Sutter Health
Sutter Roseville Medical Center

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Policy Area:	*Lab - Urinalysis*
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Applicability:	*Sutter Roseville Medical Center*

Patient Testing on the iChem, AX-4030 and the iQ200

PURPOSE

This procedure describes how to run patient samples on the iChem Velocity, Aution AX-4030, iQ 200 and how to evaluate and edit the microscopy module data for release into LIS.

Principle

The iChem and AX-4030 are automated urine chemistry systems performing measurements of urine physical and chemical constituents utilizing test strips read by Wavelength Reflectance, and specific gravity using the Refractive Index. Since the iChem and AX-4030 also determine color and clarity, a complete urinalysis is determined automatically.

The iQ 200 system auto-identifies and processes specimens by presenting a specimen sandwiched between enveloping layers of lamina to a microscope coupled to a CCD (charge coupling device) video camera which captures 500 frames per sample. The resulting pictures are evaluated and classified using size, shape, contrast and texture features via the Auto Particle Recognition (APR) software.

Specimen Requirements

- Collect urine in a clean, sterile container.
  - A "clean catch" urine is recommended to prevent the possibility of contamination.
- If a specimen is not processed within an hour after collection, cap the container tightly and store at 2-8°C. Bring the specimen to room temperature before testing.
- Urine preservative tubes have been approved for use for urinalysis testing and are stable for 72 hours. Preservative tubes cannot be used for culture.
- Mix specimen well before testing.

Specimen Volume

- Minimum requirements:
- AX-4030 = 2 mL
- iChem Velocity = 2 mL
- iQ 200 = 3 mL
- iChem/AX-4030 and iQ 200 = 4mL

- Do not overfill specimen tubes for testing.

Specimen Limitations

- Gross Hematuria:
  - iChem: Centrifuge sample. If unable to resolve color interference, then follow color interference steps below.
  - AX-4030: Centrifuge sample. If unable to resolve color interference, then follow color interference steps below.
  - iQ 200: Dilute specimens before testing or follow such specimens with a tube containing Iris Diluent to eliminate any possible carryover. Gross hematuria may cause incorrect results in subsequent samples.
  - **NOTE:** It is not required to check with the RN to determine if patient is on menstrual cycle.
- Very Dense or Viscous:
  - iQ 200: May cause flow errors or clogs and require dilution before running.
- Color Interference:
  - Spin urine and report color, clarity and manual specific gravity.
  - Perform manual microscopic.
  - Insert CINT (Color Interference comment) for other dipstick values.
- Specific Gravity:
  - Specific gravity should be resulted as INTRF if a patient had contrast x-ray dye procedure.

Loading/Running Patient Samples

<table>
<tr><th>Step</th><th>Action</th></tr>
<tr><td>1.</td><td>
<table>
<tr><th>If…</th><th>Then…</th></tr>
<tr><td>Specimen in sterile urine cup/container</td><td>Proceed to step 2</td></tr>
<tr><td>Specimen is in labeled tube/preservative tube</td><td>Proceed to step 4</td></tr>
</table>
</td></tr>
<tr><td>2.</td><td>Apply patient LIS barcode label on an empty 16 x 100 mm tube approximately ½ inch below the top of the tube.</td></tr>
<tr><td>3.</td><td>Transfer the appropriate amount of well-mixed urine into labeled tube.</td></tr>
<tr><td>4.</td><td>Place the barcode labeled tubes in the sample racks.
Note: For specimens with caps, mix well, remove caps before placing on instrument.
• Sample rack's black barcode should face to the right
• Tube's LIS barcode should face the instrument</td></tr>
<tr><td>5.</td><td>Load rack onto the right side of analyzer
• Ensure that the notch of the rack base is placed onto the Sampler Track ridge
◦ If the iChem or AX-4030 is in Standby, press the Start button.
◦ If the iChem or AX-4030 is in Measure, move rack so that it blocks the sensor at the front of the sampler, and the rack will move to the sampling position automatically.
• After sampling on the iChem or AX-4030, the sample racks will automatically be transferred to the iQ 200 via the bridge connection for processing.</td></tr>
<tr><td>6.</td><td>After specimen testing is complete on the iQ 200, the sample racks can be removed from the left side of the instrument.</td></tr>
</table>

Dilutions – iQ 200 Only

Dilutions should be performed on grossly bloody, heavy mucoid or very dense specimens in order to avoid clogging the specimen filter. (A good rule is "if you can't see through it, do something to it".)

