	Data 6	Parallel Data Line		CLINITEK 100
8	Data 7	Parallel Data Line		CLINITEK 100
9	Data 8	Parallel Data Line		CLINITEK 100
11	BUSY	BUSY Line		Printer
12	DS	Document Status or Paper Out		Printer
18	SIG GND	Signal Ground	2	N/A

NOTES:

1. STROBE-L (Data Strobe): "-L" indicates active low signal.
2. SIG GND (Signal Ground): Pins 19 through 25 are also connected to the signal ground.

Table App I-6

CLINITEK® 100
Urine Chemistry Analyzer

Instrument Serial No.

Installation Date

MANUFACTURER'S WARRANTY

(U.S. Customers Only)

Bayer Corporation, Diagnostics Division ("Bayer") warrants to the original purchaser that this instrument will be free from defects in materials and workmanship for a period of one (1) year from the later of the date of original purchase or installation (except as noted below). During the stated one-year period, Bayer shall replace with a reconditioned unit or, at its option, repair at no charge a unit that is found to be defective.

This warranty is subject to the following exceptions and limitations:

1. A 90 day warranty only will be extended for consumable parts and/or accessories.
2. This warranty is limited to repair or replacement due to defects in parts or workmanship. Parts required which were not defective shall be replaced at additional cost, and Bayer shall not be required to make any repairs or replace any parts which are necessitated by abuse, accidents, alteration, misuse, neglect, maintenance by other than Bayer, or failure to operate the instrument in accordance with instructions. Further, Bayer assumes no liability for malfunction or damage to Bayer instruments caused by the use of reagents other than reagents manufactured or recommended by Bayer.
3. Bayer reserves the right to make changes in design of this instrument without obligation to incorporate such changes into previously manufactured instruments.

Disclaimer of Warranties

THIS WARRANTY IS EXPRESSLY MADE IN LIEU OF ANY AND ALL OTHER WARRANTIES EXPRESS OR IMPLIED (EITHER IN FACT OR BY OPERATION OF LAW) INCLUDING THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR USE WHICH ARE EXPRESSLY EXCLUDED, AND IS THE ONLY WARRANTY GIVEN BY BAYER.

Limitations of Liability

IN NO EVENT SHALL BAYER BE LIABLE FOR INDIRECT, SPECIAL OR CONSEQUENTIAL DAMAGES, EVEN IF BAYER HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

For warranty service, purchaser must contact the Customer Service Department of Bayer Corporation, Diagnostics Division by calling toll free 1-800-348-8100, for assistance and/or instructions for obtaining repair of this instrument.

Information on New Tests

New products are now available for use on your CLINITEK® 100 Urine Chemistry Analyzer. Before these new tests can be used, however, the software in your instrument must be updated by installing a new Program Card, as instructed in the directions below. Once the new Program Card has been installed, you can obtain a display of each of the tests your instrument is programmed to read. When one of the new tests is placed onto the feed table and pulled into the instrument for reading, the instrument automatically determines its identity. If the test is recognized, the instrument reads it at the appropriate time(s) without any user intervention. (A message is displayed if the new test is not recognized.)

This appendix provides directions for installing the new Program Card and a description of the changes you will see in the screen displays with the new software. **Refer to the direction insert that is included with each product for information on running the test with this instrument.**

Installing the New Program Card

Before performing the instrument update, be sure all patient results have been printed and/or transmitted to a host computer (memory will be lost when the update is made). Then proceed as directed below.

1. Record your current instrument setup, as follows: From the Main Menu, enter the "Instrument Setup Routine." Highlight "Status" from the Setup Menu and press ⏎ to display the instrument setup parameters that are currently selected. Record these parameters for use in Step 4 below. Then turn the instrument *off*.

2. Remove the Program Card from the card receptacle on the front of the instrument and replace it with the new Program Card. The side containing the metal ridges is inserted into the instrument, with the label side up and the arrows on the label pointing into the instrument. Press the card firmly into the receptacle until it "snaps" into place. (Refer to Page 3.3 and Figure 3-1 in the Operating Manual.)

3. Discard the old Program Card.

4. Turn the instrument *on*. An "Instrument Warning" will be displayed; press any key to continue. After the calibration/self-test has been completed and the initial screen is displayed, press the M key (MENU) to display the Main Menu. Highlight "Set Up Instrument" and press ⏎ to display the Setup Menu. Select the desired operating parameters to match those that were previously being used, and select any new features you wish to use. Refer to Section 2, Part B, in the Operating Manual for complete information on Instrument Setup.

   NOTE: When the instrument is first turned *on*, the initial display will show the Bayer Reagent Strip that is programmed for use. If the reagent strip name being displayed does not agree with the strip to be used, contact your Bayer instrument representative. In the United States, you may call toll free 1-800-348-8100; outside of the United States, contact the nearest Bayer office. Do NOT use your instrument until the correct Reagent Strip name is being displayed; however, this step (entry of the setup parameters) may be completed.

Changes to the Displays:

You will notice three changes to the displays after the new Program Card is installed:

- The initial screen on the CLINITEK 100 Analyzer (which shows the time and date) shows the tests that can be read with the Program Card that is installed. The display lists the name of the Bayer Reagent Strip for Urinalysis that is selected for use in your laboratory. It also displays the family name(s) for the new tests (such as the CLINITEK® family of tests) ; for example:

```
Multistix 10 SG                    10-22-96
CLINITEK Tests                     03:08 pm

                Clinitek 100
                Version I3.05


MENU                                  START
```

- A new option ("Available Tests") has been added to the Main Menu display; for example:

```
Multistix 10 SG      0-001         10-22-96
                                   03:08 pm
Set Sequence No.      Available Tests
STAT Sample
Control Sample
Data Recall
Set Up Instrument
Print Load List                       MENU
```

  When this option is selected, the display shows the name of each test that can be read by your Analyzer, including each of the new tests.

- After the green ◇ (START) key is pressed, the display will now prompt "`Place Test on Table`" (rather than "`Place Strip on Table`").

Predicate Devices

CHEMSTRIP

Micral™ URINE TEST STRIPS

Chemstrip® Micral™ Urine Test Strips

Dip and Read Test For The Semi-Quantitative Determination of Microalbuminuria

Cat. No. 417146

Our medical professionals are ready to answer your questions 24 hours a day at 1-800-858-8072, or answer your Fax, toll free, at 1-800-858-8073.

Intended Use

The Chemstrip® Micral™ immunochemical test strip is a simple and rapid colorimetric assay used to detect the presence of low concentrations of albumin in urine. This measurement is useful in the evaluation of renal disorders.

FOR PROFESSIONAL USE ONLY.
FOR IN VITRO DIAGNOSTIC USE ONLY.

Summary

Microalbuminuria refers to an albumin concentration in the urine which is greater than normal, but usually not detectable with routine protein dipstick assays which permit measurement of albumin at levels of 15 mg/dL or greater. There are multiple renal disease etiologies in which laboratory findings include proteinuria.[1] Albumin is the prominent protein in most renal diseases.[1] Monitoring low concentrations of albumin in the urine is helpful for early detection in patients at risk for renal disease.

Those at risk for renal disease in which albuminuria may be present, include but are not limited to patients with Type I and Type II diabetes, hypertension[2,3] and renal disease in pregnancy.[4,5] Of all patients beginning therapy for end-stage renal disease in the United States, diabetic nephropathy is the major cause of renal failure in twenty-five percent.[6] Recent studies of the natural history of patients with long standing diabetes showed that microalbuminuria preceded clinical diabetic nephropathy.[7] Further studies indicate that normalization of blood glucose and blood pressure can prolong the progression from microalbuminuria to clinical nephropathy.[7]

Test Principle

The albumin present in the urine specifically binds with a soluble antibody-enzyme conjugate present on a zone on the test strip. Excess conjugate is retained in a separation zone containing immobilized human albumin. This allows only the conjugate-albumin immunocomplex from the sample to reach the reaction zone. In the reaction zone, β-galactosidase reacts with a substrate to produce a red dye. After 5 minutes, the intensity of the color is proportional to the albumin content in the urine.

Reagents

Monoclonal Antibodies:

Anti-human albumin IgG (mouse)	0.4 µg
Anti-human albumin IgG with β-galactosidase (E. coli)	0.03 U
Chlorophenolred galactoside	0.012 mg
Buffer	0.9 mg

Warnings and Precautions: For In Vitro Diagnostic Use. The "universal precautions" recommended by the Centers for Disease Control should be followed whenever blood or body fluids are handled. These precautions include wearing gloves.[8]

Storage and Stability: Store strips refrigerated, +36 to +46° F (+2 to +8° C), *prior* to opening. Do not freeze. **Bring strips to room temperature before testing.** Store strips at room temperature, +68 to +77°F (+20 to +25° C), *after* opening. At room temperature, opened strips will remain stable for 6 months or until the listed Use By date on box, whichever comes first. In order to avoid exposure to moisture, the vial must be closed immediately after removal of strips, using the original stopper.

Specimen Collection and Preparation

When performing a test using Chemstrip Micral test strips, the urine specimen should be collected in a clean, dry container. When a urine culture is ordered, it is necessary to collect the specimen in a sterile container.[9] Perform the culture prior to testing for microalbuminuria as the test strip will contaminate the specimen. Due to the physiological variation of albumin, it is recommended that 3 separate morning (midstream) urine samples be collected and analyzed within a given week. If testing cannot be performed within two days of collection, the urine sample should be refrigerated, but returned to room temperature before testing. The use of urine preservatives with this product has not been evaluated, therefore the use of preservatives is not recommended. Urine samples that have been allowed to stand at room temperature for more than 2 days or refrigerated for more than 14 days are considered unacceptable for analysis.[10] The sample should not be frozen.

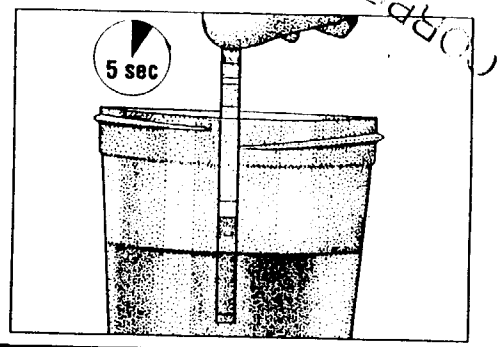
Procedure

Materials provided: 1 aluminum vial containing 30 Chemstrip Micral test strips. A visual comparison color scale for reading test results is printed on the vial label.

