

**OLIVE VIEW-UCLA MEDICAL CENTER
DEPARTMENT OF PATHOLOGY
POLICY & PROCEDURE**

**NUMBER: 11845
VERSION: 1**

SUBJECT/TITLE: UA.02 IRIS IQ WORKCELL AUTOMATED URINALYSIS SYSTEM

POLICY: The iQ® 200 System is an in-vitro diagnostic device used to automate the complete urinalysis profile, including urine test strip chemistry panel and microscopic sediment analysis. Optionally, the iQ200 Analyzer can be used as a stand-alone unit, or the results from the iQ200 analyzer can be combined with other urine chemistry results received from an LIS. It produces quantitative or qualitative counts of all formed sediment elements present in urine, including cells, casts, crystals, and organisms. A competent human operator can set criteria for auto-reporting and flagging specimens for review. All instrument analyte image decisions may be reviewed and overridden by a trained technologist.

The iQ200 Series Automated Urine Microscopy Systems (iQ Series) are in-vitro diagnostic devices intended to replace manual or other urine sediment examination methods. Three urine chemistry systems can be connected physically and electronically to an iQ Series to form the iQ200 Series Automated Urinalysis workcell. These urine chemistry systems include the semi-automated Iris iChem100, AUTION MAX™ AX-4030 Automated Urine Chemistry Analyzer and the Iris iChem®VELOCITY™ Automated Urine Chemistry System. The iQ200 workcell is used to automate the complete routine urinalysis profile, including urine test strip chemistry panel, specific gravity, color, clarity, and microscopic analysis. As an iQ200 workcell, the microscopy and chemistry results are combined for review.

PURPOSE: To provide step by step instructions in the performance of urinalysis using the IQ200 and AUTION MAX AX-4030.

DEPARTMENTS: **PATHOLOGY & LABORATORY SERVICES**

CLINICAL SIGNIFICANCE:

Glucose	The presence of glucose in the urine called glycosuria is caused by hyperglycemia or renal condition. Diabetes mellitus is the most common disease resulting in hyperglycemia. Renal conditions causing dysfunction of tubular reabsorption of glucose occur in many conditions including pregnancy.
Protein	The presence of protein in urine is often the first indicator of renal disease, but its appearance in the urine doesn't always signify renal disease. Although proteinuria may indicate nephritic syndrome, multiple myeloma,

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	glomerulonephritis, and pre-eclampsia, a transient mild proteinuria can be present after exposure to cold, strenuous exercise, high fever, dehydration, or an acute phase of a severe illness. The strip is primarily sensitive to albumin.
Bilirubin	The appearance of urinary bilirubin can be a sign of liver disease or extra-or intra-hepatic biliary obstruction.
Urobilinogen	The normal urine has a small amount of urobilinogen (less than or equal to 2.0 mg/dL). The strip is unable to detect a decreased amount, which may appear in infant patients on antibiotic therapy, or patients with obstructive disease. Increased amounts appear in hemolytic anemias and liver dysfunction.
pH	Along with the lungs, the kidneys are the major regulator of acid-base balance. Freshly voided urine has a pH of 5.0 – 6.0. The pH of urine can be controlled by dietary regulation and medication.
Blood	A positive reaction for blood may indicate red cells, hemoglobin, or myoglobin present in the urine. Hematuria can be seen due to bleeding as a result of trauma or irritation (renal calculi, glomerulonephritis, tumors, toxic or chemical exposure). Hemoglobinuria occurs when there is lysis of red cells in the urinary tract, intravascular hemolysis or transfusion reactions. Very dilute or extremely alkaline urine can also lyse the cells. Myoglobinuria indicates muscular destruction that may appear in hypothermia, convulsions, and extensive exertions.
Ketones	Ketonuria appears when there is an increased use of fat instead of carbohydrate as a source of metabolism. Conditions of ketonuria include diabetes mellitus, vomiting, and inadequate intake of carbohydrates due to starvation, weight reduction, or pregnancy.
Nitrites	A negative result during fasting can occur since nitrates will not be excreted into the urine. A nitrite concentration as low as 0.08 mg/dL may be detected and produce a positive test. This test is commonly used in diagnosing urinary tract infections . A positive nitrite test indicates that the cause of the UTI is a gram negative organism, most commonly Escherichia coli . The reason for nitrites existence in the presence of a UTI is due to a bacterial conversion of endogenous nitrates to nitrites. This may be a sign of infection, however, the other parameters such as leukocyte esterase, urine white blood cell count, and symptoms such as dysuria , urinary urgency , fevers and chills must be correlated to diagnose an infection. False negative nitrite tests in urinary tract infections occur in cases with a low colony forming unit count, or in recently voided or dilute urine. In addition, a nitrite test does not detect organisms unable to reduce nitrate to nitrite, such as enterococci , staphylococci , or adenovirus .
Leukocyte Esterase	Normal urine specimens should not produce a positive reaction. Small amounts of leukocyte esterase, causing a positive reaction, should be repeated using a fresh urine specimen, from the same patient. Positive results require further testing for pyuria. This test is commonly used in diagnosing urinary tract infections . Pyuria may be present in the septic patient, or in an older patient with pneumonia . Sterile pyuria is urine which contains white blood cells while appearing sterile by standard culturing techniques. Sterile pyuria is listed as a side effect from some medications such as paracetamol (acetaminophen) . Its occurrence is also associated with certain disease processes, such as Kawasaki Disease and renal TB . However, there are many known causes, including systemic or infectious disease, structural and physiological reasons, intrinsic renal pathology, or drugs.

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PROCEDURE

PRINCIPLE

AUTION MAX AX-4030

The AUTION MAX AX-4030 is a fully automated urinalysis chemistry analyzer intended for the determination of glucose, protein, bilirubin, urobilinogen, pH, blood, ketones, nitrite, leukocytes, specific gravity, turbidity and color-tone. AUTION Sticks 9EB multi-parameter test strips are used with the AUTION MAX AX-4030. The AUTION Sticks 9EB consist of a plastic strip containing nine pads impregnated with chemicals specific for the determination of glucose, protein, bilirubin, urobilinogen, pH, blood, ketones, nitrite and leukocytes. An additional correction pad is included to compensate for the natural color of urine and its effect on the color reactions of the pads. The AUTION MAX AX-4030 utilizes reflectance spectroscopy in combination with AUTION Sticks reagent chemistry to provide qualitative or semi-quantitative results. Specific gravity is determined by refractometry. The specific gravity is corrected for temperature and high concentrations of glucose and protein. Turbidity is determined using transmitted and scattered light. Twenty-three colors are analyzed simultaneously using reflectance values at specified wavelengths.

