

**TITLE: Iris iQ200 Elite/Arkray AX-4030 Automated Urinalysis System**

**PRINCIPLE:**

The iQ200 Automated Urinalysis System is an in-vitro diagnostic system composed of the AX-4030 chemistry module, the iQ200 microscopy module, computer and monitor. The system is used to automate the complete routine urinalysis including chemistry, specific gravity, color, clarity and the microscopic analysis of the specimen. The iQ200 performs a macroscopic and a microscopic analysis on each urine specimen.

**CLINICAL SIGNIFICANCE:**

Urinalysis is performed to aid in the diagnosis of disease, to monitor wellness, to monitor the progress of disease states and therapy/treatments.

**AX-4030 Urine Chemistry Module Principle:**

The Aution MAX AX-4030 is intended for the determination of glucose, protein, bilirubin, urobilinogen, pH, blood, ketones, nitrite, leukocytes, specific gravity, color and turbidity. Aution sticks are a multi-parameter test strip which contains nine pads impregnated with chemicals specific for the determination of each constituent. A correction pad is included on the strip to compensate for the natural color of urine and its effect on the color reactions of the reactive pads. Tests strips are dispensed from the test strip feeder and placed on the test strip tray. The sample probe mixes the sample, than aspirates an aliquot of urine onto each reagent pad. Using reflectance spectroscopy at defined wavelengths the instrument analyzes the color changes and the intensity of the reflected light from the reactive pads. Specific gravity is determined by refractometry. Turbidity is determined using transmitted and scattered light.

**CHEMICAL PRINCIPLES OF THE TEST STRIPS:**

**Glucose:** This test is based on the glucose-peroxidase-chromogen reaction, which produces a purple color.

**Protein:** This test is based on the protein-error reaction of pH indicator, which produces a blue color.

**Bilirubin:** A reddish-brown azo dye is obtained by the coupling of bilirubin with a diazonium salt.

**Urobilinogen:** A reddish-brown azo dye is obtained by the coupling of urobilinogen with a diazonium salt.

**pH:** The reagent pad contains pH indicators which give colors ranging from yellow to blue and the pH range of 5 to 9.

**Blood:** This test is based on the pseudoperoxidase activity of hemoglobin which catalyzes the oxidation of chromogen. The reaction produces a blue color.

**Ketones:** Ketones react with sodium nitroprusside to form a purple complex.

**Nitrate:** Nitrite reacts with sulfanilamide to form a diazo compound which couples with NEDA-2HCL to form a red azo dye.

**Leukocytes:** Due to esterase activity in leukocytes, indoxyl is released from the substrate. The indoxyl reacts with diazonium salt to form a purple azo dye.

**iQ200 Urine Microscopic Module Principle:**

The microscopic portion of the routine urinalysis is performed on the iQ200 module. It auto-identifies and processes specimens by mixing, sampling and analyzing the data obtained from the sample. A portion of the mixed specimen is aspirated and is sandwiched between enveloping layers of a suspending fluid. This fluid (Lamina) is positioned exactly within the depth of focus and field of view of the objective lens of a microscope that is coupled to a video camera. The iQ Lamina is used to position the formed elements in the best orientation that presents the particles with their largest profile facing the direction of view. The camera captures five hundred pictures per sample. The flash of a strobe lamp illuminates each field. The pictures are digitized and sent to the instrument processor. Individual particle images are classified into one of 12 categories using size, shape, contrast and texture. The auto-classified categories are RBCS, WBCs, WBC clumps, hyaline casts, unclassified casts (UNCC), squamous epithelial cells, non-squamous epithelial cells (NSE), bacteria, yeast, crystals (UNCX), mucus and sperm. Images that do not classify as any of these 12 types are placed in the UNCL (unclassified) category. Particle concentration is calculated using the number of images and the volume scanned. User defined criteria are checked and results are sent directly to the workstation monitor for review and editing.

At the workstation monitor, specimen results are reviewed and edited as needed. During the review process, individual images will be displayed. Images may be manually re-classified by the operator if they are not in the correct classification. Unclassified crystals (UNCX), unclassified casts (UNCC), non-squamous epithelial cells (NSE) and yeast (BYST) may be further sub-classified during the review process.

