Title: Automated Urinalysis iRICELL 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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Distributed to	# of Copies	Distributed to	# of Copies
QC	1		
Lab Bench	1		
Autolab Sharepoint Site	1		

REVISION HISTORY

Procedure #	Revision Date	Reason for Revision
SH.CP.AU.uri.0001.0004	NA	(see previous coversheet)
SH.CP.AU.uri.0001.0005	1/11/18	Procedural changes and format

TITLE: Automated Urinalysis iRICELL Procedure

I. PURPOSE

A. This procedure provides instructions for urine chemistry and microscopic analysis using the Iris iRICELL Urinalysis workstation.

II. PRINCIPLE

A. The iRICELL is a fully automated Urinalysis workstation featuring the iChem Velocity urine chemistry instrument and the iQ200 urine microscopic instrument. The iChem Velocity performs measurements on physical and chemical constituents in urine, utilizing test strips read by wavelength reflectance and specific gravity using the refractive index method. The iQ200 performs microscopic analysis through digital imagery of a hydrodynamically focused urine specimen. The images are then classified with automatic particle recognition software and presented for on-screen verification.

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

C & S	BD Culture and Sensitivity Tube – gray top
URMC	University of Rochester Medical Center
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 4 mL of urine is necessary to perform testing on the iRICELL workstation.

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. **UMIC3:** Microscopic analysis only
5. Individual tests may also be ordered, such as Bilirubin (**UBILI**)**,** Urobilinogen (**UUROB**), pH (**UAPH**) and Specific Gravity (**USG**)

VII. QUALITY CONTROL

A. **iChem Velocity:**

1. QC material:
   a. IRISpec CA/CB/CC
2. Stability
   a. Open bottle stability: 15 days, stored at 2-8°C
3. Frequency:
   a. Every 24 hours
   b. With new lot of iChem Velocity test strips
   c. After major instrument maintenance, critical part replacement or when instructed by vendor
4. Procedure:
   a. Take out iChem Velocity QC rack
   b. Pour off 3 mL of CA/CB/CC qc materials into separate 16x100mm glass tubes.
   c. Place QC tubes in the color coded positions (CA-8, CB-9, CC-10) in the QC rack.
   d. Allow aliquots to warm up to room temperature, protected from light.
   e. Load QC rack on front right side of iChem Velocity sampler. Instrument will then perform analysis on QC material.

B. **iQ200:**

1. QC material:
   a. iQ Control/Focus Set

2. Stability:
   a. Open bottle stability: 15 days, stored at 2-8°C
3. Frequency:
   a. Focus performed every 8 hours
   b. Positive and Negative controls performed every 24 hours
   c. After major instrument maintenance, critical part replacement or when instructed by vendor

NOTE: The Positive control and Negative control are always run as a pair, in that sequence to test for carryover.

4. Procedure
   a. Take out iQ200 QC rack.
   b. Remove QC material from refrigerator and bring to room temperature before use.
   c. Focus and Positive control materials are mixed with 5 hard sharp shakes, followed by 5 gentle inversions prior to use. Let sit for 1 minute following shakes to allow for air bubbles to disperse.
   d. Place 3 mL of Iris System Cleanser in a 16x100mm glass tube in position 1 of QC rack.
   e. Place 3 mL of Iris Diluent in 2 16x100mm glass tubes in positions 2 and 3 of QC rack.
   f. Place 6 mL of Focus QC material in a 16x100mm glass tube with focus label in position 5 of QC rack.
   g. Place 3 mL of Positive QC material in a 16x100mm glass tube with positive control label in position 6 of QC rack.
   h. Place 3 mL of Negative QC material in a 16x100mm glass tube with negative control label in position 7 of QC rack.
   i. Load QC rack on the right of the iQ200 instrument sampler and press the Start button on the front of the instrument.

C. **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. **iChem Velocity:** The calibration of the reflectance module and refractometer are checked on a quarterly basis using the iChem CalChek kit. Refer to Urinalysis Maintenance job aid (SH.CP.AU.jad.0163) or iChem Velocity Operators Manual for detailed procedure.

