Policies and Procedures

for use with Urisys 1100® Urine Analyzer

This is a CLIA-Waived System

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Disclaimer

Roche Diagnostics has prepared this Sample Policies and Procedures Manual as a tool for the laboratory's use in writing and adopting its own procedures document. The procedures in this document are derived from the package insert, application sheet, or method sheet for the product in effect at the time of publication. This document should not be considered a substitute for the most current version of the package insert for this product. Always refer to the package insert, application sheets, bulletins, manuals and other labeling for a more complete and specific description of instructions, procedures, precautions, limitations, and requirements for this product, and the most up-to-date information. Roche Diagnostics makes no representation or warranty that by complying solely with the information contained within this document, a laboratory will be in compliance with all applicable laws, regulations, accreditation requirements and international standards, nor is this document intended to be used for the purposes of ensuring compliance. Compliance with applicable laws, regulations, accreditation requirements and international standards remains solely the responsibility of the individual laboratory. Roche Diagnostics hereby disclaims all liability for any laboratory's approval, use, or revision of these procedures or the laboratory's failure to comply with any laws, regulations, accreditation requirements, or international standards in regards to such approval, use, or revision.

Introduction

Roche Diagnostics is pleased to assist you in developing a policies and procedures manual for use with the Urisys 1100® Urine Analyzer in your facility. This guide contains sample policies and procedures for use with the Urisys 1100® Urine Analyzer. These sample policies and procedures are intended only as a guide, and it is important that you make whatever adjustments may be required as a result of a change in policy or a change in law or regulations or their interpretation.

A total quality management program should include written policies and testing procedures that are customized for your particular facility. Any policies and procedures that involve using Chemstrip urine test strips should be written prior to the start of any urine testing. Blank spaces let you customize the policies and procedures with information specific to your facility. You are encouraged to highlight important areas and procedures currently in use.

We suggest you store a *Urisys 1100® Urine Analyzer Operator's Manual, Chemstrip urine test strip package insert* and *control package insert* in the *Product Information* section for quick reference. You may also want to include the following clinical guidelines and regulations in the *Regulatory Requirements* section.

- Joint Commission Guidelines
- CAP Guidelines
- CLIA '88 Guidelines
- State Guidelines
- Bloodborne Pathogen Standard

If you have any questions, please call Roche Diagnostics Customer Support Center at 1-800-428-4674, available 7 days per week, 24 hours a day, and 365 days per year.

Approval Process

The following policies and procedures must be approved, signed and dated by the laboratory director. If a new director is placed in charge, the procedures must be re-approved, signed, and dated by the new director. In addition, any *changes* to the manual must be approved, signed, and dated by the laboratory director.

You must maintain a copy of each procedure with the date of the initial use and the date the test was discontinued. Keep these records for at least two years after the procedure has been discontinued.

Approval date _____ Approved by: _____

Reviewed/Revised

Date	By Whom	Title
_____	_____	_____
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Purpose

To establish safe, accurate urine test results to be used for screening and monitoring patient status.

General Policies and Procedures

- The policies and procedures pertaining to urinalysis with the Urisys 1100® Urine Analyzer are reviewed at least once a year.
- Any changes to the text as they apply to methodology or testing policy are signed by the appropriate authority, dated, and inserted in the policies and procedures manual.
- Obsolete or superseded procedures are replaced in the manual, but are retained for compliance purposes.
- The most recent package inserts and the *Urisys 1100® Urine Analyzer Operator's Manual* provided by Roche Diagnostics should be referenced for the most recent procedural information.

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I. Policies and Procedures

A. Principle of Operation

The Roche Diagnostics Urisys 1100® Urine Analyzer is a semi-automated analyzer intended for *in vitro* semi-quantitative determination of urine analytes. The analyzer is designed to read and evaluate the results of Chemstrip 10MD* Urine Test Strips. These urine test strips are multiparameter strips used for the determination of specific gravity, pH, leukocytes, nitrite, protein, glucose, ketones, urobilinogen, bilirubin and blood in urine.

The Urisys 1100® Urine Analyzer is a reflectance photometer. It reads the urine test strips under standardized conditions, saves the results to memory and outputs them via its own built-in printer and/or serial interface.

The Urisys 1100® Urine Analyzer standardizes urine test strip results by eliminating factors known to affect visual evaluation of urine test strips, such as; variable lighting conditions at the workplace, individual skill levels at matching test strip pad colors, failure to keep the prescribed testing times, and clerical errors.

The test strip is placed on a sliding tray, and a stepping motor moves it under the reading head, which remains stationary. The analyzer reads the reference pad, followed by each of the test pads on the strip. The reading head contains LEDs that emit light at various wavelengths. Reading is done electro-optically as follows:

The LED emits light of a defined wavelength onto the surface of the test pad at an optimum angle. The light hitting the test zone is reflected proportionally to the color produced on the test pad and is picked up by the detector, a phototransistor positioned directly above the test zone. The phototransistor sends an analog electrical signal to an A/D converter, which changes it to digital form. The microprocessor then converts this digital reading to a relative reflectance value by referring it to a calibration standard.

Finally, the system compares the reflectance value with the defined range limits (reflectance values which are programmed into the analyzer for each parameter) and outputs a semi-quantitative result.

Each test pad is read photometrically after about 55-65 seconds. In strongly alkaline urine samples, the Urisys 1100® Urine Analyzer automatically corrects the result of the specific gravity test.

The following is a list of test principles specific to each parameter. Please reference the most recent *Chemstrip urine test strip package insert* for modifications in test principles.

- **Specific Gravity:** In the presence of cations, protons are released by a complexing agent in the test pad. The indicator bromthymol blue changes from blue via blue-green to yellow.

- **pH Test:** The test pad contains the indicators methyl red and bromthymol blue. These indicators give clearly distinguishable colors over the pH range of 5 to 9.[1, 2] Colors range from orange through yellow and green to blue.

- **Leukocyte Test:** Granulocytic leukocytes contain esterases which catalyze the hydrolysis of an indoxylcarbonic acid ester to indoxyl. The indoxyl formed reacts with a diazonium salt to produce a purple color.

- **Nitrite Test:** Nitrite, if present, reacts with an aromatic amine to give a diazonium salt, which, by coupling with a further compound, yields a red-violet azo dye.[3, 4, 5]

- **Protein Test:** The test is based on the color change of the indicator 3', 3", 5', 5"-tetrachlorophenol-3, 4, 5, 6-tetrabromosulfophthalein in the presence of protein. A positive reaction is indicated by a color change from yellow to light green/green.[6, 7, 8]

*Hospitals may use Chemstrip 10UA Urine Test Strips.