Chemical Principles of the Test Strips:

Glucose: This test is based on the glucose oxidase–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 with 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.

Nitrite: 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.

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iQ200

The microscopic portion of a routine urinalysis is performed on the iQ200 Analyzer. The iQ200 Analyzer 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 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 (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, normalization factor and the volume scanned. Additionally, 27 predefined sub-classifications are available for identifying specific types of casts, crystals, non-squamous epithelial, dysmorphic, and others.

User defined criteria for the auto-release of results is checked and results are sent either directly to the host computer and/or printer or to the workstation monitor for verification.

Only non-autoreleased specimens will appear on the system screen for verification. The operator may manually reclassify digital images when necessary and in accordance with the laboratory’s policy. Unclassified crystals (UNCX), unclassified casts (UNCC), and non-squamous epithelial cells (NSE) may be further sub-classified during the verification process.

D. SPECIAL SAFETY PRECAUTIONS

STANDARD PRECAUTIONS:

Standard Precautions are to be applied to the handling of all “wet” laboratory specimens, including quality control material. All such specimens are considered potentially hazardous materials. Use safety barrier, face shields or goggles with mask gloves and protective long sleeved garment when handling opened specimen containers. Eye and mucous membrane protection is not mandatory when handling closed specimen containers but may be worn if desired. Dispose of contaminated materials in RED BIOHAZARD waste receptacles ONLY. Dispose of glass and needles in RED SHARPS container ONLY.

E. Specimen requirement and collection:

Refer to Quality Assurance in Urinalysis Procedure (DHS UA 1.xxx)

F. Equipment:

Iris iQ Workcell

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G. Reagents and Supplies:

1. Purified Water with a minimum quality of Type II water.
2. A 1:10 Iris Cleanser solution must be made to clean SG flow cell on AX4030. Using 300 µL Iris Cleanser to 4.70 mL Type II water. It must be made fresh, and discarded after use.
3. **Disposable Test Tubes 16 x 100 (Part No 660-3021):** 250/pack Used for the processing of QC for both AX-4030 and iQ200.
4. **Wash Concentrate (Part No. 79053):** 1 L per bottle; ready to use concentrated solution used in the preparation of the “Working” Wash Solution. Stored at room temperature. Open bottle stability is until the expiration date on the bottle.
5. **“Working” Wash Solution:** Prepared from Wash Concentrate. Stored at room temperature. The stability is 15 days and is prepared as follows:
 - a. Place 1800 mL of deionized water in the “Working” Wash Solution container.
 - b. Add 200 mL of Wash Concentrate.
 - c. Cover with parafilm and mix by inversion.
6. **Aution 9EB Test Strips (Part No. 73627):** 100 per bottle; ready to use strips containing pads that have been impregnated with chemicals used to perform the chemical analysis portion of the urinalysis. Stored at room temperature. Open bottle stability is 31 days in the bottle and 3 days on the instrument.
7. **iQ Lamina (Part No. 800-3102):** 7 L per bottle; 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. Stored at room temperature. Open bottle stability is until the expiration date on the bottle. Note: There is a filter in each case of iQ Lamina. Change the filter when replacing the first iQ Lamina bottle from a new case.
8. **Iris Cleanser (Part No. 800-3203):** 425 mL/bottle; ultra-pure, particle-free hypochlorite solution used to cleanse the instrument. Stored at room temperature. Open bottle stability is the expiration date on the bottle.
9. **Iris Diluent (Part No. 800-3202):** 425 mL/bottle; an isotonic, particle-free fluid used to dilute specimens and rinse the instrument after Iris System Cleanser. Stored at room temperature. Open bottle stability is until the expiration date on the bottle.
10. **Bio-Rad Urinalysis Controls, Level 1 and 2 (Part No. 435):** mL/bottle; supplied in liquid form, requiring no pretreatment or dilution. They are prepared by adding various compounds to human urine so that the desired reaction occurs during quality control. Preservatives have been added to prevent bacterial growth. Stored at 2-8 °C. Open bottle stored at 2-25 °C and stability is 30 days.
11. **iQ Calibrator (Part No. 800-3103):** 125 mL/bottle; ready to use bottles of suspended fixed human red blood cells in a particulate-free, buffered, isotonic balanced solution.

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Stored at 2-8 °C. Open bottle stability is 24 hours. (Each bottle is intended for a single calibration only. Do not save left over material or mix calibration material from different bottle.)

12. **iQ Positive, iQ Negative Controls and iQ Focus (Part No. 800-3104):** 125 mL/bottle; ready to use bottles of suspended fixed human red blood cells in a particulate-free, buffered, isotonic balanced solution. Stored at 2-8 °C. Open bottle stability is 30 days.
13. **SG Calibrator H (Part No. 100672):** 10 mL/bottle; intended for the calibration of the specific gravity measurement system in the Aution MAX AX-4030. Open bottle stability is 24 hours.
14. **Sample tubes:** BD Urinalysis preservative tube, 16x100 mm round bottom plastic tube, KOVA economy tube. The plastic tube should be used for cellular-control material.
15. **Sample Racks/Routine Racks (Part No. 700-3040):** Used to hold specimens for processing through the instrument. They are silk-screened with barcodes representing numbers from 1 – 9 and have the corresponding number on the opposite end. They also have black lines across the front representing 3 and 6 mL fill marks.
16. **QC Racks/Maintenance Rack (Part No. 700-3007):** Used for Chemistry and Microscopy QC: one for the AX-4030 module and one for the iQ Series module.
17. **iQ Calibrator Rack (Part No. 700-3008):** Used for monthly maintenance on the iQ200. The rack is kept as not to be confused with any other rack.
18. **Dilution Barcode Labels (Part No. 800-3211):** Secondary barcodes are available for identifying the dilutions on the iQ Series module. Any specimen that has been diluted must have a dilution barcode in order for the iQ Series module to process results accurately.
19. **Check Strip Set (Part No 1172):** Calibrated test strips to measure reflectance of instrument.
20. **Thermal Paper (Part No. 11721):** 6 rolls/pack; used to record raw data and error codes from the AX-4030. Thermal paper deteriorates over time due to light exposure.

H. Calibration

The AX-4030 and the iQ200 modules have separate calibration materials. Calibrations are performed as part of the maintenance schedule.

Calibration is also performed when:

1. QC shows an unusual trend or shift or are outside of the laboratory's acceptable limits.
2. After major preventive maintenance or change of critical instrument component.
3. When recommended by the manufacturer.

