Title: iChem100 Urinalysis Procedure

Author:	Effective Date: *Note: The Effective Date is assigned after all approval signatures are obtained*	Supersedes Procedure #
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Approval Signature	Approval Date
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QC	1		
Lab Bench	1		
Autolab Sharepoint Site	1		

REVISION HISTORY

Procedure #	Revision Date	Reason for Revision
uri.0009.0001	8/1/12	NEW
uri.0009.0002	1/11/18	Update procedure to reflect iChem100 platform only

TITLE: iChem100 Urinalysis Procedure

I. PURPOSE

A. This procedure provides instructions for urine chemistry analysis using the Iris iChem100 semi-automated urinalysis instrument.

II. PRINCIPLE

A. The Iris iChem100 is a semi-automated Urinalysis instrument that performs chemical analysis of urine. The instrument measures the chemical constituents in urine by utilizing test strips that are read by wavelength reflectance. The iChem100 serves as a backup chemistry instrument to the fully automated iRICELL workstation and is used to perform chemical analysis on samples that are low volume, cloudy or viscous.

III. SCOPE

A. This procedure will be used by the UR Medicine Labs – Hematology-Chemistry Laboratory.

IV. RESPONSIBILITIES

Group/Person	Responsibility
Quality Assurance	• Supports the development of this document. • Review and approval of this document.
Medical Director	• Ensures that the procedure is followed. • Review and approval of this document.
Supervisor	• Ensures that the procedure is followed. • Review and approval of this document.
Technical Staff	• Follows the procedure.

V. ACRONYMS/DEFINITIONS

URMC	University of Rochester Medical Center
HH	Highland Hospital
RR	Ridgeland Road Laboratory
SMH	Strong Memorial Hospital

VI. SPECIMENS

A. **Specimen Type:** A “clean catch” specimen collected in a sterile urine container. The specimen is then transferred to a 16x100 BD urinalysis preservative tube. Specimens received in the original container, a non-preservative tube or a BD C&S gray top tube with boric acid preservative may also be used. For specimens received in the gray top C&S tubes, add the comment @SBAT (interpret with caution, sample collected with boric acid) to the comment section for specimen color in Soft.

B. **Specimen Volume:** A minimum volume of 1 mL of urine is necessary to perform testing on the iChem100 urinalysis instrument.

C. **Stability:** Urine specimens collected in BD urinalysis preservative tubes are stable at room temperature for 72 hours. Non preserved urine specimens are stable at room temperature for 2 hours. Non preserved urine may be stored at 2-8° C for 24 hours. Specimens collected in BD C&S gray top tubes with boric acid preservative are stable for 24 hours.

D. **Types of Orders:**

1. **UAR:** Chemical analysis with reflex to Microscopic analysis if positive for Blood, Protein or Leukocyte Esterase
2. **UARM:** Chemical and Microscopic analysis
3. **UARWC:** Follows rule for **UAR**, will also reflex an Aerobic Culture if Nitrites = POS, WBC > 5 /HPF or Bacteria > 1+ /HPF.
4. Individual tests may also be ordered, such as Bilirubin (**UBILI**)**,** Urobilinogen (**UUROB**), pH (**UAPH**) and Specific Gravity (**USG**)

VII. QUALITY CONTROL

A. **QC material:**

1. IRISpec CA/CB/CC

B. **Stability:**

1. Open bottle stability: 15 days, stored at 2-8°C

C. **Frequency:**

1. Every 24 hours
2. With every new bottle of iChem 10 SG test strips
3. After major instrument maintenance, critical part replacement or when instructed by vendor

D. **Procedure:**

1. Pour off 3 mL of CA/CB/CC QC materials into separate 16x100mm glass tubes.
2. Allow aliquots to warm up to room temperature, protected from light.
3. Log in to the iChem100 using user name “IRIS”.
4. Press the **F2** key on the keyboard to open up the “Run Patient” screen.
5. Using the barcode scanner, scan the QC label for the CA material that is posted on the front of the instrument. There are barcode labels corresponding with each of the three levels.
6. Dip a test strip into the tube of CA QC material until all of the pads are saturated, then remove the test strip from the tube, dragging the edge of the strip against the side of the tube as it is removed.
7. Blot the test strip by touching the edge of the strip to a paper towel. Do not blot longer than is necessary, or too much liquid will be blotted off the pads. Touch the edge of the strip against the paper towel only, not the pads.
8. Place the test strip with pads facing up onto the transport belts that are on the left hand side of the instrument. Slide the strip forward until it touches the back of the instrument and triggers the red LED light. The strip will be processed by the instrument.