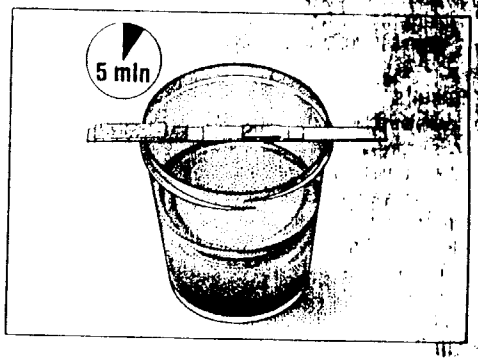
Materials Required, But Not Provided: a timer and a clean specimen collection container. It is also recommended that commercial control products be used for quality control checks.

Assay: Bring test strips to room temperature before testing.

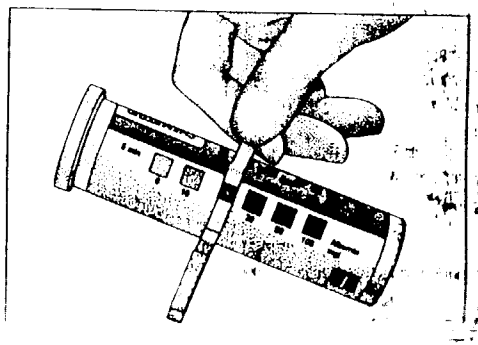
1. Dip the white zone of the test strip into the urine for 5 seconds. Make sure the lower white zone is immersed, but do not dip into the blue zone. Withdraw the strip carefully and avoid touching the sides of the collection cup.



2. Place the strip on a non-absorbent surface or across the lip of the collection cup to allow excess urine to drain.



3. After **exactly 5 minutes,** match the color on the test strip with the color scale on the test strip vial.



Calibration

Calibration of Chemstrip Micral urine test strips by the user is not required.

Quality Control

Quality control for this procedure consists of following good laboratory techniques, ensuring that reagents have been properly stored and specimens handled according to instructions. The analyst should be aware of the sources of error outlined under *Limitations.* Each laboratory should establish its own goals for adequate standards of performance.

Commercially prepared control solutions should be used on a regular basis, as established by your institution's quality control protocols. *The value range of the controls should be within Chemstrip Micral test strip reading range of 0-100 mg/L.*

If the expected results are not obtained and repetition of the assay excludes errors in technique, the following steps should be taken:

1. Check the Use By date on the vial label.
2. To verify that the Chemstrip Micral urine test strip has not

been exposed to heat extremes or moisture, open a new vial of test strips and retest.

3. For further information, contact the Boehringer Mannheim Medical Service Department in Indianapolis, 1-800-858-8072, available 24 hours a day.

Results

Results are obtained by direct visual comparison with the color scale printed on the vial label. The levels of the color blocks are as follows: 0 mg/L, 10 mg/L, 20 mg/L, 50 mg/L and 100 mg/L. No calculations are necessary. The visual color chart is intended to represent semi-quantitative findings and serves as a screening mechanism. If quantitative results are desired, it is recommended that further testing of the urine be carried out utilizing a reference procedure.

Limitations

The amount of albumin excreted in the urine can vary according to changes in posture, amount of hydration, physical activity, blood pressure in the individual and during pregnancy. Because of this individual variation, it is recommended that at least three separate samples be collected and analyzed within a given week to obtain an accurate assessment of the patient.[11] Urine samples should not be obtained following strenuous physical activity.

Acute illnesses that present with fever are known to cause an increase in urinary albumin excretion, such as Urinary Tract Infection, bleeding into the urinary tract, or acid-base abnormalities. Therefore, a decision of the usefulness of the test must be made by the professional. It is recommended that testing of individuals be performed when there is no longer an acute illness present.

No cross-reactivity exceeding 0.5% has been found with IgA, IgG, Bence-Jones proteins, ∂_1-antitrypsin, ∂-acid glycoprotein, ∂-amylase, retinol binding protein, hemoglobin, transferrin or Tamm-Horsfall proteins.[12]

Urine samples with elevated glucose levels of 250 and 2500 mg/dL and urea levels of 550 and 1800 mg/dL did not interfere with recovery of Chemstrip Micral test strips at any of the measurement levels.[10]

Urine samples with pH values of 4.58-8.76 and samples with specific gravity levels of 1.005-1.027 showed no effect on recovery at any of the measurement levels.[10]

No drug interference has been indicated, but it is recommended that the test be repeated after medication has been discontinued.[10]

Specimens should not be collected in containers that have been cleaned with strong oxidizing agents.

Expected Values

The albumin concentration of an average urine specimen should not exceed 15- 20 mg/L.[7]

Clinical diabetic nephropathy is indicated when microalbuminuria (> 20 mg/L) is present in at least two of the three morning urine samples.[11]

A normal microalbuminuria value does not rule out renal disease.[1]

Performance Characteristics

The performance characteristics of the Chemstrip Micral product have been determined in both the laboratory and clinical tests. Parameters of importance to the user are sensitivity, specificity, accuracy, and precision. Generally, the tests have been developed to be specific for the constituent to be measured with the exception of interferences listed previously.

For visually read strips, accuracy is a function of the manner in which the color blocks on the vial label are determined and the discrimination of the human eye in reading the tests. Precision is difficult to assess in a test of this type because of the variability of the human eye. It is for this reason that each user is encouraged to develop his own standards for performance.

Studies in a sample population prone to renal pathology were conducted to compare Chemstrip Micral semi-quantitative results with values obtained from a quantitative RIA method and a semi-quantitative RID method.[10]

Performance Comparison to Reference Methods

RIA (Radioimmunoassay)

Twenty-four hour urine specimens were collected from patients under the care of endocrinologists, internal medicine physicians, and family and general practitioners and assayed by a quantitative RIA method and by Chemstrip Micral test strips. The following results were obtained:

		RIA Method Albumin Concentration (mg/L)	
		≥20	<20
Chemstrip Micral Test Strips Albumin Concentration (mg/L)	≥20	574	79
	<20	68	302

n = 1023
Sensitivity = 89%
Specificity = 79%
Accuracy = 86%

ELISA

Random urine specimens were collected from patients under the care of endocrinologists, internal medicine physicians, and family and general practitioners and assayed by the ExoCell semi-quantitative ELISA method and by Chemstrip Micral test strips. The following results were obtained:

		ELISA Method Albumin Concentration (mg/L)	
		≥20	<20
Chemstrip Micral Test Strips Albumin Concentration (mg/L)	≥20	138	36
	<20	9	249

n = 432
Sensitivity = 94%
Specificity = 87%
Accuracy = 89.5%

Precision Performance

Within Run - Ten replicates of five urine specimens at different levels were assayed by three operators. The level of precision was determined based on the frequency with which each operator obtained replicate readings on the same specimen. The following percents of replicate readings were obtained:

Target Concentration (mg/L)	Operator 1	Operator 2	Operator 3
0	100%	100%	100%
10	98%	100%	100%
20	90%	87%	97%
50	95%	90%	100%
100	98%	100%	100%

Lot-to-Lot - Ten replicates of each level were assayed on three lots of Chemstrip Micral test strips by three operators. The following percents of replicate readings were obtained:

Target Concentration (mg/L)	Operator 1	Operator 2	Operator 3
0	100%	100%	100%
10	86%	87%	83%
20	92%	83%	99%
50	94%	79%	95%
100	98%	100%	100%

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Items Available From Boehringer Mannheim Corporation

CHEMSTRIP 10 with SG urine test strips, 100 tests	Cat. No. 417145
CHEMSTRIP 9 urine test strips, 100 tests	Cat. No. 417109
CHEMSTRIP 8 urine test strips, 100 tests	Cat. No. 417117
CHEMSTRIP 7 urine test strips, 100 tests	Cat. No. 417126
CHEMSTRIP 6 urine test strips, 100 tests	Cat. No. 417135
CHEMSTRIP 4 THE OB urine test strips, 100 tests	Cat. No. 417144
CHEMSTRIP 2 GP urine test strips, 100 tests	Cat. No. 200743
CHEMSTRIP 2 LN urine test strips, 100 tests	Cat. No. 417152

For the diabetic patient's needs:

CHEMSTRIP uG urine test strips, 100 tests	Cat. No. 00511
CHEMSTRIP uGK urine test strips, 100 tests	Cat. No. 00513
CHEMSTRIP UGK urine test strips, 50 tests	Cat. No. 00514
CHEMSTRIP K urine test strips, 100 tests	Cat. No. 00515
CHEMSTRIP K urine test strips, 25 tests	Cat. No. 00516

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Available 24 hours a day

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In the United Kingdom Call:
0734-772693
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Antibody Reagent Set for Microalbumin

SPQ™ Test System

For the quantitative determination
of human albumin in urine

Instruction Manual

Catalog No.: 86072

Atlantic Antibodies, An INCSTAR Company

INCSTAR Corporation – Stillwater, Minnesota, U.S.A.

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INTRODUCTION

Intended Use

FOR IN VITRO DIAGNOSTIC USE.
The SPQ™ TEST SYSTEM is designed for the quantitative determination of human albumin by automated immunoprecipitin analysis.

Summary and Explanation

Changes in albumin levels often become clinically important with respect to diagnostic decision making. This is true with albumin concentrations in serum, cerebrospinal fluid and urine.

Normal urinary excretion of albumin for adults is less than 10-15 mg/L. Microalbuminuria is defined as a condition characterized by urinary albumin excretion above this level in the absence of clinically detectable nephropathy.[1-3] A number of investigators using immunoassays for albumin have established a range of 15 or 30 mg/L to 150 mg/L as diagnostic for microalbuminuria.[4-6] Individuals with an established diagnosis of diabetes or essential hypertension represent the most important groups to be followed for elevations in albumin excretion rates.[7]

Newly diagnosed diabetics usually have base line levels of urinary albumin within the normal range. In such individuals, exercise is likely to lead to increased levels which can be eliminated in the short term by careful metabolic control.[8-11] If care is taken to minimize the effects of exercise and improper metabolic control, urinary albumin level is an excellent indicator of the progress of overt nephropathy in both insulin-dependent and non-insulin-dependent diabetes.[4-6, 12, 13] The predictive value of urinary albumin measurement has been summarized to state that it is unlikely that a diabetic individual with resting levels of less than 15 mg/L will progress to overt nephropathy within 10 years.

