IRIS iQ200 System
Beckman Coulter, IRIS Diagnostics Division

Technical Procedure 3340

Principle

Intended Use

The iQ® 200 SPRINT Automated Urinalysis System (iQ Series System) is an in-vitro diagnostic system. The system is composed of the automated AUTION MAX® AX-4280 chemistry module Automated Urine Chemistry Analyzer, the iQ200 Automated Urine Microscopy Module, results/analysis processor, computer monitor, mouse and keyboard. The iQ200 SPRINT system provides a fully integrated, automated chemical and microscopic analysis of urine.

The AX-4280 instrument performs the chemistry panel, determines the specific gravity, the color and the clarity of a urine specimen. The chemistry panel is performed using a test strip, which detects the presence of 9 elements – glucose, protein, bilirubin, urobilinogen, pH, blood, ketones, nitrite, and leukocyte esterase. Specific gravity is determined by measuring the refraction angles of light passing through a prism. Color is determined by comparison to four wavelengths of different colors and passing a light beam through the sample and measuring the scattered light measure clarity.

The iQ200 performs the microscopic portion of the urinalysis and provides a qualitative or quantitative count of formed elements such as cells, casts, crystals, and organisms. The iQ200 photographs particles as they are passed in front of the camera. The images are classified, counted and stored for verification by the user.

The workstation consists of a computer that is interfaced with an approved chemistry analyzer and the iQ200 module. At the workstation, results of the chemistry profile and the microscopic are collated, compared to user-defined criteria for auto-release, and stored for review. The user can verify results including the images of the formed elements. As needed, the user may sub-classify, reclassify, or verify results. After verification the results may be sent to the host computer and/or printed.

AX-4280 Urine Chemistry Module Principle

The AX-4280 is a urine chemistry analyzer that measures the chemical constituents of the urine using AUTION 9EB strips, which are read by a dual wavelength reflectance system. The AUTION plastic strip contains 9 pads impregnated with chemicals specific for the determination of a particular constituent. The nine analytes measured are: glucose, protein, bilirubin, urobilinogen, pH, blood, ketones, nitrite, and leukocyte esterase. A correction pad is included on the strip to compensate for the natural color of urine and its effect on the color of the reaction pads. Test strips are dispensed from the test strip feeder and placed on the test strip tray. The sample probe mixes the sample, aspirates an aliquot of urine and dispenses it onto each reagent pad. At defined wavelengths, the AX-4280 analyzes the color changes and the intensity of reflected light from the reaction pads. These measurements are used to calculate clinically meaningful results.

Test Methodology of AUTION Strips

See the individual test procedures for each of the 9 test pads.

Glucose: Glucose Oxidation reaction

Protein: Protein-error reaction.

Bilirubin: Azo-coupling reaction.

Urobilinogen: Azo-coupling reaction.

pH: pH indicator.

Blood: Activity measurement of pseudoperoxidase in hemoglobin.

Ketones: Legal reaction.

Nitrite: Griess reaction.

Leukocytes: Measurement of leukocyte esterase activity.

iQ Series Instrument Principle

The microscopic portion of a routine urinalysis is performed on the iQ200 module. The iQ200 auto-identifies and processes specimens by mixing, sampling and analyzing the data obtained from the sample. Approximately 1mL of the mixed specimen is aspirated and is sandwiched between enveloping layers of a suspending fluid. This fluid or "lamina" is located 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 so that the particles appear with their largest profile facing the direction of view. The camera captures five hundred frames 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 (WBCC), hyaline casts, unclassified casts (UNCC), squamous epithelial cells, non-squamous epithelial cells (NSE), bacteria, budding yeast, unclassified crystals (UNCX), mucus, and sperm. Any images that do not classify into any one of these 12 categories are placed in the UNCL category. The particle concentration is calculated using the number of images, a normalization factor and the volume scanned. Results are sent to the workstation monitor for verification.

Workstation Principle

At the workstation monitor, specimen results are verified. During the verification process, individual images are displayed. The operator may manually reclassify images. Unclassified crystals (UNCX), unclassified casts (UNCC), and non-squamous epithelial cells (NSE) must be further sub-classified during the verification process. Once the verification has been completed and [Accept] has been chosen, the results will be sent to the LIS.

Specimen Collection

A clean freshly voided midstream specimen should be collected in a clean container for routine analysis, and a sterile container for UACII requests. Infant bag collections are acceptable for children ≤ 2 years of age. Other acceptable specimens include catheterized specimens, and suprapubic, ostomy, and OR kidney or bladder collections. Grey-topped boric acid tubes are unacceptable for Urinalysis.

BD tiger top urinalysis preservative tubes must be filled to a level between the marked minimum and maximum tubes (7-9 mL). Under-filled or over-filled tubes are unacceptable.

For best results, BD yellow top urinalysis tubes without preservative requires eight (8) mL for UA or UACII. Urine specimens with a volume < 3 mL will be diluted for microscopic analysis if possible. Urine specimens with a volume < 1 mL may not have enough volume for microscopic analysis.

All specimens must be capped tightly. Specimens that leak are unacceptable for analysis.

Specimens exhibiting gross hematuria cannot be tested undiluted on the iQ Series and not at all on the AX-4280. Gross hematuria may cause incorrect results in subsequent samples.

The specimen volume placed on the iQ System must be at least 3 mL. If testing on the AX-4280 module only,the minimum volume is 2 mls. If testing on the iQSeries module only, the minimum volume is 2 mL.

Sample Stability and Handling

Urine collected without preservative at room temperature must be delivered to the lab within 1 hour of collection.

Urine collected without preservative and immediately placed on ice must be delivered within 4 hours of collection.

