Dignity Health Central Coast Service Area

**SUBJECT**: iQ Workcell Automated Urinalysis

**ORIGIN:** Clinical Laboratory/Urinalysis

| **Document Category:** | | | |
| --- | --- | --- | --- |
| ☒ Policy | ☒Procedure | ☐Standardized Procedure | ☐Other: |

| **Applies to:** | | |
| --- | --- | --- |
| ☐ Santa Maria Campus,  Marian Regional Medical Center | ☐Arroyo Grande Campus,  Marian Regional Medical Center | ☒French Hospital Medical Center |
| ☐St. John’s Pleasant Valley Hospital | ☐St. John’s Regional Medical Center | |

# purpose:

This procedure provides instructions for the iQ Workcell Automated Urinalysis system. This system includes 2 instruments: the AX-4030 which performs chemistry analysis of urine, and the iQ200 which performs microscopic analysis of urine.

# SPECIMEN COLLECTION:

### Fresh “clean catch” urine specimens are the specimen of choice. Fresh urine samples should be delivered to the laboratory for analysis within 1 hour or be refrigerated at 2-8°C. Refrigerated specimens must be brought to room temperature before analysis. All primary urine containers and urine tubes submitted to the laboratory for testing are properly labeled at the time of collection with a minimum of the patient’s first and last names as well as the patient’s date of birth. The collection date/time, receipt date/time, and collector’s information are documented in the laboratory information system.

### Stability:

###### Unpreserved urine samples for urinalysis or urine culture are stabile for 2 hours at 18-25 °C (room temperature) and up to 24 hours refrigerated at 2-8 °C.

###### The stability of unpreserved urine for other laboratory testing varies. Refer to individual procedures/reference manuals for stability requirements of testing other than urinalysis or culture.

###### Red/Yellow UA preservative tubes are stable for 72 hours at temperatures of 2-25 °C.

### Volume:

###### For chemistry and microscopic analysis, the minimum volume is 4mL. For chemistry analysis only, the minimum is 2mL and for microscopic analysis only, the minimum is 3mL.

### Specimen rejection criteria:

###### Grossly hemolyzed or turbid specimens must not be run on the iQ Workcell. Turbid specimens may be diluted and run on iQ200 for microscopic analysis. See dilution procedure.

###### Do not run gray top tubes on the iQ Workcell.

###### All improperly labeled specimens other than suprapubic taps and surgically collected samples are rejected.

###### Samples submitted to the laboratory which have not been properly preserved, stored, transported, or are outside stated stability are rejected and recollected if possible.

###### Underfilled/overfilled preservative tubes, samples submitted in improper preservative, specimens collected in non-sterile containers, and specimens submitted with inadequate volume will be rejected and recollected.

# REAGENTS/SUPPLIES:

AUTION Sticks 9EB Test Strips

AUTION CHECK Plus

Check Strip Set

Concentrated Washing Solution 3

Thermal Paper

SG Calibrator

IQ® Lamina

Iris System Cleanser

Iris Diluent

iQ® Calibrator

iQ® Control/Focus Set

Dilution Code labels

16x100mm polystyrene tubes

# CALIBRATION:

Calibration is required monthly and is detailed as Monthly Maintenance.

# QUALITY CONTROL:

### AX-4030:

###### QC is run once daily in the AX QC rack.

###### 2 levels of Aution Check QC material are run to check the integrity of the Aution 9EB strips.

###### After bringing controls to room temperature and gently inverting, place Level 1 QC is in position 8 of the AX QC rack and Level 2 QC in position 9. The minimum volume is 2mL.

### iQ200:

###### QC is run once daily on the iQ QC rack, along with Cleanser and Diluent.

###### QC material includes iQ Focus, iQ Positive Control and iQ Negative Control. Each box has target values and limits encoded within the lot-specific barcodes for each QC material. Place these barcodes on 16x100mm polystyrene plastic tubes.

###### After bringing controls to room temperature, mix iQ Positive Control and iQ Focus by holding the bottle upside down and giving five hard sharp shakes followed by five gentle inversions.

###### ***Do not mix iQ Negative Control.***

###### Arrange iQ QC rack as follows:

###### Position 1: 3mL of Iris Cleanser

###### Position 2: 3mL of Iris Diluent

###### Position 3: 3mL of Iris Diluent

###### Position 4: Leave empty

###### Position 5: 6mL of Focus reagent

###### Position 6: 3mL of Positive Control

###### Position 7: 3mL of Negative Control

* Positions 8 and 9 are used to run lot to lot comparisons with Position 8 being for the New Lot Positive Control and Position 9 for the New Lot Negative Control.