Diabetics with resting albumin levels greater than 15-30 mg/L while in good metabolic control will show average yearly increases of excretion of 25 mg/L.[5]

Method Description

The SPQ TEST SYSTEM for MICROALBUMIN permits the quantitative determination of human albumin by automated immunoprecipitin analysis. Standards, Control and patient samples are pipetted into sample cups. Microvolumes of these samples and polymeric enhancer are automatically pipetted into individual cuvettes. Following an initial incubation and measurement of sample blank, undiluted antiserum is added to the cuvettes. The sample (antigen) solution and antiserum are then mixed in the reaction cuvettes. Insoluble antigen-antibody complexes begin to form immediately, producing turbidity in the mixture and thus increasing the amount of light scattered by the solution. Following an incubation period lasting approximately 5 minutes, the absorbance of the solution is measured at the analytical wavelength.

A calibration curve is generated by assaying a series of standards with known concentrations of albumin and using the instrument's data reduction capability or manually plotting the change in absorbance versus concentration. Concentrations for the Control and patient samples are interpolated from the calibration curve.

REAGENTS

Materials Supplied

1. **Antibody Reagent**
2.0 mL of antibody monospecific for albumin.
Contains 0.1% Sodium Azide.
Store at 2-8°C.

2. **Polymer Diluent II**
60 mL of a polymeric enhancer solution.
Contains 0.1% Sodium Azide.
Store at 2-8°C.

3. **Sample Diluent: Diluent B**
25 mL Diluent B
Contains 0.1% Sodium Azide.
Store at 2-8°C.

Materials Required but not Supplied

SPQ™ Calibration/Control Set for Microalbumin
Cat. No. 86106 - Includes Standards and Control.
Contains 0.1% Sodium Azide.

Warning: Potential Biohazard, See Instruction Manual.
Store at 2-8°C.

WARNINGS AND PRECAUTIONS

FOR IN VITRO DIAGNOSTIC USE.

Reagents Containing Human Source Material

Treat as potentially infectious.

Each serum/plasma donor unit used in the preparation of this product has been tested by an FDA approved method and found non-reactive for the presence of HBsAg, antibody to HCV and antibody to HIV. While these methods are highly accurate, they do not guarantee that all infected units will be detected. This product may also contain other human source material for which there is no approved test. Because no known test method can offer complete assurance that hepatitis B virus, hepatitis C virus (HCV), Human Immunodeficiency Virus (HIV) or other infectious agents are absent, all products containing human source material should be handled in accordance with good laboratory practices using appropriate precautions as described in the Centers for Disease Control and Prevention/National Institutes of Health Manual, "Biosafety in Microbiological and Biomedical Laboratories," 3rd ed., 1993. HHS Publication No. (CDC) 93-8395.

Reagents Containing Sodium Azide

CAUTION: Some reagents in this kit contain sodium azide. Sodium azide may react with lead or copper plumbing to form highly explosive metal azides. On disposal, flush with a large volume of water to prevent azide build-up. For further information, refer to "Decontamination of Laboratory Sink Drains to Remove Azide Salts," in the Manual Guide-Safety Management No. CDC-22 issued by the Centers for Disease Control and Prevention Atlanta, GA, 1976.

European Communities Hazardous Substance Risk Phrases (Council Directive 88/379/EEC)

R20/21/22 - Harmful by inhalation, in contact with skin and if swallowed.
R32 - Contact with acids liberates very toxic gas.
S28 - After contact with skin, wash immediately with plenty of water.

General Precautions

1. It is expected that good laboratory practices will be followed. Do not pipet by mouth; do not allow any reagents to come in contact with open wounds.
2. All reagents are stable until stated expiration date on the vials, provided recommended storage conditions are followed and maintained. Inability to recover Control values may indicate reagent instability or inconsistent handling of Standards and Control.

SPECIMEN REQUIREMENTS

Collection and Preparation

Albumin in Urine: A timed 3 hour, overnight or 24 hour collection of urine should be obtained for assay. Record the time-duration and total volume on the collection container. Samples should be mixed well and **not acidified.** Urine samples should be cleared of particulate matter or turbidity by centrifugation or filtration prior to assay. Bloody urine samples should not be used.

For interfering substances, see Limitations section.

Specimen storage: Patient samples may be stored at 2-8°C for up to 7 days. Samples may be stored frozen (-20°C) for up to 2 months. Allow samples to come to room temperature before assaying.

PROCEDURE

Set-up and Programming

INSTRUMENT: The SPQ Antibody Reagent Set is designed for use in instruments capable of immunoprecipitin analysis. Refer to instrument parameters section of this insert.

PREPARATION: Prepare Reagents and program analyzer as directed by the appropriate instrument parameter section of this insert.

Prepare the instrument per instructions provided by the instrument manufacturer.

INSTRUMENT PARAMETERS

COBAS BIO®

Materials Required but not Provided

1. SPQ Calibration Set for Microalbumin (INCSTAR Cat. No. 86106)
2. COBAS BIO centrifugal analyzer
3. Consumables and Disposables from Roche:
   a. Sample cups with lids (Product No. 06789)
   b. Reagent rack (Product No. 06762)
   c. Cuvette rotors (Product No. 211840)
4. Purified water
5. Pipets which can accurately deliver 10-500 µL

Set-up

1. Prepare the instrument per the COBAS BIO Operator's manual.
2. Pipet Polymer Diluent II directly into the Primary Reagent cavity of the reagent rack. Pipet Antibody Reagent into the largest (right most) well of the reagent rack (see FIGURE 1).
3. To conserve reagents and time, urines should be screened by a method such as Albustix® prior to assay on the COBAS BIO. Albustix-negative urines are assayed neat (undiluted). Albustix-positive urines should be diluted 1-10 (e.g., 20 µL urine plus 180 µL Diluent B) directly into sample cups. Cups with diluted samples should be inverted several times to assure proper mixing of sample and diluent.
4. Pipet Standards, Control and test samples directly into sample cups in the following order:

Position	Sample
CS-5	Standards 1-6 (ascending order)
6	Control
7-24	Test Samples

5. Place a new reagent tip onto the reagent arm.
6. Place a cuvette rotor in the photometer section of the analyzer and clamp the cuvette retaining ring onto the rotor. Close the photometer arm.

COBAS BIO REAGENT RACK

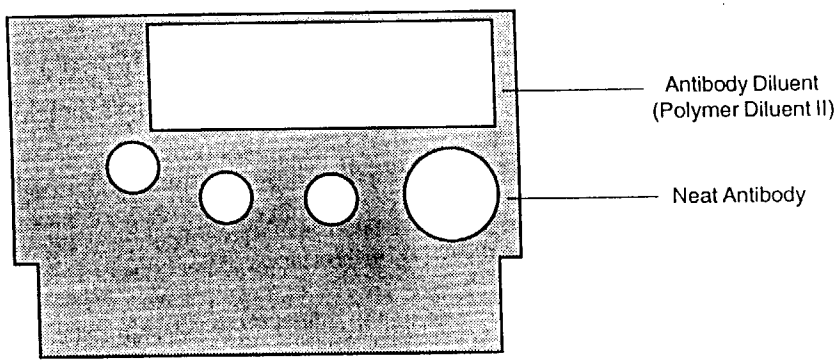

FIGURE 1

Programming

1. Initial entry of assay parameters
   (For specific instructions, refer to COBAS BIO Operator's manual.)
   a. Press the **TEST NR** key and select the test number for the assay.
   b. Press the **alpha** key and enter "11" to indicate a positive reaction direction. Press the **TEST NR** key and select the test number for the assay again.
   c. Enter the parameters found in TABLE I. The "Type of Analysis," parameter No. 8, **must** be entered **before** entering the other parameters.

   NOTE: For each new lot of SPQ Calibration Set for Microalbumin, new Standard values may need to be entered into the calibration parameters.
2. Using Stored Assay Parameters
   If the assay parameters have previously been stored according to the above method, then proceed as follows:
   a. Press the **TEST NR** key and select the assay's numeric code.
   b. Ensure that the assay parameters are correct by pressing the **LIST** key. Make any changes to the parameter list that are necessary.
   c. Stored calibration curve information may be used for 2 weeks. Control must be run with every assay to assure accuracy. To use stored calibration curve information, be sure parameter 19 is "0".

   NOTE: Recalibration of the COBAS BIO is necessary whenever a new lot of SPQ Antibody Reagent Set II, Polymer Diluent II or Calibration Set is used.

TABLE I – ASSAY PARAMETERS - WITH DENS

General Parameters:

1.	Units	6 (mg/L)
2.	Calculation Factor	1000
3.	Standard 1 Concentration	Enter values
	Standard 2 Concentration	found on
	Standard 3 Concentration	the Calibration
	Standard 4 Concentration	Set Values
	Standard 5 Concentration	insert for
	Standard 6 Concentration	Microalbumin
4.	Standard 2	Not Applicable
5.	Standard 3	Not Applicable
6.	Limit	0
7.	Temperature	25°C
8.	Type of Analysis	7.6
9.	Wavelength	340 nm
10.	Sample Volume	10 µL
11.	Diluent Volume	10 µL
12.	Reagent Volume	200 µL
13.	Incubation Time	10 seconds
14.	Start Reagent Volume	10 µL
15.	Time of First Reading	0.5 seconds
16.	Time Interval	180 seconds
17.	Number of Readings	2
18.	Blanking Mode	1
19.	Printout Mode	1[1,2]

[1] If delta Absorbance (Δ A) data is desired after a run to evaluate a sample out of range, change parameter No. 8 to analysis type "6" and access the data by setting parameter No. 19, Printout Mode, to "1". The data is in the form of rates (rates = Δ A X 1000).

[2] After an initial run, the instrument will display a "0" under Printout Mode, parameter No. 19. This indicates that curve parameters are stored for additional assays. If a new calibrator curve is desired, change Printout Mode back to "1".

Assay Procedure

Once test Set-Up is complete and the instrument is programmed, the assay may be initiated.

1. Press the **START** button.
2. Those instruments equipped with the DENS option will print out the concentration of albumin for each Control and test sample in the units programmed.

QUALITY CONTROL

SPQ TEST SYSTEM Control for Microalbumin should be included in each assay performed. Other controls of known albumin concentration may also be included in the assay. The value determined for the SPQ Control should fall within the stated recovery limits of the value assigned to the Control (see the Calibration/Control Set insert). The validity of the assay is in question if the value for the Control generated by the assay's calibration curve does not fall within this recovery range.