Urine collected in BD urinalysis preservative tubes will be accepted up to 48 hours after collection.

All specimens should be handled using the principles of Universal Precautions.

Reagents and Supplies

1. Wash Solution Concentrate is a ready-to-use concentrated solution used in the preparation of the Stock Wash Solution. It is provided in 1000 mL containers, which are stored at room temperature and are stable until the expiration date on the label.
2. Stock Wash Solution is prepared from the wash solution concentrate. The stock solution is stored at room temperature and is stable for one week. Prepare as follows:
    a. Place 1800 mLs of distilled or deionized water in the container for the wash solution.
    b. Add 200 mLs of AX-4280 Wash Solution Concentrate.
    c. Date and initial a new Stock Wash Solution label and put on bottle.
3. AUTION 9EB Test Strips - 100 per vial - are ready-to-use strips containing pads that have been impregnated with chemicals used to perform the chemical analysis portion of the urinalysis. They are stored at room temperature and are stable unopened until the expiration date on the vial. Loaded on the instrument, the strips expire in 72 hours.
   1 - 200 strips may be loaded at one time. Load a quantity of strips appropriate to the testing volume to be performed. To prevent strips from jamming, load less than 50 strips at a time. When you empty a vial of test strips, always replace the desiccant on the instrument with one in the strip container.
4. iQ® Lamina™ is an isotonic fluid used to stabilize the flow in the focal plane of the microscope objective and to hydrodynamically orient the particles so that their largest profile is toward the microscope during image capture. It is stored at room temperature and is stable until the expiration date on the container. There is a filter in each case of two iQ Lamina bottles. Change the filter when replacing the first iQ Lamina bottle from a new case, i.e., every second bottle.
5. Iris Diluent is an isotonic, particle free fluid used to dilute cloudy specimens and rinse the instrument after Iris System Cleanser. The diluent is stored at room temperature and is stable until the expiration date on the container.
6. IRISpec CA™ and CB™ Controls are ready to use bottles of simulated human urine comprised of appropriate chemicals, biological matter, buffer salts, and preservatives. They are stored at 2° - 8°C and aliquots are brought to room temperature before use. Return bottles to the refrigerator immediately after pouring off the aliquots to be used each day. CA/CB controls expire 15 days after being opened and should be kept out of the light.
7. iQ® Positive, iQ® Negative Controls and iQ® Focus are ready to use bottles of suspended fixed human red blood cells in a particulate-free, buffered, isotonically balanced solution. Unopened boxes are stored at 2° - 8°C and are stable until the expiration date on the bottle. The products must be brought to room temperature before use. Barcodes are supplied with these materials and must be used when running QC. They expire 30 days after being opened.
8. The following sample tubes are suitable for use: 16 x 100 mm round bottom plastic (polystyrene) or glass tubes, Kova economy tubes or Urisept tubes.
9. Sample Racks/Routine Racks are racks that hold specimens for processing through the instrument. They are silk- screened with barcodes representing numbers from 1 – 10 and have the corresponding number on the opposite end. They also have lines across the front representing 3 and 6 mL fill volumes.
10. iQ® Calibrator Rack is used for monthly maintenance on the iQ Series module.
11. QC Racks/Maintenance Rack- The iQ Series maintenance rack is used for daily maintenance and QC. Refer to the *IRIS iQ Operator's Manual* for information.
12. Barcode Labels are generated by the host computer and are used to identify a patient sample.
13. Dilution Barcode Labels- secondary barcodes are available for dilutions on the iQ Series module.
    Any specimen that has been diluted must have a dilution barcode properly placed in order for the iQSeries module to process results accurately.

Calibration

The AX-4280 and the iQ Series modules have separate calibration materials. Calibrations are performed as a part of the maintenance schedule.

AX 4280 Module Calibrations

Calibration Verification is performed weekly using one white and one gray check strip. Refer to the *IRIS AX-4280 Operator's Manual*, weekly scheduled maintenance.

The specific gravity is calibrated monthly using deionized water and the SG High Calibrator. Refer to the *IRIS AX-4280 Operator's Manual*, monthly scheduled maintenance.

iQ Series Module Calibration

The iQ Series module is calibrated monthly as part of the iQ Series monthly maintenance schedule. Refer to the *IRIS iQ Operator's Manual* for instructions.

Quality Control

Quality control is performed as part of the daily maintenance for both the AX-4280 and the iQ Series module. For the AX-4280 module, quality control is performed every shift. Refer to the Iris Quality Control procedure for instructions.

Controls will also need to be tested on the AX-4280 module when a new shipment or a new lot number of AUTION 9EB test strips is received. Parallel testing between the old shipment or lot number and the new shipment or lot number will be done to assure proper performance.

Values obtained should fall within the ranges provided by the manufacturer of the material.

Quality control results should be evaluated and handled with respect to the Clinical Chemistry Quality Control Procedure #3000.T.

Procedure

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 Logon screen.
3. Use the pull-down menu to select your logon from the list.
4. Type your password in the password field. The password is case sensitive.
5. Click "OK" to logon and close the logon screen.
6. Note that the Operator ID appears in the upper corner of the Instrument screen.

Sample Preparation

1. Place the patient's bar code label on a sample tube. Apply it 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 should it be required. **If the sample is more than slightly turbid, it should be diluted.**
2. Transfer at least 3 mL of a well-mixed urine specimen into the bar coded tube.
3. Put the sample tube in a sample rack so that the bar code is centered between the uprights and facing toward the instrument when the rack is placed correctly on the system.