- **Glucose Test:** Glucose detection is based on the enzymatic glucose oxidase/peroxidase (GOD/POD) method. The reaction utilizes the enzyme glucose oxidase to catalyze the formation of gluconic acid and hydrogen peroxide from the oxidation of glucose. In turn, a second enzyme, peroxidase, catalyzes the reaction of hydrogen peroxide with the chromogen tetramethylbenzidine to form a green dye complex. A positive reaction is indicated by a color change from yellow to green.[9, 10]

- **Ketone Test:** Based on the principle of Legal's Test, sodium nitroprusside and glycine react with acetoacetate and acetone in an alkaline medium to form a violet dye complex. A positive result is indicated by a color change from beige to violet.[11, 12]

- **Urobilinogen Test:** Urobilinogen is coupled with 4-methoxybenzene-diazonium-tetrafluoroborate in an acid medium to form a red azo dye.[13]

- **Bilirubin Test:** The detection of bilirubin is based on the coupling reaction of a diazonium salt with bilirubin in an acid medium. The reaction yields a pink to red-violet color proportional to the total bilirubin concentration.[14] (Some users may describe this as a cream to peach color.)

- **Blood Test:** Hemoglobin and myoglobin, if present, catalyze the oxidation of the indicator by the organic peroxide contained in the test pad. Intact erythrocytes hemolyze on the test pad and liberate hemoglobin, which produces a green dot. Since the test pad absorbs several microliters of urine, more erythrocytes become visible than would correspond to 1µL.[15-19] Separate sets of color blocks are representative of erythrocytes and hemoglobin. Scattered or compacted green dots on the yellow test pad are indicative of intact erythrocytes, or myoglobin.

- **Compensation Pad:** The compensation area is not impregnated with reagent. This pad allows the instrument to compensate for the intrinsic color of urine, which may affect test results.

B. Specimen Collection

Policy

- Use a freshly voided urine specimen, first-morning urine specimen, or post-prandial urine specimen.
- When testing urine specimens, every precaution must be taken to avoid contamination of the specimen and the operator.
- Because of the potentially hazardous nature of handling urine and the possibility of its contamination with blood, it is recommended that disposable latex gloves and laboratory coats be used when collecting specimens. Consult your facility's infection control policy.
- Instructions for collection of a clean-catch midstream urine specimen may be found in *Section V. Appendix*.

Procedure

1. Follow physician's order(s).
2. Assemble appropriate supplies.
    - Cleansing towelette
    - Water-saturated sponge
    - Clean urine container with lid
3. Instruct patient to wash genital area (do not use towelettes with strong cleansing agents), rinse with water, and then obtain a clean-catch midstream urine sample in the clean container. Refer to *Section V. Appendix* for instructions.
4. Test urine as soon as possible after collection to avoid deterioration of specimen. If specimen cannot be tested within *two* hours of collection, refrigerate immediately (at 2°-8°C) in a closed container. Bring specimen to room temperature before testing. Mix thoroughly before testing.
5. If urine is not tested immediately, mix specimen thoroughly by capping container and swirling several times before testing to avoid incorrect results. Do not centrifuge or add preservatives to the urine specimen.

C. Test Strip Storage and Stability

Policy

- Store Chemstrip urine test strips at 2 °C (36 °F) – 30 °C (86 °F). Do not freeze.
- Opened Chemstrip urine test strips are stable until the expiration date on the vial label when stored in the original capped vial. The vial must be closed immediately after use, using the original cap.

D. Calibration of the Urisys 1100® Urine Analyzer

(with Chemstrip 10MD* Test Strips)

Policy

- Calibration is required when using the Chemstrip 10MD Test Strips.
- The Urisys 1100® Urine Analyzer must be calibrated every seven days or when indicated by the analyzer.
- The Chemstrip Urine Analyzer Calibration Strips (Catalog Number 11379194160) should remain in the vial until just before use. Do not touch the elevated gray areas on the strips.
- The calibration strips should be used only *once*.
- If you do not obtain a successful calibration, the analyzer will not process samples.
- Calibration should be documented on the *Preventive Maintenance Log.*

Procedure

1. Plug the power cord provided with the analyzer into the power outlet at the rear of the analyzer and then into a wall outlet. Turn the analyzer on. The analyzer will then automatically perform a self check. If the self check is completed successfully, the message “self check OK” prints along with the time and date.
2. Make sure the test strip tray is clean and dry.

Note: After a successful self check, the operator may have to enter an operator ID and password (if these options have been selected).

3. If the message “REPEAT CALIBRATION” is in the display, press START. If the analyzer is in Ready-to-Measure mode, press the left function key to select “Calibr”. The message, “START CALIBRATION” appears on the display.
4. Remove a calibration strip from its container, being careful not to touch the pads. Do not allow the calibration strip to come into contact with urine.
5. With the retaining bar open, place the calibration strip, pads facing upward, onto the test strip tray and insert the front edge of the strip under the plastic clip.
6. Press the START button. The display will then read, “Heat up! Please wait xx sec left.” Once the countdown is finished, the measurement begins. If calibration results are acceptable, the message “CALIBRATION O.K..” is displayed. The tray moves to the start position and the retaining bar opens.
7. Remove the calibration strip and discard. Remember that each calibration strip is used only once.
8. If the calibration is valid, results are stored in memory, and a report with the reflectance values, time, and date automatically prints. Reflectance values for positions 1 through 11 for the orange LED are printed in the middle column and for the green LED in the right column.

9. If the results for the reference pad or the calibration strip are outside the programmed tolerances, one of the following messages appears on the display:

    - “REFERENCE PAD ERROR”
    - “CALIBRATION INVALID” or
    - “CALIBRATION ERROR”

If a calibration error occurs, repeat the calibration procedure using a new calibration strip.

1. Press the START button and the display will return to the “START CALIBRATION” menu.
2. Place the new calibration strip on the test strip tray and press the START button again.
3. If the calibration is valid, the message “CALIBRATION OK” prints.
4. If the calibration fails a second time and a calibration error appears on the display, refer to the Operator’s Manual or call Roche Diagnostics Customer Support Center at 1-800-428-4674, 7 days a week, 24 hours a day, and 365 days per year.

E. Testing with the Urisys 1100® Urine Analyzer

Policy

- Only a certified operator may perform a urine test with the Urisys 1100® Urine Analyzer.
- Because of the potentially hazardous nature of handling urine and the possibility of its contamination with blood, it is recommended that disposable latex gloves and laboratory coats be used when collecting specimens and performing test procedures. Consult your facility's infection control policy.
- Urine should be handled at Biosafety Level 2 as recommended for any potentially infectious material in the Centers for Disease Control/National Institutes of Health manual, *Biosafety in Microbiological and Biomedical Laboratories*, 1988.[24] Universal precautions may apply if the urine is contaminated with blood or if required by the infection control policy of the facility.
- Outdated Chemstrip urine test strips are discarded.

Procedure

1. The following equipment is assembled prior to testing:

   Urisys 1100® Urine Analyzer

   Chemstrip urine test strips

   Patient specimen

   Disposable latex gloves (if required by facility)

   Laboratory coat (if required by facility)

   Absorbent paper

2. Check the expiration date on the Chemstrip urine test strip vial prior to testing.
3. Plug the power cord provided with the analyzer into the power outlet at the rear of the analyzer and then into a wall outlet. Turn the analyzer on. The analyzer will then automatically perform a self check. If the self check is completed successfully, the message "self check OK" prints along with the time and date.