Dilutions are run on the iQ 200 only. Do not perform dilutions for the iChem or AX-4030. Identify specimens that require a dilution before placing specimen on the system.

Step	Action
1.	Run the undiluted sample on the iChem or AX-4030. Ensure there is at least 2 ml in the tube. Place this tube in rack #23 and run. (Chemistry specimens must be run using rack #23 [orange rack]. This rack is specially labeled not to be processed by the iQ 200. This rack will skip the sampling station and be transferred automatically to the unloading station for retrieval. Note: Grossly Hematuria specimens should not be run on the iChem or AX-4030, perform manual dipstick. Centrifuge prior to performing testing.
2.	Label a second test tube that has a matching patient LIS barcode label with the appropriate dilution label. Fix label below patient barcode. Dilution Table:

Label	Dilution
URN1	X2 (ex. 1 part sample plus 1 part Iris Diluent)
URN2	X5 (ex. 1 part sample plus 4 parts Iris Diluent)
URN3	X10 (ex. 1 part sample plus 9 parts Iris Diluent)
URN4	X20 (ex. 1 part sample plus 19 parts Iris Diluent)

3.	Prepare dilution using Iris Diluent in this tube using either urine from the original container or from the test tube containing undiluted urine that was run on the iChem or AX-4030. *Total volume must be at least 3 ml.*
4.	Place the diluted specimen tube into a regular specimen rack (do not use rack #23).
5.	Load rack directly onto the iQ 200 and press Start to run the sample.
6.	Results will consolidate on the workstation.

Performing On-Screen Verification of Results

The auto-release feature is enabled, urines that qualify for auto-release will not appear on the Work List screen. Instead, the report will automatically print. The released results can be viewed using the Found list screen after a search has been performed.

Specimens that do not qualify for auto-release will appear on the Work List screen.

Step	Action
1.	Select the Work List button located on the top right part of the instrument screen to bring up all unreleased samples.
2.	To review a specimen, double-click the specimen row, or select the row and select Specimens button.
3.	Clear flags that are displayed before results are verified or deleted. There are two types of flags:

<table>
<tr><td></td><td>recoverable and non-recoverable.
If a flag is recoverable, the Review Flagged Specimen and the Delete Flagged Specimen buttons are displayed. After selecting the Review Flagged Specimen and Accept, the Specimen Results screen will be refreshed. If the results match the auto-release criteria, they are automatically transmitted to the printer after the flag is cleared.
Cleared flags will be displayed on the Chemistry Information pane. If the "Validate" flag is displayed, hover the pointer over the flag to see instructions.
If a flag is non-recoverable, only the Delete Flagged Specimen is displayed. The cause of the flag will need to be resolved before the specimen can be run again.</td></tr>
<tr><td>4.</td><td>Click Edit to Verify auto-classified particles. (Note: Do not select "Turbo Edit" as this reduces the number of images shown.)
The user will be directed to the first yellow particle category.
<table>
<tr><th>If…</th><th>Then…</th></tr>
<tr><td>The classification of the particle is acceptable</td><td>Continue the verification by clicking on the right arrow to move forward.</td></tr>
<tr><td>The classification is not acceptable</td><td>Reclassify the misidentified particle(s) as follows:
Determine whether or not reclassification will make a clinical difference (Refer to Reclassification Rules below)
Reclassify particles only when it will make a clinical difference
Click on the particle type that the image(s) should be classified into (use right-hand button).
Click on the image(s) to be moved.
Press the forward arrow to proceed to the next category.
Note: If all images of a category are misclassified, click on the particle type and then click on the right arrow to move to the next category.</td></tr>
</table>
Reclassification Rules:
50% Rule:
Do not reclassify any particles if >50% are classified correctly
Reclassify misclassified particles if >50% are classified incorrectly
Particles in the following categories must be reclassified (i.e. 50% rule does not apply):
UNCX (Unclassified Crystal)
NSE (Non-Squamous Epithelial)
UNCC (Unclassified Cast)
UNCL (Unclassified)
All other identifiable particles in the UNCL category are already accounted for and used in the instrument's calculations for the determination of grades and counts. These particles simply were not the best examples and therefore, not put in a classified category.</td></tr>
<tr><td>5.</td><td>Observe backgrounds of WBC, WBCC, SQEP, and MUCS classifications to manually grade bacteria.</td></tr>
<tr><td>6.</td><td>Press Accept to release the results when verification is complete.</td></tr>
</table>

Common Flags

For a complete list of flags, refer to the Operating Manual.