The presence of the following elements requires a manual microscopic review for ID and confirmation:

* Oval Fat Bodies
* Fat
* Trichomonas (confirm presence of flagella by motility)
* Cellular casts (if the cell type is questionable)

 Once the review has been completed and “Accept” has been chosen, the results will be sent to the LIS.

**SPECIMEN REQUIREMENTS:**

A minimum sample requirement to run a urine specimen on both the Arkray and iQ200 is 4mL. The specific minimum volume for each instrument is as follows: Arkray 2mL (1 mL for analysis and 1 ml for dead space) and the iQ200 3mL (2mL for analysis and 1 mL for dead space).

The optimal specimen is a first morning clean catch urine sample collected in a clean container. A freshly voided clean catch random urine sample is also acceptable. If a specimen cannot be examined within 2 hours of collection it must be kept refrigerated (the urine must be warmed to room temperature before testing).

Other acceptable samples include: urine pedibag and urine collected via catherization from pediatric or adult patients.

If a sub-optimal specimen is received contact the patient’s nurse or ordering physician. If the RN or physician desires the results, run the sample and add a disclaimer to the results stating the specimen is not optimal for testing.

**REJECTION CRITERIA:**

1. Transport/Storage- Specimens >2 hours old that have not been refrigerated.

2. Contaminates- Specimens contaminated with feces, blood, barium or urine preservatives, disinfectant or detergent.

3. Unlabeled or mislabeled specimens.

4. Leakage- specimens with lids not tightly secured and have leaked into the transport bag.

5. QNS- Specimens <4mL of urine will not be rejected but needs a qualifying comment added indicating the volume may lead to inaccurate results. Smaller samples can be run but will need to be diluted for the iQ200 to run the microscopic portion.

6. If a sample volume is too small and additional sample can’t be collected, the specimen may be run by the back-up method.

**REAGENT AND SUPPLY REQUIREMENTS:**

A. Equipment requirements

 1. Iris iQ200/Arkray AX-4030 Automated Urinalysis Analyzer

B. Reagent Requirements

 1. Wash Solution concentrate

 a. Store at room temp

 b. Preparation of 10% wash solution

 1. Add 200mL of Wash Solution Concentrate(3) to 1800 mL of DI Water

 2. Stable for 15 days

 2. Aution 9EB Test Strips

 a. Store at Room Temperature

 b. Keep bottle on its side

 c. Once opened the bottle expires in 30 days

 d. Once loaded on the instrument, the strips expire in 72 hours

 3. iQ Lamina

 a. Store at Room Temperature

 b. Stable until the expiration date printed on bottle

 4. Iris Diluent

 a. Store at Room Temperature

 b. Stable until date printed on bottle

 5. Iris System Cleaner

 a. Store at Room Temperature

 b. Stable until date printed on bottle

C. Supply Requirements

 1. Dilution Barcode Labels

a. Secondary barcodes are available for 1:2, 1:3, 1:5, 1:10, 1:20 dilutions on the iQ200 module.

b. Any specimen that has been diluted must have a dilution barcode in order for the iQ200 module to process results accurately. See dilution section of procedure for instructions on diluting tests manually.

c. Specimens run on the AX-4030 do not get diluted.

 2. SG Calibrator

 a. Store at 2-8°C

 b. Stable until the expiration date on package

 c. Allow the bottle to come to room temperature before use

 d. Discard after use

 3. Urine centrifugation tubes, round or conical bottom- do not use flat bottom tubes

**QUALITY CONTROL**

The AX-4030 and iQ200 have separate control material. Quality controls are to be performed every 24 hours. The must also be performed following calibration, major maintenance and repairs.