B. **iQ200:** The iQ200 is calibrated on a monthly basis using the iQ200 REF calibrator. Refer to Urinalysis Maintenance job aid (SH.CP.AU.jad.0163) or iQ200 Operators Manual for detailed procedure.

C. Calibration can also be performed after major instrument maintenance, critical part replacement or when instructed by 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 iChem Velocity Urine Chemistry Instrument
2. Iris iQ200 Urine Microscopy Instrument
3. iRICELL view station
4. Iris QC, Calibration and Patient sample racks

B. **Supplies:**

1. Disposable transfer pipettes
2. 16x100mm plastic sample tubes
3. 16X100mm glass qc/calibration tubes

C. **Reagents:**

1. **iChem Velocity:**
   a. iChem Velocity Urine Test Strips
   b. iChem Wash Solution
   c. IRISpec CA/CB/CC qc material
   d. iChem Calchek Kit
2. **iQ200**

a. iQ Lamina
b. Iris Diluent
c. Iris System Cleaner
d. iQ Control/Focus Set
e. iQ REF calibrator

XI. MAINTENANCE

Maintenance is performed on the iRICELL workstation on daily, weekly and monthly 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. **Logging on to the iRICELL view station:**

1. Access the Instrument Screen.
2. Click the Log On Button.
3. Enter user initials and password, then click OK.

B. **Sample Preparation:**

1. Place a patient barcode label on a 16x100mm plastic sample tube.
2. Aliquot a minimum of 4 mL of well mixed patient urine specimen into the barcoded tube.
3. Place tube in a sample rack so that the barcode is centered between the uprights in the rack and facing toward the instrument when the rack is placed on the sampler.

C. **Dilutions:**

1. Cloudy and Bloody specimens need to be diluted prior to performing testing on the iQ200 Microscopic instrument. Dilutions must NOT be used on the iChem Velocity or for other Urinalysis Chemistry testing.
2. All dilutions are made with the Iris Diluent reagent. The dilution made is based on the cloudiness of the specimen.
3. There are 5 predefined dilutions that may be used: 1:2, 1:3, 1:6, 1:10 and 1:20. Each dilution has a specific barcode that is placed below the patient barcode on the dilution tube to identify to the iQ200 instrument what dilution was used.
4. When making a dilution for microscopic analysis, use the dilution chart that is with the barcode labels for appropriate volumes of diluent and specimen.
5. Prior to reviewing the microscopic results of a diluted sample, it is necessary to verify that the instrument read the dilution barcode correctly. The sample dilution information is found with the patient and sample information on the top right side of the “Specimen” screen on the view station.

D. **iChem Velocity and iQ200 Operation:**

1. Place rack with patient specimen tubes on the front, right hand side of the iChem Velocity sampler.
2. Ensure that the notch on the rack base is placed into the track ridge.
3. The instrument will automatically advance the rack.
4. Once the patient barcode is read, the instrument will begin analysis for the ordered test.
5. After the samples have been analyzed on the iChem Velocity chemistry instrument, the rack will proceed to the iQ200 instrument where any samples that require microscopic analysis will be analyzed.