Note: After successful self check, the operator may have to enter their operator ID and password if these options have been activated.

4. The Urisys 1100® Urine Analyzer is ready for measurement as long as valid calibration values are stored in the analyzer. Refer to *Section I.D. Calibration of the Urisys 1100® Urine Analyzer* of this manual.
5. Verify the test strip tray is clean of any residue. If there is residue on the tray, refer to *Section II. Preventive Maintenance* of this manual for the cleaning procedure. Urine residue on the test strip tray may result in inaccurate results.
6. If the sample has been refrigerated, allow it to come to room temperature. Mix the specimen by capping the container and swirling several times if not freshly voided.

7. Remove the cap from the test strip vial and remove one Chemstrip urine test strip.

8. Dip the test strip for one second in the urine sample. Draw the edge of the test strip along the rim of the specimen container. Dab the long edge of the strip lightly on absorbant paper to remove excess urine. Make sure that each pad is blotted.

9. If the analyzer is in Standby mode, press START to return to Ready-to-Measure mode. The test strip tray and the retaining bar must be in the open position. Place the test strip, with the pads facing upward, onto the test strip tray and insert the front edge of the strip under the plastic clip. It is important that the strip is correctly positioned and the START button is pressed within 5-10 seconds of dipping the strip.

10. Press the START button. The display will read, "Measurement starts in xx sec." The display counts down until start. During this time, the strip incubates and the reatining bar remains open.

11. If the test strip is not correctly located in the middle of the tray, move it gently to the side until it is properly aligned under the retaining bar. Be careful not to move the tray.

12. After the strip incubates, the measurement begins with the Reference pad and then all test strip pads are read. The tray returns to the Start position and the retaining bar opens.

13. The results are printed and the next sample number appears on the display.

14. Remove and dispose of the test strip. Wipe any urine residue from the tray with a lint-free cloth. Refer to Section II. Preventative Maintenance of this manual for the cleaning procedure.

15. Properly dispose of the urine, urine container and test strip.

Guidelines

- Mechanical problems are evident when the analyzer displays an error message. A chemistry problem may become evident with an unexpected result. Abnormal results are flagged with an asterisk. If you obtain an unexpected result on any chemistry, refer to the *Limitations and Performance Characteristics* sections of the *Chemstrip urine test strip package insert*.

- If you are comparing the analyzer values against the visual strip values and the deviation is more than one concentration block, one of the following may have occurred:

    - Test strip is not positioned correctly in the test strip tray

    - Power supply failure or high frequency interference by other devices

    - Visual strip is deteriorated

    - Improper testing technique

If one of the above situations has occurred, repeat the measurement with a new test strip, being very careful to properly position the test strip. Remove any external source of interferences.

- The following is a list of error messages and suggestions on how to eliminate the problem:

Error Code	Error Description	Cause	Action
E1	Reference pad error	Gray reference pad on the test strip tray soiled or damaged.	Switch off the instrument. If not visibly damaged, clean and dry the pad. Insert the tray and wait for the self-check to finish. If the error message reoccurs, call Roche Customer Support Center.
E2	Wrong strip	The test strip used is different from the one for which the analyzer has been programmed for (either Chem 10, Chem 5, or Chem 7). See Operator's Manual.	Press the START button. Repeat the measurement using the test strip that the instrument has been programmed for.
E3	Strip measurement	a) No test strip present on the tray. b) Test strip is incorrectly positioned on the tray. c) Urine on the test strip has dried. d) Test strip has not been dipped in urine.	Press the START button. Repeat the measurement with a new test strip. Make sure the strip is inserted correctly and that the retaining bar properly closes after the START button is pressed.
E4	Calibration Error	Calibration values differ from those obtained in the last valid calibration.	Press the START button. Repeat the calibration using a new calibration strip. Make sure the calibration strip is properly positioned under the clip on the test strip tray.
E5	Calibration Invalid	Calibration values out of tolerance.	Check the reference pad for soil or damage. Clean the reference pad or use the spare tray. Repeat the calibration with a new calibration test strip. If the error reappears, call Roche Customer Support Center.
E6	Chip Error	The chip module underneath the printer cover is missing, not making contact, or is defective.	Switch off the analyzer, insert the chip module and switch the instrument on again. If the error message appears again, call Roche Customer Support Center.
E7	Missing Tray	Test strip tray is missing or not inserted far enough to engage the motor.	Insert the test strip tray correctly. (See Section 4 of Operator's Manual.) Press the START button.
E8	Tray Position Error	The positioning hole in the tray is dirty or still wet after cleaning; the retaining bar is open while the tray is advancing; or the retaining bar mechanism is contaminated with urine and blocked.	Clean, blow through, or dry the positioning hole on the test strip tray using a lint-free cloth. Remove any urinary deposits on both the top and bottom of the test strip tray. Insert the tray again and press the START button. If the message error persists, call Roche Customer Support Center.
E9	Wrong tray	The test strip tray is not the one programmed for the analyzer or the gray reference pad is missing from the tray. Gray reference pad is scratched or dirty.	Press the START button. The strip type menu is displayed. The strip type must match the tray type. (See Operator's Manual, Section 4.2.) Use the correct tray and make sure the gray reference pad is clean. Press the START button.
E10	Light Barrier Error	The light barrier used to control the position of the test strip is defective or the tray transport is blocked.	Pull out the tray and return it to the start position. Press the START button. If the error message persists, call Roche Customer Support Center.
E11	Motor Step Error	The stepping motor drive is out of tolerance or the advance of the test strip tray is blocked.	Carefully clean the tray. Clean and dry the positioning hole using a lint-free cloth. Remove any urinary deposits on both the top and bottom of the test strip tray. Insert the tray again and press the START button. If the message error persists, call Roche Customer Support Center.
E12	Optics Error	The reference pad is missing from the test strip tray or an LED or phototransistor is defective.	Attach the reference pad. Press the START button. If the error message appears again, call Roche Customer Support Center.
E13	Printer Error	Printer connection fault or paper jam. This message will not appear if there is no paper.	Switch off the analyzer. If there is a paper jam, clear it. Switch the analyzer on again. If the error message appears again, call Roche Customer Support Center.