 1. Quality Control Materials

 a. AUTION Check Plus Control (Low and High)

 1. Store at 2-8°C

 2. Stable until the expiration date on package when unopened

 3. The controls expire in 30 days once opened

 4. Products must be brought to room temperature before use

 b. iQ Positive, iQ negative and Focus

1. Unopened bottles are stored at 2-8°C and are stable until the expiration date on the box.

2. Stable for 30 days after opening.

3. Products must be brought to room temperature before use.

2. Performing Quality Control

 i. AUTION Check Plus Control

 a. Remove one bottle of each level and warm to room temp.

 b. If opening a new bottle, write the new exp. Date on the bottle (30 days).

 c. Invert bottle several times to ensure homogency

 d. Pour 2mL of each level into a separate sample tube.

e. Place Level 1 in position 8 and Level 2 in position 9 on the AX-4030 QC rack.

f. Return bottles to the refrigerator immediately.

g. Place the rack on the AX-4030 sampler.

h. When testing is complete the results will print out.

ii. iQ Positive, iQ Negative and Focus

 a. Before use shake the iQ Focus and iQ positive control

1. Holding bottles upside down- give each bottle 5 hard shakes followed by 5 gentle inversions.

2. Do Not shake or invert the negative control. This will introduce air bubbles that may be read as particles by the instrument.

3. Let bottles sit about 1 minute until the air bubbles are gone.

b. Place reagent specific bar code labels on the appropriate tubes with the control name on the left side.

1. Use the barcode labels from the current box and be sure to use the correct barcode label for each product. Do not mix barcode labels from different lots.

c. Load iQ200 QC rack as follows:

|  |  |  |  |
| --- | --- | --- | --- |
| **POSITION** | **CONTENT** | **VOLUME** | **BARCODE LABEL** |
| 1 | Iris System Cleanser | 3 mL | No |
| 2 | Iris Diluent | 3 mL | No |
| 3 | Iris Diluent | 3 mL | No |
| 4 | Empty |  |  |
| 5 | iQ Focus | 6 mL | Yes |
| 6 | iQ Positive Control | 3 mL | Yes |
| 7 | iQ Negative Control | 3 mL | Yes |
| 8 | Empty |  |  |
| 9 | Empty |  |  |
| 10 | Empty |  |  |

d. Load rack onto the sampling area on the right side of the instrument and press start.

e. The instrument will process the rack and the results will print out.

f. If QC fails repeat process

g. On the maintenance log record the date and initials of when you completed these procedures

**NOTE: It is very important that you follow the mixing instructions exactly as written in order to ensure quality results and valid shelf life of the materials.**

3. QC Failure: If the QC is not within acceptable limits.

a. Do not report patient test results.

b. Rerun the QC material that failed

c. If results are still not acceptable, repeat using a fresh bottle of QC material

d. If the iQ200 QC fails, repeat the cleaning rack and re-run the Focus followed by freshly poured QC

e. If results are still not acceptable notify a Lead Technologist, Super-User or contact the Iris Diagnostics Technical Services- the number is posted on the front of the analyzer.

**CALIBRATION**

The AX-4030 and the iQ200 modules have separate calibration materials. Calibrations are performed monthly as stated on the maintenance schedule. Calibration must also be performed if QC falls out of the acceptable limits.

 1. The S.G. Calibration on the AX-4030 is required monthly

a. Bring the S.G. calibrator to room temperature. Make sure the analyzer is in stand-by mode.

b. Pour 2 mL of DI water into a sample tube and place in port 1 of a sample rack

c. Pour 2mL if S.G. Calibrator into a sample tube and place in port 2 of the sample rack

d. Load the rack onto the sampler and from the screen press S.G. Calibration. Then press “OK”

e. Press “START”

f. A message “measurement complete” will appear when the calibration is done. Press “Go Back” to return to the standby screen

 g. Remove the rack from the sampler

 h. Always perform QC following a calibration

 i. Attach the calibration print-out to the back of the maintenance log

j. Run AUTION Controls levels 1 and 2 after performing the S.G Calibration

 2. To calibrate the iQ200- required monthly

 a. Bring the iQ calibrator to room temperature.

 b. Run the rack with the cleaner, diluent, and Focus

c. Shake the iQ calibrator bottle as described: 5 hard, sharp shakes followed by 5 gently inversions, then let sit 1 minute to disperse air bubbles.