AX-4280 and/or iQ Series Instrument Operation

A sample may be run on the AX-4280 instrument alone, the iQ Series instrument alone, or on both instruments.

1. If the sample is to run on both instruments or on the AX-4280 module alone, place the sample rack containing specimens on the right side of the AX-4280 Sampler. Ensure that the track on the right side of the Sampler is properly placed in the notch in the rack base.
2. Press the "START" button located on the upper left side of the AX-4280 module. Note: if the blue "Measure" light is lit, place the rack in the forward right corner to block the sensor. This automatically starts the instrument.
3. The sample rack will be moved along the sample transport tray to the bar code reader.
4. After the bar code is read, the sample aspirator mixes the sample, aspirates an aliquot, analyzes the SG, color, clarity and dispenses the sample onto a test strip.
5. When the sample processing is complete, the sample rack will be automatically transferred, via the bridge, to the iQ Series module.
6. If the specimen does not need to be run on the iQ Series module, it may be removed from the instrument at this point.
7. After the rack is transferred via the bridge to the iQ Series module, the sample rack will be moved along the iQ200 Series Sampler to the bar code reader.
8. The bar code reader reads the specimen bar code.
9. If a microscopic will be done (as defined by the criteria), the sample aspirator mixes the sample, aspirates an aliquot and performs the microscopic examination. If a microscopic examination is not to be performed, the tube will be passed. (NOTE: Samples with barcode read errors on the AX, or those without barcodes will be tested on the iQ Series module regardless of sieve criteria.)
10. After sample processing is complete, the sample racks can be unloaded from the left side of the iQ Series sampler.
11. If the specimen needs to be run only on the iQ Series module, place the sample rack on the right side of the iQ Series Sampler (on-load station) and press the start button on the upper left side of the instrument.
12. The iQ Series module will process the specimen. When processing is complete the rack may be unloaded from the left side of the instrument.

Reviewing Instrument Test Results

AX-4280 Instrument

1. The AX-4280 module has an on board thermal printer that can be set to print the results of the chemistry portion of the urinalysis. This printout may be reviewed by technical personnel as needed.
2. The results of samples that do not need a microscopic examination will be transmitted to the host computer.
3. The specimen can then be verified at the LIS.
4. If the sample has abnormal or flagged results that meet the criteria requiring a microscopic examination, the results can be reviewed at the workstation along with the microscopic findings.

iQ Series Instrument

1. If a specimen has a microscopic analysis performed, results will not be transmitted to the host computer. The results are to be reviewed at the workstation monitor.

Auto-release will not be turned on. All specimen results must be reviewed.

2. To review specimens, click on "Work List".
3. This brings up the Work List screen, which contains all specimen results for review.
4. On this screen, a specimen may be deleted or undeleted.

5. The default list order is time order, oldest first, with any flagged specimens at the top. The list may be sorted for any parameter by choosing Sort Specimen List, or by clicking on the heading desired at the top of the row. Clicking a second time will reverse the order; i.e., oldest to newest, newest to oldest or highest specimen number to lowest or vice versa. The small triangle in the header indicates which header is being used to sort at any time.
6. To review a specimen result, double click on it or highlight it then click on "Specimen" at the top of the screen.
7. The Results screen for that specimen will be displayed. On the right side are the chemistry results and on the left are the microscopic results. Correlate positive chemistries such as protein, blood, leukocyte esterase and nitrite, with microscopic results. Look for the presence of casts, RBCs, WBCs and bacteria in the microscopic images. See *Urinalysis Correlation Chart*. (Attachment A)
8. The microscopic screen (from left to right) lists the particles, their concentration and a graphic representation of the particle concentration.
9. If the concentration is normal the green bar will display. If the concentration is abnormal the red bar will display. The abnormal color is based upon the user-defined abnormal threshold.
10. If flags are displayed on the right side of the screen, they must be acknowledged before any particle type detail can be reviewed.
11. Click on "Review Flagged Specimen" to remove the flag. Then click on "Accept".
12. In the specimen screen click on the button of the first particle to be verified.
13. Images of the particles in that classification will be displayed. Note: there may be multiple pages of the same particle type.
14. If the classification of particles is acceptable continue to verify by clicking on the right arrow on the right side near the top of the screen. This takes you to the next set of images. Clicking on the left arrow takes you to the previous screen.
15. Continue verifying until you return to the specimen screen.
16. If everything is acceptable after review, click on the "Accept" button at the bottom right of the screen. The results will be transmitted to the host computer.
17. Verify the results in the LIS following the Laboratory Results Reporting Procedure.

Subclassifying or Reclassifying Particles

1. In the specimen screen click on the button of the first particle to be verified.
2. Images of the particles in that category will be displayed. Note: there may be multiple pages of the same particle type.
3. If there are images that are incorrectly classified, they may be reclassified if the reclassification will affect the clinical result. If you are reclassifying less than half of the images, it will not affect the clinical result.

   Example 1: you look at WBC and find 24 images of WBCs and 2 of artifact. Do not reclassify the artifact as it will not affect the clinical result.

   Example 2: you click on BYST and see 6 images of amorphous or artifact. Click on ART and leave the screen. This removes the BYST category from the report and is appropriate.
4. On the right side of the screen, all the categories are listed. To reclassify, click on the particle type that an image is to be classified into and then click on the image(s) in question. This transfers the image to the chosen category. Note: if you click on an image in error, re-click on the space to return the image to the screen before you go to the next screen.
5. Continue to reclassify by clicking on the category and then clicking on all the images that should go into it. If

images are grouped together they can be moved at one time by using the click and drag feature. Much of the time all the particles will be sub-classified or reclassified into the same category. In this case, leaving the screen moves all images on the screen into the category indicated by the lit button on the right. This saves the time and effort of clicking on the individual images.