E. **Reviewing Microscopic analysis test results:**

1. On the Iris view station, access the specimens that require a Microscopic analysis review by clicking on the Work List button in the top right corner of the view station screen.
2. If a specimen meets the criteria for auto release, review is not necessary and results are automatically sent to the Soft LIS interface and verified.
3. On the Work List screen, specimens pending microscopic review are sorted in a list according to time analyzed.
4. Specimens are reviewed in the same order as they are tested on the instrument for the purpose of detecting any possible carryover of sediment from sample to sample during analysis. Click on the small arrow on the Date-Time header in the Worklist to resort by time analyzed if the list becomes sorted by any of the other parameters.
5. To review a specimen result, double click on the order on the Work List, or highlight the sample and click on the “Specimen” button at the tip right corner of the view station screen.
6. The results for the patient specimen are now displayed on the screen. On the right hand side of the screen, the Chemistry results are displayed. On the left hand side, and main portion of the screen, the Microscopic results are displayed.
7. It is important to refer to the Chemistry results while editing the microscopic images, as they are useful in helping to identify certain types of sediment. For example, a positive Hemoglobin result may correspond with the presence of red blood cells. Leukocyte Esterase may correspond with increased white blood cells, Nitrite corresponds with bacteria and Protein with casts.
8. The Microscopic results are displayed in categories based on how the particle recognition software sorted the sediment images that were taken during sample analysis.
9. Microscopic results are edited using the Edit Free Release software methodology. The Turbo Edit button on the bottom right hand corner of the Specimen Screen should NOT be highlighted in orange, to ensure that the review method is followed correctly.
10. Categories are color coded based on whether or not they need to be reviewed. Not all categories are necessary to review for every specimen. Categories that are highlighted in Green have results in the normal range, those highlighted in Red have results in the high abnormal range. It is not always necessary to review these categories. Categories that are highlighted in Yellow are reviewed.
11. Click on the Edit button on the bottom of the Specimen screen to begin editing a sample. If there is an instrument alert or flag associated with the microscopic results, it will be necessary to acknowledge the flag before proceeding with the review.

12. The first category of images that require review will be displayed on the screen. If the images are classified correctly, click on the "Next" button at the top right hand corner to move to the next page or category of images.
13. It is not necessary to edit every single image that may be incorrectly categorized. If a category has more than 1/3 incorrect images, or if removing a small amount of images will have a significant effect on the result, it is necessary to edit.
14. The final category that is reviewed is the Un-Classified section. If there is any sediment in this section that was not previously categorized, it is necessary to do so.
15. When all categories have been reviewed, the Specimen screen is displayed again for a final review of results. At this time, it may be necessary to review categories that the user was not presented. Individual categories may be edited by selecting the associated button on the left hand side of the screen. Of note, the Bacteria category is never displayed during the initial review. Return to this category after the initial edit to ensure that the images are classified correctly.
16. Once the sample is correctly edited, press the "Accept" button at the bottom right corner of the screen to release the results to the Soft LIS.

F. **Editing and Reclassifying images:**

1. If more than 1/3 of the images in a particular category are incorrect, or if editing the category will significantly change the result, the images will need to be reclassified.
2. On the right hand side of the screen, there are buttons for each available category. Click on the sediment type that an image is to be reclassified into. Then click on the image in question. This transfers the image into the new category.
3. Continue moving images until all have been classified correctly.
4. When finished moving images, the button for the original category must be reselected before pressing the "Next" button to move on the the next category or page of images. If the next button is selected before pressing the original category button, all of the remaining images will be moved to the category that was highlighted.
5. Images that contain types of sediment that are not reported by the lab may be placed in the artifact category.
6. There are many categories that the instrument provides to categorize sediment. Not all of these categories are used. Only use categories for types of sediment that are routinely reported in the lab or for sediment that doesn't require a microscopic review.

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. **Specimen Quality:** Specimens exhibiting gross hematuria, increased viscosity or increased macroscopic particulate may not be run on the instruments. Analysis on these specimens must be performed manually.

C. **Instrument error codes:**

1. **High Concentration:** The high concentration flag indicates that there was too much sediment for the instrument to photograph. Often, these samples have images that are

difficult to identify or that are out of focus. It may be necessary to make a dilution on the sample and retest.

2. **Flow Alarm:** This alarm indicates that the flow of the specimen in the instrument was in some way inhibited. It is NOT ok to review samples with this error. Delete microscopic results with this error and either make a dilution or perform the test manually. Also, following this error the iQ200 Clean/QC rack with system cleaner and diluent tubes must be run to clean out the specimen path.
3. **Carryover:** This warning occurs as a pop-up window after reviewing a specimen. The warning will indicate which microscopic parameter has potential carryover from the previous specimen. If the parameter in question correlates with the chemistry results, it is acceptable to release. If the parameter does not correlate with the chemistry results, it is necessary to delete the results and rerun the specimen. For example, in a sample with elevated WBC's, a Carryover flag occurs, indicating the WBC parameter as potential carryover from the previous specimen. It is acceptable to release the results if the Leukocyte Esterase result is positive. If the Leukocyte Esterase result is negative, it is necessary to delete the results and rerun the sample.
4. For all other errors, consult the instruments Operation Manual for further assistance.