Flag	Causes	Remedies
CHEM N/A	Chemistry results not available. May appear if barcode not read on iChem or AX-4030.	• Make sure sample was placed for processing on chemistry side. • Check barcode label • Re-run sample
FLOW	The flowcell may be obstructed or the fluids slowed due to the specimen, an obstruction, a clogged specimen filter or a pinched tube in one of the peristaltic pumps.	• Reject the flag to remove the results from the Work List. • Run a control rack with Iris System Cleanser and Iris Diluent. • Re-run sample. Consider dilution on iQ 200.
Short Sample	There was not enough specimen in the sample tube or distilled water was run.	• Reject the flag to remove results from the Work List. • Refill the sample tube with appropriate volume (or run on manual method).
High Concentration	The specimen contained a high concentration of at least one particle type, it is possible that other particles in low concentrations may be missed.	• If the following sample is abnormal and the chemistries support the microscopic results, do not rerun. • If the following sample is reporting abnormal results for the same particles seen in the High Concentration sample and the chemistries do not match the microscopic results, rerun the sample.
Possible Amorphous	The specimen may contain significant quantities of amorphous crystals.	• Review the flagged specimen.
Sperm Present	The specimen may contain sperm.	• Male: classify in digital images and report • Female: pour off and spin down and look under microscope ◦ For underage (<18) call to care team as a courtesy/informational call. • Run a cleaning cycle after. • NOTE: On the next sample the flag ”previous sample had sperm” is auto generated and doesn’t indicate an actual carry over of sperm contamination.
Previous Sample Had Sperm	The previous specimen had sperm results or Sperm Present Flag. The flag is used to signal a possible carryover.	• NOTE: On the next sample, the flag ”previous sample had sperm” is auto generated and doesn’t indicate an actual

		carry over of sperm contamination. • If sperm is actually seen in the following sample then it is recommended to rerun the sample from the same aliquot to verify. ◦ Per technical support, the aspirator does a 2 cycle cleanse in between every patient and, therefore, repeating from the original container is not necessary.

Resulting

Step	Action
1.	In Sunquest, select Urinalysis Result Entry.
2.	Select the RVURN keyboard and click OK.
3.	Enter accession number. Results that have been released from the analyzer will cross-over into Sunquest.
4.	Enter required fields (i.e. CTYP) as prompted.
5.	To make any alterations to results (i.e. after manual review of urine on a microscope), select desired field and edit grading as needed using the keyboard.
6.	A final QC review of the results must be performed prior to selecting SAVE.

Technical Limits - Automated Microscopy

Element	Technical Limit
WBC	0 to >100 /HPF
RBC	0 to >100 /HPF
Casts	None to >100 /LPF
Mucous	None to Many
All others	None to 4+

Note: WBC and RBC are required reporting parameters, other microscopic elements are not reported if they are not present.

Procedure Notes

Specimen tubes that have been run through the analyzer cannot be used for additional testing methods – i.e. Automated Chemistry methods (ex. UDOA) or manual kit testing (ex. Urine Pregnancy). They can be used for additional urinalysis (ex. Refractometer, Clinitek, microscopic examination).

APR will auto-classify bacilli >3 microns in size as isolated images. Reclassification of additional images is not necessary. Bacteria <3 microns in size are too small to be automatically identified and require a tech to identify and grade. Bacteria <3 microns falls into All Small Particle (ASP) count. All particles <3 microns (i.e.

amorphous crystals, bacteria) are included in the ASP count.

Manual microscopic confirmations:

- Trichomonas (motility) – If pear-shaped cells with tails appear, most likely seen in WBC category, verify by slide microscopy.
- Fat/Oval Fat Bodies – verify by polarized light
- Cellular Casts which cannot be definitively identified on the iQ 200. Some users can identify cell type for cellular casts without using manual confirmation.

Limitations/Interferences

Specific gravity measurement range is 1.000 to 1.050. See table below if results are >1.050

NOTE: Urines that are clear, colorless or straw should present with a low specific gravity.

