**Purpose**

To provide instruction to run daily QC for routine urinalysis

**Materials**

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| **Reagents** | **Supplies** | **Equipment** |
| * *MAS® Liquid Assayed Urinalysis Control, Thermo Scientific* CHEMSTRIP® 10 UA Urine Test Strips (Catalog Number 11895354160).
* Store CHEMSTRIP 10 UA Urine Test Strips at temperatures between +2°C and 30°C (86°F). Do not freeze.
* Opened CHEMSTRIP 10 UA 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 tightly and immediately after use, using the original cap.
* Clinitest tablets
* Ictotest kit
 | * Cen-slide urine tubes
* PPE, gloves
 | * Roche Diagnostics URISYS1800 urine analyzer
* Cen-slide 60 centrifuge
* Microscope
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**Quality Control**

* Handle the UA Control in the same manner as patient specimens. Consistent handling of the control is necessary for uniform results.
* Quality control testing will be performed with a minimum of two (2) quality control levels.
* At a minimum, quality control testing should be performed:
* Once per **24 hours**
* With every lot change of **test strips** prior to use
* With every lot change or shipment of **control material** prior to use
* When **calibration** is performed
* If a quality control test result falls within the acceptable control range, it is acceptable to proceed with patient testing.
* Any quality control result that falls outside of the acceptable control range, along with any repeats and corrective action to restore that result to acceptable range, must be recorded on the *UAs Daily QC Log*.
* The controls should be stored at the proper temperatures according to the manufacturer’s recommendations. Unopened vials are stable until expiration date on the label. Once opened, vials of control are stable for **6 weeks** when stored tightly capped **at RT (18-25°C).** **Do not freeze**.
* Any outdated test strips or controls will be discarded.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 10 UA Urine Test Strips. This information must be recorded in the *Urinalysis Quality Control Log* or other quality control log.
* CHEMSTRIP 10 UA Urine Test Strips must be stored at temperatures between +2° and +30° C. **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.
* Run confirmation testing for Bilirubin on all pos tests with Ictotest—report Ictotest result.
* Run Clinitest QC on all children ≤ 2 yr.