6. When all images are not being moved to the same category, move the fewest images individually, then choose the category for the rest of the images and leave the screen.

   Example: You are reviewing 10 images in the UNCC (unclassified casts) category. Two of the images are of Cellular casts (CELL) and the rest are Granular (GRAN). Click on the CELL button. Click on the images that are cellular casts. They will disappear from the screen. Then choose GRAN and leave the screen. All the remaining images are now sub-classified as granular casts.

7. If the remaining images are to remain in the original category, click on that category at the upper left corner. This confirms all the images on the screen in their original category. If you do not confirm the images, all the images on the screen will go to whichever category is highlighted at that time.

8. When everything has been verified, return to the specimen screen by clicking on the Results button at the bottom or by continuing through the screens using the right arrow.

9. Use the *Microscopic Review Sheet* (Attachment B) to note sediment requiring manual microscopic review. Once all iQ classification and quantification is acceptable, click on the "Accept" button at the bottom right of the screen.

10. Review samples manually, if required, and manually enter reviewed results. Verify the results in the LIS following the Laboratory's Results Reporting Procedure.

Putting Sample on Hold

The iQ Series software allows the user to start verifying a sample and then save all the changes that have been made without accepting the results. This is accomplished by the use of the "HOLD" button which is part of the verification screen. The "HOLD" button only becomes active after something in the specimen has been changed.

NOTE: Do not use the Hold button to make changes after reviewing the results manually. Manually recorded and entered results must be reviewed by another CLS in the LIS for accuracy of manually entered results and clinical correlation in accordance with Technical Procedure 3005, Reporting and Review of Results.

1. In the specimen screen click on the button of the first particle to be verified.

2. Images of the particles in that category will be displayed. Note: there may be multiple pages of the same particle type.

3. Verify the sample as usual.

4. If there is a need to leave this specimen before the verification process is complete, click on the Results button.

5. Click on the "Hold" button. This will save the changes that have been made and return this specimen to the Worklist.

6. When ready to further verify this specimen, highlight it on the Worklist and click on Specimen.

7. All changes previously made will still be present. Continue to verify the specimen and click on Accept when complete.

Manual Orders

The iQ Series allows the user to use Manual Orders in situations where a barcode is not available. The patient identification can be entered and the rack the samples will be placed in selected. Manual orders work only for the iQ Series and not the AX-4280.

1. From the Specimen Screen, click on Manual Orders.

2. Click on the button that corresponds to the rack the specimens will be placed in.

3. In the first field enter the patient identification information.
4. The second field (Fluid Type) can if left blank if the specimen is a urine.
5. In the third field enter the dilution, if needed.
6. The fourth field will automatically change to "**RUN**".
7. Continue to enter manual orders until up to 10 specimens have been entered.
8. Continue to select racks and enter patient information until all have been entered.
9. Click on [**OK**] or [**OK & Print**] to return to the instrument screen.
10. Load specified racks with specimens.
11. Run racks on iQ Series.
12. Review specimens as above (*Reviewing Instrument Test Results, iQ200 Series Instrument*).

Dilutions

Diluted samples cannot be run on the AX 4280 module.

Cloudy ,bloody, or mucoid specimens will need to be diluted before testing on the iQ Series module. Samples with particle counts above the AMR (>182 particles/HPF) must be diluted to ensure accurate results. Some result flags require dilution. Additionally, low-volume samples (< 3 mL) are diluted to provide sufficient volume for analysis on the iQ microscopic module. (Refer to Table #1, below.) Samples containing amorphous sediment can be diluted if the chemistry results do not match the microscopic results, or if there is concern that the amorphous particles are covering other cells.
Refer to Table #2 for the user-defined dilutions available and the volumes of urine and Sample Diluent to be used.

NOTE: Grossly bloody or pyuric specimens cannot be tested using the AX-4280 module. Significant carryover will occur in subsequent specimen(s). Grossly cellular specimens must be tested using the iChem100 instrument. The specimen can then be diluted and run on the iQ Series to obtain the microscopy result. Do not dilute samples more than x101. For grossly bloody or pyuric samples which cannot be accurately evaluated even with a dilution, enter **N** (packed) in the appropriate field, and append the mnemonic **UHW** ("Unable to perform microscopic due to presence of very large numbers of white blood cells") or **UHR** ("Unable to perform microscopic due to presence of very large numbers of red blood cells").

All dilutions are made with Iris Diluent. Use the mnemonic **GMBD** ("Microscopic performed by dilution") in the Specimen Comment field when samples are diluted.

Table #1: USING DILUTIONS TO TEST LOW-VOLUME CLEAR OR SLIGHTLY TURBID SAMPLES

METHOD	< 1.0 mL	1.0 – 1.9 mL	2.0 – 2.9 mL	≥ 3.0 mL
iChem	YES	YES	NO	NO
AX 4280	NO	NO	YES	YES
iQ200, Straight	NO	NO	NO	YES
iQ200, Diluted X2	NO	YES*	YES*	NO
Manual Microscopic	YES	NO	NO	NO

YES=Use this method to perform testing
NO=Do NOT use this method to perform testing.
*Attach mnemonic **GMBD**

Example 1: Two (2) mL of urine is received in the appropriate collection tube. Run the sample undiluted on the AX- 4280, remove the sample and dilute sample x2 before running on the iQ200 automated microscopy module.