RESULTS

Calibration and Value Determination

1. The COBAS BIO will use the delta absorbances (Δ A) of the 6 Standard Levels, along with the respective assigned concentrations of the Standards, to develop a calibration curve with a four parameter logit function when programmed as described in Programming Section. Using this calibration curve, the instrument will determine values for the Control and test samples. These values (in mg/L, or in other units programmed by the operator) will be reported in the printout. Values above the curve are flagged "TOO HIGH"; values below the curve are flagged "TOO LOW". Samples flagged as being above the curve should be diluted 1:10 (1 part sample and 9 parts Diluent B) and reassayed; samples flagged as being below the curve should be reported as having a concentration of albumin that is less than the concentration in Standard 1.
2. Results reported by the COBAS BIO for diluted test samples are not corrected for the dilution factor. These results must be multiplied by the dilution factor (e.g., for a 1:10 dilution multiply by 10) to obtain the proper result.

Limitations of the Procedure

1. Microalbuminuria may have causes other than incipient diabetic nephropathy. Subclinical elevations in urinary albumin excretion rates may be caused by urinary tract infections, congestive heart disease, hypertension, exercise, non-diabetic renal disease and poor diabetic control.
2. Several common urinary components will not interfere with assay performance at the following levels:

Bilirubin	200 µg/mL
Creatinine	2,800 µg/mL
Human IgG	2,000 µg/mL
Transferrin	100 µg/mL
Urea	700 µg/mL

3. Apparent hemolysis may be indicative of contamination of urine by plasma (e.g., menstrual flow). Since the concentration of albumin in plasma is 3,000 times the level normally found in urine, contamination by plasma may cause grossly inaccurate results. Bloody urine samples should not be used.

4. Urine samples should be cleared of particulate matter either by centrifugation or filtration prior to assay.
5. Sample cups and reagent racks should be kept dust free. All reagents should be covered immediately after use.
6. The instrument will not correct results for a dilution of sample. If a diluted sample is assayed, multiply the result by the dilution factor to obtain the actual sample value (see Results section).

EXPECTED VALUES

Normal Range

The following expected values were obtained in assays of overnight and timed 3 hour urine collections from 42 apparently healthy male and female subjects. They are intended to be used only as a guideline. Each laboratory should establish its own normal range to account for regional population differences.

Range of values (mg/L)	Number of samples	% of total
≤ 6.3	21	50
<10	33	79
<15	39	93
<30	42	100

Increased Levels

Slight Microalbuminuria	15 - 30 mg/L
Significant Microalbuminuria	30 - 200 mg/L
Proteinuria	> 200 mg/L (Albustix - positive)

PERFORMANCE DATA

This performance data was obtained using properly maintained instruments (as per Operator's manual) and trained personnel.

Accuracy

Over 100 urine samples were assayed for albumin using the SPQ TEST SYSTEM for Microalbumin with the COBAS BIO system. In addition, these test samples were assayed using a double antibody radioimmunoassay, a turbidimetric adaption of a manual spectrophotometric assay and a radial immunodiffusion method. The data from the SPQ TEST SYSTEM was compared to the other assays using linear least-squares regression analysis.

Comparison assay	RIA	Turbidimetry	Radial Immunodiffusion
n =	95	99	32
r =	0.99	0.999	0.999
slope =	1.05	1.01	1.07
Y-intercept =	- 9.45 mg/L	-1.42 mg/L	0.388 mg/L

Precision

Within-Run Precision

Five samples were assayed in 20 different sample cups (n = 20).

Mean Concentration (mg/L)	% C.V.
11.1	2.8
16.3	3.0
33.4	2.2
60.7	1.8
125	1.7

Between-Run Precision

Eleven samples that were representative of 4 ranges of urinary albumin were assayed in 11 different runs using a calibration curve stored from the first run (n = 11).

Mean Concentration (mg/L)	% C.V.
10 - 20	2.2
20 - 50	4.3
50 - 200	3.9
200 - 1500	2.4

INSTRUMENT PARAMETERS

COBAS MIRA®

Materials Required but not Provided

1. COBAS MIRA turbidimetric analyzer
2. Consumables and Disposables from Roche:
   a. Sample cups with lids (Product No. 06789)
   b. Reagent cups – 4 mL (Product No. 34634)
   c. Reagent cups – 15 mL (Product No. 37307)
   d. Cuvette segments (Product No. 29894)
   e. 35 mL R-5s reagent container (Product No. 37293)
3. Purified water
4. Pipets which can accurately deliver 10 - 500 µL
5. SPQ Calibrator Set for Microalbumin (Cat. No. 86106)

Set-up

1. Prepare the instrument per the COBAS MIRA Operator's manual.
2. Urine samples to be assayed for albumin by the COBAS MIRA are pipetted directly into sample cups in the "SAMPLE 30" rack. Standards are placed in 6 available positions in the "CAL CS 30" rack (for example, in positions 11 through 16). Control is placed in the appropriate position in the Control rack. Suggested volume for each sample cup is 200 µL for the Standards and 120 µL for the Control and samples.
3. Neat Antibody Reagent is placed in "START REAGENT 1" position of the "REAGENT 5s" rack. Polymer Diluent II is placed in the "AB DILUENT" position of the "REAGENT 5s" rack (see FIGURE 2).
4. To conserve reagents and time, urines may be screened by a method such as Albustix® prior to assay on the COBAS MIRA. Albustix-negative urines are assayed neat (undiluted); Albustix-positive urines should be diluted 1-10 (e.g., 20 µL urine plus 180 µL Diluent B) directly into sample cups. Cups with diluted samples should be inverted several times to assure proper mixing of sample and diluent.

COBAS MIRA REAGENT 5s RACK

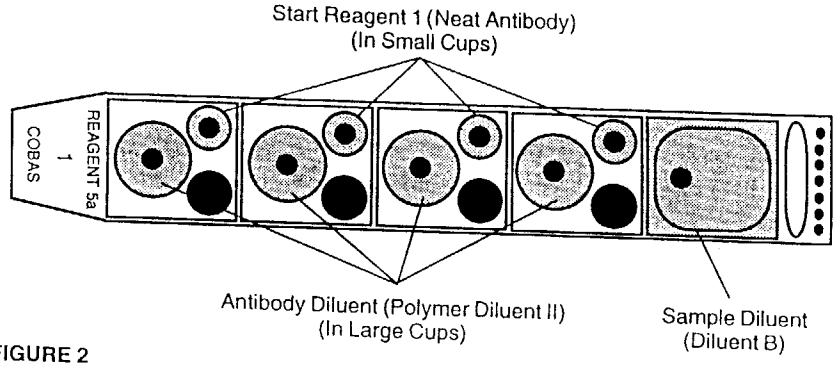

FIGURE 2

Programming

Refer to the COBAS MIRA Operator's Manual for operation of this instrument. To program assay specific parameters, refer to TABLE II.

TABLE II — INSTRUMENT SETTINGS FOR THE COBAS MIRA®

GENERAL	
Measurement Mode:	Absorb
Reaction Mode:	R-S-SR1 (3)
Calibration Mode:	STD NONLIN (4)
Reagent Blank:	REAG/DIL (2)
Cleaner:	Before (2)
Wavelength:	340 nm
Decimal Position:	1
Unit:	mg/L (8)
ANALYSIS	
Sample Dil. Name:	H_2O (00)*
Post Dil. Factor:	8.00*
Conc. Factor:	1.50*
Sample Cycle:	1
Vol.:	30 µL
Dil.:	10 µL
Reagent Cycle:	1
Vol.:	200 µL
Start Reagent 1 Cycle	2
Vol.:	15 µL
Dil.:	10 µL
CALCULATION	
Sample Limit:	No
Reac. Direction:	Increase (1)
	Check: ON (1)
Antigen Excess:	No
Convers. Factor:	1.00000
Offset:	0.00000
Norm. Range	
Low:	User Defined
High:	User Defined
Number of Steps:	1
Calc. Step A:	Endpoint
	Readings
	First: 1
	Last: 9

* These parameters apply only to COBAS MIRA® equipped with on-board dilution software.

CALIBRATION	
Calib. Interval:	On Request (3)
Reagent Blank	
Reag. Range	Low: User Defined
	High: User Defined
Blank Range	Low: No
	High: No
Stand. Nonlinear Cup-Pos:	11
1: (STD 1)	2: (STD 2) mg/L
3: (STD 3)	4: (STD 4) mg/L
5: (STD 5)	6: (STD 6) mg/L
7: No	8: No mg/L
Replicate:	Triplicate
Deviation:	No
Calc. Model:	LOGIT/LOG 4
Correction Std:	No
CONTROL	
CS1	Pos: 1
Low:	(See Control Insert)
	mg/dL
Assigned	(See Control Insert)
	mg/dL
High:	(See Control Insert)
	mg/dL
CS2	
POS:	No
CS3	
POS:	No

Assay Procedure

Once test set-up is complete and the instrument is programmed, the assay may be initiated. Press the **START** button.

QUALITY CONTROL

The SPQ TEST SYSTEM Control for Microalbumin should be included in each assay performed. Other controls of known microalbumin concentration may also be included in the assay. The value determined for the SPQ Control should fall within the stated recovery limits of the value assigned to the Control (see the Calibration/Control Set insert). The validity of the assay is in question if the value for the control generated by the assay's calibration curve does not fall within this recovery range.

RESULTS

Calibration and Value Determination

1. The COBAS MIRA will use the delta absorbances (Δ A) of the 6 Standards, along with the respective assigned concentrations of the Standards, to develop a calibration curve with a four parameter logit function when programmed as described. Using this calibration curve, the instrument will determine values for the control and test samples. These values (in mg/L, or in other units programmed by the operator) will be reported in the printout. Values above the curve are flagged "> TEST RANGE"; values below the curve are flagged "< TEST RANGE".
2. With on-board dilution software, samples flagged as being above the curve will be automatically reassayed using a smaller sample volume; samples flagged as being below the curve will be automatically reassayed with a larger sample volume. Results for diluted test samples reported by the COBAS MIRA with on-board dilution software are corrected for the dilution factor.
3. For COBAS MIRA without on-board dilution software, samples flagged as being above the curve should be diluted 1:10 (1 part sample and 9 parts Diluent B) and reassayed; samples flagged as being below the curve should be reported as having a concentration of albumin that is less than the concentration in Standard 1. Diluted test samples are not corrected for the dilution factor. These results must be multiplied by the dilution factor (e.g., for a 1:10 dilution, multiply by 10) to obtain the proper result.
4. Stored calibration curve information may be used for 2 weeks. The Control must be run with every assay to assure accuracy of results.