Error Code	Error Description	Cause	Action
E14	Interface Error	Unable to transfer data to PC or host in bi-directional mode.	Check the data cable. Verify that the PC or host is ready to receive data. Use the “Send” function to transfer data or press “Home” to resume Ready-to-Measure status.
E15 REFERENCE PAD ERROR BOTTOM!		The bottom portion of the reference pad on the tray is soiled or damaged.	see E1
E16 REFERENCE PAD ERROR TOP!		The top portion of the reference pad on the tray is soiled or damaged.	see E1
E17 INVALID PASSWORD!		The entered password doesn’t match.	Enter correct password.
E18 INVALID OP.ID!		The entered Operator ID is not valid.	Enter a valid Operator ID.
E19 LIST DOWNLOAD FAILED		The new Operator ID list download failed.	No action. After 2 seconds next state starts with old list if there was.
E20 NO VALID LIST!		There is not a valid list at all in device.	Try to download an Operator ID list from the host or continue without authenticated operator.
Check Measurement	Analyzer prints out software and chip version number and 3-digit numbers without naming the parameters	Service function is activated.	Press the “Back” function key to return to the main menu.
	Values obtained do not compare with those from visual examination.	a) Test strip incorrectly positioned on the test strip tray. b) Uncharacteristic test pad colors. c) The wrong test strip, such as the calibration strip, was used. d) Electromagnetic interference from other devices. e) Improper storage or technique.	Repeat the measurement with a new test strip. Follow the procedure carefully and make sure the test strip is inserted properly. Repeat calibration, if necessary. Move the analyzer to another location if external interference is suspected.
	No printout	“Printer: Off” is selected or the printer/software is defective.	Choose “Printer: On” to reactivate the printer. Request a patient report through the “Print” function. If this fails, activate the “Linefeed” function. If there is still no response, call Roche Customer Support Center.
	The analyzer will not read, even though the sequence number is displayed.		Switch the analyzer off and back on again.

F. Documentation of Urinalysis Results

Policy

- The date, time, initials of the operator, patient name/patient ID number, and parameter values are recorded on the patient chart or the appropriate log for your facility.
- Test requisitions, test authorizations, and test results are retained for a minimum of two years.
- Test requisition or authorization includes:

  Patient's name

  Name and address (or other identifier) of the person requesting the test

  Test to be performed

  Date the sample was obtained

  Date the test was performed

- An audit trail exists, linking the patient test with the Chemstrip test strip lot number and control lot number used.

Procedure

1. Record the date, time, initials of the tester, patient name/patient ID number, and test values on the *Urinalysis Report Form* of this guide or the appropriate log for your facility.
2. Indicate the type of specimen (first morning, random, clean-catch midstream, etc.) on the appropriate log.

(See Section VI. Log Sheets for sample log sheets.)

G. Expected Values

Guidelines

Please refer to the most recent *Chemstrip urine test strip package insert* for any changes to the expected values information.

- **Specific Gravity:** Random urine specimens vary from 1.001 to 1.035. Twenty-four hour urine specimens from normal adults with normal diets and fluid intake will have a specific gravity of 1.016 to 1.022. [22]

- **pH:** Urine pH values generally range from 5 to 9. The most frequent pH values for first-morning specimens in healthy subjects are between 5 and 6.

- **Leukocytes:** Normal urine should produce no color reaction. "Trace" indicates a possible borderline situation, and the test should be repeated on a fresh urine sample from the patient. Positive and repeated trace findings indicate the need for further testing of the patient and/or urine sample in accordance with the medically accepted procedures for pyuria.

- **Nitrite:** A nitrite concentration as low as 0.05 mg/dL will produce a slightly pink coloration of the test pad. This indicates a positive result.

- **Protein:** A color change from yellow to light green/green will occur if protein is present in urine. The concentrations given on the vial label correspond with the albumin concentration in urine. Pathological proteinuria usually will produce persistent values above 30 mg/dL. Clinical significance of the trace result should be determined by additional testing.

- **Glucose:** Due to the test's sensitivity, glucose should not be detectable in normal urine. Therefore, any positive reaction should be followed by further diagnostic evaluation of the patient, such as a quantitative blood glucose or a glucose tolerance test.

- **Ketones:** Ketone bodies should not detected in normal urine with this test. Fasting or starvation diets may cause positive results. In known pathological conditions such as diabetes, the presence of ketones may be useful as an index of metabolic status.

- **Urobilinogen:** Concentrations are usually greater in the afternoon than during the remainder of the day. Values up to 1 mg/dL are usually considered normal. [13]

- **Bilirubin:** In normal urine, bilirubin should not be detectable with this test. However, the test is very sensitive to bilirubin (0.5 mg/dL will produce positive results), and any positive reaction indicates that further diagnostic evaluation of the patient is needed.

- **Blood:** Erythrocyte excretion up to 5 Ery/uL may be expected in normal urine.[17, 18] Levels above this may require further evaluation of the patient.

H. Quality Control Procedure

Policy

- Quality control testing will be performed with a minimum of two (2) quality control solutions according to your facility's policy.

- It is required to run a positive and negative control daily and when a new vial of test strips is opened (including every lot change). Values obtained for these controls should fall within the limits established by the laboratory or the control manufacturer.

- Check the appropriate boxes for your facility's additional quality control frequency, being sure to meet all standards of your regulatory agencies.

  - ❑ Each _____ (when? day, shift, etc.).

  - ❑ When the test strips have been exposed to extreme heat, humidity or cold.

  - ❑ When test results contradict clinical symptoms.

  - ❑ As a way of checking operator competency.

  - ❑ Other _____.

- If a quality control test result falls within the acceptable control range, it is acceptable to proceed with patient testing.

- If a quality control test result falls outside of the acceptable control range, repeat the test with a fresh Chemstrip urine test strip. Check the stability of the control being used. The problem must be corrected before proceeding with patient testing.

- Any quality control result that falls outside of the acceptable control range, along with any corrective action to restore that result to acceptable range, must be recorded in the *Urinalysis Quality Control Log* or other quality control log.

- The controls should be stored at the proper temperatures according to the manufacturer's recommendations.

- Any outdated test strips or controls will be discarded.

- The urine test strip lot number and expiration date are found on the label of each vial of Chemstrip urine test strips. This information should be recorded in the *Urinalysis Quality Control Log* or other quality control log.

- Chemstrip urine test strips must be stored at temperatures between 2° C (36° F)–30° C (86° F). Do not freeze. Test strips are stable until the expiration date. Test strips must be stored in the same capped vial in which they were packaged, and the vial cap must be immediately replaced after removal of a test strip.

- Commercially available controls for use with the Urisys 1100® Urine Analyzer are KOVA-Trol® and KOVA® Liqua-Trol™ (HYCOR Biomedical Inc.), the Dipper Urine Dipstick Control (Quantimetrix) and Liquichek™ (BIORAD). Refer to *Section V. Appendix* for more information about these controls.

- Insert your facility's quality control preparation information after this page.

Procedure

1. The following equipment is needed for quality control testing:

   Urisys 1100® Urine Analyzer

   Chemstrip urine test strips

   Commercially prepared urinalysis control

   Disposable latex gloves (if required by facility)

   Laboratory coat (if required by facility)

   Absorbent paper

2. Prepare controls according to the manufacturer's instructions.

3. Check the expiration date on the Chemstrip urine test strip vial prior to testing.

4. The Urisys 1100® Urine Analyzer is ready for measurement as long as valid calibration values are stored in the analyzer. Refer to *Section I.D. Calibration of the Urisys 1100® Urine Analyzer* of this manual.