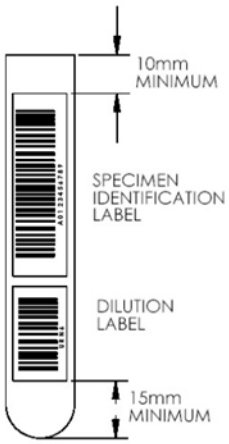
Example 2: 0.5 mL of urine is received in the appropriate collection tube. Run the sample with the iChem100 and perform a manual microscopic on the remaining urine.

Example 3: Four (4) mL of urine is received in the appropriate collection tube. Run the sample on the AX4280 and the iQ200 automated microscopy module.

Table #2: MAKING iQ200 DILUTIONS

LABEL NUMBER	DILUTION	URINE VOLUME	IRIS DILUENT VOLUME
1	x2	1 mL	1 mL
2	x3	1 mL	2 mL
3	x6	250 uL	1.25 mL
4	x11	250 uL	2.5 mL
5	x21	100 uL	2.5 mL
6	x51	100 uL	5.0 mL
7	x101	50 uL	5.0 mL

Do not dilute samples greater than x101.



How to Run Chemistry Testing and a Microscopic Dilution Simultaneously

(Results for both portions will appear on the Work List together)

1. Make the appropriate dilution. (Refer to Table #2, above.) Diluted samples should appear clear or very slightly turbid. Particle count on diluted samples must not exceed AMR. Place the correct dilution (secondary) barcode below the patient barcode. Do not cover the patient barcode. Make sure there is at least ¼ inch between the last black line of the patient barcode and the first black line of the dilution barcode. The white area of the barcodes may overlap. (See image at right.)
2. Set the diluted sample aside.
3. Run the original specimen on the AX-4280 module.
4. Before the sample is transferred to the iQ Series module, remove it from the AX-4280 rack. You may place the iQ Series offline to prevent the rack from moving from the AX-4280 to the iQ Series.
5. Place the diluted sample in the rack before the rack reaches the accession area of the iQ Series module. Verify that the barcodes are oriented correctly.
6. After testing is complete, check above the Chemistry results column. The correct dilution factor must be displayed under the sample information (1:2, 1:3, 1:6, etc.). If a 1:1 is displayed, the dilution was not recognized and the microscopic results were not calculated appropriately on the diluted sample. The displayed results can be multiplied manually and edited in the LIS. A comment should be entered into the Edit Comment section documenting the manual change in concentration.
7. Edit the sample as usual and click “Accept” when finished.

Run a Dilution Without Repeating Chemistry Testing

(Chemistry and Microscopic results will be released separately and will not appear on the Work List together)

1. Because the Chemistry portion is not being repeated, you will need to accept the Chemistry results on the original sample. You may do this in either of two ways. From the specimen results review screen, Select “Other” on the bottom right.
    a) Select “All ART” to move all the particles in the microscopic portion to the Artifact category.
    b) Select “Separate chemistry and microscopic results”. Delete the separated microscopic results.

   This will allow Chemistry results to be sent to the LIS without the risk of reporting an incorrect microscopic. Click “Accept” on the iQ Series Results Screen.

2. Make the appropriate dilution. Apply the correct dilution barcode to the patient tube below the patient barcode.
3. Place the diluted sample in the rack and place the rack on the iQ Series Sampler. Press the Start button in the top left hand corner on the instrument.
4. The CHEM N/A alarm will be displayed. Check the iQ Series Results Screen to ensure the dilution was processed. The dilution factor should be displayed under the sample information (1:2, 1:3, 1:11, etc.). If a 1:1 is displayed, the dilution was not recognized and the microscopic results were not calculated appropriately on the diluted sample. The displayed results can be multiplied manually and edited in the LIS. A comment should be entered into the "Edit Comment" section documenting the manual change in concentration.
5. The microscopic results will consolidate with the Chemistry results in the LIS.

Flags/Alarms Obtained During Analysis

The iQ Series instrument monitors certain errors and will give an alarm if any one of the monitored flags occurs in the last three samples run (**SEQUENTIAL FLAGS)**. When an alarm is raised because of a Sequential Flag, testing is halted. The monitored flags are: **FLOW**, **ILLUMINATION**, **IMAGE ACQ**, **LIGHT FLUCTUATION**, and **SHORT SAMPLE**. They are all errors that affect the basic analysis process and may produce erroneous patient results. To avoid wasted specimen and iQ Lamina, the instrument will stop until the problem is solved.

1. Select "Delete Flagged Specimen" to remove the results from the Work List.
2. Check the last three sample results in the Work List to determine if there is a Sequential error.
3. If the errors are sequential, resolve the problem prior to rerunning the sample.

   Example 1: If the observed error is **IMAGE ACQ**, check the connection on the large cable connecting the iQ Series Camera to the Results Processor.

   Example 2: If the observed error is **FLOW**, the sample may be mucoid, and/or the flowcell may require cleaning or is obstructed. Run the iQ Control rack with Iris System Cleanser, Iris Diluent, iQ Focus, iQ Positive and iQ Negative controls. (Consult the Iris iQ User Manual on the S-drive for maintenance and troubleshooting guidelines.)

Most samples may simply be re-run but it is good practice to visually inspect the specimen and determine whether a dilution should be performed and, if so, the appropriate dilution to make.

Limitations and Interferences

See the individual test procedures for each of the test pads.