Limitations of the Procedure

1. Microalbuminuria may have causes other than incipient diabetic nephropathy. Subclinical elevations in urinary albumin excretion rates may be caused by urinary tract infections, congestive heart disease, hypertension, exercise, non-diabetic renal disease and poor diabetic control.
2. Several common urinary components will not interfere with assay performance at the following levels:

Bilirubin	200 µg/mL
Creatinine	2,800 µg/mL
Human IgG	2,000 µg/mL
Transferrin	100 µg/mL
Urea	700 µg/mL

3. Apparent hemolysis may be indicative of contamination of urine by plasma (e.g., menstrual flow). Since the concentration of albumin in plasma is 3,000 times the level normally found in urine, contamination by plasma may cause grossly inaccurate assay results. Bloody urine samples should not be used.
4. Urine samples should be cleared of particulate matter either by centrifugation or filtration prior to assay.

5. Sample cups and reagent containers should be kept dust free. All reagents should be covered immediately after use.
6. Instruments without on-board dilution software will not correct results for a dilution of sample. If a diluted sample is assayed, multiply the result by the dilution factor to obtain the actual sample value (see Results section).

EXPECTED VALUES

Normal Range: The following expected values were obtained in assays of overnight and timed 3 hour urine collections from 42 apparently healthy male and female subjects. They are intended to be used only as a guideline. Each laboratory should establish its own normal range to account for regional population differences.

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Over 100 samples were assayed for albumin using the SPQ TEST SYSTEM for Microalbumin with the COBAS MIRA. In addition, these test samples were assayed using a double antibody radioimmunoassay, a turbidimetric adaption of a manual spectrophotometric assay and a radial immunodiffusion method. The data from the SPQTEST SYSTEM was compared to the other assays using linear least-squares regression analysis.

Comparison assay	RIA	Turbidimetry	Radial Immunodiffusion
n =	96	100	32
r =	0.99	0.999	0.99
slope =	1.11	1.06	1.19
Y-intercept =	-12.26 mg/L	-3.04 mg/L	-5.05 mg/L

Precision

Within-Run Precision

Five samples were assayed in 20 different sample cups (n = 20).

Mean Concentration (mg/L)	% C.V.
10.3	1.8
15.0	3.9
33.2	1.3
53.4	1.2
137	1.8

Between-Run Precision

Eleven samples that were representative of 4 ranges of urinary albumin were assayed in 11 different runs using a calibration curve stored from the first run (n = 11).

Mean Concentration (mg/L)	% C.V.
10 - 20	3.6
20 - 50	5.7
50 - 200	6.0
200 - 1,500	5.2

SEE LAST PAGE FOR REFERENCES

REFERENCES

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13. Viberti, G.C., et al., "Long Term Correction of Hyperglycemia and Progression of Renal Failure in Insulin Dependent Diabetes," **Brit. Med. J.,** 286:598-602, (1983).

ROCHE

Leading the way in biodiagnostics

4 x 100 mL — tem No. 44905
20 x 3 mL — tem No. 44027

ROCHE® REAGENTS

Reagent for

CREATININE

INTENDED USE:

The ROCHE® Reagent for CREATININE is an *in vitro* diagnostic reagent system intended for use on the COBAS® Chemistry Instruments for the quantitative determination of creatinine in serum, plasma and urine.

INTRODUCTION:

Serum creatinine is a waste product formed by the spontaneous dehydration of body creatine. Most of the body creatine is found in muscle tissue where it is present as creatine phosphate and serves as a high energy storage reservoir for conversion to adenosine triphosphate. The rate of creatinine formation is fairly constant with about 2 percent of the body creatine being converted to creatinine every 24 hours.[1] Serum creatinine and urea levels are elevated in patients with renal malfunction, especially decreased glomerular filtration. In the early stages of kidney damage, the rise in the serum urea levels usually precedes the increase in serum creatinine. This advantage is offset by the fact that serum urea levels are affected by factors such as diet, degree of hydration and protein metabolism. Serum creatinine levels on the other hand tend to be constant and unaffected by factors affecting serum urea levels. Thus serum creatinine is a significantly more reliable renal function screening test than serum urea.[2] A considerably more sensitive test for measuring glomerular filtration is the creatinine clearance test.[1] For this test a precisely timed urine collection (usually 24 hours) and a blood sample are needed.

Most creatinine assays are based on a modification of the original Jaffe reaction.[3] In many of these procedures the sample is added to an alkaline picrate solution and the absorbance is read after the reaction has reached end point. Although relatively simple and convenient, the end point assays are somewhat non-specific and subject to interferences by serum metabolites. Improvements in the end point assays have been made by using cation-exchange resins and Lloyd's reagent to remove the creatinine from the sample.[4] Though effective, these procedures are time consuming and require centrifugation or filtration steps. More recently, kinetic assays using the Jaffe reaction have been developed to increase the specificity for creatinine and to reduce the interference by serum metabolites.[5]

The ROCHE Reagent for Creatinine chooses a time interval for measuring the reaction where the non-creatinine interferents react only minimally.

TEST PRINCIPLE:

The ROCHE Reagent for CREATININE uses a kinetic modification of the Jaffe reaction.

$$\text{Creatinine} + \text{picric acid} \xrightarrow[\text{pH}]{\text{creatinine}} \text{red complex}$$

The rate of formation of the red colored complex is measured at 520 nm. Starting with the time of first reading at 35 seconds after mixing, the reaction rate is followed over a 90 second interval. A surfactant has been added to suppress protein interference.

REAGENT COMPOSITION:

The Creatinine Buffer Reagent and Picric Acid Reagent are aqueous solutions having the following formulations:

Reactants	Concentration (mmol/L)
Buffer Reagent	
Sodium Borate Buffer	215
Surfactant	
pH 13.1 ± 0.2 at 25°C	
Picric Acid Reagent	
Picric Acid	52
Sodium Borate Buffer	35
Surfactant	
pH 8 at 25°C	

WARNINGS AND PRECAUTIONS:

1. For *In Vitro* Diagnostic Use.
2. Specimens should be handled as if potentially infectious, using safe laboratory procedures such as those outlined in *Biosafety in Microbiological and Biomedical Laboratories* (HHS Publication Number (CDC) 84-8395).
3. Avoid contact of reagents with eyes, skin and clothing. Do not pipette reagents by mouth. Do no ingest. Wash hands after use.
4. As with any diagnostic test procedure, results should be interpreted considering all other test results and the clinical status of the patient.
5. Do not use rewashed cuvette rotors.

INSTRUCTIONS FOR REAGENT USE:

The ROCHE Reagent for CREATININE is available in kits of two 100 mL bottles of Buffer Reagent and two 100 mL bottles of Picric Acid Reagent (Item #44905) for use on the COBAS BIO® and COBAS FARA™. The working creatinine reagent is prepared by mixing equal volumes of the two reagents prior to use. The ROCHE Reagent for CREATININE is also available in reagent rack compatible kits of ten 3.0 mL bottles of Buffer Reagent and ten 3.0 mL bottles of Picric Acid Reagent (Item #44027) for use on the COBAS MIRA™. The working creatinine reagent is pre-

pared by pouring the contents of one bottle of Buffer Reagent into one bottle of Picric Acid Reagent. Mix well.

STORAGE AND STABILITY:

Store the Buffer Reagent and the Picric Acid Reagent at 20° to 30°C. Keep reagent bottles tightly closed when not in use. Discard reagents after expiration date on bottles. The combined (working) Creatinine Reagent is stable for 14 days if stored in an airtight amber container and for 8 hours if stored in an open container exposed to the atmosphere. Occasionally a precipitate may appear in the ROCHE Reagent for CREATININE during storage at low temperature. If this occurs gently warm the solution to 30°C (in the closed container) until the precipitate dissolves and mix well before using. The performance of the reagent will not be affected.

INDICATIONS OF INSTABILITY OR DETERIORATION:

1. Physical Appearance: The Buffer Reagent should be clear and colorless and the Picric Acid Reagent should be clear and yellow in color.
2. Control Values: Failure to obtain values within the expected range may indicate reagent deterioration.
3. Discard reagents if turbidity develops which cannot be removed by warming (see STORAGE AND STABILITY) as this may indicate microbial contamination.

SPECIMEN COLLECTION AND HANDLING:

Either serum, plasma or urine may be used. Urine should be ★ diluted 1:50 with deionized water before assaying. Remember to correct the results by the dilution factor. Serum creatinine is reported to be stable for 7 days at room temperature. Urine creatinine is reported to be stable for 4 days at room temperature.[4] Specimens kept for longer periods should be refrigerated at 2° to 8°C or frozen at -20°C.

INTERFERING SUBSTANCES:

The following compounds at the indicated levels gave less than 0.1 mg/dL interference as apparent creatinine when added to a normal serum pool.

– acetoacetic acid	100 mg/dL –
acetone	25 mg/dL
– ascorbic acid	20 mg/dL –
– albumin	3 g/dL --
pyruvate	0.2 mmol/L
fructose	200 mg/dL
glycerol	30 mg/dL
– glucose	1000 mg/dL –
hemoglobin	6.5 g/L
β-hydroxybutyrate	1.0 mmol/L
urea	1000 mg/dL
uric acid	20 mg/dL

Bilirubin interference as apparent creatinine was tested using both conjugated and unconjugated bilirubin spiked samples. Both types of bilirubin yielded similar results. On the COBAS BIO, for every 1.0 mg/dL bilirubin present in the sample, a corresponding loss of 0.01 mg/dL apparent creatinine was observed. On the COBAS MIRA, for every 1.0 mg/dL bilirubin present in the sample, a corresponding loss of 0.034 mg/dL apparent creatinine was observed. Thus, care should be taken in the interpretation of low creatinine values when high levels of bilirubin are present.

Young et al[6] gives a list of drugs and other substances that alter plasma creatinine levels and interfere with creatinine measurement.

MATERIALS REQUIRED BUT NOT PROVIDED:

1. Creatinine Calibrator. Use ROCHE Standards for CREATININE, Item No. 44907 or COBAS Calibrator Serum, Item No. 44406.
2. Pipettes for preparation of the combined (working) Creatinine Reagent.

GENERAL INSTRUCTIONS:

Prepare the necessary amount of working Creatinine Reagent by combining equal volumes of Creatinine Buffer Reagent and Picric Acid Reagent.