D. **Image Quality:**

1. The photographic quality of the iQ200 microscopic instrument, along with the varying degree of sediment quality in certain specimens can lead to inconsistent image quality. Not all images of the same type of sediment look alike. Not all images have been focused on correctly. The image quality may vary, depending on what type of sediment is pictured. If there is any doubt as to identity of sediment in a group of pictures, the results should be deleted and the microscopic analysis should be performed manually.
2. Specimens that contain increased amounts of non-Hyaline casts and renal epithelial cells should be deleted and the microscopic analysis should be performed manually.
3. Specimens that contain uncommon pathologic urine crystals should be deleted and the microscopic analysis should be performed manually.
4. Specimens that contain Trichomonas vaginalis should be deleted and the microscopic analysis should be performed manually to observe motility.

E. **Interferences:** Ascorbic acid is a common interfering substance found in urine that may affect the chemical analysis. The iChem Velocity 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 Velocity 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. iChem Velocity chemistry results are reported as follows:

1. Bilirubin: NEG, 1+, 2+
2. Urobilinogen: NORM, 1+, 2+
3. Ketones: NEG, TRACE, 1+, 2+
4. Ascorbic Acid (non-reportable): Neg, 20, 40 mg/dL
5. Glucose: NORM, 50, 150, >=500 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, TRACE, 1+, 2+, 3+
11. Specific Gravity: 1.000 - 1.060

B. iQ200 microscopic results are reported quantitatively and semi-quantitatively on high and low power fields. The Linearity ranges for formed particles are as follows:

1. 0-182 per high power field
2. 0-2900 per low power field

Particles that exceed the instrument linearity are reported as >182/HPF and >2900/LPF

XVII. REFERENCE RANGES

A. **iChem Velocity Chemistry**

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

B. **iQ200 Microscopic**

1. RBC: 0-2 /HPF
2. WBC: 0-5 /HPF
3. Bacteria: None /HPF

4. Epithelial Cells:
   a. Squamous: 0-1+ /LPF
   b. Transitional: 0-1+ /HPF
   c. Renal: None /HPF
5. Casts:
   a. Hyaline: 0-2 /LPF
   b. Granular: 0 /LPF
   c. Cellular: 0 /LPF
   d. Waxy: 0 /LPF
6. Crystals:
   a. Amorphous: None
   b. Calcium Oxalate: None
   c. Leucine: None
   d. Cystine: None
   e. Tyrosine: None
7. Miscellaneous Sediment:
   a. Yeast: None /HPF
   b. WBC Clumps: None /HPF
   c. Oval Fat: None
   d. Trichomonas: None

XVIII. PROFICIENCY TESTING

Proficiency testing is performed twice a year for macroscopic and microscopic analytes.

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. iChem Velocity Operators Manual 301-7146 English Rev BA 9/2015
B. iQ200 Operators Manual 300-4320-English North America Rev CA 9/2015
C. iChem Velocity Test Strips Reagent Insert
D. Urinalysis Maintenance Job Aid SH.CP.AU.jad.0163
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 NOT necessary to run QC on the iChem velocity when loading a new lot of test strips.
2. True or False — Urine stored in BD preservative tubes are stable at room temperature for 72 hours
3. True or False — It is NOT acceptable to run a sample exhibiting gross hematuria or increased viscosity on the iRICELL workstation
4. True or False — It is acceptable to report microscopic results on a sample that has a FLOW alarm
5. True or False — Certain types of sediment such as Cellular casts, Waxy casts and Trichomonas should NOT be reviewed at the view station and must be reviewed manually at the microscope

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 80% OR GREATER

_____
Employee name (print)

_____ _____
Employee signature **(Date)**

_____
Supervisor/Manager name (print)

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