If the specific gravity	**Then**
>1.050 (exceeds measurement range) and it is due to an interfering substance (i.e. high glucose, contrast dye)	Report **INTRF** • *Do not perform a dilution.*
>1.050 (exceeds measurement range) and unable to determine if is due to an interfering substance (i.e. high glucose, contrast dye)	Report **>1.050-INT** • *Do not perform a dilution.*

Analyte	**Causes of False Negative Results**	**Causes of False Positive Results**
Bilirubin	• Elevated concentrations of nitrite may inhibit the reaction. • Bilirubin is light sensitive and prolonged exposure of urine specimens to light may result in diminished or false negative values. • Ascorbic acid concentrations ≥300 mg/dL may interfere with the test. • MESNA concentrations ≥1140 mg/dL may cause false negative results.	• Some urine specimens may contain impurities such as food dyes and therapeutic pigments to produce a yellowish or reddish discoloration of the test pad that may lead to the interference. • Elevated Urobilinogen concentrations may slightly enhance the response to this test pad. • Ascorbic acid concentrations ≥300 mg/dL may interfere with the test.
Urobilinogen	• This test is inhibited by elevated concentrations of formaldehyde and nitrite concentrations ≥10 mg/dL. • Prolonged exposure to light may lead to diminished or false negative values.	• Food dyes and medications that have an intrinsic red color in acidic medium such as red beets, azo dyes, phenazopyridine and *p*-aminobenzoic acid may produce false positive results.
Ketones	• Elevated concentrations of phenylpyruvic	• MESNA may produce false

	acid may interfere with the test pad and produce a variety of colors. • Phthaleins and anthraquinone derivates exhibit a red color in alkaline medium and this may mask the response. • Large amounts of levodopa and medications containing sulfhydryl groups may produce atypical color reactions.	positive results.
Ascorbic Acid	• Samples at a pH of 9.0 may interfere with the test.	• MESNA may produce false positive results. • Samples at a pH of 9.0 may interfere with the test.
Glucose	• Ascorbic acid concentrations ≥300 mg/dL may interfere with the test. • Acetoacetic Acid concentrations of up to 200 mg/dL did not interfere with glucose assay test results (no false negative results). • High specific gravity, acidic pH values and gentisic acid may inhibit color formation.	• Cleaning agents such as hypochlorite and peroxide may lead to false positive results. • MESNA may produce false positive results. • Ascorbic acid concentrations ≥300 mg/dL may interfere with the test.
Protein	• Food dyes such as red beets and therapeutic pigments such as methylene blue and pyridium may mask the coloration of the test pad. • Interference may occur with high specific gravity. • Interference may also occur with disinfectants, wetting agents and blood substitutes (quaternary ammonium compounds, polyvinylpyrolidone, chlorohexidine).	N/A
Blood	• Reducing agents such as ascorbic acid, uric acid, glutathione and gentisic acid may cause false negative results. • Samples with a pH of 5 may interfere with this test. • High concentrations of nitrite can delay the reaction. • MESNA concentrations ≥1400 mg/dL may cause false negative results. • Ascorbic acid concentrations ≥10 mg/dL may interfere with the test.	• Preservatives (formalin) and cleaning agents such as hypochlorite may result in false positives.
pH	No interferences reported.	No interferences reported.

Nitrite	• A negative response in the presence of bacteriuria may be caused by the following: non-nitrite producing microorganisms, low nitrate diet, antibiotic therapy, strong diuresis, or insufficient urinary retention time in the bladder. • MESNA concentrations ≥1400 mg/dL may cause false negative results. • Ascorbic acid concentrations ≥300 mg/dL may interfere with the test.	• Food dyes and therapeutic pigments such as red beets and pyridium may cause false positive responses. • Ascorbic acid concentrations ≥300 mg/dL may interfere with the test.
Leukocytes	• High concentrations of protein, glucose, cephalexin and gentamicin may diminish the color response. • The test can be negative in the presence of visible leukocytes if they have not lysed and/or are not granulocytes. • Cephalosporins >11 mg/dL may interfere with the test. • Boric acid concentrations ≥500 mg/dL may interfere with the test.	• False positive results may occur in the presence of preservatives such as formaldehyde and formalin. • Test results may be positive in the absence of observable cells if the granulocytes have lysed. • Cephalosporins >11 mg/dL may interfere with the test. • Boric acid concentrations ≥500 mg/dL may interfere with the test. • MESNA may produce false positive results.

References

- iChem Velocity Urine Chemistry Strips, Package Insert, REF 800-7212
- iChem Velocity Instructions for Use, October 2017
- iQ 200 Series Instructions for Use, January 2019
- AX 4030 Operators Manual, May 2019

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Attachments

No Attachments

Approval Signatures

Step Description	Approver	Date
Medical Director	Lindsey Westerbeck: Dir, Lab	1/14/2021
Laboratory Director	Lindsey Westerbeck: Dir, Lab	12/30/2020