AX-4030 Calibration

Specific Gravity (S.G.) Calibration is performed monthly.

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1. If the instrument is in running mode, press Stop to go to Standby.
2. Low Calibrator: pour 2 mL of deionized water into tube.
3. High Calibrator: pour 2 mL of S.G. Calibrator High into tube.
4. In a sample rack, place Low Calibrator in position 1 and High Calibrator in position 2.
5. On the Standby screen, press S.G. Cal.
6. Enter 1.000 for the Low solution.
7. Refer to the S.G. Calibrator package for the high value and enter it for the High solution.
8. Press OK to save your entries.
9. Press Start to start calibration.
10. Evaluate the printed results:
 - a. SG CAL OK: results are acceptable.
 - b. E120: SG calibration failure. Refer to AX-4030 IFU to troubleshoot.
 - c. Repeat Bio-Rad Level1 and 2 QC.

iQ200 Calibration

The iQ200 calibration is performed monthly.

1. Run iQ Focus
 - a. Place barcode label on tube for Focus.
 - b. Mix Focus by holding the bottle upside down and giving five hard shakes followed by five gentle inversions.
 - c. Allow Focus to set 1 minute until air bubbles are dispersed.
 - d. Pour the following into tubes and place in the iQ200 QC rack:
 - i) Position 1: 3 mL of Iris Cleanser
 - ii) Position 2: 3 mL of Iris Diluent
 - iii) Position 3: 3 mL of Iris Diluent
 - iv) Position 4: Empty
 - v) Position 5: 6 mL of Focus
 - e. Place the rack on the iQ200 sampler and press START.
2. Run iQ Calibration
 - a. Place ten tubes into the Calibration rack.
 - b. Place barcode label for Calibrator on the tube in position 1.
 - c. Mix Calibrator by holding the bottle upside down and giving five hard shakes followed by five gentle inversions.
 - d. Allow Calibrator to set 1 minute until air bubbles are dispersed.
 - e. Pour 3 mL of Calibrator into each tube.
 - f. Place the rack on the iQ200 sampler and press START.
 - g. After successful calibration, the date/time and new REF value will be displayed in the Last Calibration field on the Instrument screen.
 - h. Repeat Focus, and Positive and Negative controls.

I. Quality Control

Quality control materials are to be assayed daily as part of the daily maintenance for both the AX-4030 and the iQ 200 modules, (weekly for evening and night shifts), or as needed for instrument troubleshooting.

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AX-4030 Instrument

1. In the AX S/CTRL rack:
 - a. Transfer 3.0 mL of Bio-Rad Liquicheck Urinalysis Control Level 1 into a tube and place in position 8.
 - b. Transfer 3.0 mL of Bio-Rad Liquicheck Urinalysis Control Level 2 into a tube and place in position 9.
2. Place the rack on the right side of the AX-4030. If the instrument is in Standby, push the Start button.
3. Evaluate the printed results.

New lot of AX-4030 Controls

New lots of controls should be checked against the insert ranges before being put into use.

1. Verify that the current lot of QC has passed.
2. On the Instrument screen, click on Consumables to change the control lot information to the new lot.
3. Run the new lot of controls.
4. Verify that the new lot is acceptable.
5. Change the lot back to the current lot if desired.

AX-4030 – New lot of AUTION 9EB Strips:

New lots of AUTION 9EB Strips should be checked against the previous lot before being put into use. To update the lot information: on the Instrument screen, click on Consumables to change the Test Strip lot information.

iQ200 Instrument

1. Bring controls to room temperature before use.
2. Place barcode labels on tubes for Focus, Positive and Negative.
3. Mix Focus and Positive control by holding the bottle upside down and giving five hard shakes followed by five gentle inversions.
4. Focus and Positive Control to set 1 minute until air bubbles are dispersed.
5. Do not mix the Negative control.
6. Pour the following into tubes and place in the iQ 200 QC rack:
 - a. Position 1: 3 mL of Iris Cleanser
 - b. Position 2: 3 mL of Iris Diluent
 - c. Position 3: 3 mL of Iris Diluent
 - d. Position 4: Empty
 - e. Position 5: 6 mL of Focus
 - f. Position 6: 3 mL of Positive control
 - g. Position 7: 3 mL of Negative control
7. Place the rack on the iQ 200 sampler and press START.
8. Evaluate the printed results.

New Lot of iQ200 Controls

Parallel testing between the old shipment/lot number and the new shipment/lot number ensures that the system is operating within acceptable criteria.

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1. To run the new control materials in parallel, add the following tubes to the regular QC run:
 - a. Position 8: 3 mL of new lot Positive control
 - b. Position 9: 3 mL of new lot Negative control

2. QC Correction Action

- a. When a QC result is out of range (exceeds the manufacturer limits) or if the supervisor notes a shift or trend, corrective action must be taken and documented. Follow one or more of the general steps defined steps below:

Troubleshooting Steps
Rerun the control using the same bottle of control material.
Rerun QC using a sample from a new bottle of control material.
Control run in wrong rack or wrong position in rack.
Wrong control, rerun with correct control.
Check QC and reagent lot numbers/expiration date.
Rerun with correct lot number.
Recalibrate assay, run QC.
Check test strips integrity/expiration date.
Troubleshoot and document in action log.
Instrument malfunction, perform corrective action. Run QC.
Call for service, document ref. no. on communication board and in action log.
Instrument not in use, no patient testing performed.
Notify supervisor or designee.

- b. If necessary, repeat the affected patient test(s).
- c. Previously tested results should agree and fall within one grade, or +/- 0.005 for specific gravity.
- d. Document steps taken, once the QC has successfully passed, in the corrective action taken when approving/releasing the outlier QC results in ARE.
- e. When the controls are still out after corrective action, the analyzer must not be used until it is fixed and the controls are within acceptable limits.

B. SPECIMEN ACCEPTABILITY AND REJECTION

Refer to Quality Assurance in Urinalysis Procedure (DHS UA 1.xxx)

C. PROCEDURE

Instrument Logon

1. Access the Instrument screen.
2. Click on the Logon button.
3. Click on the down arrow.
4. Select your identifier.
5. Enter your password and click OK.

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Instrument Operation

1. Ensure that sufficient supplies and consumables are loaded.
2. Place rack with specimens on the right side of the AX-4030 if the sample is to run on both instruments.
3. Ensure that the notch of the rack base is placed onto the Sampler track ridge.
4. The remainder of the processing is performed automatically on the system.
5. The sample rack will be moved along the sample transport tray to the barcode reader.
6. The iQ200 Analyzer barcode reader reads the specimen barcode.
7. After sample processing is complete, unload the sample racks from the left side of the iQ200 Analyzer.

