

LOURDES HOSPITAL
169 Riverside Drive
Binghamton, New York 13905
LAB MANUAL

SUBJECT: Urine Chemstrip Analyzer 101

ORIGIN DATE: 8/04

REVIEWED: 7/31/2015

REVISED:

REGULATORY REFERENCES:

CROSS REFERENCES:

POLICY

As a screening test, the Roche Diagnostics Chemstrip 101 Urine Analyzer is a reflectance photometer designed to read and interpret the results of Chemstrip 10 UA urine strips from Roche Diagnostics. The Chemstrip 101 Urine Analyzer reads the strips under standardized conditions thus eliminating variable lighting conditions at the workplace, different people's skill at matching colors, failure to keep the prescribed testing times and clerical errors.

Each test pad is read photometrically after an incubation time of 55-65 seconds. The system compares the reflectance value of each pad with the defined range limits (reflectance values which are programmed into the analyzer for each parameter) and prints out a semi-quantitative result.

The Chemstrip7 urine test strips are multi-parameter test strips used to measure specific gravity, pH, leukocytes, nitrite, protein, ketones, urobilinogen, bilirubin, and blood in urine. These measurements are useful in the evaluation of renal, urinary and metabolic disorders.

PROCEDURE:

REAGENTS AND MATERIALS

- Chemstrip 101 Urine Analyzer
- Chemstrip 10 UA test strips
- Chemstrip Urine Analyzer Calibration Strips
- Quantimetrix Controls, Levels 1 and 2
- Patient specimen

STORAGE AND HANDLING

- Chemstrip 10 UA urine test strips stored below 30E C (86EF) Do not freeze
- Opened Chemstrip 10 UA urine test strips are stable until the expiration date on the vial. The vial must be closed immediately after use, using the original cap.
- Chemstrip Calibration Strips stored in tightly closed vial at temperatures under 30 C. Do not freeze or expose to direct sunlight.
- If the urine specimen cannot be tested within *one* hour of collection, refrigerate immediately (2E - 8EC) in a closed container. Bring specimen to room temperature before testing. Mix thoroughly before testing.

SPECIMEN TYPE- Freshly voided urine specimen. If the urine specimen cannot be tested within one hour of collection, refrigerate immediately (2-8C) in a labeled, closed container. Bring the specimen to room temperature before testing. Mix thoroughly before testing.

COLLECTION- Freshly voided urine specimen, clean catch specimen.

IDENTIFICATION and LABELING The patient will be identified using 2 identifiers, patient name and date-of-birth specimen will be labeled with the 2 identifiers.

TEST PERFORMANCE

1. Assemble all needed equipment.
2. Check the expiration date on the Chemstrip 10 UA urine test strip vial prior to testing.
3. Turn the analyzer on. After 5 minutes of inactivity, the analyzer automatically turns to

Standby

Mode, the tray advances slightly, the retaining bar closes and the date and time are shown on

the

display. Press the START button and the message "INSERT STRIP" will appear.

4. Remove the cap from the test strip vial and remove one Chemstrip 10 UA urine test strip. Replace the cap and close tightly.
5. Mix the specimen by swirling several times with the lid capped tightly. If the specimen has been refrigerated, allow it to come to room temperature before mixing.
6. Dip the test strip in the urine sample (no longer than one second). Draw the edge of the strip across the rim of the specimen container. Touch a long **edge** of the strip (not the reaction pads) to a piece of absorbent paper for one second to remove excess urine from the pads. Touch the back (not the pads) of the test strip on the absorbent paper to remove excess urine from the back of the strip.
7. Insert the test strip, with the pads facing up, all the way onto the tray so that the front end of strip fits under the clip at the back. It is important that the strip is correctly positioned and the START button pressed 5-10 seconds after the strip is dipped.
8. Press the START button. You will hear a beep and the tray will advance and the retaining bar closes.
9. Seventy seconds after the START button is pressed, all test strip pads will be read. The results will print and the next sample number and the message "INSERT STRIP" will appear.
- 10 The test strip tray will return to the start position and the retaining bar will open. Remove and discard the used test strip. Wipe the test strip tray as needed with a lint-free cloth to remove any urine residue

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the

RESULT REPORTING

The patient's results must be recorded in the patient's chart as well as the accession log with the date, time of the test, and signature of the person performing the test. The accession record must also have the Chem UA lot number with expiration date. The results that print off the analyzer must be copied if being kept for records as the print disintegrates and disappears with time.