d. Pour at least 4mL of iQ calibrator into 10 16X100 test tubes

e. Place one calibration barcode label on the tube that is in the 1st position in the calibrator rack

f. Load the calibration rack onto the right side of the iQ200 sampler

g. Press START. The rack will process the calibration automatically.

h. When the calibration is successful, the date/time and new REF value will be displayed in the Last Calibration field on the **Instrument** screen

i. Always perform QC following a calibration

j. Attach the calibration print-out to the back of the maintenance log

**MAINTENANCE:**

1. **Maintenance on AX-4030**

 Quality controls should always be performed following these maintenance procedures.

a. **Daily** (for more detailed directions see pages 4-3 thru 4-5 in the operator’s manual)

 i. **Clean strip waste box**

1. Discard used test strips

2. Sterilize the box with alcohol

3. Rinse with water

4. Re-install the waste box ensuring it is seated properly inside the tray.

b. **Every 3 days** (for more detailed directions see pages 4-8 thru 4-12 in the operator’s manual)

 i. **Clean strip feeder**

1. Make sure the AX-4030 is in standby mode

2. Turn the locking lever to open the cover

3. Remove test strips, clean the inside of the feeder with the blower brush

4. Remove as much dust as possible by rotating the roller

5. Return strips to feeder and close the cover

 ii. **Clean test strip stopper**

 1. Make sure the AX-4030 is in standby mode

2. Remove test strips from the feeder and open the maintenance covers

3. Tilt the feeder down to the right

4. Unscrew the thumb screw and remove the strip stopper

4. Slide the stopper forward to remove it from the feeder

5. Using the blower brush, remove the dust from under the stopper and the roller

6. Re-install the strip stopper and tighten the screw

7. Close the cover

iii. **Wash introduction tray**

1. Make sure the AX-4030 is in standby mode, turn off power

2. Open covers and tilt feeder unit down to the right

3. Remove the introduction tray

4. Wash the introduction tray using alcohol

5. Rinse thoroughly with water.

6. Using a cloth, dry the tray being careful to avoid scratching it.

7. Re-install the introduction tray and close the covers.

c. **Weekly** (for more detailed directions see pages 4-24 thru 4-25 in the operator’s manual)

 i. **S.G. cell wash**

 1. Make sure the AX-4030 is in standby mode.

2. Place 2 mL of Iris cleaner into a sample tube and load into the STAT port

3. While pressing the “PUSH” mark, slide the STAT port backward and push it into place.

4.Gently pull the port out to make sure it is locked with the stopper.

5. On the stand-by screen, press “MENU” then press “5” for the “maintenance screen”.

6. Press 1 to go the “S.G. cell washout” and press “START”

7. When process is completed, the maintenance screen will appear again.

8. Press “GO BACK” twice to return to the standby screen.

9. Press the “PUSH” mark backward to unlock the STAT port and then slide the port toward you.

10. Remove the tube from the port.

 ii. **Clean transport tray**

 1. Make sure the AX-4030 is in standby mode.

 2. Press MENU on the standby screen

3. Press “5” then go to the maintenance screen.

4. Then press “2” “Clean washing bath and tray” this will move the nozzle out of the way.

5. Turn off the Power switch and open the front cover.

6. Remove the introduction tray 1st then remove the transport tray.

7. Wash and sterilize the tray with alcohol and warm water.

8. Reinstall the transport tray and then the introduction tray by sliding them into place until you hear a click.

9. Close the cover.

d. **Replace the washing solution**

 i.Replace every 15 days or sooner if required.