Standard Reporting Format - Chemistry

VOLUME	Report number of milliliters if < 8 mL urine specimen submitted AND manual microscopic analysis is indicated.
COLOR	None, Yellow, Orange/Amber, Brown, Red, Green, and Other
CLARITY	Clear, Slightly Turbid, Turbid and Opaque
SPECIFIC GRAVITY	Refractive index reported quantitatively with a value to 3 decimal places, ranging from 1.000 to1.050 in 0.001 increments
pH	Quantitative pH units
GLUCOSE, PROTEIN, KETONES, UROBILINOGEN	Semi-Quantitatively in mg/dL
BILIRUBIN, BLOOD LEUKOCYTES	Negative, Trace, Small, Moderate or Large
NITRATE	Negative or Positive

Standard Reporting Format – Automated and Manual Microscopic

A microscopic analysis is only performed when the following sieve criteria are met.

Color - other than Yellow or none

Clarity – other than clear

Leukocyte Esterase ≥ trace

Nitrite - positive

Blood ≥ trace

Protein ≥ trace

WBC/HPF	AUTOMATED: 0-182 negative, 0-5, 6-25, 26-100, >100, packed append canned text "**UHW**" ("Unable to perform microscopic due to presence of very large numbers of white blood cells.") **NOTE:** Report clumping
RBC/HPF	AUTOMATED: 0-182 negative, 0-5, 6-25, 26-100, >100, packed append canned text "**UHR**" ("Unable to perform microscopic due to presence of very large numbers of red blood cells.") **NOTE:** Report clumping and dysmorphic RBCs
BACTERIA/HPF	few = approximately 1-10/HPF moderate = approximately 11-100/HPF many = approximately greater than 100/HPF **NOTE:** Each chain or cluster should be counted as one.
CRYSTALS/HPF	few, moderate, many **NOTE:** Identify using references and biochemical tests as necessary. If unable to identify, crystals should be reported as CRYSTALS, OTHER, and a description that includes shape, solubility, birefringence, other identifying characteristics included as a comment.
EPITHELIAL CELLS/HPF	AUTOMATED: 0-182 negative, 0-5, 6-25, 26-100, >100, packed Identify as squamous, transitional, or renal tubular cells.
MUCUS/HPF	few, moderate, many
CASTS/LPF	AUTOMATED: 0-182 negative, 0-5, 6-25, 26-100, >100, packed Identify casts by type seen. **NOTE:** Suspected cellular casts must be classified by cell type. If unable to do so, report number of CELLULAR CASTS/LPF and add the LIS mnemonic "**NODIST**" – "Unable to distinguish cell type." as a comment. Mixed cell casts must have cell types noted in a result comment.
SPERM, TRICHOMONAS, AMORPHOUS SEDIMENT	Report as PRESENT if seen.
YEAST	Report as PRESENT if seen. Report as BUDDING and/or HYPHAE yeast.
OTHER	Comment on the presence of any other elements found.

For manual microscopic result entry see Attachment C.

Confirmatory Test

Sulfosalicylic Acid Test is performed on urines that have both a positive protein result and a pH $\geq$ 8.0. See the individual policy.

Analytical Measurement Range

1. pH is measured from 5.0 to 9.0 in 0.5 increments.
2. Specific Gravity is measured from 1.000 to 1.050 in 0.001 increments, or > 1.050.
3. Microscopic particles are measured by the IRIS iQ200 from **0-182**/HPF, or **0–2857**/LPF

Reference Intervals

Chemistry Results

Color	None - Yellow
Clarity	Clear – Slightly Turbid
Specific Gravity	1.002 – 1.030
pH	4.8 – 7.8
Glucose	Negative
Ketones	Negative
Bilirubin	Negative
Urobilinogen	Negative – 2.0 mg/dL
Protein, Qualitative	Negative – Trace
Blood	Negative
Leukocyte Esterase	Negative
Nitrite	Negative

Microscopic Results

WBC	0-5/HPF	CRYSTALS	
WBC Clumps	Absent	Amorphous	Absent/Present
RBC	0-5/HPF	Calcium Oxalate	Negative-Few/HPF
RBC Clumps	Absent	Uric Acid	Negative-Few/HPF
Dysmorphic RBC	Absent	Triple Phosphate	Negative-Few/HPF
Bacteria	Negative-Few/HPF	Calcium carbonate	Negative-Few/HPF
Squamous Epithelial Cells	0-5/HPF	Calcium Phosphate	Negative-Few/HPF
Transitional Epithelial Cells	0-5/HPF	Leucine	Negative/HPF
Renal Epithelial Cells	0-5/HPF	Cystine	Negative/HPF
Mucus	Negative-Few/LPF	Tyrosine	Negative/HPF
CASTS			
Hyaline Casts	0-5/HPF	Budding Yeast	Absent
Granular Casts	Negative/LPF	Hyphae Yeast	Absent
WBC Casts	Negative/LPF	Oval Fat Bodies	Negative/HPF
RBC Cast	Negative/LPF	*Trichomonas sp.*	Absent
Epithelial Cell Casts	Negative/LPF	Sperm	Absent
Cellular Casts (ID if possible)	Negative/LPF		
Mixed Cell Casts (ID cells)	Negative/LPF		
Waxy Casts	Negative/LPF		
Broad Casts	Negative/LPF		
Fatty Casts	Negative/LPF		

References

1. Iris AX-4280 Operators Manual, Rev D 7/2003

2. Iris iQ200 Operators Manual, Rev B 09/2010

Prepared By	Date Adopted	Supersedes Procedure #
Michael Inn	07/09/2008	New

Revision Date	Type of Revision	Revised by	Review/Annual Review Date	Reviewed By
			07/09/2008	G. Kost
			09/15/2009	G. Kost
			10/12/2010	G. Kost
			11/16/2011	G. Kost
11/18/2012	General revision and update	M. Inn	09/17/2013	G. Kost
12/07/2014	Specimen stability, reference interval, dilution reporting update	kdagang		