Reviewing Instrument Results

AX-4030 Instrument

1. The AX-4030 module has an on board thermal printer that will print the results of the chemistry portion of the urinalysis.
2. This may be reviewed by technical personnel as needed.
3. A sample with normal chemistry results, that does not need a microscopic examination, will have results transmitted to the host computer.
4. The specimen can then be verified at the LIS following the Laboratory's Reporting Procedure.
5. If the sample is abnormal or has flagged results that meet the criteria requiring a microscopic examination, the chemistry results can be reviewed at the workstation along with the microscopic findings.

Microscopic examination will be performed for the following conditions:

Glucose: 1000 or >1000 mg/dL
Blood: Trace, Small, Moderate or Large
Protein: 30, 50, 70, 100, 200, 300, 600 or >600 mg/dL
Leukocytes: Trace, Small, Moderate or Large
Nitrite: Positive
Clarity: Cloudy or Turbid
Specific Gravity: >1.040
Patient Age: <30 days
Patient Registered Location: See APPENDIX A
Dipstick is UNREADABLE

iQ200 Instrument

1. If a specimen has an abnormal microscopic result, it will not be auto-released to the host computer. The results must be reviewed at the workstation monitor.
2. For quick verification, click on "Work List".
3. This brings up the Work List screen, which contains all unreleased specimen results.
4. On this screen, a specimen may be deleted or undeleted.
5. The default list arrangement order is by: 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.

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6. To review a specimen result, double click on the specimen barcode 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.
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 abnormal threshold that is user-defined.
10. If flags are displayed on the lower right side of the screen, they must be acknowledged before any particle type detail can be reviewed.
 - a. Click on “Review Flagged Specimen”.
 - b. Then click on “ACCEPT”.
 - c. If “Auto-Release” has been enabled and the only parameter preventing auto-release is the flag, the result will be auto-released as soon as the flag is cleared. If the specimen results do not meet the laboratory’s criteria for auto-release, the specimen will be moved to the Work List in the time slot it would have occupied, had it not had a flag.
 - d. It is most efficient to handle all flagged specimens first, then move on to the regular timed list.
11. In the Specimen screen, color indicators are used to show which categories need review.
 - a. Green: Results are below the minimum verification value and are accepted as Normal.
 - b. Yellow: Results are within the particle verification range or have exceeded the measuring range, and need to be reviewed by the operator.
 - c. Red: Results are above the maximum verification value and are accepted as Abnormal.
12. To review the yellow categories, click on the “Edit” button.
13. Images of the particles of the first yellow category will be displayed. Note: there may be multiple pages of the same particle type.
14. If the classification of particles is acceptable, continue the verification by clicking on the right arrow to move forward. **Classification is acceptable if more than 50% of the particles have been classified correctly.**
15. Re-visit the WBC, Mucus, Epithelial pictures particle buckets for the presence of bacteria (especially cocci bacteria), especial if ASP events exceeds 7500/uL. See manufacturer job aid “Suggested Bacteria Grading Chart” to help estimate the relative bacteria concentration.

Grading Bacteria:

 - a. One or two bacteria in the total background or one or two bacteria in individual isolated images = Trace. This value is reported as negative!
 - b. More bacteria than above but not in ½ of backgrounds = few (1+).
 - c. Bacteria in ½ backgrounds = moderate (2+).
 - d. Bacteria in most of the backgrounds = many (3+)
16. If the sample is cloudy/turbid with amorphous precipitate, it may make estimating cocci bacteria difficult. If the bacteria count is negative (the IQ200 will only detect rod bacteria >3.0 microns), It may be necessary to warm the sample at 37 degrees C for 20-30 minutes and retest sample. Be sure to perform a manual microscopic analysis if there are other indicators of infection like WBCs >10, Leukocyte Esterase, and/or Nitrite positive chemistries.

Note:

- i. Cocci Bacteria are nitrite negative.

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- ii. Lymphocytes are leukocyte esterase (LE) negative, and LE is usually detected in urine with 10-25 WBC/hpf. Fewer WBCs may be negative for LE.
 - iii. Alkaline or hypotonic urine (<1.010 specific gravity) can increase WBC lysis, increasing presences of LE, even in the presence of few or no detectable WBCs.
17. Always reclassify particles appearing in UNCX, NSE and UNCC categories.
 18. Important: If images are left in the NSE and UNCC particle bucket the data will not cross into the patient report!
 19. UNCL category – check for the following (do not apply the 50% rule)
 - a. Renal epithelial cells
 - b. Transitional epithelial cells
 - c. Casts
 20. Be sure to classify a particle or formed element if it is not defined in the list of particles. For example, if yeast is found in UNCL and is not defined in the list of particles, reclassify them.
 21. Re-visit the WBC pictures for the presences of Trichomonas. It best detected by the presences of a flagellum and the characteristic shape & placement of nucleus. Note: Trichomonas is best recognized in fresh urine (<2 hrs at room temperature) by its mobility. Trichomonas must be confirmed by manual microscopic review.
 22. If the classification of particles is unacceptable, follow Subclassifying or Reclassifying Particles steps below.
 23. Continue verifying until you return to the Specimen screen.
 24. If everything is acceptable, click on the “ACCEPT” button at the bottom right of the screen. The results will be transmitted to the host computer.
 25. Verify the results in the LIS following the Laboratory Results Reporting Procedure.

Sub-classifying or Reclassifying Particles

1. If more than 50% of the images in the category are classified incorrectly, reclassify the particles to another category or place into the artifact category.
2. To reclassify, click on the particle type category that an image is to be sub-classified or reclassified into.
3. Then click on the image(s) to be moved.
4. This transfers the image to the chosen category. Note: if you click on an image in error, re-click on same space to return the image to the screen.
5. If images are grouped together, they can be moved at one time. Use the “click and drag” feature to move images.
6. If all particles in a category must be sub-classified or reclassified into the same category, click on the category that the particles will be sub-classified or reclassified into and then click on arrow in the top right corner of the screen. This will move all images on the screen into the chosen category [indicated by the lit button on the right]. This saves the time and effort of clicking on the individual images.
7. When images are to be sub-classified or reclassified, but are NOT to be moved to the same category, move the fewest images individually. Then choose the category for the rest of the images and click on the arrow in the top right corner of the screen.