COBAS Chemistry Instrument Application:

For use on the COBAS BIO or COBAS FARA pour the necessary amount of working creatinine reagent into the primary receptacle of the reagent tray. Place the reagent tray in the appropriate position/reagent rack on the instrument. For use on the COBAS MIRA or COBAS FARA place the reagent bottle into the proper reagent rack and position it on the instrument. Place the ROCHE Standards for CREATININE or the COBAS Calibrator Serum in the appropriate positions on the instruments.

CALIBRATION AND QUALITY CONTROL:

To establish a calculation factor, suitable creatinine standards must be assayed under the same conditions as the patient sera and controls. ROCHE Standards for CREATININE, Item No. 44907 or COBAS Calibrator, Item No. 44406 are recommended. Also normal and abnormal controls should be included in each set of assays. Commercial control material with established data may be used for quality control.

CALCULATIONS:

After completion of the assay, the COBAS Chemistry Instrument calculates a factor using the following formula:

$$F = \frac{1}{3}\left[\frac{\text{conc}(St_1)}{\Delta A(St_1)-\Delta A_{RB}} + \frac{\text{conc}(St_2)}{\Delta A(St_2)-\Delta A_{RB}} + \frac{\text{conc}(St_3)}{\Delta A(St_3)-\Delta A_{RB}}\right]$$

then:

$$\text{Concentration of the sample (mg/dL)} = (\nabla A\ \text{sample} - \nabla A_{RB}) \times F$$

where:

conc = Concentration in mg/dL
St_1 = Standard One
St_2 = Standard Two
St_3 = Standard Three
∇A = Change in absorbance per minute
RB = Reagent Blank

The creatinine clearance is calculated using the following formula:

$$\text{Creatinine clearance (mL/min)} = \frac{U}{P} \times V \times \frac{1.73}{A}$$

where:

U = Concentration of creatinine in the urine (measured COBAS value x dilution factor).
P = concentration of creatinine in the serum or plasma
V = Volume of urine in mL/min
A = body surface area in square meters
1.73 = average body surface in square meters

The patients body surface may be calculated using the following formula or obtained more conveniently from an available nomogram.[7]

$$\log A = (0.425 \log W) + (0.725 \log H) - 2.144$$

where:

A = The body surface area in square meters.
W = The weight of the patient in kg.
H = The height of the patient in cm.

PROCEDURAL LIMITATIONS:

The assay is linear to 20 mg/dL.

Samples that have creatinine values greater than 20 mg/dL should be diluted with saline and reassayed. Be sure to correct the results for the dilution factor.

EXPECTED VALUES:

A study was made of a total of 49 samples from normal blood donors using the ROCHE Reagent for CREATININE. The expected values were found to be 0.7 - 1.4 mg/dL. In the creatinine clearance study consisting of 10 female donors and 8 male donors, the expected values were found to be 84 - 155 mL/min.

It is recommended that each laboratory establish the normal range for the geographical area in which it is located. The values quoted were derived from serum and urine samples of male and female donors from the metropolitan New York area.

PERFORMANCE CHARACTERISTICS:

DAY-TO-DAY PRECISION: Two commercial controls were assayed for ten consecutive days on the COBAS BIO and the following data were obtained:

	Level I	Level II
Mean (mg/dL)	1.65	3.90
S.D.	0.03	0.05
C.V. (%)	1.8	1.3

WITHIN RUN PRECISION: Two commercial controls were assayed (one rotor each, 25 samples) and the following within run precision was obtained:

	Level I	Level II
Mean (mg/dL)	1.66	3.92
S.D.	0.03	0.04
C.V. (%)	1.7	1.1

ACCURACY:

The following table lists the data obtained for serum in comparisons of the ROCHE Reagent for CREATININE run on the COBAS BIO with a similar creatinine reagent also run on the COBAS BIO. The values from ROCHE Reagent for CREATININE were used as the ordinate.

Number of Samples	50
Slope	1.010
Y-Intercept	0.102
Correlation Coefficient	0.996

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COBAS BIO PROGRAM PARAMETERS:

Alpha	+ (enter 11)
1. Units	mg/dL (enter 8)
2. Calculation Factor	0
3. Standard 1 Conc	corresponding to
4. Standard 2 Conc	the standard
5. Standard 3 Conc	concentration
6. Limit	20 mg/dL
7. Temperature	37.0°C
8. Type of Analysis	4
9. Wavelength	520 nm
10. Sample Volume	20µL
11. Diluent Volume	40µL
12. Reagent Volume	200µL
13. Incubation Time	10 sec.
14. Start Reagent Volume	0
15. Time of First Reading	35 sec.
16. Time Interval	10 sec.
17. Number of Readings	10
18. Blanking Mode	1
19. Printout mode	2

COBAS FARA PROGRAM PARAMETERS:

GENERAL

Measurement Mode	Absorb	
Reaction Mode	R1-I0-S-A0	
Calibration Mode	Calib.	
Reagent Blank	Reag/Dil	
Wavelength	520 nm	
Temperature	37.0°C	
Decimal Position	2	
Unit	mg/dL	

ANALYSIS

Reagent		
Vol.	200	
Incubation	10	
Sample		
Vol.	20	
Dil.	40	
Readings		
First	35.0	
Number	10	
Interval	10	

CALCULATION

Convers. Factor	1.00000	
Offset	0.00000	
Reac. Direction	Increase	
Check	On	
Sample Limit	No	
Test Range Low	0.00	High: 20.00
Norm. Range Low	0.7	High: 1.4
Calc. Steps	1	
Calc. Steps A	Kinetic	
Readings First	1	
Last	10	
Reac. Limit	No	

CALIBRATION

Calib. Interval	On Request	
Calibrator	*	Pos.: 1
Replicate	Duplicate	
Deviation	5%	
Reag. Range Low	-0.0300	High: 0.0660
Blank Range Low	-0.0020	High: 0.0020

* *enter appropriate value*

COBAS MIRA PROGRAM PARAMETERS:

GENERAL

Measurement Mode	Absorb
Reaction Mode	R-S
Calibration Mode	Calibrator
Reagent Blank	Reag/Dil
Cleaner:	No
Wavelength	500
Decimal Position	1
Unit	mg/dL

ANALYSIS

Sample Dil. Name	H_2O
Post Dil. Factor	No
Conc. Factor	No
Sample Cycle	1

Vol.	20.0
Dil	40.0
Reagent Cycle	1
Vol	200
Sample Limit	0.2000
Point	T1
Reac. Direction	Increase
Check	On
Convers. Factor	1.00000
Offset	0.00000

CALCULATION

Test Range Low	0.0	High: 20.0
Norm. Range Low	0.7	High: 1.4
Number of Steps	1	
Calc Step A	Kinetic	
Readings First	2	
Last	6	
Reaction Limit	No	

CALIBRATION

Calib. Interval	On Request	
Reag. Range Low	-0.0120	High: 0.3200
Blank Range Low	-0.0030	High: 0.0222
Cup-Pos	*	
Cal-1	*	
Replicate	Dupl	
Deviation	5	

* *enter appropriate value*

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DCA 2000®

For Use With DCA 2000® Analyzer

A Quantitative Assay for Microalbumin/Creatinine in Urine

Reagent Kit

INTENDED USE

The DCA 2000® Microalbumin/Creatinine assay is a convenient, quantitative method for measuring low concentrations of albumin, creatinine and the albumin/creatinine ratio in urine. The method has been designed for decentralized testing using random, overnight or timed specimens with results available to the patient within seven minutes. Testing for microalbuminuria (low concentrations of albumin in the urine) is recommended in patients with insulin-dependent diabetes mellitus (IDDM) as well as patients with non-insulin dependent diabetes mellitus (NIDDM).[1,2] This assay is intended for use in both screening for, and monitoring treatment of, microalbuminuria.[3,4]

The DCA 2000 Microalbumin/Creatinine assay is for use in laboratories such as physician office laboratories, clinics, and hospitals.

SUMMARY AND EXPLANATION

Subjects with both IDDM and NIDDM are at increased risk of kidney damage. Diabetic nephropathy is the number one (30–40%) cause of need for kidney dialysis and/or kidney transplant, and is the cause of serious morbidity and mortality in diabetes mellitus. Microalbuminuria is the earliest stage of diabetic nephropathy. Early recognition of kidney disease associated with diabetes may lead to early medical intervention with the possibility of delaying or halting the future need for kidney dialysis. Reduction of protein intake in the diet, control of hypertension by drug therapy, and near normalization of blood glucose, have been shown to be successful in delaying the progression of the disease.[5,6]

Historically microalbuminuria has been detected by measuring the albumin excretion rate (AER) using 24-hour or other timed urine specimens. Recently, calculation of the albumin to creatinine ratio has been shown to eliminate the need for timed collections as the albumin concentration is normalized using the creatinine concentration.[3,4,7] The DCA 2000 Microalbumin/Creatinine assay allows both the measurement of the AER, and the albumin to creatinine ratio.

CHEMICAL PRINCIPLES OF PROCEDURE

All of the reagents for measuring albumin and creatinine are contained in the DCA 2000 Microalbumin/Creatinine Reagent Cartridge (Figure 1). Both the concentration of albumin and creatinine are measured in the reagent cartridge. The albumin and creatinine concentrations, and the ratio are reported on the same display screen of the DCA 2000 Analyzer.

DCA 2000 Microalbumin/Creatinine Reagent Cartridge

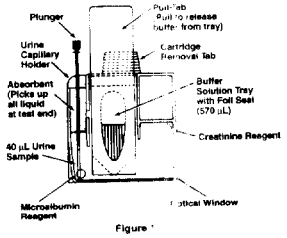


Figure 1

For the measurement of albumin, a specific antibody binds with albumin in the presence of polyethylene glycol. The albumin-antibody complexes that are formed cause increased turbidity which is measured as absorbance at 531 nm. The albumin is then quantified using a calibration curve of absorbance versus albumin concentration.

The creatinine assay is based on the Benedict/Behre chemistry[1] in which creatinine complexes with 3,5 dinitrobenzoic acid at high pH to form a colored complex which is measured at 531 nm. The creatinine is then quantified using a calibration curve of absorbance versus creatinine concentration.

The albumin to creatinine ratio, A/C is then calculated.

All measurements and calculations are performed automatically by the DCA 2000 Analyzer. The instrument's screen displays albumin concentration (mg/L), creatinine concentration (selectable as mg/dL or mmol/L), and albumin to creatinine ratio (no units displayed) at the end of the assay.