 1. Make sure the AX-4030 is in standby mode.

2. Uncap the washing solution bottle and discard the remaining solution, rinse out the bottle with purified water

3. Prepare the new washing solution by filling the bottle to the 1800mL marker on the bottle with DI water.

4. Add 200mL of concentrated washing solution 3 to the DI water.

5. Using Parafilm over the mouth of the bottle, gently invert the bottle to mix but do not froth the solution.

6. Remove the Parafilm from the bottle and recap the bottle into its place.

7. Date the bottle with the new expiration date (15 days from the date of preparation)

e. **Monthly** (for more detailed directions see pages 4-26 through 4-29 in the operator’s manual)

 i. **Clean Wash bath**

1. On the standby screen, Press “MENU”, Press “5” to get into the maintenance screen.

2. Press “2” Clean washing bath and tray” to move the nozzle.

3. Turn off the Power switch and open front cover.

4. Using cotton swabs moistened with water wipe off the washing bath and port.

5. Close the cover and turn the power switch back on.

 ii. **Replace the washing solution filter**

1. Make sure the instrument is in standby mode and switch the power switch to off.

2. Turn the filter holder by hand to disassemble it and remove the filter with tweezers.

3. Fit a new filter into the recess of the filter holder.

4. Screw the filter holder back into place.

5. Turn the power switch back on and check for leaks

 iii. **Clean the air filter**

1. Remove the filter cover from the back of the AX-4030 by pulling the cover back toward you and remove the filter

2. Wash the filter thoroughly under running tap water and gently wring out to dry.

3. Re-install the filter and cover.

iv. S.G cell calibration – see calibration section of this procedure for detailed instructions

f. **As-needed maintenance** (See section 4 of the operator’s manual or online assistance for detailed instructions)

 i. Replace printer paper

 ii. Replace the drain pinch valve tube

 iii. Replace the white plate

 iv. Check measurement

2. **Maintenance on the iQ200** (See section 8 “Maintenance and Service” of the electronic procedure manual for more detailed instruction on any of the following procedures.)

 a. **Daily**

 i. **Run Cleaning/QC rack**

1. Using the iQ200 control rack, prepare the rack as defined in the below table.

 

2. Load the control rack on the right side of the Microscopy module sampler and Press the “START” button.

 ii. **Clean Instrument surfaces**

1. Clean the instrument using a paper towel moistened with a 1:10 dilution of Iris system cleanser (1:10 diluted cleanser should be prepared fresh daily)

2. Wipe again using DI water and then another paper towel to dry.

3. To prevent sample transport problems, immediately clean any spills.

 iii. **Clean the sampler**

1. Clean the instrument sampler using a kimwipe moistened with 1:10 dilution of Iris system cleanser (Do not use gauze)

2. Check under the belts and pulleys to remove any deposits

3. Wipe again using DI water and then another clean wipe to dry.

 iv. **Check Lamina supply**

1. When the Lamina container is low a message will appear.

 v. **To Replace the iQ Lamina Container and Filter**

1. A new filter comes with every case of Lamina (2 bottles/case).

\* It is best practice to replace the filter when loading the 1st bottle in the new case

 2. Remove the cap from the old and the new bottles.

3. Remove the straw and replace the filter if necessary.

4. To replace the filter, grasp the tube above the filter and pull the old filter straight off.

5. Remove the new filter from the package and push it straight on to the tubing. It only will fit one way.

6. Do not mix or dilute the contents of the Lamina bottle.

7. Position the new bottle into the old bottles place and reconnect the tubing.

 b. **Monthly**

i. Perform instrument calibration (see calibration section of this procedure for detailed instructions).

 c. **As-needed maintenance**

 i. Clean Rinse/Waste bath

 ii. Clean sample tube detector

 iii. Clean barcode reader window

 iv. Clean optical sensors

 v. Clean sample filter

**PROCEDURE:**

 A. Instrument start-up

 1. Make sure computer is on.

 2. Start the iQ200 by pressing the switch on back of the microscopy module.

3. When instrument screen is on, press the green button on the front of the iQ200 module.

4. Turn on power for the AX-4030 by pressing the power switch located on the front of the instrument.

Note: The microscopy module requires 1-2 hours to warm up and is strongly recommended that the instrument remain on at all times.

B. Log on:

1. At the workstation, access the Logon menu by clicking on “Instrument” which is located at the top right of the computer screen.

2. Click on “Logon” to access the screen.

3. Use the drop-down menu to select your logon name (Technologist is the universal user ID)

4. Type your password – (Tech1 is the universal user password)

5. Click “OK”

C. Sample Preparation:

 1. If a sample has been stored in the refrigerator ensure it has warmed to room

temperature.