Example: You are reviewing UNCC (unclassified casts). A couple 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 click on the GRAN button. This

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will reclassify the remaining particles as granular casts. Then click on the arrow in the top right corner of the screen.

8. After a specific particle is sub-classified or reclassified, if the remaining images on the screen are to remain in the original category, click on that category at the upper left corner. This retains all the images on the screen in their original category. If you do not, all the images on the screen will go to whichever category is highlighted.
9. When the verification process is through, return to the Specimen screen by clicking on the Results button at the bottom or by continuing through the all of the screens using the right arrow in the top right corner.
10. Verify the results.
11. Once all classification is acceptable, click on the “ACCEPT” button at the bottom right of the screen.
12. Verify the results in the LIS following the Laboratory Results Reporting Procedure.

Criteria for Manual Microscopic Review

The presence of the following elements require a manual microscopic review for identification and confirmation:

1. Oval fat bodies – confirm using polarized light microscopy.
2. Fat – confirm using polarized light microscopy.
3. Trichomonas – confirm presence of flagella by motility.
4. Any cellular cast to identify the cell type if the cell type is questionable.
5. Sperm - Refer to Previous Sample Had Sperm under error codes.
6. Amorphous precipitate – May cloud the identification of cocci bacteria, given other markers of bacterial infection are present.

Urine Culture Indicator Checklist

1. Locate the Urine Culture Indicator Checklist on the Specimen screen.
2. One or more abnormal particles/chemistries indicate the possible presence of bacteria.
3. Look for bacteria within the backgrounds of the WBC, WBCC, SQEP and MUCS classifications. The visual quantification is the same as what is used for manual microscopy and can be reported as Few/Moderate/Many.
4. Bacteria <3 microns in size are too small to be automatically identified by APR and require an operator to identify and grade manually.

Putting Sample on Hold

The iQ200 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 a particle has been reclassified.

1. In the Specimen screen, click on the Edit button.
2. Images of the particles of the first yellow category will be displayed. Note: there may be multiple pages of the same particle type.
3. Verify the sample as usual. If you need to leave this specimen before the verification process is complete, click on the Results button.
4. Click on the “**Hold**” button. This will save the changes that have been made and return this specimen to the Worklist.

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5. When ready to further verify this specimen, highlight it on the Worklist and click on Specimen.
6. All changes previously made will still be present. Continue to verify the specimen and click on “ACCEPT” when complete.

Manual Orders

1. The iQ Series allows the user to use Manual Orders in situations where a barcode is not available [example: LIS downtime]. Patient identification can be entered and rack positions for each sample selected. **Manual Order capability applies to only the iQ Series and not the AX-4030.**
2. From the Instrument Screen, click on Manual Orders.
3. Click on the rack button that corresponds to the rack the specimens will be placed in.
Enter:
 - a. “Specimen Identifier”.
 - b. “Fluid Type”.
 - c. “Dilution code, if one is needed.
4. The fourth field will change to ‘Run’ automatically.
5. Repeat steps 3-4 for each specimen to be run for the selected sample rack [Note: up to 10 specimens can be entered per rack].
6. Continue to select additional racks and enter patient information until all have been entered.
7. Click ‘OK’ to save manual entries or ‘OK & Print’ to save entries and print a worklist
8. Return to the Instrument screen.
9. Load specified racks with specimens according to the manual order worklist.
10. Run racks on iQ System.
11. Verify specimens as usual.

Dilutions on the iQ200

Samples that are dense, viscous, short in volume (< 3 mL) or exhibit gross hematuria must be diluted before performing testing on the iQ200 module.

Specimens exhibiting gross hematuria cannot be assayed on the AX-4030.

Dense, viscous samples and short sample specimens must be run *without dilution* on the AX-4030 and must be diluted prior to being run on the iQ200 module. It is possible that specimens having sufficiently high particle counts may clog the flow cell. Very viscous specimens may require examination via conventional slide microscopy.

Amorphous samples can be diluted if the chemistry does not match the microscopic result or if there is a concern that amorphous crystals are covering other cells.

If microscopy is indicated for urine samples that are sent with < 3 mL, identify if there is sufficient amount of sample for an acceptable dilution on the iQ200.

Reminder: Do not run diluted specimens on the AX-4030 module.

How to Perform Chemistry Testing and a Microscopic Dilution Using Barcodes

1. Fix identical patient barcodes onto two separate tubes.

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2. Pour 3 mL of well-mixed urine into one tube.
3. Place this tube in the orange rack (rack number 23).
4. Run on the AX-4030. This rack does not need to be removed before going through the iQ module.
5. Label the second tube with an appropriate secondary dilution barcode below the primary barcode.
6. Prepare the dilution in this tube using Iris diluent, making sure the total volume will be at least 3 mL.
7. Place the diluted tube in a normal sample rack.
8. After the orange rack has crossed the bridge, add the sample rack containing the diluted sample on right side of the IQ module.
9. The Chemistry and Microscopic results will merge automatically.
10. Verify results as usual.

How to Process Grossly Bloody Urine Specimens

1. Before running the sample, prevent autoverification for the accession in the LIS.
2. Note color and clarity of original sample.
3. Fix identical patient barcodes onto two separate tubes.
4. Centrifuge enough urine to obtain 3 mL of supernatant and pour into one tube.
5. Place this tube in the orange rack (rack number 23).
6. Run on the AX-4030. This rack does not need to be removed before going through the IQ module.
7. Label the second tube with the appropriate secondary dilution barcode below the primary barcode.
8. Use the following dilution code Barcodes:

Barcode	Dilution
1	1:2
2	1:2
3	1:3
4	1:3
5	1:3
6	1:6
7	1:6
8	1:10
9	1:10

9. Prepare dilution in this tube using Iris diluent, making sure that the total volume will be at least 3 mL.
10. Place the diluted tube in a normal sample rack.
11. After the orange rack has crossed the bridge, add the sample rack containing the diluted sample on right side of the IQ module.
12. The Chemistry and Microscopic results will merge automatically.
13. Verify results as usual.
14. When releasing the results in the LIS:
 - a. Report the color and clarity of the original sample.
 - b. Include comment that “Grossly bloody specimen received, chemical analysis and specific gravity were performed after the sample was centrifuged.”

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- c. Note: If the supernatant is too deeply colored to be read, report the dipstick results as UNREADABLE.