Note: If creatinine units are selected to be mg/dL, then the albumin to creatinine ratio is reported as mg/g. If the creatinine units are selected to be mmol/L, the albumin to creatinine ratio is reported as mg/mmol.

KIT CONTENTS:

10—Reagent Cartridges
10—Urine Capillary Holders with Plungers
1—Calibration Card
1—Package Insert

REAGENTS

Albumin Reagent: 3.3–10% purified polyclonal goat anti-human albumin antiserum in 50 mM TRIS, 8.6% w/v non-reactive ingredients (15 µL dried in each reagent cartridge).

Creatinine Alkaline Reagent: 28% potassium hydroxide, 5% non-reactive ingredients (30 µL dried in each cartridge).

Buffer Solution: 0.22% w/v 3,5-dinitrobenzoic acid, 4% polyethylene glycol in 25 mM HEPPS buffer, with 2% non-reactive ingredients (0.57 mL in each cartridge).

WARNINGS AND PRECAUTIONS

DCA 2000 Microalbumin/Creatinine Reagent Cartridges are for *in vitro* diagnostic use.

STORAGE

Store reagent cartridges refrigerated at 2° – 8°C (36° – 46°F). Capillary holders may be stored refrigerated or at room temperature (15° – 30°C/59° – 86°F).

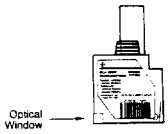
USE LIFE

Reagent cartridges can be kept for up to three months at room temperature anytime before the expiration date. Record on the carton, the date the carton was placed at room temperature.

RECOMMENDED PROCEDURES FOR HANDLING REAGENT CARTRIDGES

Do not use scissors to cut open the foil pouch. Scissors can damage the reagent cartridge, the flexible pull-tab on the cartridge, or the sack containing desiccant. To open foil pouch, tear down from corner notch (until entire *long* side of pouch is open).

When handling the reagent cartridge, do not touch (or otherwise contaminate) the optical window or erroneous test results may occur.

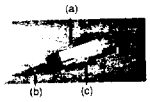


Discard the reagent cartridge if the cartridge is damaged, the flexible pull-tab is loose or missing, the desiccant is missing, or if loose desiccant particles are found inside the foil pouch.

Upon removal from refrigerated storage, allow the reagent cartridge to warm up naturally at room temperature for 15 minutes (in unopened foil pouch). Failure to allow a reagent cartridge to come to room temperature may cause condensation on the optical window inside the cartridge. This occurrence causes erroneous results or an error message. After opening foil pouch, the reagent cartridge must be used within 10 minutes. Do not refrigerate the reagent cartridge after the foil pouch has been opened.

RECOMMENDED PROCEDURES FOR HANDLING URINE CAPILLARY HOLDERS

Unused urine capillary holders and plungers may be saved and used with any lot of reagent cartridges. Discard the urine capillary holder if any of the following are missing from the holder: (a) absorbent pad, (b) glass capillary, (c) latching mechanism. Also discard if the starch plug is missing or at the bottom of the capillary tube.



STABILITY OF REAGENT CARTRIDGES

Reagent cartridges are stable through the last day of the expiration month.

SPECIMEN COLLECTION AND PREPARATION

The urine sample may be random, overnight, or 24-hour. Use no preservative.

Urine specimens may be stored at 2°–8°C (36°–46°F) for up to two weeks. **Do not freeze.** Allow urine specimens to reach room temperature naturally. Mix urine specimen thoroughly before use. Turbid specimens should be clarified by centrifugation or filtration before use.

TESTING PROCEDURE

See the DCA 2000 Analyzer Operating Manual for detailed illustrated directions.

CALIBRATION

Instrument: The DCA 2000 Analyzer is calibrated by the manufacturer. Thereafter, the instrument automatically self-adjusts during first-time power-up and during each assay. In the event the system is unable to make appropriate internal adjustments, an error message is displayed.

Reagent: Before reagent cartridges are released by the manufacturer, each lot of reagent cartridges undergoes a thorough analysis and characterization. Values of calibration parameters are determined which provide for optimal reagent performance. The values for the calibration parameters are encoded onto the calibration card provided with each lot of reagent cartridges. Prior to use of each new lot of reagent cartridges, the calibration bar code is read by the instrument.

Before the sample can be analyzed, the reagent cartridge bar code (containing the lot number and test name) is scanned. This accesses the appropriate calibration parameter values (calibration curve) for the particular lot number of reagent cartridges in use. If no calibration curve is in the instrument for the particular lot number of cartridges in use, the instrument prompts the user to scan the calibration card.

The instrument can store two calibrations for the DCA 2000 Microalbumin/Creatinine Assay. Each of the two calibrations is for a different lot number.

When reagent cartridges are stored and used properly, acceptable performance up to the expiration date is ensured. To verify proper functioning of the DCA 2000 System, analyze DCA 2000 Microalbumin/Creatinine Controls (refer to Quality Control section).

The calibrators used to determine the calibration parameter values are made using a liquid preparation of albumin known to consist of ≥99% monomer, which is the form of albumin found in urine. The calibrators have been assayed against the Reference Preparation for Proteins in Human Serum (RPPHS*), and have been shown to produce identical results.

*RPPHS is a certified reference material developed conjointly through the College of American Pathologists (CAP), the Bureau Communita de Reference (BCR) and the International Federation of Clinical Chemists (IFCC).

QUALITY CONTROL

Run two DCA 2000 Microalbumin/Creatinine Controls (one Low and one High) for each new lot number of reagent kits. Thereafter, run one control** per kit of 10 reagent cartridges and also run one control at scheduled intervals to assess and maintain operator proficiency. Retain a permanent record of control results. Only when controls are used routinely and are within acceptable limits can accurate results for patient samples be assured.

Establish a quality control program which includes proper sample collection and handling practices, acceptable limits on controls, on-going evaluation of control results, proper storage of reagent cartridges, etc.

All DCA 2000 Microalbumin/Creatinine Control results should be within the acceptable ranges specified in the control package insert. If the bar code on the control card (included in the DCA 2000 Microalbumin/Creatinine Control Kit) was scanned before running the control, the instrument will automatically indicate (via display screen) whether the control results are within or out-of-limits.

If control results are out-of-limits, do not proceed with specimen analysis. Check reagent cartridges, instrument, environmental conditions, and technique.

Correct any problems and then re-assay controls to verify that control results are now within acceptable limits.

If the problem cannot be corrected, or the reason for an out-of-limits result cannot be determined, contact the Bayer Corporation, Customer Service Department at 1-800-348-8100 (USA) or 1-800-268-7200 (Canada) or the nearest Bayer Diagnostics Office. In the United Kingdom, contact the Clinical Diagnostics Support Group 01635 566211.

**Alternate use of low and high control.

RESULTS

Albumin: The displayed test result requires no further calculation. Albumin concentrations in the following range are reported: 5 to 300 mg/L. The test is linear throughout this range.

Creatinine: The displayed test result requires no further calculation. Creatinine concentrations in the following range are reported: 15 to 500 mg/dL (1.3 to 44.2 mmol/L). The test is linear throughout this range.

Albumin/Creatinine Ratio: The displayed test result requires no further calculation. Albumin/Creatinine ratios can be reported in the following range: 1 to 2,000 mg/g (0.11 to 226 mg/mmol).

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[illegible] lower limit of the test (under range). This [illegible] does not provide for re-assay using a larger sample.

Albumin or Creatinine result preceded by a greater than sign (>): A greater than sign in the display indicates a concentration above the upper limit of the test (over range). This method does not provide for re-assay using a diluted sample. To obtain a more quantitative test value, use another test method.

Ratio result preceded by a less than (<) sign or greater than (>) sign or (---): If the albumin and/or creatinine result is under or over range, the ratio will also be reported under or over range. In certain cases, no ratio will be reported.

Example 1: If the albumin result is >300 mg/L and the creatinine result is 100 mg/dL (8.84 mmol/L), then the ratio will be reported as >300 mg/g (>26.5 mg/mmol).

Example 2: If the albumin result is 75 mg/L and the creatinine result is <15 mg/dL (<1.33 mmol/L), then the ratio will be reported as >500 mg/g (>56.4 mg/mmol).

Example 3: If the albumin result is >300 mg/L and the creatinine result is >500 mg/dL (>44.2 mmol/L), then no ratio will be reported (---).

Example 4: If the albumin result is <5 mg/L and the creatinine result is <15 mg/dL (<1.33 mmol/L), then no ratio will be reported (---).

All laboratory tests are subject to random error. If the test result is questionable, or if clinical signs and/or symptoms appear inconsistent with test results, re-assay the specimen or confirm the result using another method.

LIMITATIONS OF PROCEDURE

Avoid using urine specimens which are visibly hemolyzed or highly pigmented. Urine specimens containing in excess of 5,000 mg/L of albumin may give assay results within the range of the DCA 2000 System because of the antigen excess effect for direct agglutination assays. If such gross proteinuria is suspected, assay the sample using Multistix® 10 SG Reagent Strips or Albustix® Reagent Strips.

The amount of albumin excreted in the urine can vary according to changes in posture, amount of hydration, physical activity, blood pressure in the individual, and during pregnancy. Urine samples should not be obtained following strenuous activity. The test should not be performed if the sample exhibits significant bacterial growth or if the patient shows signs of a urinary tract infection.

Interferences

Albumin Assay: No cross-reactivity exceeding 5% has been found with IgG, hemoglobin, transferrin, or microglobulin. Elevated glucose (2,500 mg/dL or 138.8 mmol/L) and urea (2,400 mg/dL or 400 mmol/L) interference has been shown by drugs commonly found in the urine or prescribed to persons with diabetes.

Creatinine Assay: Elevated glucose (2,500 mg/dL or 138.8 mmol/L) and urea (2,400 mg/dL or 400 mmol/L), ascorbate (80 mg/dL or 4.5 mmol/L), bilirubin (3.6 mg/dL or 0.06 mmol/L), acetoacetate (80 mg/dL or 7.8 mmol/L), and hemoglobin (30 mg/dL or 4.7 µmol/L) have been shown not to affect the assay results. No interference has been shown by drugs commonly found in the urine or prescribed to persons with diabetes.

EXPECTED VALUES:

The reference ranges suggested by the study shown below should be regarded as guidelines only. Because of differences which may exist between laboratories and locales with respect to population, diet, laboratory technique and selection of reference groups, it is important for each laboratory to establish by similar means the appropriateness of adopting the reference ranges suggested by this study.