5. Verify the test strip tray is clean of any residue. If there is residue on the tray, refer to *Section II. Preventive Maintenance* of this manual for the cleaning procedure. Any residue on the test strip tray may result in inaccurate results.

6. Remove the cap from the test strip vial and remove one Chemstrip urine test strip.

7. Dip the test strip for one second in the control. Draw the edge of the test strip along the rim of the container. Dab the long edge of the strip lightly on absorbant paper to remove excess control. Make sure that each pad is blotted.

8. If the analyzer is in Standby mode, press START to return to Ready-to-Measure mode. The test strip tray and the retaining bar must be in the open position. Place the test strip, with the pads facing upward, onto the test strip tray and insert the front edge of the strip under the plastic clip.

9. Press the START button. The display will read "Measurement starts in xx sec." The display counts down until start. During this time, the strip incubates and the retaining bar remains open.

10. If the test strip is not correctly located in the middle of the tray, move it gently to the side until it is properly aligned under the retaining bar. Be careful not to move the tray.

11. After the strip incubates, the measurement begins with the Reference pad and then all test strip pads are read. The tray returns to the Start position and the retaining bar opens.

12. The results are printed and the next sample number appears on the display.

13. Remove and dispose of the test strip. Wipe any urine residue from the tray with a lint-free cloth. Refer to Section II. Preventative Maintenance of the manual for the cleaning procedure.

14. Properly dispose of the urine, urine container and test strip.

I. Documentation of Quality Control Results

Policy

- Quality control records are retained for a minimum of two years.
- The date, time, initials of the operator, and quality control result are recorded in the *Urinalysis Quality Control Log* or other quality control log. The log should also include the lot number and expiration date of the control solutions and urine test strips.
- Any quality control result that falls outside the acceptable control range, along with any corrective action to restore that result to acceptable range, is recorded in the *Urinalysis Quality Control Log* or other quality control log.
- An appropriate authority or an appointed individual reviews the *Urinalysis Quality Control Log* for completeness and notes any trends that could indicate potential problems. Such trends include gradual drifting of values, sudden shifts in urine control values while using the same lot of strips, and operator performance. The log is reviewed _____ (when? weekly, monthly, quarterly).
- An audit trail should exist to link the control test values to the patient test values performed that day by listing the appropriate Urisys 1100® Urine Analyzer, Chemstrip urine test strip and control solution lot number used.
- Insert your facility's policy for who is responsible for the performance and documentation of quality control.

_____

_____

_____

_____

_____

_____

J. Limitations of the Procedure

Please reference the most recent *Chemstrip urine test strip package insert* for modifications in the limitations of procedure.

- **Specific Gravity:** The chemical principle of the test may cause slightly different results compared with other specific gravity methods when elevated amounts of certain constituents are present. Glucose and urea concentrations greater than 1% may cause a low specific gravity reading relative to other methods. In the presence of moderate amounts of protein (100-500 mg/dL) or ketoacidosis, readings may be elevated.

- **pH Test:** No known interferences when handled according to instructions.

- **Leukocyte:** This test is not affected by erythrocytes in concentrations up to 10,000/µL or by bacteria common in urine. Do not collect specimens in containers that have been cleaned with strong oxidizing agents. Do not use preservatives. The drugs cephalexin and gentamicin have been found to interfere with this test. Nitrofurantoin colors the urine and thus causes interference with visual interpretation of the test strip. High levels of albumin (>500 mg/dL) in the urine may interfere with the test results. Studies show that formaldehyde (stabilizer) and medication with imipenem, meropenem and clavulanic acid may cause false positive reactions.*

- **Nitrite:** Large amounts of ascorbic acid (see under glucose) decrease the sensitivity of the test. False positive readings may be produced by medication that colors the urine red or that turns red in an acid medium (e.g., phenazopyridine).

- **Protein:** False positive results may be found:

  In strongly alkaline urine (pH of 9 or higher).

  During therapy with phenazopyridine.

  When infusions of polyvinylpyrrolidone (blood substitutes) are administered.

  When residues of disinfectants containing quaternary ammonium groups or chlorohexidine are present in the urine container.

- **Glucose:** The effect of ascorbic acid (vitamin C) retained in the urine due to ingestion of vitamin tablets, antibiotics, or fruit juices has been eliminated at glucose concentrations of 100 mg/dL and above so that false negative readings rarely occur, even at high concentrations of ascorbic acid. False positive readings may be produced by strongly oxidizing cleaning agents in the urine container.

- **Ketone:** Red-orange to red color shades, which are readily distinguished from the colors obtained with ketone bodies, can be produced by phenylketone or phthalein compounds administered for liver and kidney function tests. 2-Mercaptoethane sulphonate sodium (MESNA) or other sulfhydryl-containing compounds may cause false positive results. [21]

*Beer JH, et al, False positive results for leukocytes in urine dipstick test with common antibiotics. BMJ 313:25, 1996

- **Urobilinogen:** The total absence of urobilinogen cannot be detected. Most urine specimens give a slight pink reaction. This test gives the same color reaction with urobilinogen as with stercobilinogen; however, the differentiation is not of diagnostic importance. Urine from patients treated with phenazopyridine may show a false positive reaction. Nitrite concentrations above 5 mg/dL or formalin concentrations above 200 mg/dL (used as a preservative) may cause a decrease in color reaction.

- **Bilirubin:** Large amounts of ascorbic acid present in the urine following the ingestion of medication containing vitamin C or fruit juices lower the sensitivity of the test. In case of doubt, repeat test on urine voided at least 10 hours after the last administration of vitamin C. Elevated concentrations of nitrite, as in urinary tract infections, may result in lower bilirubin values. Large amounts of urobilinogen in the urine affect the color change of the bilirubin test, but not enough to give a positive result. False positive results may be produced by medications that color the urine red or turn red in an acid medium (e.g., phenazopyridine).

- **Blood:** False negative readings are obtained when formalin is used to preserve the urine. Nitrite in excess of 10 mg/dL in the urine (which is rare in urinary tract infections) delays the reaction. False positive results can be produced by residues of strongly oxidizing cleaning agents in the urine container. Urine from menstruating females occasionally yields a positive result. This test has not been found to be affected by the ingestion of reasonable quantities of ascorbic acid.

II. Preventive Maintenance

Policy – Cleaning the Analyzer

- Clean and disinfect the exterior of the Urisys 1100® Urine Analyzer by using a cloth dampened with a suitable disinfectant such as 10% bleach or isopropyl alcohol. Be sure that no liquid enters the analyzer.
- Clean the test strip tray every day.

Procedure

1. Turn off the power.
2. Remove the test strip tray.
3. Rinse the tray under running water.
4. Remove any crystalline deposits, especially those contaminating the retaining bar mechanism, with a soft brush.
5. Wipe down the test strip tray with 70% isopropyl alcohol or 10% bleach.
6. Dry with a soft, lint-free cloth.
7. Install the test strip tray by holding the tray opposite the side with the gray reference pad and inserting the tray into the slot below the function keys. Do not touch the gray reference pad.
8. Switch on the instrument. During the self-check process, the system will verify that the reference pad is in suitable condition for reading test strips. If not, an error message will be displayed.