9. Repeat steps 5-8 for the remaining 2 levels of QC.

E. **Evaluating QC results:**

1. QC results are transmitted to the Soft LIS interface and are also available on the instrument view station.
2. Post QC results from Soft LIS interface to laboratory QC software.
3. If QC results are within appropriate ranges, procedure is complete.
4. If any parameter fails, the operator should:
   a. Document in QC rejection log.
   b. Observe instrument to ensure normal operation.
   c. Repeat control using new aliquot. Post results to QC software, and if results are acceptable, procedure is complete.
   d. If still not acceptable, repeat control using new vial of QC material. Post results to QC software, and if results are acceptable, procedure is complete.
   e. If still not acceptable, notify Supervisor or Technical Specialist to perform appropriate troubleshooting/maintenance on instrument.

VIII. CALIBRATION

A. The iChem100 performs an internal one-point calibration when powered on, as well as prior to each specimen measurement using a fixed standard.

B. A two-point calibration using the fixed standard and a secondary movable standard can be performed if the single point calibration falls outside of the acceptable limits. No external reagents are required Refer to the Urinalysis Maintenance job aid (SH.CP.AU.jad.0163) or iChem100 Operators manual for detailed procedure

C. Calibration can also be performed after major instrument maintenance, critical part replacement or when instructed by the vendor.

IX. SPECIAL SAFETY PRECAUTIONS

A. All patient specimens should be considered potentially infectious and must be handled with precautions used for human blood, as described in CDC (Center for Disease Control) recommendations and in compliance with the Federal OSHA (Occupational Safety and Health Administration) Blood-borne Pathogen Standard, 29 CFR (Code of Federal Regulations) part 1910.1030. All animal products should be treated as potentially infectious. Avoid contact with skin and eyes. Do not empty into drains. Wear suitable protective clothing. Follow specimen handling as outlined by Laboratory Safety Policy, (SH.CP.AU.gen.0005).

X. MATERIALS

A. **Equipment:**

1. Iris iChem100 Urine Chemistry Instrument
2. Barcode reader
3. Keyboard

B. **Supplies:**

1. Disposable transfer pipettes
2. 16x100mm plastic sample tubes
3. Paper towel

C. **Reagents:**

1. iChem 10 SG urine chemistry strips

XI. MAINTENANCE

Maintenance is performed on the iChem100 urinalysis instrument on a daily and weekly basis according to Iris operational procedures. Refer to the shift specific Urinalysis maintenance form (SH.CP.AU.frm.0231) for the list of maintenance procedures performed and their frequency. Maintenance procedures can be found in the Urinalysis Maintenance job aid (SH.CP.AU.jad.0163).

XII. PROCEDURE – (STEP/ACTION)

A. **iChem100 Operation**

1. Log into instrument using the User Name “IRIS”.
2. Press the **F2** key on the keyboard to open up the “Run Patient” screen
3. If not already, a well-mixed patient specimen should be aliquoted into a 16x100mm tube for analysis.
4. Using the barcode scanner, scan the patient barcode label.
5. Using the barcode scanner, scan the clarity barcode on the front of the instrument that corresponds with the clarity of the specimen.
6. Dip a test strip into the patient specimen tube until all of the pads are saturated, then remove the test strip from the tube, dragging the edge of the strip against the side of the tube as it is removed.
7. Blot the test strip by touching the edge of the strip to a paper towel. Do not blot longer than is necessary, or too much liquid will be blotted off the pads. Touch the edge of the strip against the paper towel only, not the pads.
8. Place the test strip with pads facing up onto the transport belts that are on the left hand side of the instrument. Slide the strip forward until it touches the back of the instrument and triggers the red LED light. The strip will be analyzed by the instrument.

B. **Transfusion Reaction Procedure**

1. If a Transfusion Reaction is ordered on a specimen, it will be ordered with a UAR or UARM test.
2. Follow the iChem100 Operation procedure to perform a urine chemistry analysis on the specimen.
3. If the Hemoglobin result is positive:
   a. Centrifuge the sample for 5 minutes at 1500 RPM
   b. Aliquot the supernatant into a new tube

c. Follow the iChem100 Operation to perform a urine chemistry analysis on the supernatant

d. If the Hemoglobin result for the supernatant is positive, enter the canned text @SPH (Supernatant POS for HGB) in the comment field for UBLD in Soft.

e. If the Hemoglobin result for the supernatant is negative, enter the canned text @SNH (Supernatant NEG for HGB) in the comment field for UBLD in Soft.