How to Perform Chemistry Testing and a Microscopic Dilution When Barcodes Not Available

1. Put the iQ Elite Offline.
2. Fix identical patient barcodes onto two separate tubes.
3. Pour 3 mL of well-mixed urine into one of the tubes.
4. Prepare a dilution in the other tube.
5. Set the diluted sample aside.
6. Place the undiluted tube in a sample rack.
7. Run on the AX-4030.
8. The chemistry results will be displayed in the Work list with ID ERROR.
9. Click on the Instrument screen and click on Manual Orders.
10. Choose the rack number that will be used to run the diluted specimen.
11. Fill in the fields: Specimen Identifier, URN dilution code number, work order “run”.
12. Click OK or OK & Print.
13. Place the diluted specimen into the designated position within the designated rack.
14. Place on the iQ200 and press Start.
15. To merge the chemistry and microscopy results, click on the ID ERROR sample in the Work List.
16. The Specimen screen will show that an ID Flag must be resolved.
17. Click on “Review Flagged Specimen”.
18. A Pop-up window will appear prompting you to enter a “Specimen Identifier”.
19. Enter the same patient’s Specimen ID that you entered when creating Manual Orders.
20. Check the “Consolidate Chemistry and Microscopy” check box.
21. Click OK.
22. Click “ACCEPT” to consolidate the two results.
23. Verify results as usual.

How to Run a Microscopic Dilution without repeating Chemistry Testing

1. Write down the Specimen ID of the patient’s specimen you are working with.
2. From the Work List, double-click on the patient’s Specimen ID [on the Work List screen].
3. The Specimen screen will appear.
4. Click “Other”.
5. A pop-up window will appear.
6. Select “Separate Chemistry and Microscopy Results”.
7. Click “ACCEPT” [to separate chemistry and microscopy results].
8. The Microscopic and the Chemistry portions of the result will now appear as two separate entries on the Work List [both labeled with same Specimen ID].
9. Double-click on both entries to determine which entry contains the Chemistry result and which contains the Microscopic result.
10. Highlight the correct Specimen ID and the correct result portion.
11. Delete the microscopic portion only.
12. Make the appropriate dilution of the patient’s sample.
13. Identify the sample and the dilution code [either by using barcodes or through manual orders].
Note: The Specimen ID of the diluted sample must match the Specimen ID of the Chemistry portion.

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14. Run the sample on the iQ200.

15. The Chemistry results will now consolidate with the new Microscopic results.

iQ Error Codes

Besides visual inspection of a specimen to determine if a dilution is needed, a sample that has the following alarm displayed on the results in the Results Screen may need a dilution or to be repeated.

1. HIGH CONCENTRATION FLAG

a. CAUSE

i) Often caused by a very turbid specimen. There is a high possibility of carry-over to the next sample. Also, the instrument will truncate the analysis by reducing the volume tested once 10 MB of data is collected. This will increase the chances of missing particles in low concentration.

b. REMEDY

i) This flag could be cleared. Particles should be placed into various APR categories. Edit as usual. If the microscopic results do not match the chemistries rerun the sample:

- Undiluted on the AX 4030, and
- Diluted (be able to partially see thru sample) before placing the sample onto the IQ 200.

2. SEQUENTIAL FLAGS

a. CAUSE

i) The iQ Series instrument checks for ongoing problems by monitoring certain flags. If any one of the monitored flags occurs in all three of the last samples run, the alarm is raised and 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. To avoid wasted specimen and iQ Lamina, the instrument will stop until the problem is solved.

b. REMEDY

- i) Select "Delete Flagged Specimen" to remove the results from the Work List.
- ii) Check the last three sample results in the Work List to determine the error that has caused the sequential flag.
- iii) If the error is IMAGE ACQ, check the connection on the large cable connecting the iQ Series Camera to the Results Processor.
- iv) In all cases: Run an iQ QC rack with Iris System Cleanser, Iris Diluent, iQ Focus, iQ Positive and iQ Negative controls.

3. FLOW

a. CAUSE

i) The flowcell may be obstructed. Unless this triggers a Sequential error you may monitor further occurrences and simply re-run the specimen.

b. REMEDY

- i. Select "Delete Flagged Specimen" to remove the results from the Work List.
- ii. 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, what dilution to make.
- iii. Run a control rack with Iris System Cleanser and Iris Diluent
- iv. Re-run the specimen.

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4. CLOG
 - a. CAUSE
 - i. The fluidic system may be obstructed. Unless this triggers a Sequential error you may monitor further occurrences and simply re-run the specimen.
 - b. REMEDY
 - i. Reject the flag to remove the results from the Work List.
 - ii. Run a control rack with Iris System Cleanser and Iris Diluent.
 - iii. 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, what dilution to use.
5. CARRYOVER
 - a. CAUSE
 - i. This flag may occur on the sample following a Runfile Overflow or High Concentration flag. The sample that caused the carryover error on the flagged sample i.e., the specimen that ran before the flagged sample, may need to be diluted. In the following remedy section the Runfile Overflow or High Concentration flagged specimen is referred to as Specimen #1 and the Possible Carryover? Flagged specimen is referred to as Specimen #2.
 - b. REMEDY
 - i. Clear the flag.
 - ii. Open Specimen #2 to the Results screen and review the results. If they are all normal, release the specimen as usual as no significant carryover has occurred.
 - iii. If some results are abnormal, compare the abnormal results in Specimen #2 to the chemistry results from the previous specimen, Specimen #1. If Specimen #2 contains a high particle count that was also present in Specimen #1, Specimen #2 should be re-run.
 - iv. Particles that may cause a Runfile Overflow or High Concentration with no correlation on the Chemistry result are crystals and yeast. If a Possible Carryover sample shows low abnormal yeast particles, the decision should be delayed until Specimen #1 is ruled out for yeast.
 - v. A tube containing Iris Diluent may be run to eliminate carryover on subsequent specimens.
6. Previous Sample Had Sperm

Reusable probes can have carryover issues, especially when dealing with a sticky substance such as sperm. As a result, subsequent tubes may contain sperm from a previous specimen. Such carryover can result in a reportable event depending on the age and gender of the individual from which the contaminated sample came from.

Before verifying results, operators must acknowledge and take action to clear the flag:

- a. When the patient is a female ≤ 13 yrs old or male ≤ 9 years old, correlate the acceptability of the result findings.
- b. Any low level detection of sperm in the specimen immediately following the specimen with a high concentration of sperm should be considered a suspicious sample.

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- c. For suspicious samples, users should retrieve the original specimen container and re-test to confirm presence of sperm.