Policy – Replacing Printer Paper

Replace the printer paper **the day it runs out**, following the instructions in Section 4.2 of the *Urisys 1100® Operator's Manual*. This will ensure a paper print-out of calibration results will be available the next day if calibration is performed upon instrument start up.

Policy – Documentation and Replacement

- Any maintenance, calibration or replacement is documented on the *Preventive Maintenance Log*.
- Replaceable parts are available. They can be ordered from your local Roche Diagnostics distributor or are available from _____(location in your facility).

  Replaceable parts for the Urisys 1100® Analyzer are:

Replaceable Part	Catalog Number
Test strip tray – Type C for Chemstrip 10MD	03666735001
AC Adapter	08747385001
Power cord	04340612001
Reference pads – 5 pcs	11907131001
Thermal printer paper (20 rolls)	06431321001
Interface connection cable	11906186001
Keyboard	11248693001
QuickScan™ QD2131 linear imager (barcode reader for use with Urisys 1100 SW version 6.3 or greater)	07945809001

- If staff are unable to correct a problem with the Urisys 1100® Urine Analyzer, they are instructed to contact _____(location in your facility) or call Roche Customer Support Center at 1-800-428-4674.
- The appointed individual reviews the *Preventive Maintenance Log* for completion _____(when? weekly, monthly, quarterly).
- Insert your policy for who is responsible for performing and documenting preventive maintenance.

Name	Title
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____

III. Infection Control Guidelines

Policy

- Because of the potentially hazardous nature of handling urine and the possibility of its contamination with blood, it is recommended that disposable latex gloves and laboratory coats be used when collecting specimens and performing test procedures. Consult your facility's infection control policy.

- Disposable latex gloves and laboratory coats are to be removed and hands washed thoroughly with soap and water after completing the test procedure and prior to handling equipment not related to the procedure.

- Urine specimens should be handled at Biosafety Level 2 as recommended for any potentially infectious material in the Centers for Disease Control/National Institutes of Health manual, *Biosafety in Microbiological and Biomedical Laboratories*, 1988. Universal precautions may apply if the urine is contaminated with blood or if required by the infection control policy of your facility.[24]

- If a spill should occur, disinfect the area with a 1:10 bleach solution (1 part bleach plus 9 parts water) or follow the infection control procedures of your facility.

IV. Operator Certification/Recertification

Policy

- Operators receive appropriate certification to perform tests with the Urisys 1100® Urine Analyzer according to your facility's policy.
- Certification is documented and maintained on the *Operator Certification Log* and *Skills Checklist*. A *Knowledge Test* is also provided.
- Only certified operators may use the Urisys 1100® Urine Analyzer.
- Operator competency checks (recertification) will be performed *yearly* and recorded on the *Operator Certification Log* and *Operator Competency Log*.

Procedure – Operator Competency

The following procedure may be used to certify/recertify your operators and check their competency on the use of the Urisys 1100® Urine Analyzer.

Note: A valid calibration is required before performing the following within-run precision.

Within-Run Precision

1. The following equipment is assembled prior to testing:

   Urisys 1100® Urine Analyzer

   Chemstrip urine test strips

   Quality control material–1, 2, or 3 levels (according to your facility's policy) prepared according to the manufacturer's instructions

   Disposable latex gloves (if required by facility)

   Laboratory coat (if required by facility)

   Absorbent paper

   Operator Competency Log

2. Run control 20 times consecutively on the Urisys 1100® Urine Analyzer. Refer to *Section I.H. Quality Control Procedure* for instructions.
3. Record results on the *Operator Competency Log*.
4. Determine the result that occurs most frequently (mode) for each parameter and record the result.

5. Determine the color block variation (plus or minus the number of color blocks from the mode) for each parameter in the run of 20. Record the result for each parameter.

6. The color block variation (number of color blocks away from the mode) for each chemistry of the 20 analyses should be no greater than ± one color block. Refer to *Section 1.H. Quality Control Procedure* if the color block variation exceeds plus or minus one.

   Example 1: If 20 consecutive glucose results produce 20 results of 100 mg/dL, the mode is 100 mg/dL and the color block variation is 0. This is acceptable performance.

   Example 2: If 20 consecutive glucose results produce 15 results of 100 mg/dL and 5 results of 250 mg/dL, the mode is 100 mg/dL and the color block variation is + one color block. This is acceptable performance.

   Example 3: If 20 consecutive glucose results produce two results of 50 mg/dL, 16 results of 100 mg/dL and two results of 250 mg/dL, the mode is 100 mg/dL and the color block variation is + one and - one color block. This is acceptable performance.

   Example 4: If 20 consecutive glucose results produce two results of "normal", 16 results of 100 mg/dL and two results of 250 mg/dL, the mode is 100 mg/dL and the color block variation would be + one and - two color blocks. This is unacceptable performance.

Control Recovery

1. Record the control package insert acceptable ranges for the Urisys 1100® Urine Analyzer on the *Operator Competency Log*. The Urisys 1100® results should be compared to the *visual* acceptable ranges if the Urisys 1100® Analyzer is not referenced on your control package insert.

2. Compare the acceptable ranges stated in the package insert to the results obtained from the within-run precision step 4.

3. The mode results should fall within the acceptable control ranges. Refer to *Section I.H. Quality Control Procedure* for instructions if the results fall outside the acceptable control ranges.

Guidelines

Insert your policy for who is responsible for training and documenting operator certification / recertification with the Urisys 1100® Urine Analyzer.

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V. Appendix

Instructions for Collections of a Midstream Urine

When examining urine specimens, every precaution must be taken to avoid contamination. Therefore, make sure your patients follow the instructions below carefully so that reasonable test results are obtained.

It is important to note that some cleansing towelettes may use soaps that contain oxidizing agents. Oxidizing agents may interfere with some parameters on the urine test strips. Therefore, it is extremely important that thorough rinsing take place after cleansing the genitals.

Procedure

1. Do not open the specimen container until immediately prior to use.

2. Procedure

Female

- Kneel or squat over a bedpan or stand astride a toilet bowl.
- Separate labia minor.
- Cleanse meatus (opening of urethra) three times.
- Rinse area with sterile, water-saturated sponge. Do not dry.
- Void forcibly, allowing initial stream of urine to pass into the lavatory.
- Collect midstream in sterile container.

Male

- Cleanse glans three times.
- Rinse area with sterile, water-saturated sponge. Do not dry.
- Void forcibly, allowing initial stream of urine to pass into the lavatory.
- Collect midstream in sterile container.

Infant

- Cleanse genitalia three times.
- Rinse area with sterile, water-saturated sponge. Do not dry.
- Supporting infant in a face down position, stimulate urination by stroking paraspinal muscles.
- If infant fails to void, place sterile bag over genitals.
- If infant does not void within 45 minutes, re-prep the area and apply a new bag.
- Collect urine in a sterile container.
- Do not allow the container to touch the body.