Definition of microalbuminuria: Generally accepted definitions of microalbuminuria are:

Concentration	Excretion Rate	
Early Morning Urines	24-h Collection	Timed (Other)
30–300 mg/L	30–300 mg/24h	20–200 µg/min

Adjusted for Urine Creatinine

US and Elsewhere	Europe and Elsewhere
30–300 mg/g creatinine	2.5–25 mg/mmol creatinine

Albumin Timed specimens: A total of 95 timed, 24 hour and overnight urine samples were collected from normal volunteers at two widely separated laboratories and assayed with the DCA 2000 Microalbumin/Creatinine Reagent Kit. The albumin results ranged from <5 to 45.6 mg/L. The average of the 90th and 91st (95th percentile) sample results was 15 mg/L albumin, which was established as the upper limit of the normal range.

Albumin Random specimens: A total of 95 random urine samples were collected from normal laboratory volunteers at two widely separated laboratories and assayed with the DCA 2000 Microalbumin/Creatinine Kit. The results ranged from <5 mg/L to 92.1 mg/L albumin. The average of the 90th and 91st (95th percentile) sample results was 37 mg/L which was established as the upper limit of the normal range.

Creatinine specimens: Normal daily creatinine excretion varies widely depending on muscle mass, fluid intake, and physical activity. The ranges of creatinine concentration obtained in 109 normal individuals were <15 mg/dL (1.3 mmol/L) to 500 mg/dL (44.2 mmol/L) for random specimens, and from 36 mg/dL (3.2 mmol/L) to >500 mg/dL (44.2 mmol/L) for timed specimens.

SPECIFIC PERFORMANCE CHARACTERISTICS

The precision and correlation data are results obtained by the staff at separate physician offices and a large diabetes treatment/research center. The statistical calculations were performed following NCCLS procedures.

Precision: Multiple DCA 2000 Microalbumin/Creatinine assays of two different commercially prepared artificial urine base controls were performed by three independent investigators. The assigned values listed were determined from studies conducted by the manufacturer. Within-run precision was evaluated by including low and high controls, in duplicate, in each run of clinical specimens.

Albumin

Control	Site No.	Assigned Value (mg/L)	Mean Value (mg/L)	No. Runs	No. Assays	Within-Run S.D.	Within-Run %C.V.	Overall S.D.	Overall %C.V.
Low	1	30.8	31.8	27	54	1.37	4.3	1.85	5.8
Low	2	30.8	33.0	31	62	2.00	6.1	2.02	6.1
Low	3	30.8	32.9	33	66	1.54	4.7	2.18	6.6
High	1	200	202	27	54	3.42	1.7	5.41	2.7
High	2	200	216	31	62	6.31	2.9	7.46	3.4
High	3	200	217	33	66	6.17	2.8	7.37	3.4

Creatinine

Control	Site No.	Assigned Value (mg/dL)	Mean Value (mg/dL)	No. Runs	No. Assays	Within-Run S.D.	Within-Run %C.V.	Overall S.D.	Overall %C.V.
Low	1	99.9	104	28	56	2.03	2.0	2.95	2.8
Low	2	99.9	106	31	62	2.30	2.2	2.81	2.6
Low	3	99.9	106	33	66	2.19	2.1	3.80	3.6
High	1	396	412	28	56	5.51	1.3	8.92	2.2
High	2	396	421	31	62	7.41	1.8	10.88	2.6
High	3	396	424	33	66	9.09	2.1	11.42	2.7

Correlation: The concentration of albumin and creatinine in clinical specimens ranging from 5 mg/L–350 mg/L albumin and 15 mg/dL (1.3 mmol/L)–370 mg/dL (32.7 mmol/L) creatinine was determined using the DCA 2000 Microalbumin/Creatinine System (x) and RIA, turbidimetry and nephelometry (x) for albumin, and automated Jaffe (x) for creatinine. At Site 1 random, timed overnight, and 24-hr timed specimens were collected. At Sites 2 and 3 random and timed overnight specimens were collected. Results are as follows:

Albumin

Site No.	Sample Type	Comparative Method	No. of Assays	Regression Line	Standard Error of Estimate	Correlation Coefficient
1	Random	RIA	281	$y = (-)1.0 + 0.869x$	8.0	0.99
1	Timed Overnight	RIA	221	$y = (-)0.4 + 0.878x$	6.8	0.99
1	24-hr. Timed	RIA	67	$y = (-)0.5 + 0.855x$	10.4	0.99
2	Combined Random and Timed Overnight	Turbidimetry	137	$y = 0.1 + 0.857x$	6.2	0.99
3	Combined Random and Timed Overnight	Nephelometry	129	$y = 0.6 + 1.06x$	7.0	0.99

Creatinine

Site No.	Sample Type	Comparative Method	No. of Assays	Regression Line (mg/dL)	Standard Error of Estimate	Correlation Coefficient
1	Random	Automated Jaffe	276	$y = (-)0.2 + 1.06x$	5.1	0.99
1	Timed Overnight	Automated Jaffe	266	$y = (-)2.1 + 1.08x$	4.2	1.00
1	24-hr. Timed	Automated Jaffe	70	$y = (-)3.2 + 1.08x$	3.8	1.00
2	Combined Random and Timed Overnight	Automated Jaffe	224	$y = (-)2.3 + 1.02x$	5.6	1.00
3	Combined Random and Timed Overnight	Automated Jaffe	196	$y = (-)3.0 + 1.12x$	4.9	0.99

AVAILABILITY

DCA 2000 Microalbumin/Creatinine Reagent Kit is available as Product No. 6011.
DCA 2000 Microalbumin/Creatinine Low and High Control Kit is available as Product No. 6012.

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Studies

Part 1

Internal Report

Bayer Corporation
CLINITEK® Microalbumin Reagent Strips
510(k) Premarket Notification

APPENDIX -- STUDIES Part I

IN-HOUSE EVALUATION OF CLINITEK® MICROALBUMIN REAGENT STRIPS

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Part 2

Part 2

Internal Report

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APPENDIX -- STUDIES Part II

CLINICAL EVALUATIONS

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Internal Report

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APPENDIX B

CLINITEK MICROALBUMIN PERFORMANCE TRIAL PROTOCOL

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CLINICAL EVALUATION OF MICROALBUSTIX PERFORMANCE AND DECODE DEVELOPMENT

CLINICAL TRIALS DEPARTMENT
BAYER CORPORATION

September 17, 1996

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APPENDIX C

CLINITEK MICROALBUMIN POINT-OF-CARE TRIAL PROTOCOL

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Part 3

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Safety
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Effectiveness

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510(k) SAFETY AND EFFECTIVENESS SUMMARY

Prepared: July 17, 1997

Submitter: Bayer Corporation, Business Group Diagnostics

Address: 1884 Miles Avenue, P.O. Box 70
Elkhart, IN 46515
(219) 262-6929

Contact: Rosanne M. Savol, R.A.C.
Manager, Regulatory Affairs

Device:
Trade/Proprietary Name: CLINITEK® Microalbumin Reagent Strips
Common/Usual Name: Test for microalbumin in urine
Test for creatinine in urine
Document Control Number: K97_____

Classification: Division of Clinical Laboratory Devices
Panel - Clinical Chemistry and Toxicology
Classification Code - 75 JIR (Urinary Protein or Albumin)
75 CGX (Alkaline Picrate, Colorimetry, Creatinine)

Predicate Devices: Micral-Test® strips (Boehringer Mannheim Corporation); Microalbumin Assay/Array® Analyzer (Beckman Instruments Inc.); SPQII™Reagent(INCSTARCorp.)/Roche COBAS-FARA® II Analyzer/Ciba-Corning Express Plus; Microprotein Reagent (Sigma Diagnostics)/Roche COBAS MIRA Analyzer/Paramax® Analytical System/DuPont XL System; Quantimetrics BGR Total Protein (Quantimetrics)/TECHNICON RA® 1000 Random Access Analyzer; CX3 Creatinine Reagent (Beckman)/ Beckman CX3 SYNCHRON® Analyzer; Paramax® Creatinine Reagent (Dade Diagnostics)/Paramax Analytical System; Miles Creatinine Reagent (Bayer)/TECHNICON RA 1000 Random Access Analyzer; Dade® Creatinine Reagent/DuPont XL System; DCA 2000+ Microalbumin/Creatinine Assay (Bayer)

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Device Description:

CLINITEK® Microalbumin Reagent Strips are firm plastic strips that contain two reagent areas to test for microalbumin (low concentration of albumin) and creatinine in urine. CLINITEK Microalbumin Reagent Strips are dipped into a urine specimen and "read" instrumentally by the CLINITEK® 50 or CLINITEK® 100 Urine Chemistry Analyzer. In addition to providing an albumin and a creatinine result, an albumin-to-creatinine ratio is also determined. Semi-quantitative results are available within one minute.

Intended Use:

CLINITEK® Microalbumin Reagent Strips are for screening urine specimens for microalbuminuria as an aid in the detection of patients at risk for developing kidney damage. CLINITEK Microalbumin Reagent Strips are for professional use in point-of-care testing locations such as physician office laboratories, clinics, and hospitals.

Technological Characteristics:

The CLINITEK® Microalbumin assay is a dip-and-read reagent strip allowing detection of urinary albumin at 20 to 40 mg/L, and the albumin-to-creatinine ratio of 30 to 300 mg/g. The albumin test is based on dye binding using a high affinity sulfonephthalein dye. At a constant pH, the development of a blue color is due to the presence of albumin. The creatinine test is based on the peroxidase-like activity of a copper creatinine complex that catalyzes the reaction of diisopropylbenzene dihydroperoxide and 3,3',5,5'-tetramethylbenzidine. The color of the reagent areas are read by the CLINITEK® 50 and CLINITEK® 100 instrument at specified times and the results are displayed or printed in clinically meaningful units.

Assessment of Performance:

The performance of CLINITEK® Microalbumin Reagent Strips was studied in clinical settings by typical users of the system and results compared to currently used tests for microalbumin and creatinine in urine. The studies demonstrated that typical users in decentralized, point-of-care laboratories can obtain clinical test results that are substantially equivalent to current methods.

Conclusion:

CLINITEK® Microalbumin Reagent Strips for use with the CLINITEK® 50 and CLINITEK® 100 Urine Chemistry Analyzers provide a convenient method for screening for microalbumin and creatinine in urine. Studies show that the system can be used in decentralized and point-of-care laboratories and provide clinical results comparable to other test methods in current clinical laboratory practice.