2. Mix sample thoroughly

 3. Minimum sample required is 2mL.

4. Remove cap from urine tube and place in sample rack ensuring the bar-code is centered and facing toward the instrument.

5. If sample is received in a cup or pedi-bag, pour sample into a urine tube and labeled with an aliquot label.

6. Bloody specimens must be spun down and placed in a yellow rack prior to running on the AX-4030 (save an unspun aliquot to run a dilution on the iQ200).

D. AX-4030 and iQ200 Instrument Operation

1. A sample may be run on the AX-4030 instrument alone, the iQ200 instrument alone or on both instruments.

2. If the screen on the AX-4030 displays “waiting for rack” the instrument is on and ready to process specimens, otherwise press the Start button.

3. The AX-4030 will run a microscopic analysis on every urine sample regardless of the macroscopic results.

4. If the specimen needs to be run only on the iQ200 module (for dilutions) place the sample rack on the right side of the iQ200 sampler and press the start button.

5. When processing is complete the rack will be moved to the left side of the iQ200 analyzer

6. If a UMCRI (urinalysis with reflex to a culture) is ordered, a urine culture will automatically be ordered and the technologist will bring the specimen to the department.

E. Reviewing Instrument Test Results:

 There are 2 test codes for ordering a urinalysis on the iQ200:

* + - * UMACI- a macroscopic and microscopic will be performed on every urine specimen
			* UMCRI- a macroscopic and microscopic will be performed on every urine specimen and if the criteria is met, a urine culture order will be reflexed

1. The AX-4030 results are to be reviewed at the workstation along with the iQ200 microscopic findings

 a. To view specimen results and edit, click on “WorkList”

 b. Select “Search” at the bottom of the screen- you can select your search criteria

 c. Select “OK”

 d. This screen contains all results of un-released specimen results within your search criteria

 e. Double-click on the specimen then chose “Specimen” at the top of the screen

f. The results are displayed, the Chemistry results are located on the right and the microscopic results are on the left

g. The microscopic results display the particles and their concentration in a graph.

h. If the concentration is normal the green bar will display, if the concentration is abnormal a red bar will display. A yellow bar indicates a review is needed.

i. If a flag is displayed, it must be cleared before any particles can be reviewed.

 1. To remove a flag- click on “Review flagged specimen” and then “Accept”.

2. Sub-classifying or Re-classifying Particles.

a. In the specimen screen click on the “Edit” button to begin reviewing the particles.

b. Images of the particles in that category will be displayed (there may be multiple pages of images)

c. If the classification of particles is acceptable continue the review by clicking on the arrow at the top right side of the screen. (the right arrow goes to the next set of images and the left arrow goes back to the previous screen.)

e. If there are images that are incorrectly classified, they must be re-classified which will change the clinical results.

f. To re-classify an image select the correct category which the image belongs.

g. Choose the images you wish to move, this will transfer the image to the chosen category.

h. If all remaining images are defined correctly, click back to the correct category in the upper left corner to keep those images in that category.

i. All Unclassified images (UNCL) and Unclassified casts (UNCC) must be reviewed

j. When everything has been reviewed and edited, return to the specimen screen by clicking on the results button at the bottom.

k. Click on “Accept” at the bottom of the screen. This will send the results over to the LIS.

F. Resulting the urinalysis in SOFT

 a. The macroscopic chemistry analysis will not auto verify when:

* The glucose is >1000, this is considered a critical result and needs to be called to the nurse of physician
* The clarity of the specimen is not clear, modify the clarity of the specimen in SOFT before reporting
* The color of the specimen is abnormal, modify the color in SOFT before reporting
* Every urinalysis will have a microscopic resulted

b. The microscopic results will not auto-verify, the tech will review the specimen in the iQ200 and re-classify images when necessary. After the review is complete, the Tech will select “Accept”. This will send the result to the SOFT. The results will still need to be verified in SOFT

c. Always verify that the microscopic result matches the macroscopic result (ex. if blood and leukocyte esterase are positive in the macroscopic you should see cells in the microscopic)

d. S.G. “OVER” results could be falsely elevated due to radiologic dyes, confirm with the nurse to determine if the patient recently had a procedure using dye. If so, add a canned text comment to the result: “Specific Gravity could be falsely elevated due to the patient’s exposure to a radiologic dye or other medications”