3. Close the container and present it immediately for urinalysis.

Routine Urinalysis Controls Compatible with the Urisys 1100® Urine Analyzer

Several commercial controls are available. Controls may vary in number of levels or components, necessity for reconstitution or ready to use, type and volume of container, and usefulness as a control for microscopic examination.

When selecting a control, consider the above-mentioned variables to identify the control most suitable for your facility's needs. Controls typically can be ordered through medical/surgical supply distributors or directly from the manufacturer.

Refer to the following table to determine which control best meets the needs of your facility's quality control requirements.

Urine Controls Chart				
Brand Name	KOVA-Trol® Urinalysis Control	KOVA® Liqua-Trol™ Urinalysis Control	Dipper Urinalysis Dipstick Control	Liquichek™ Urinalysis Control
Manufacturer	Kova International Inc.	Kova International Inc.	Quantimetrix Corporation	BIO RAD
Website	www.kovaintl.com	www.kovaintl.com	www.quantimetrix.com	www.bio-rad.com
Address	7272 Chapman Ave., Ste. B Garden Grove, CA 92641	7272 Chapman Ave., Ste. B Garden Grove, CA 92641	2005 Manhattan Beach Boulevard Redondo Beach, CA 90278	4000 Alfred Nobel Dr Hercules, CA 94547
Toll-free No.	855-217-6399	855-217-6399	800-624-8380	800-224-6723
Phone No.	714-902-1700	714-902-1700	310-536-0006	510-724-7000
Fax No.	714-908-7945	714-908-7945	800.845.1834	510-741-6373
Product Information Requests	cs@kovaintl.com	cs@kovaintl.com	orders@quantimetrix.com	diagcs@bio-rad.com
Distribution	Cardinal, Fisher, PSS, McKesson, Owens & Minor, Henry Schein	Cardinal, Fisher, PSS, McKesson, Owens & Minor, Henry Schein	Direct, online thru website , Cardinal Health, Fisher, Infolab, Labsco, McKesson, Owens & Minor, PSS	Direct, online catalog on website, Cardinal, PSS, Labsco, McKesson
Number of Levels	3: Negative Norm Low Abnormal High Abnormal/ High Abnormal w/urob.	2: Normal Abnormal	2: Normal Abnormal	2: Level 1- Negative/Norm. Level 2- Positive/Abnormal
Preparation	Reconstitution	Ready to use	Ready to use	Ready to use
Package Size	4 x 15 mL 4 x 60 mL 8 x 60 mL	6 x 15 mL	6 x 15 mL	12 x 12 mL
Stability / Unopened	Until exp. date on vial (24mo.)	Until exp. date on vial (27mo.)	Until exp. date on vial	Until exp. date on vial
Stability / Opened	7 days after recon 1 mo. frozen	Until exp. date on vial at 2-8°C, 30 days at room temp.	90 days 2-8°C	30 days 2-25°C
Microscopic Values	Yes	Yes	No	Yes

VI. Log Sheets

This section contains the following blank log sheets that may be copied and used for documentation for the Urisys 1100® Urine Analyzer in your facility.

Operator Certification Log – for recording the names of trained Urisys 1100® operators and tracking yearly competency checks.

Operator Competency Log – for recording yearly competency checks for each operator, within-run precision data, and control recovery data.

Reagent Log – for recording the date received, lot numbers and expiration dates of Chemstrip urine test strips, Chemstrip Calibration Strips and controls.

Urinalysis Report Form – for recording patient results.

Quality Control Log – for recording quality control information.

Preventive Maintenance Log – for recording the dates on which maintenance was performed.

Temperature Log (2) – for recording Urisys 1100® Urine Analyzer operating temperatures and Chemstrip urine test strip storage temperatures.

Knowledge Test – for written documentation of operator certification.

Skills Checklist – for documenting operator skills while training on the Urisys 1100® Urine Analyzer

Operator Certification Log

Urisys 1100® Urine Analyzer

Date of Initial Certification	Operator	ID No.	Competency Checks Date	Observer / Reviewer Initials / Date

Operator Competency Log

Urisys 1100® Urine Analyzer

Operator Name:_____ Date:_____

Chemstrip Cat. No. _____ Lot No.: _____ Exp. Date:_____

Control Name and Level:_____ Lot No.: _____ Exp. Date:_____

Within-Run Precision

	SG	pH	LEU	NIT	PRO	GLU	KET	UBG	BILI	BLD
1										
2										
3										
4										
5										
6										
7										
8										
9										
10										
11										
12										
13										
14										
15										
16										
17										
18										
19										
20										
Mode										
Color block variation										

Note: The color block variation should be no greater than +/- one color block from the mode for acceptable performance.

Operator Competency Log

Urisys 1100® Urine Analyzer

Control Recovery

	Control Package Insert Ranges	Urisys 1100® Urine Analyzer Mode Result from Within Run Precision
SG		
pH		
LEU		
NIT		
PRO		
GLU		
KET		
UBG		
BILI		
BLD		

Note: Reference the visual acceptance range if the Urisys 1100® Urine Analyzer is not referenced on your control package insert.

Reagent Log

Urisys 1100® Urine Analyzer

Chemstrip Urine Test Strips				Chemstrip Urine Analyzer Calibration Strips				Controls			
Date Rec'd	No. Vials	Lot No.	Exp. Date	Date Rec'd	No. Vials	Lot No.	Exp. Date	Date Rec'd	No. Vials	Lot No.	Exp. Date

Urinalysis Report Form

Urisys 1100® Urine Analyzer

Patient Name: _____

Age: _____ M F

Physician's Name: _____

Collection Date: _____ Test Date: _____ Operator's Initials: _____

Physical Examination

Color:	colorless	yellow	amber	other
Appearance:	clear	hazy	cloudy	turbid

Chemical Examination

Specific Gravity	1.000	1.005	1.010	1.015	1.020	1.025	1.030
pH	5	6	6.5	7	8	9	
Leukocytes	neg	25	75	500			
Nitrite	neg	pos	(any pink color is considered positive)				
Protein	neg	trace	30	100	500		
Glucose	norm	50	100	250	>1000		
Ketones	neg	15	50	150			
Urobilinogen	norm	1	4	8	>12		
Bilirubin	neg	1	3	6			
Blood	neg	trace	50	250			

Comments:

_____

_____

Attach the Patient Report printout here if required by your facility.

Quality Control Log

Urisys 1100® Urine Analyzer

Name of control solution used by your facility: ____________________

Control Lot No.: ____________________ Exp. Date: __________

Chemstrip Cat. No.: ____________________

Chemstrip Lot No.: ____________________ Exp. Date: __________

Operator's Initials: ____________________

	Date	SG	pH	LEU	NIT	PRO	GLU	KET	UBG	BILI	BLD	Yes/ No	Initials	Corrective Action
Level 1														
Level 2														
Level 1														
Level 2														
Level 1														
Level 2														
Level 1														
Level 2														
Level 1														
Level 2														
Level 1														
Level 2														
Level 1														
Level 2														
Level 1														
Level 2														
Level 1														
Level 2														
Level 1														
Level 2														
Level 1														
Level 2														
Level 1														
Level 2														

Note: Reference the visual acceptable range if the Urisys 1100® Urine Analyzer is not referenced on your control package insert.