### Q.C. Procedure

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| **Step** | **Action** |
| 1 | Store controls according to the manufacturer’s instructions. Use *MAS® Liquid Assayed Urinalysis Control, Thermo Scientific,* control material for testing. Open bottles are stored at room temperature on shelf in urinalysis area, unopened containers should be refrigerated. |
| 2 | Check the expiration date on the CHEMSTRIP 10 UA Urine Test Strip vial and control vial prior to testing. Record information of the Q.C. Daily Log. |
| 3 | The analyzer should be left ON. If not, the URISYS 1800 Urine Analyzer ON/OFF switch is located at the back of the analyzer. The URISYS 1800 Urine Analyzer will perform a brief initialization and then the login screen is displayed. |
| 4 | Login to the URISYS 1800 analyzer. Highlight the name of the operator <tech> and then type the password <1>. Select the <Enter> button. If the analyzer requires calibration, please refer to calibration section in this procedure or to the *URISYS 1800 Urine Analyzer Operator’s Manual*. |
| 5 | Touch Workplace and Run Control. Select the level of control that will be processed. Select Control level, <Enter>, “*Please press ok first and then place the test strip for control 1(or 2)!”* is displayed. Remove a test strip from the test strip vial and replace the vial cap. |
| 6 | Carefully mix the UA Control before each use to ensure reproducible results.  |
| 7 | Pour a 5mL aliquot of each level (1 & 2) control material into a CenSlide urine tube (following the same steps as with patient samples).  |
| 8 | Drain excess control material (tap strip on top edge of tube-do not blot the strip). |
| 9 | Place the test strip with the reagent areas facing upward onto the loading area of the Test Strip Tray. The end of the strip must be supported by the rear inside edge of the tray.  |
| 10 | After 20 seconds, the test strip is transported into the measuring position. The measuring head moves forward and checks if a test strip is at the measuring position. The screen returns to “Run Control – Control 1 /Control 2” screen. *Press Control 2: Abnormal* to measure next control. |
| 11 | Each test strip is measured 60 seconds after it is dipped. When each test strip measurement is complete, the results are automatically printed. |
| 12 | The URISYS 1800 Urine Analyzer checks to see if a test strip is present at the measuring position. If there is a strip present, strip measurement continues. If there is not a strip present, a message “Strip missing” may appear, the URISYS 1800 Urine Analyzer automatically returns to “READY - <Start>”. |
| 13 | Place the tube of level 2 (Abnormal) material into the centrifuge. Spin this tube for the Microscopic QC.Properly dispose of control solution and urine test strips. |
|  | **Microscopic QC** |
| 1 | Using the same tube as the strip QC, Level 2, centrifuge the tube for 1 minute. (CenSlide centrifuge) |
| 2 | Count the cells under high power.  |
| 3 | Expected results can be found on the product insert and are written on the *Urinalysis Daily Control Sheet.* |
| 4 | Record microscopic results on the QC log. Results should reflect patient results (i.e., wbc = 0-5, 5-20, 20-50, 50-200, >200) |
|  | Refractometer QC |
| 1 | Use *MAS® Liquid Assayed Urinalysis Control, Thermo Scientific* **each day of use** or at least **annually**. Use 2 levels when testing for specific gravity. See package insert for control values. Distilled water (*sp. gr. = 1.000*) may be used on the T.S. meter as an alternative. |
|  | **Manual tests QC** |
| 1 | Ictotest Test (daily)* Place 2 squares of absorbent test mat supplied in kit on a paper towel.
* Place 10 drops of Normal control to one square and 10 drops Abnormal control to the second square.
* Place one Ictotest reagent tablet on each moistened mat.
* Place one drop of water onto the tablet. Wait 5 seconds. Place a second drop of water onto the tablet so that the water runs off the tablet onto the mat.
* Blue or purple color indicates a positive result. Lack of color (ignoring pink or red) indicates a negative result. Record results on Q.C. log.
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| 2 | Clinitest Test (day of use) (Alternately use 2-drop method, compare color to 2-drop color chart)* Label 2 10ml test tubes: Normal and Abnormal
* Place 5 drops of Normal control into one tube.
* Place 5 drops of Abnormal control into other tube.
* Add 10 drops of water to each tube.
* Drop one Clinitest tablet into each tube. Watch while reaction takes place. Do not shake tube during reaction or for 15 seconds after boiling has stopped.
* At the end of 15-second waiting period, shake test tube gently to mix.
* Compare color to color chart. Record results on Q.C. log.
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**Acceptable Limits**

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| **Analyte** | **Level 1 (Normal)** | **Level 2 (Abnormal)** |
| Specific Gravity | 1.000-1.020 | 1.005 - 1.030 |
| pH | 5.0-7.0 | 6.9 - 9.0 |
| Leukocyte Esterase | Negative | 25(+) - 500(+++) |
| Nitrite | Negative | Positive |
| Protein | Negative | 25(+) - 500(+++) |
| Glucose | Negative | 50(+) - 1000(++++) |
| Ketones | Negative | 5(+) - 150(++++) |
| Urobilinogen | Normal | 1(+) - 12(++++) |
| Bilirubin | Negative | 1(+) - 6(+++) |
| Blood | Negative | 10(+) - 250(++++) |

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| **Microscopic Elements** | **Level 1 (Normal)** | **Level 2 (Abnormal)** |
| Red Cells | 0/hpf | 1-65/hpf |
| White Cells | 0/hpf | 1-64/hpf |
| Crystals | Absent | Absent-Present |
| Casts | 0 | 0 |
| **Appearance/Color** | Clear/Colorless to Slight Yellow | Clear/Yellow to Dark Amber |