**e. Do not report sperm unless specifically requested to do so by the physician**

**Urine specimens from a female <12 years of age- if Trichomonas and/or sperm are seen on the microscopic analysis, confirm results by performing a manual microscopic review. If Trichomonas or sperm are still present request another specimen to be collected. If the re-collected specimen is still positive for Trichomonas or sperm call the physician with the results.**

f. Store all urine specimens in the refrigerator for 24 hours

G. Dilutions: (\*reminder-if you can’t read through it, you must dilute it!)

Grossly Bloody, Viscous/milky, Dense/grossly amorphous and short specimens will need to be diluted before performing on the iQ200 module.

 **Do not run a diluted specimen on the AX-4030**

There are 2 ways a specimen can be diluted on the iQ200

**1. Preferred method for running dilutions on the iQ200**

1. Reprint a second patient barcode label

2. Place the undiluted specimen in a yellow rack on the AX-4030 (this will prevent the iQ200 from running the microscopic analysis)

3. After the Macroscopic (chemistry) is completed, in a separate tube, prepare a manual dilution of the specimen using sample diluent

4. Place a pre-printed dilution label under the patient’s bar-code, leaving a small gap between the barcodes.

5. Place this dilution tube into a grey Iris rack, and place it on the right side of the iQ200

6. Press “Start” on the iQ200

7. The results will merge together

8. When reviewing the results, make sure the correct dilution is displayed under the patient information. If 1:1 is displayed the dilution was not performed correctly.

**2. Alternate method for diluting specimens**

 After running the microscopic analysis and the results indicate the need for a dilution due to a “high concentration” or “flow” flag you must separate the chemistry and micro results by following these steps:

 a. On the specimen screen, click “review flagged specimen”

 b. Click “Accept”

 c. Click “Other”

 d. Choose “Separate Chemistry and Micro” then “OK” then “accept”

 e. Go back to “found list” –Select “Search” search “today” and click “OK”

 f. Results will appear twice- “released” (dipstick) and “review” (micro)

 g. Delete the “review” (micro) before running the diluted specimen

 h. Make the proper dilution using the dilution bar-code label

i. Make sure the bar-code label and dilution label are facing the correct way

j. Place specimen on grey rack and place on the iQ200 (Never run a diluted specimen on the AX-4030)

k. After testing is complete, the macroscopic and microscopic results should have matched up.

l. Look above the chemistry results, the dilution factor should be displayed under the sample information.

m. If a “1:1” is displayed, the dilution was not processed properly. You should re-run the sample.

n. Edit the sample as usual and click “Accept” when finished.

3. Dilution Guidelines

Dilute sample with Iris Diluent.

 a. Perform a 1:2 dilution for neonatal, pediatric or low volume samples

 b. Perform a 1:3, 1:5 or 1:10 dilution for mildly turbid to turbid samples

 c. Perform a 1:20 for very turbid or bloody samples

d. If a 1:20 dilution still gives a “high concentration” or “flow” error, a traditional microscopic exam must be performed

e. A Back-up methodology and manual microscopic examination may be used for the specimens as well. When running a urine on the back-up analyzer the order code in SOFT must be changed to UMAC,UMIC.