4. Transfusion Reactions are performed on all shifts. See Flow Chart: SH.CP.AU.jad.0120

XIII. LIMITATIONS

A. **Stability:** Chemistry and Microscopic results may be affected in samples that have past the stated stability or in samples that have been incorrectly processed or stored.

B. **Specific Gravity:** Specific Gravity Results of 1.000 are held on the Soft Interface and the result is changed to Check Result. For these specimens, perform the specific gravity test on the manual refractometer.

C. **Interferences:** Ascorbic acid is a common interfering substance found in urine that may affect the chemical analysis. The iChem 10 SG test strips have an Ascorbic acid test pad to help identify this substance. For a complete list of other interfering substances for each chemistry parameter, refer to the iChem 10 SG test strip insert.

XIV. CALCULATIONS

Not Applicable

XV. INTERPRETATION

Abnormal Chemical and Microscopic Urinalysis results may be used to aid in the diagnosis of metabolic disorders, kidney function anomalies, urinary tract infections and liver function.

XVI. RESULT REPORTING

A. iChem100 chemistry results are reported as follows:

1. Bilirubin: NEG, 1+, 2+, 3+
2. Urobilinogen: NORM, 2, 4, 8, 12 mg/dL
3. Ketones: NEG, 1+, 2+, 3+
4. Ascorbic Acid (non-reportable): NEG, 20, 40 mg/dL
5. Glucose: NORM, 50, 150, 500, >=1000 mg/dL
6. Protein: NEG, 30, 100, >=500 mg/dL
7. Blood: NEG, 1+, 2+, 3+
8. pH: 5.0, 6.0, 7.0, 8.0, 9.0
9. Nitrite: NEG, POS
10. Leukocyte Esterase: NEG, 1+, 2+, 3+
11. Specific Gravity: 1.000, 1.005, 1.010, 1.015, 1.020, 1.025, 1.030, 1.035

XVII. REFERENCE RANGES

A. **iChem100**

1.	Bilirubin:	NEG
2.	Urobilinogen:	NORM
3.	Ketones:	NEG
4.	Glucose:	NORM
5.	Protein:	NEG
6.	Blood:	NEG
7.	pH:	5.0 - 8.0
8.	Nitrite:	NEG
9.	Leukocyte Esterase:	NEG
10.	Specific Gravity:	1.002 – 1.030
11.	Color:	Yellow
12.	Clarity:	Clear

XVIII. PROFICIENCY TESTING

A. Proficiency testing is performed on surveys from:

1. College of American Pathologists (CAP)

XIX. TRAINING

A. Staff is initially trained by a laboratory designated trainer and a training record is completed and signed by both trainer and trainee.

Role	Training Needed
Management	Read
Technical Staff	Read Knowledge Check

XX. REFERENCES

A. iChem100 Operators Manual 300-4410 English Rev C 01/2007

B. iChem 10 SG Test Strips Reagent Insert

C. Urinalysis Maintenance Job Aid SH.CP.AU.jad.0163

D. Transfusion Reaction Flow Chart SH.CP.AU.jad.120

E. Laboratory Safety Procedure SH.CP.AU.gen.0005

Automated Urinalysis iRICELL procedure - Knowledge Check

In the event of a question answered incorrectly: Single-line through the incorrect answer, initial & date, then select the correct answer.

ALWAYS HAVE CHANGES INITIALED BY YOUR TRAINER.

Circle True or False for each of the following statements.

1. True or False — It is necessary to run QC on each new bottle of strips that is opened
2. True or False — Urine stored in BD preservative tubes are stable at room temperature for 24 hours
3. True or False — When the instrument reports a Specific Gravity result of 1.000 to Soft, no additional action is necessary
4. True or False — Transfusion Reactions are performed on only the Day shift.

Any incorrect answers I may have initially written have been discussed and corrected. I now understand the answers I may have gotten wrong.

PASSING GRADE IS 75% OR GREATER

_____
Employee name (print)

_____ _____
Employee signature **(Date)**

_____
Supervisor/Manager name (print)

_____ _____
Supervisor/Manager signature **(Date)**