URINALYSIS CORRELATION

COLOR VERIFY ABNORMAL COLOR	CORRELATIONS
amber, orange	positive bilirubin pyridium (thick orange pigment, interferes with strip readings) other medications: acriflavine, nitrofurantoin, phenindione
yellow-green/brown	bilirubin oxidized to biliverdin=false negative test for bilirubin
green, blue-green	pseudomonas infection drugs/ingestibles: amitriptyline, robasin, indicant, methylene blue, phenol
pink, red	RBCs, hemoglobin, myoglobin, porphyrins, menstrual contamination, rectal bleeding, ingestibles: rifampin, beets
brown, black	positive blood = RBCs or hemoglobin oxidized to methemoglobin melanin, melanogen, homogentisic acid, phenol derivatives, methyldopa, levodopa, flagyl (often darken on standing)

CLARITY	CORRELATIONS
clear, slightly turbid, turbid, opaque	be sure clarity correlates to particle count/verify visually

REAGENT STRIP TEST	CORRELATIONS
blood	sensitivity = ~10 RBC/uL (~2-3 RBC/HPF), check for RBCs more sensitive to lysed RBCs **FALSE +**: peroxidases (vegetable, bacterial), oxidizing agents (e.g., bleach) **FALSE –**: ascorbic acid, elevated specific gravity, elevated protein
leukocyte esterase	sensitivity = ~25 wbc/uL (~5 wbc/HPF), check for wbcs **FALSE +**: formaldehyde **FALSE –**: glucose >500 mg/dL, protein > 300 mg/dL, low pH, increased specific gravity
nitrite	sensitivity = ~10^5 organisms/mL (nitrate reducing), look for bacteria around squamous cell and mucus images **FALSE +**: old specimen, highly pigmented urine **FALSE –**: non-nitrate-reducing bacteria, ascorbic acid, elevated specific gravity, urine not in bladder at least 4 hours, inadequate nitrate in diet, large numbers of bacteria reduce nitrates to nitrite and then to nitrogen, antibiotics
protein	sensitivity = 10 mg/dL, most sensitive to ALBUMIN, check for casts **FALSE +**: ph > 8.0 (old urine, bacteria), large hemoglobin, disinfectants (quaternary ammonium compounds), contrast media **FALSE –**: pH < 3.0 (physiologically impossible/due to contamination)
glucose	**FALSE +**: oxidizing compounds, pH < 4 **FALSE –**: ascorbic acid

MICROSCOPIC IMAGES	CORRELATIONS and POSSIBLE CONFUSIONS
red blood cells	positive blood, color and turbidity **?? CALCIUM OXALATE, YEAST, AIR BUBBLES, OIL DROPLETS**
white blood cells	positive leukocyte esterase, turbidity check nitrite, check for bacteria, look for trich images check pH and specific gravity (wbcs lyse rapidly in dilute alkaline urine, swell in hypotonic urine) **?? RENAL TUBULAR CELLS, TRICHOMONAS IF LARGE LEUKOCYTE ESTERASE AND FEW WBCS**
squamous epithelial cells	turbidity **?? FOLDED CELLS MAY RESEMBLE CASTS**
transitional epithelial cells (urothelial cells)	**?? SPHERICAL CELL FORMS MAY RESEMBLE RENAL TUBULAR CELLS** **CONFIRM UNDER SCOPE**
renal tubular cells	check leukocyte esterase, nitrite (pyelonephritis) **?? SPHERICAL TRANSITIONAL EPITHELIAL CELLS, WBCs, GRANULAR CASTS** **CONFIRM UNDER SCOPE**
oval fat bodies	turbidity, protein, free fat globules and/or fatty casts **CONFIRM UNDER POLARIZING SCOPE –** maltese cross
hyaline casts	protein **?? MUCUS, FIBERS, HAIR,** use phase, polarizer for fibers
granular casts	protein, check for cellular casts, RBCs, wbc. **?? CLUMPS OF SMALL CRYSTALS ON MUCUS STRAND, AMORPHOUS CRYSTALS ON HYALINE CASTS, COLUMNAR RENAL TUBULAR CELLS** **CONFIRM UNDER SCOPE**
waxy casts	protein, check for other casts, wbcs, RBCs **?? FIBERS, FECAL MATERIAL** **CONFIRM UNDER SCOPE**
RBC casts	blood, protein, RBCs **?? RBC CLUMPS** **CONFIRM UNDER SCOPE**
WBC casts	leukocyte esterase, protein, wbcs, check for bacteria **?? WBC CLUMPS** **CONFIRM UNDER SCOPE**
epithelial cells casts	protein, renal tubular cells **?? WBC CAST**
fatty casts	MUST have large protein, check for free fat, oval fat bodies **?? FECAL MATERIAL** **CONFIRM, POLARIZING SCOPE**
bacteria	nitrite, leukocyte esterase, check pH, wbcs **?? AMORPHOUS CRYSTALS, CHECK IN SQUAMOUS/MUCUS IMAGES** **CONFIRM UNDER SCOPE**
yeast	leukocyte esterase, check glucose and pH, look for wbcs **?? RBCs, CALCIUM OXALATE** **CONFIRM UNDER SCOPE, VERIFY RBC COUNT**
trichomonas	leukocyte esterase, LOOK CAREFULLY IN WBC IMAGES if discrepancy **?? WBCs, RENAL TUBULAR CELLS** **CONFIRM UNDER SCOPE**