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| **Refractometer(Room temp)** | **Level 1 (Normal)** | **Level 2 (Abnormal)** |
| Specific Gravity | 1.000-1.010 | 1.010-1.035 |
| **Ictotest** | Negative | Positive |
| **Clinitest (5 drops)** | Negative | ¼ - >2 % |

* 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 10 UA Urine Test Strip. Check the stability of the control being used. Ensure test strip is inserted correctly on the transport tray with reagent area facing upward. (The end of the strip must be supported by the rear inside edge of the tray.) 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 Daily 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.
* New lots of test strips and controls must be tested prior to use.
* The urine test strip lot number and expiration date are found on the label of each vial of CHEMSTRIP 10 UA Urine Test Strips. This information must be recorded in the *Urinalysis Daily Quality Control Log*.
* CHEMSTRIP 10 UA Urine Test Strips must be stored at temperatures between +2° and +30° C. 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.
* Urine controls recommended for use with the URISYS 1800 Urine Analyzer are KOVA-Trol® and KOVA® Liqua-Trol™(HYCOR Biomedical Inc.), the Dipper Urine Dipstick Control (Quantimetrix), and Liquichek™ (BIORAD) and **MAS UA control (Medical Analysis Systems, Inc.).**
* Controls are tested in the same manner and by the same personnel as patient samples.
* The results of controls are verified as acceptable before reporting patient results.

Troubleshooting Guidelines* Mechanical problems are evident when the analyzer generates an alarm message. The operator will know an alarm has occurred when the LED for the Global Alarm button is yellow or red. Touch the Global Alarm to view the alarm. Refer to the *URISYS 1800 Urine Analyzer Operator’s Manual* for the list of possible alarms and corrective actions.
* A chemistry problem may display a data flag, or may become evident with an unexpected result. Refer to the *URISYS 1800 Urine Analyzer Operator’s Manual* for an explanation of the data flags. If an unexpected result is obtained on any chemistry, refer to the Limitations and Performance Characteristics sections of the CHEMSTIP 10 UA Urine Test Strip package insert.

If it becomes necessary to consult the **Roche Technical Support Center at 1-800-428-2336** to resolve an analyzer problem, have the following information available before calling:• account number - **55042879**• analyzer serial number - **1061**• description of the problem including relevant error code• description of what was attempted to correct the problem and any analyzer/maintenance informationIf staff is unable to correct a problem with the URISYS 1800 Urine Analyzer, they are instructed to contact Joan Goetteman 952-448-5422 or call the Roche Technical Support Center at 1-800-428-2336. |
| Documentation of Quality Control Results* 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*. 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.
* The Lead Tech (Joan Goetteman) or designee, reviews the *Urinalysis Quality Control Log* for completeness, and notes any sudden shifts in urine control values while using the same lot of strips, and operator performance. The log is reviewed monthly.
* An audit trail should exist to link the control test values to the patient test values performed that day by listing the appropriate URISYS 1800 Urine Analyzer, CHEMSTRIP 10 UA Urine Test Strip and control solution lot number used.
* Periodically the control files will become “Full” and an error message will appear as “**QC Memory Full**” with an audible “ping” and a warning light lit. To manage the QC file (erase old records) > **Workplace > Control List > Send > enter Date Range,** saving only the last month’s data (From: change to previous year, To: change to previous month) > **Delete.**
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**Safety**

1. Handle all specimens as if capable of transmitting disease.
2. Dispose of biohazards in marked containers.

**References**

1. Tietz Textbook of Clinical Chemistry, Edited by Burtis and Ashwood. 3rd Edition, W. B. Saunders Co., 1999, pp. 1834t.
2. URISYS 1800 urine analyzer, Operator's Manual. Roche Diagnostics, Indianapolis, IN,
3. 2004.
4. NCCLS URISYS 1800 Procedure. Roche Diagnostics, Indianapolis, IN, 2004.
5. MAS® Liquid Assayed Urinalysis Control, Thermo Scientific, Microgenics Corp., Fremont, CA. Pkg insert, 2011.