###### ***Note: The control rack must be run immediately after pouring the Focus and the controls to prevent the particles from settling.***

###### Place the rack on the iQ200 sampler and press the START button located at the upper left corner of the iQ200, if the instrument is in the standby mode (green light). If in measure mode (blue light), the rack will be detected and processed automatically.

###### Review results under:

###### Quality Review screen

* QC Statistics

###### Review QC to ensure all QC passed before running patient samples.

###### If QC Failed:

###### Look at the message code to see why the control failed. Adjust positions, if necessary. Positions are color coded!

###### ***Note: If the control failed due to an identification error or QC out of order, resolve this error.***

###### Pour fresh aliquots and re-run control.

###### If results are still not acceptable, notify Beckman Coulter Clinical Support.

### ***Note: The system will “lock out” patient testing for microscopy when microscopy controls fail.***

# procedure:

1. Bring samples to room temperature. Refrigerated samples with precipitated amorphous should be rewarmed by placing the sample in warm water for ten (10) minutes.
2. Make sure AX-4030 has enough test strips in the feeders. Each feeder can hold up to 200 test strips but the quality of the strips is assured for only three days. Also make sure to attach the desiccant bag to the feeder cover. One desiccant is required for 100 strips, and two desiccants are needed for 200 strips. The first desiccant attaches to the side panel and the second desiccant attaches to the top feeder.
3. Label an empty 16 x100mm glass tube (or polystyrene plastic) with patient identifier.
4. Apply the barcode to the tube so that the start of the barcode (not the label edge) is approximately ½ inches from the top of the tube.  This leaves room for the dilution label if needed.
5. Mix the sample thoroughly by inversion and pour a minimum of 4ml of well-mixed specimen into a labeled tube for chemistry and microscopic analysis. A minimum of 2mL is required for the AX only and is to be run on the YELLOW rack (iQ does not sample from this rack). A minimum of 3mL is required for microscopic analysis only and the rack is placed directly on the iQ side.
6. Put the sample tube in position number 1 on the sample rack and load up to 10 samples in each rack in consecutive positions.

***Note: The rack’s black barcode should be facing to the right. The tube’s barcode should face the instrument.***

1. Place the sample rack on the instrument (AX-4030 or iQ200) and push the START button on the machine. The sample rack will be moved along the sample transport tray to the barcode reader.
2. For chemistry analysis: After the barcode is read, the AX-4030 probe mixes the sample, aspirates an aliquot, analyzes the SG, color, clarity and dispenses the sample onto a test strip.
3. When the sample processing is complete, the sample rack will be automatically transferred, via the bridge, to the iQ200 Analyzer.
4. After the rack is transferred via the bridge to the iQ200 Analyzer, the sample rack will be moved along the iQ200 Sampler to the barcode reader. For microscopic analysis only, place a sample rack on the iQ200 and press START.
5. The iQ200 Analyzer barcode reader reads the specimen barcode. If a microscopic examination is to be done (as determined by the user-defined criteria), the probe will mix the sample, aspirate an aliquot and perform the microscopic examination.  If a microscopic examination is not to be performed, the tube will be passed.
6. After sample processing is complete, unload the sample racks from the left side of the iQ200 Analyzer.

***Note: Completed, auto-released results will appear on the Found List and be printed automatically. Everything requiring review is found on the Work List.***

1. Verify any pending, flagged results on the Work List as follows in the next section of this document.

# REPORTING OF RESULTS:

### Verification of Flagged Specimens:

###### Green and Red colored categories of microscopic results will be auto-released. These results are within or outside of normal results with no elements seen which remain uncategorized.

###### Yellow categories require on-screen review. These categories have cellular elements which were unable to be positively identified by the analyzer because of size, texture, clumping or some other aberration from the norm.

###### Click on the **Work List button** located on the top right part of the instrument screen to bring up all unreleased samples.

***Note: Samples may be sorted by Specimen ID, Date-Time, Rack/Pos or Status by header at the top of the row.  (Clicking a second time will reverse the order.)***

###### Select the specimen to be verified by double clicking or by selecting the specimen identified, click the **Specimen** button.