7. Alarm #7

- a. Review Primary Negative Control Failed: Causes and Remedies.
- b. If it appears the fluidic sub-system is dirty place onto the instrument the control Rack with three tubes of cleaners and three tubes diluents placing the first cleaner tube in position 1. Be sure to put in at least 3.0 mL in each tube.
- c. Repeat the normal controls per the order defined in the QC section of this SOP.
- d. If this fails clean the filter on the IQ 200 or replace the filter.
- e. Document issues in the appropriate corrective action log.

Result of OVER for Glucose or Protein

If a sample has a result of “OVER” for Glucose or Protein, the chemistry results will not automatically transmit to the LIS due to the CHEM CONFIRM flag.

Clear the flag to review the sample.

Verify results as usual. This will transmit the chemistry results to the LIS.

From the Work List screen, select Search.

Search for the sample that was verified.

In the Found List, highlight the sample to be transmitted and select Re-Report.

In the Destination section, uncheck “Screen” and check “LIS”. Select OK. This will transmit the microscopy results to the LIS.

Select Search to return to the Work List.

Result of OVER for Specific Gravity

If a sample has a result of “OVER” for Specific Gravity, the chemistry results will not automatically transmit to the LIS due to the CHEM CONFIRM and CHEM TRANSLATE flags. The results will also not be autoverified in the LIS due to this result.

1. Clear the flags to review the sample.
2. Verify results as usual. This will transmit the chemistry results to the LIS.
3. From the Work List screen, select Search.
4. Search for the sample that was verified.
5. In the Found List, highlight the sample to be transmitted and select Re-Report.
6. In the Destination section, uncheck “Screen” and check “LIS”. Select OK. This will transmit the microscopy results to the LIS.
7. Select Search to return to the Work List.
8. Retrieve the results in Result Entry. The results should be in Performed status.
9. Confirm the Specific Gravity of the sample by manual refractometer or other validated method.
 - a. If the Specific Gravity is 1.045 or less, enter the value manually with a comment stating how the result was obtained:
 - i. UASGREF – Specific gravity performed by Refractometer.
 - ii. Or other validated method used.
 - b. If the Specific Gravity is confirmed to be >1.045, enter the value manually with a comment stating how the result was obtained:
 - i. UASGREF – Specific gravity performed by Refractometer
 - ii. Or other validated method used.

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- c. If the Specific Gravity cannot be determined, convert the result to Free Text with the result reading See Comment and add the following comment:
 - i. Unable to determine Specific Gravity. Extremely high specific gravity values (above 1.050) may be seen in patients who have recently had urinary tract diagnostic studies that use iodine-containing X-Ray contrast media.
10. Verify the results in Result Entry.

Instrument Shutdown / Restart

- 1. Select "Go Off line".
- 2. From the instrument screen, select Maintenance, then Shutdown. When the confirm window appears, select Yes.
- 3. Press the Power button on the bottom left of the iQ module.
- 4. Press the Power button on the bottom left of the AX module.
- 5. Start the PC Module.
- 6. When the Instrument screen is displayed, press the Power button on the bottom left of the iQ module and the Power button the bottom left of the AX module.

Instrument Quality Control (QC) and Preventative Maintenance (PM)

Consult the manufacturer user guide for instructions regarding the QC and PM.

AX-4030

Daily:
Clean Instr. Surface (1:10 Cleaner)
Clean Strip Waste box (alcohol)
Check Washing Solution Level
Run Bio-Rad Urine Controls L1 & L2. Use "AX S/CTRL" Rack Positions 8 & 9.
Every 3 Days:
Clean Test Strip Stopper
Clean Strip Feeders
Replace Strips
Wash Introduction Tray. Soap and Water or Alcohol. Dry Completely!
Weekly:
Perform S.G. Cell Wash using 1:10 Bleach
Clean Transport Tray. Soap and Water or Alcohol. Dry Completely!
Every 2 Weeks (If Needed):
Replace Washing Solution
Monthly:
Clean the Wash Bath

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Replace the Washing Solution Filter/O-ring
Clean Air filter
S.G. Cell Calibration (Attach Results to Chart): Cal. Lot #: _____ Exp. Date: _____. Attach Print out from AX4030 to this form.
As Needed Maintenance:
Replace Printer Paper
Replace the Drain Pinch Valve Tube
Replace White Paper
Check Measurement

iQ200

Daily:
Check Lamina Supply
Clean Instrument (1:10 Cleaner)
Run Focus, Pos. & Neg. Controls Using the "IQ CTRL" rack.
Monthly:
Perf. Instr. Calibration Cal. Lot #: _____ Exp.Date: _____ REF#: _____. Use the "IQ CAL" Rack. Please label first tube, fill rack with 10 aliquots of CAL.
As Needed Maintenance
Replace Filter Every Case of Lamina (Filter is placed in Every Case). Lot #: _____ Exp. Date: _____
Clean Sample Filter
Clean Rinse / Waste Bath
Clean Sample Tube Detector
Clean Barcode Reader Window
Clean Optical Sensors

B. TEST CALCULATIONS

Not applicable.

C. REPORTING RESULTS / INTERPRETATION OF RESULTS

Test			Units
Glucose	Semi-quantitative	Negative, 30, 50, 70, 100, 150, 200, 300, 500, 1000, >1000	mg/dL
Protein	Semi-quantitative	Negative, Trace, 30, 50, 70,	mg/dL

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		100, 200, 300, 600, >600	
Bilirubin	Semi-quantitative	Negative, Small, Moderate, Large	-
Urobilinogen	Semi-quantitative	<2.0, 2.0, 3.0, 4.0, 6.0, 8.0, 12.0, >12.0	mg/dL
pH	Quantitative	5.0, 5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0	-
Blood	Semi-quantitative	Negative, Trace, Small, Moderate, Large	-
Ketone	Semi-quantitative	Negative, Trace, 10, 20, 40, 60, 80, 100, 150, >150	mg/dL
Nitrite	Semi-quantitative	Negative, Positive	-
Leukocytes	Semi-quantitative	Negative, Trace, Small, Moderate, Large	-
Clarity	Quantitative	Clear, Cloudy, Turbid	
Color		Colorless, Yellow, Orange, Amber, Brown, Red, Violet, Blue, Green. In addition, a "Light" or "Dark" designation will be indicated with the colors as indicated. The color may be changed in the LIS to reflect the appropriate color, if needed.	
Specific gravity	Quantitative	1.001 to 1.045 in 0.001 increments	

- RBCs and WBCs are reported as cells counted per HPF
- WBC clumps are reported as None Seen or Present per HPF
- Squamous, Transitional and Renal epithelial cells are reported as cells counted per LPF
- Bacteria are reported as None Seen, Few, Moderate or Many per HPF
- Crystals are reported by type and as None Seen, Few, Moderate or Many per LPF
- Casts are reported by type and as casts counted per LPF
- Yeasts (budding or pseudohyphae) are reported as None Seen or Present per HPF
- Sperm, Trichomonas are reported as None Seen or Present per HPF.
- Oval Fat Bodies are reported as None See or Present per LPF.
- Mucous is reported as None-Few, Moderate or Many per LPF.