QUALITY CONTROL

Quantimetrix controls levels 1 and 2 are to be used. Controls are to be tested daily in the same manner as a patient sample, whenever a new vial of strips is opened, all lot changes and whenever a calibration is performed to insure the integrity of the test strips and the testing procedure. Results are compared to the Quantimetrix package insert reference for the appropriate test method.

EXPECTED VALUES

Refer to the most recent Chemstrip 10 UA test strip package insert for any changes to the

expected values information.

! Specific Gravity:	1.001 to 1.015
pH	5 to 9
Leukocytes	negative - trace
Nitrite	negative
Protein	negative*
Glucose	negative
Ketones	negative
Urobilinogen	negative**
Bilirubin	negative***
Blood	negative

An abnormal screening result may be used by the practitioner as a diagnostic tool for determining the treatment regimen. Urine culture may be added if warranted by results.

* Pathological proteinuria usually will produce persistent values above 30 mg/dL. Clinical significance of the trace result should be determined by additional testing.

**Concentrations are usually greater in the afternoon than during the remainder of the day. Values up to 1 mg/dL are usually considered normal.

*** positives are recommended to be sent the urine to Lourdes Hospital Lab for confirmation with the Ictotest

Trace chemstrip results for blood, leukocyte esterase and or protein rarely correlate with abnormal microscopic findings.

FOLLOW UP RECOMMENDATIONS

An abnormal screening result may be used by the practitioner as a diagnostic tool for determining the treatment regimen. Urine culture may be added if warranted by results.

INSTRUMENT MAINTENANCE AND FUNCTION TESTS

CALIBRATION

- The Chemstrip 101 Urine Analyzer must be calibrated every seven days or when indicated by the analyzer..
- The Chemstrip Calibration Strips should remain in the vial until ready to use. Do not touch the elevated gray areas of the strip.
- The Calibration Strip is to be used only once.
- The analyzer will not process any tests unless a valid calibration has been obtained

CALIBRATION PROCEDURE

1. Make sure that the test strip tray is clean and dry.
2. If the message "REPEAT CALIBRATION" appears 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" is displayed.
3. Remove a calibration strip from its container, being careful not to touch the pads. Do not let the calibration strips come in contact with urine.
4. With the retaining bar open, place the calibration strip, pads facing upwards, onto the strip

- tray and insert the front edge of the strip under the plastic clip.
5. Press the START button. You will hear a beep and the tray advances slightly, the retaining bar closes, and the calibration strip is read. When calibration is complete the tray moves back to the starting position, the retaining bar opens and a report is printed.
 6. Remove the calibration strip and discard. Remember that each calibration strip is used only once.
 7. If the calibration is valid, the results are stored in memory and a report with the reflectance values, time and date is printed. 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. Record on the log and attach the printout.
 8. 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”
“CALIBRATION ERROR”

Repeat the calibration procedure using a fresh calibration test 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” displays and the report prints out. Record on the log and attach the printout.
4. If the calibration fails a second time refer to the Users Manual. If unable to resolve the problem contact Lab Point of Care Coordinator and/or Technical Service Center at 1-800-428-4674.

ROUTINE MAINTENANCE

Performed daily at the end of the shift and document on the monthly maintenance chart

1. Turn the instrument off.
2. Pull the test strip tray out of the instrument.
3. Rinse under running water.
4. Remove any crystalline deposits, especially those contaminating the retaining bar, with a soft brush.
5. Wipe the test strip tray with isopropyl alcohol or another suitable disinfectant such as 10% bleach. CAUTION: Be careful not to damage the gray reference pad during the cleaning process. Make sure the reference pad and the positioning hole on the side of the tray are completely clean and dry before proceeding to read test strips.
6. Install the test strip tray by holding the tray opposite the end with the gray reference pad and inserting the tray into the slot below the function key. Do not touch the gray reference pad.
7. Turn the instrument on. During the self-check process, the system will verify that the reference pad is in suitable condition for reading strips. If not an error message will appear.
8. If you get an error message refer to the Users Manual for troubleshooting and if unable to resolve problem call the Roche Technical Service Center at 1-800-428-4674.

References: Roche Urysis 1000 Operators Manuel 2012; Roche Chemstrip 10 UA Urine Dipstick

Next Review:
AUTHORIZATIONS:

Medical Director

Date

Clinical Manager

Date