IF YOU GET…	BE SURE TO CHECK FOR…
positive blood	red blood cells, if none/few seen, check for low specific gravity
positive LE	white blood cells, bacteria; if no wbc/few wbc seen, check for *Trichomonas sp*. (especially if many squamous cells present)
positive nitrite	bacteria
positive glucose, low pH	yeast
moderate-large protein	casts
red blood cells	positive blood (sensitivity ~2-3/HPF)
white blood cells	positive leukocyte esterase (sensitivity ~5/HPF)
casts	positive protein
red blood cell casts	positive blood, positive protein, red blood cells
white blood cell casts	positive leukocyte esterase, protein, white blood cells
epithelial cell casts	positive protein, renal tubular cells
If you see CELLULAR CASTS, you typically will see the SAME TYPE OF CELLS ELSEWHERE IN THE URINE. If you think you are looking at white blood cell casts, but only renal tubular cells are in the urine sediment, it's more likely to be a renal tubular cell cast. Do not quantify casts under the "cellular casts" category in LIS. IDENTIFY THE CELLS IN THE CASTS, and then quantify the casts in the proper category. Using phase-contrast microscopy and/or Sedi-Stain can be very helpful. If you absolutely cannot identify the cells within the casts, quantify Cellular Casts/HPF and append the canned text comment "**NODIST**" – "Unable to distinguish cell type."	
oval fat bodies, fatty casts	MUST have large protein, maltese cross with polarized light
cholesterol crystals	MUST have large protein, check for fatty casts, oval fat bodies

University of California, Davis Health Systems
Department of Pathology and Laboratory Medicine
Automated Chemistry/Urinalysis

IRIS iQ200 System, Technical Procedure 3340
Attachment B

BAR CODE ID/UA#	SSA	CLINITEST	MICROSCOPIC CHECK			
			WBC	Mucus		
			RBC	Hyaline Casts		
			Bacteria	Granular Casts		
			SQ Epithelial	AMORPHOUS CX		
Place Label Here			TRANS Epithelial	*Trichomonas sp.*		Sperm
COMMENTS	UA CHEM ONLY		RENAL Epithelial	YEAST	Budding	Hyphae
	MICROSCOPIC CHECKED					

BAR CODE ID/UA#	SSA	CLINITEST	MICROSCOPIC CHECK			
			WBC	Mucus		
			RBC	Hyaline Casts		
			Bacteria	Granular Casts		
			SQ Epithelial	AMORPHOUS CX		
Place Label Here			TRANS Epithelial	*Trichomonas sp.*		Sperm
COMMENTS	UA CHEM ONLY		RENAL Epithelial	YEAST	Budding	Hyphae
	MICROSCOPIC CHECKED					

BAR CODE ID/UA#	SSA	CLINITEST	MICROSCOPIC CHECK			
			WBC	Mucus		
			RBC	Hyaline Casts		
			Bacteria	Granular Casts		
			SQ Epithelial	AMORPHOUS CX		
Place Label Here			TRANS Epithelial	*Trichomonas sp.*		Sperm
COMMENTS	UA CHEM ONLY		RENAL Epithelial	YEAST	Budding	Hyphae
	MICROSCOPIC CHECKED					

BAR CODE ID/UA#	SSA	CLINITEST	MICROSCOPIC CHECK			
			WBC	Mucus		
			RBC	Hyaline Casts		
			Bacteria	Granular Casts		
			SQ Epithelial	AMORPHOUS CX		
Place Label Here			TRANS Epithelial	*Trichomonas sp.*		Sperm
COMMENTS	UA CHEM ONLY		RENAL Epithelial	YEAST	Budding	Hyphae
	MICROSCOPIC CHECKED					

BAR CODE ID/UA#	SSA	CLINITEST	MICROSCOPIC CHECK			
			WBC	Mucus		
			RBC	Hyaline Casts		
			Bacteria	Granular Casts		
			SQ Epithelial	AMORPHOUS CX		
Place Label Here			TRANS Epithelial	*Trichomonas sp.*		Sperm
COMMENTS	UA CHEM ONLY		RENAL Epithelial	YEAST	Budding	Hyphae
	MICROSCOPIC CHECKED					

University of California, Davis Health System
Department of Pathology and Laboratory Medicine
Automated Chemistry/Urinalysis

Technical Procedure 3340
Attachment C

URINALYSIS KEYBOARD ENTRY

KEY/RESULT		USE FOR RESULTING:	
MICROSCOPIC RESULTS			
A	0-5	WBC	Hyaline Casts
S	6-25	RBC	Granular Casts
Q	26-100	Squamous Epithelial Cells	WBC Casts
W	>100	Transitional Epithelial Cells	RBC Casts
N	Packed	Renal Epithelial Cells	Renal Epithelial Cell Casts
			Cellular Casts
			Mixed Cell Casts
			Waxy Casts
			Fatty Casts

F	Few	Mucus	Ammonium Urate
M	Moderate	Bacteria	Calcium Phosphate
, (comma)	Many	Calcium Oxalate	Calcium Carbonate
		Uric Acid	Sulfa, other medications
		Triple Phosphate	Crystals, other (describe in result comments)

P	Present	WBC Clumps	Budding Yeast
N	Absent	RBC Clumps	Hyphae Yeast
		Dysmorphic RBCs	*Trichomonas sp.*
		Amorphous Crystals	Sperm

P	Positive	Leucine
N	Negative	Cystine
		Tyrosine

STRIP/CHEMISTRY RESULTS		
P	Positive	Sulfosalicylic Acid
N	Negative	

T	Trace	Occult Blood
S	Small	Bilirubin
M	Moderate	Leukoctye Esterase
L	Large	Nitrites

Numeric Result	
	Specific Gravity
	pH
	Urobilinogen

[F9] Look-Up		
	Collection	Glucose
	Color	Ketones
	Clarity	