**Reference Ranges:**

|  |  |
| --- | --- |
| **Specific Gravity** | **1.000-1.030** |
| **pH** | **5-8** |
| **Leukocyte Esterase** | **NEG** |
| **Nitrite** | **NEG** |
| **Protein** | **NEG** |
| **Glucose** | **NEG** |
| **Ketones** | **NEG** |
| **Urobilinogen** | **0.2-1.0** |
| **Bilirubin** | **NEG** |
| **Blood** | **NEG** |
| **Color** | **YELLOW** |
| **Clarity** | **CLEAR** |
| **WBC** | **0.5** |
| **RBC** | **0.5** |
| **Hyaline Casts** | **NONE SEEN** |

**SHUT-DOWN:**

 1. Click the instrument button

 2. Click the Go-Offline button. The system status will change to offline

 3. Click the Maintenance button

4. Click the shutdown button. The system will prompt “Do you want to shut-down the instrument”. Click yes and the computer will shut off, wait for the screen to go dark before proceeding to the next step

5. Turn off the microscopy module by pressing the green button

6. Turn off the AX-4030 by pressing the green button

Note: Restart the Microscopy module as soon as possible. Do not allow the instrument to cool down. This could have an impact on the Focus.

**UTILIZING ON-LINE HELP:**

1. Access Instrument Screen

 2. Select “?” icon

 3. Operator’s Manual will appear as a PDF, click on PDF to open the manual

 4. Find topic desired and click on Table of Contents

**LIMITATIONS:**

|  |  |  |
| --- | --- | --- |
| Analyte | Causes of false negative results | Causes of false positive results |
|  |  |  |
| Glucose | Large amounts of ascorbic acid | Presence of oxidizing substances such as chlorineor hypochlorite, urine with a pH <4.0 |
|  |  |  |
| Protein | pH < 3.0 | Large amount of hemoglobin, contrast medium, disinfectants including quaternary ammonium compounds, urine with a pH >8.0 |
|  |  |  |
| Bilirubin | Ascorbic acid, uric acid, and nitrites | Urobilinogen, Ethodolac |
|  |  |  |
| Urobilinogen | N/A | Carbapenem |
|  |  |  |
| Blood | Elevated specific gravity or protein, large amounts of ascorbic acid | Oxidizing substances such as chlorine or hypochlorite |
|  |  |  |
| Ketones | N/A | L-DOPA, BSP, PSP, Phenylketone, Cephalosporine, Aldose reductive antienzyme |
|  |  |  |
| Nitrite | Ascorbic acid, elevated specific gravity  | N/A |
|  |  |  |
| Leukocytes | Glucose > 500 mg/dL,Protein > 300 mg/dL,Urine with low pH or elevated specific gravity | Formaldehyde |
|  |  |  |
| pH | N/A | N/A |
| Specific Gravity |  | Radiologic dyes or other medications |

**Once a sample has been processed on the iQ200 for a microscopic analysis the sample can no longer be used for any other laboratory testing, with the exception for a manual microscopic review. This is due to the sample being contaminated with Lamina.**

**Substances that cause abnormal urine color, such as drugs containing azo dyes, may affect the readability of the test strips. These results may have to be resulted as “color interference”.**

**Gross Hematuria may cause incorrect results in subsequent samples. Do not test samples exhibiting gross hematuria.**

**TROUBLESHOOTING:**

G. Instrument Flags: See “Instructions for use” for more detailed information on resolving error flags

1. **High concentration-** indicates the specimen needs to be diluted. Run cleaning rack before re-running a specimen on dilution (cleaning rack may need to be run multiple times)

2. **Flow-** indicates the specimen needs to be diluted. Run cleaning rack before re-running a specimen on dilution (cleaning rack may need to be run multiple times)

3. **Sequential Flags**- 3 flags in consecutive order will trigger this flag- run the cleaning rack to resolve

 4. **Carry over**- resolve by running a cleaning rack, then re-run the sample

 5. **Clog**- Indicates the iQ200 filter may need to be flushed with diluent

6. **Chemistry Confirmation/Chemistry Translate**- Elevated chemistry results, correlate with microscopic results before reporting

Technical Support- Beckmancoulter.com

Hotline assistance: 1-800-223-0130

Account # 7533-1679-1679

Arkray AX-4030

SID: 70765848
SN: 11912006

iQ200

SID: 71661078

SN: C15893

**REFERENCES:**

1. Iris AX-4030 Operators Manual

2. Iris iQ200 Operators Manual

3. Rush-Copley Medical Collection and Dispatch of Specimens 4840-LCC-117