Preventive Maintenance Log

Urisys 1100® Urine Analyzer

Check the box if you have performed the task. Date and initial the top of the column.

Date																												
Initials																												
1. Adequate urine test strip supply available.																												
2. Urine test strips within expiration date.																												
3. Adequate supply of calibration strips.																												
4. Adequate supply of controls available.																												
5. Controls within expiration date.																												
6. Clean exterior of analyzer with 10% bleach solution.																												
7. Clean the tray of analyzer with 10% bleach solution.																												
8. Calibrate the analyzer. Perform weekly.																												
9. Replace printer paper on the day it runs out.																												
10. Operator's manual and test strip package insert available.																												

Refer to the Urisys 1100® Urine Analyzer Operator's Manual for specific procedural instructions.

Temperature Log

Urisys 1100® Urine Analyzer

Location: _____

Year: _____

Acceptable Range (° C): _____ (° F): _____

	Jan	Feb	Mar	Apr	May	June	July	Aug	Sept	Oct	Nov	Dec
1												
2												
3												
4												
5												
6												
7												
8												
9												
10												
11												
12												
13												
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20												
21												
22												
23												
24												
25												
26												
27												
28												
29												
30												
31												

Temperature Log

Chemstrip Urine Test Strips

Cat. No. _____

Location: _____

Year: _____

Acceptable Range (° C): _____ (° F): _____

	Jan	Feb	Mar	Apr	May	June	July	Aug	Sept	Oct	Nov	Dec
1												
2												
3												
4												
5												
6												
7												
8												
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22												
23												
24												
25												
26												
27												
28												
29												
30												
31												

Knowledge Test

Urisys 1100® Urine Analyzer

Name: _____ ID No.: _____

Date: _____ Unit: _____

Mark "T" if the statement is true and "F" if the statement is false.

_____ 1. You must check the expiration dating on the vial each time you perform a patient or quality control test.

_____ 2. Dip the Chemstrip urine test strip briefly (no longer than 1 second) in the urine sample.

_____ 3. Strong oxidizing cleaning agents interfere with the blood patch results.

_____ 4. Correct placement of the Chemstrip urine test strip in the tray of the analyzer is necessary to obtain accurate results.

_____ 5. It is necessary to bring refrigerated samples to room temperature before testing.

_____ 6. The sample should be in sufficient volume to allow all test pads to be completely wetted.

_____ 7. Running the side of the Chemstrip urine test strip along the rim of the container removes excess sample.

_____ 8. If you do not obtain a successful calibration, the analyzer will still process samples.

_____ 9. A positive nitrite test is not normal in fresh, clean-catch midstream urine specimens.

_____ 10. Urine residue on the tray of the analyzer may result in inaccurate results.

_____ 11. Green spots on the blood patch are indicative of unlysed erythrocytes.

Fill in the blanks.

12. The specimen should be tested within _____ hour(s) of collection, otherwise, refrigerate it in a closed container.

13. Replace the _____ to avoid deterioration of the test strips.

14. When using Chemstrip 10MD Test Strips, the Urisys 1100® Urine Analyzer must be calibrated every _____ days.

15. Reasonable amounts of ascorbic acid do not affect the _____ test.

16. The specimen must be thoroughly _____, as red cells sink to the bottom and could cause false positive results.

17. Rinse the test strip tray with a suitable disinfectant _____ (when?).

Answer Key

1. T
2. T
3. T
4. T
5. T
6. T
7. T
8. F
9. T
10. T
11. T
12. one
13. vial cap
14. seven
15. blood or glucose
16. mixed
17. daily

Skills Checklist

Urisys 1100® Urine Analyzer

The trainer should check each activity as it is demonstrated. All activities must be completed before the trainee is certified to use the Urisys 1100® Urine Analyzer.

Specimen Collection

1. User assembles specimen collection supplies
    - ❑ Specimen container
    - ❑ Cleansing towelette
    - ❑ Water-saturated sponge
2. User reviews specimen collection
    - ❑ States patient preparation steps
    - ❑ Explains specimen storage and stability
    - ❑ Describes clean-catch, midstream urine technique

Testing Procedure

1. User assembles testing supplies
    - ❑ Urisys 1100® Urine Analyzer
    - ❑ Chemstrip Urine Test Strips
    - ❑ Chemstrip Urine Analyzer Calibration Strips
    - ❑ Patient specimen
    - ❑ Disposable latex gloves and laboratory coat
    - ❑ Absorbent paper
2. User preparation
    - ❑ Checks expiration date on test strip vial
    - ❑ Puts on disposable latex gloves and laboratory coat

3. Sample preparation

   - ❑ States if refrigerated, bring sample to room temperature
   - ❑ Mixes sample by swirling capped container several times

4. Calibration *(when using Chemstrip 10MD or Chemstrip 10UA Test Strips)*

   - ❑ Removes one Chemstrip urine analyzer calibration strip
   - ❑ Does not touch elevated gray areas on strip
   - ❑ Places calibration strip(pad side up) onto the test strip tray
   - ❑ Presses START button
   - ❑ Documents calibration on the *Preventive Maintenance Log*

5. Testing

   - ❑ Removes one Chemstrip urine test strip
   - ❑ Replaces vial cap immediately
   - ❑ Ensures analyzer test strip tray is clean
   - ❑ Briefly dips test strip vertically into specimen
   - ❑ Draws strip edge along rim of container to remove excess urine
   - ❑ Dabs strip to absorbent paper
   - ❑ Places the test strip (pad side up) onto the test strip tray
   - ❑ The handle end of the strip should be held by the clip at the insertion slot
   - ❑ Obtains results from the printout
   - ❑ Removes test strip
   - ❑ Wipes tray with dry lint-free cloth. If there is any residue on the tray, follows proper maintenance as outlined in the *Urisys 1100® Urine Analyzer Operator's Manual*.

6. Results

   - ❑ Documents results as appropriate for your facility

7. Quality control

   - ❑ States when to perform QC tests
   - ❑ Performs test like routine urine.
   - ❑ Documents results
   - ❑ Reviews procedure if the test results fall outside the acceptable range
   - ❑ If problem persists, calls Roche Customer Support Center at 1-800-428-4674

8. Infection control

   - ❑ Properly disposes of specimen, used test strips and container
   - ❑ Cleans and decontaminates the work area according to infection control policy
   - ❑ Removes and disposes of disposable latex gloves

Operator Signature Date

Trainer Signature Date

Contact your Roche Diagnostics Account Manager for training certificates.

VII. Regulatory Requirements

VIII. Product Information

Product	Catalog Number
Urisys 1100® urine analyzer	03617556001
Chemstrip 10 MD urine test strips (100/vial)	03260763160

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