Manually Reporting Results

If results must be manually result into the LIS, the following tests are translated as follows:

Test									
Bilirubin	Instrument:	0.5	1.0	2.0	3.0	4.0	6.0	10.0	>10.0
	LIS:	Few		Moderate			Many		
Blood	Instrument:	0.03		0.06	0.10		0.20		0.50
	LIS:	Trace		Few			Moderate		Many
Leukocytes	Instrument:	25		75			250		500
	LIS:	Trace		Few			Moderate		Many

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If the following are identified in the patient sample, the results must be manually entered using the drop down choices provided in ARE. See above for choices that are available.

Particle/Formed Element
UA Am Biur Crys
UA Amorph PO4
UA Amorph Urate
UA Ampicil Crys
UA Bacti Casts
UA Bili Crystal
UA Ca Sulf Crys
UA Cast
UA Chol Crystal
UA Coarse Gran
UA Crystals
UA E vermicular
UA Fine Gran
UA HGB Casts
UA Hipp Crys
UA Hyalwgran
UA MX Cell Cast
UA Other
UA RTE Casts
UA S haematobiu
UA Sod Urat Cry
UA Sulfa Crys
UA Xray Dye

REFERENCE interval / critical values / Linearity

Reference Intervals

<u>Chemistry results</u>	<u>Range</u>	<u>Units</u>
Glucose	Negative	mg/dL
Protein	Negative	mg/dL
Bilirubin	Negative	
Urobilinogen	< 2.0	mg/dL
pH	5.0 – 8.0	
Blood	Negative	
Ketones	Negative	mg/dL
Nitrite	Negative	
Leukocyte Esterase	Negative	
Specific Gravity	1.005 – 1.030	

Microscopic Results

	<u>Range</u>	<u>Units</u>
RBC	Male: 0 – 2 Female: 0 – 3	/HPF /HPF
WBC	0 – 3	/HPF

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Bacteria	None Seen	/HPF
Squamous epithelial	0 – 3	/LPF
Transitional epithelial	0 – 3	/LPF
Renal epithelial	None Seen	/LPF
Hyaline casts	0 – 4	/LPF

Critical Values

None.

Analytical Sensitivity and Measurement Range

Reagent Pad	Analytical Sensitivity	Measurement Range
Glucose	30 mg/dL	30 – 1000 mg/dL
Protein	10 mg/dL	10 – 600 mg/dL
Bilirubin	0.5 mg/dL	0.5 – 10.0 mg/dL
Urobilinogen	2.0 mg/dL	2.0 – 12.0 mg/dL
pH	0.5 unit within pH range of 5.0-9.0	pH 5.0 – 9.0
Blood	Hemoglobin 0.03 mg/dL Erythrocyte ~10 Ery/uL	Hemoglobin 0.03 – 1.0 mg/dL
Ketones	Acetoacetic acid 5 mg/dL	5 – 150 mg/dL
Nitrite	Nitrite 0.08 mg/dL	0.08 – 0.5 mg/dL
Leukocytes	Approximately 25 Leu/uL	25 – 500 Leu/uL

Specific Gravity is measured from 1.001 to 1.045 in 0.001 increments.

Microscopic particles are measured from 0–1000/uL, 0-2900/LPF, & 0–182/HPF. Review if linearity is exceeded. An exception to this is UNCL.

E. LIMITATIONS

Analyte	Causes of false negative results	Causes of false positive results
Glucose	<ul style="list-style-type: none"> Large amount of ascorbic acid 	<ul style="list-style-type: none"> Oxidizing substances such as hypochlorite and chlorine Urine with a pH < 4.0
Protein	<ul style="list-style-type: none"> Urine with pH < 3.0 	<ul style="list-style-type: none"> Urine with large amount of hemoglobin Contrast medium Disinfectants including quarternary ammonium compounds Urine with pH > 8.0
Bilirubin Unstable at room temperature and in light	<ul style="list-style-type: none"> Ascorbic acid, uric acid and nitrite 	<ul style="list-style-type: none"> Urobilinogen Etodolac
Urobilinogen Urine with high bilirubin causes development of green color		<ul style="list-style-type: none"> Carbapenem. Bilirubin
pH Old urine increases in alkalinity		
Blood	<ul style="list-style-type: none"> Urine with elevated specific gravity Urine with elevated protein Large amount of ascorbic acid 	<ul style="list-style-type: none"> Presence of oxidizing substances such as chlorine or hypochlorite

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Ketones		<ul style="list-style-type: none">• L-Dopa, BSP, PSP, Phenylketone, Cephalosporin,• Aldose reductive antienzyme
Nitrite	<ul style="list-style-type: none">• Ascorbic acid• Urine with elevated specific gravity	
Leukocytes	<ul style="list-style-type: none">• Glucose more than 500 mg/dL• Protein more than 300 mg/dL• Urine with low pH• Urine with elevated specific gravity	<ul style="list-style-type: none">• Formaldehyde

PROCEDURE FOR PROCESSING SPECIMENS WITH ABNORMAL URINE COLOR DUE TO SUBSTANCES SUCH AS DRUGS

Substances causing abnormal urine color such as drugs containing azo dyes (e.g. Pyridium, Azo Gantrisin, Azo Gantanol, Nitrofurantoin Macrochantin and Furadantin, etc.) may interfere with color reactions on the dipstick on the AX-4030. Abnormal color should be noted by the CLS visually prior to placing on the instrument. If the dipstick results are primarily positive or color interference is suspected. Report the chemistry portion as "unreadable" (except for color, clarity and specific gravity), with the comment UACINTERF- Dipstick unreadable due to color interference. Perform a microscopic.

INOPERABLE CONDITIONS

In the case where all test systems are inoperable for the particular analyte,

1. Notify the Laboratory Director/designee
2. Notify affected providers of a delay in testing.
3. Store routine test specimens adhering to specimen stability requirements, completion of testing and pending return of system operability.
4. Stats and long term test system downtime may include Send out to County Shared Labs or the use of contract reference laboratories.
 - a. Refer to each sites procedure manual for County courier information.

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