### Verify consolidated Chemistry and Microscopy results.

###### Clear flags that are displayed before results are verified or deleted as follows:

###### To **Review Flagged Specimen** click the **Review Flagged Specimen** button and click **Accept.**

###### To **Delete Specimen results** (if the result must be discarded), click the **Delete Flagged Specimen** button and click **Accept.**

###### Verify auto-classified particles as follows:

###### Click on “Edit”

###### ***Note: You will be directed to the first yellow particle category***

* If the classification of the particle is acceptable, continue the verification by clicking on the right arrow to move forward to the next yellow category, if applicable.
* If the classification is not acceptable, reclassify the misidentified particle(s) as follows:
* Determine whether or not reclassification will make a clinical difference.
* 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.***

###### Press ACCEPT to release the results when verification is complete.

###### Use the microscope in the following instances:

###### Oval fat bodies - use polarized light to discern the presence of the Maltese crosses.

###### Fat - view using polarized light.

###### Trichomonas - view with light microscopy to discern motility.

###### Cellular casts - use when the operator cannot make a definite identification of the cell type using the iQ200.

###### Sperm - view to confirm presence.

# LIMITATIONS:

1. Grossly bloody specimens should not be run on the AX-4030. Use an alternate method of chemistry strip analysis.
2. Refrigerated specimens with obviously precipitated amorphous crystals should be rewarmed by placing the specimen in warm water for 10 minutes prior to analyzing the sample.
3. Dense or mucoid/viscous specimens must be diluted prior to running on the iQ200 using the procedure below.

**IX: DILUTING SPECIMENS:**

***Note: Dilutions are only run on the iQ200 analyzer ONLY. Do not perform dilutions***

***on the AX-4030 Analyzer.***

### If you have a barcoded specimen:

###### Obtain a Dilution (YELLOW) rack for the AX-4030.

###### Print identical patient barcodes and place them on two tubes. One for yellow rack (AX-4030) and one for the dilution to run on the iQ200.

###### Pour 3mL urine into the first tube and run on the YELLOW rack on AX-4030.

###### ***Note:  The rack will proceed to the iQ200 but will not sample.***

###### Remove the rack from the AX-4030.

###### Label matching second tube with the appropriate secondary barcode dilution label (fix label below the patient barcode leaving a small space between the two labels so each barcode can be read by the analyzer).

###### Prepare dilution in this tube, using Iris Diluent according to the information found in SETTINGS and the Dilutions Binder. Each label is assigned a specific dilution. The analyzer makes its calculations based on how that label is read.

###### Replace the undiluted sample that was used for the Chemistry analyzer with the diluted tube and place the specimen into a patient (GRAY) rack.

###### Put the rack on the iQ200 analyzer and press START to run the sample.

###### Results will consolidate with the chemistry results.

###### If auto-release has been enabled, results will auto-release as the user has defined, unless flagged.

###### Verify results only for samples that did not auto-release (refer to previous sections of this document).

1. If you are not using barcodes:
   1. Obtain a Dilution (YELLOW) rack.
   2. Click on Manual Orders and choose the patient rack and position number that will be used to run the assay.
   3. Identify the specimen ID, select URN, Dilution code and Work order = run.
   4. Put the sample into the correct position in Dilution (YELLOW) rack number 23.
   5. Pour 3 ml urine into the corresponding unlabeled tube.
   6. Place the rack on the right hand side of the Chemistry analyzer and run.

***Note: the Dilution rack will not be aspirated by the iQ200.***

1. The Chemistry Result will be displayed as ID\_ERROR.
2. After Chemistry has completed, remove the rack.
3. Perform appropriate dilution according to the dilution protocol in SETTINGS and Dilution Binder.
4. Place the diluted sample in the patient rack and position number that was programmed manually.
5. Place the rack on the iQ200 analyzer and press START to run the sample.
6. Consolidate results with Chemistry manually by following prompts.
7. If auto-release has been enabled, results will auto-release, as the user has defined, unless flagged.
8. Verify results only for samples that did not auto-release (refer to previous sections of this document).

# references:

### Iris Automated Urinalysis: iRICELL™ Procedure

### Aution MAX AX-4030 Operating Manual

### Iris iQ200 Operators Manual

### Fundamentals of Urine and Body Fluid Analysis, Nancy A. Brunzel, 2nd edition, 2004.

### Urinalysis and Body Fluids, Susan King Strasinger, 5th edition, 2008.

### GP16-A2: CLSI Urinalysis and Collection, Transportation, and Preservation of Urine Specimens; Approved Guideline-Second Edition