

Automated Urine Chemistry and Urine Microscopy, Urinalysis

Test Name: Automated Urine Chemistry using AUTION MAX AX-4030 and Automated Urine Microscopy using the IRIS iQ200

Method Name: 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.

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.

Results: Urine Chemistry results are measured quantitatively, except for Color and Clarity.

Urine Microscopy results are measured either numerically per low power field (LPF) or high-power field (HPF). Additionally, some particles are measured as either present or absent.

Reference Ranges:

Urine Chemistry Reference Ranges :

Glucose: Normal- 70 mg/dL

Protein: Negative- 30 mg/dL

Bilirubin: Negative- 0.5 mg/dL

Urobilinogen: Normal- 2.0 mg/dL

pH: 5.0-8.5

Blood: Negative- 1+

Ketones: Negative- 10 mg/dL

Nitrites: Negative- 1+

Leukocyte Esterase: Negative- 75 mg/dL

Clarity: Clear- Turbid

Specific Gravity: 1.000- 1.031

Color: Color result will vary depending on the specimen

Urine Microscopy Reference Ranges:

RBC: NONE-3/HPF

WBC: NONE-5/HPF

SQEP: NONE-10/HPF

BACT: NONE-Rare

MUCS: NONE-Many

Clinical Significance: Viral transmission is person to person through direct contact with upper respiratory droplets containing virus from symptomatic and asymptomatic carriers. Symptoms range from mild to severe including severe acute respiratory distress (ARDS) with fever, cough, and shortness of breath. Some patients have also demonstrated sore throat and gastrointestinal distress and/or renal failure.

The iQ 200 Analyzer can be used as a stand-alone unit to perform a urine microscopic urine sediment analysis, or the results from the iQ 200 analyzer can be combined with other urine chemistry results received from an LIS. The analyzer produces quantitative or qualitative counts of all formed sediment elements present in urine, including cells, casts, crystals, and organisms. Criteria can be set for auto-reporting and flagging specimens for review. All instrument analyte image decisions may be reviewed and overridden by a trained technologist.

Submission Criteria: Specimen types include freshly voided urine collected in a sterile urine collection container. Urines in a BD Vacutainer Plus UA Preservative tubes are also acceptable. A minimum of 2 mL for Urine Chemistry, 3 mL for Urine Microscopy, and 4 mL for a complete Urinalysis is required.

Fresh urine specimens must be completed within one hour of collection if stored at room temperature, or within 24 hours if stored at 2-8°

Urines in BD Vacutainer Plus UA Preservative specimens must be completed within 48 hours of collection when stored at 2-8°C.

Rejection Criteria: Rejection criteria include but are not limited to those with:

1. Mismatched requisitions
2. Specimens without patient identifiers
3. Specimens stored or shipped incorrectly
4. Specimens collected using expired BD Vacutainer Plus UA Preservative tubes
5. Specimens with inappropriate preservatives such as formalin or formaldehyde, disinfectant, or detergent added
6. Specimens not analyzed within the appropriate time frame
7. Specimens with quantity not sufficient
8. Hematuria
9. Specimens contaminated with fecal matter
10. Specimens submitted without approval

Authorization: Diagnostic testing can only be performed with approval from an authorized provider/agency.

Turn Around Time: Within 24 hours of receiving specimens

Instructions for Urinalysis Submission

General Information

Urinalysis is analyzed on the AUTION MAX AX-4030 and the IRIS iQ200. Freshly voided specimens in a sterile collection container and urine in a BD Vacutainer Plus UA Preservative tubes are the acceptable specimens for Urinalysis.

Specimens must be collected and stored at 2-8°C (36-46°F) if not analyzed within 1 hour. Please be aware that storing specimens at $\leq -70^{\circ}\text{C}$ ($\leq -94^{\circ}\text{F}$) is not permissible.

Specimens **MUST** be received at Reditus Laboratories within 24 hours of collection of fresh specimens, and within 48 hours for BD Vacutainer Plus UA Preservative tubes.

Collection Instructions for Urine Specimens

1. Do not use expired urine collection tubes. Store urine collection tubes as per manufacturers recommendations. Use sterile collection containers for collecting samples.
2. Ensure that the patient's name, date-of-birth, and time/date of collection are recorded on the specimen tube along with the name or initials of the individual collecting the sample.
3. Complete all the demographic information on a sample requisition form available through the approved electronic submission process
4. Refrigerate the specimen between 2-8°C (36-46°F) and ship or courier the specimen(s) within 24 hours on cold packs.
5. The specimen(s) *must* be received at the laboratory **no later than** 24 hours *from the time of collection*.
 - a. **Avoid shipping specimens over weekends or holidays** as they may not be received at the laboratory and cold-packs will not maintain the required 2-8°C (36-46°F) specimen temperature.
 - b. Ensure that specimens shipped by commercial carrier are shipped with **overnight delivery**. If shipping on a Friday for Saturday delivery, ***you must include Saturday Delivery*** during shipment or the specimens will not be received until the following non-holiday business day. Failure to receive specimens within 24 hours of shipment will result in specimens being rejected from testing.
6. For any questions pertaining to sample collection, storage, or shipping, please contact the Reditus Laboratories using the below contact information.

Instructions for Specimen Transport

7. **Messenger/Courier by ground transport.** Place specimen(s) into a biohazard labeled bag and seal securely. Place the test requisition(s) on the outside of the biohazard labeled bag. Place the sealed biohazard bag and test requisition(s) inside the shipping container. Place cold packs, which have been frozen for at least 24 hours, in the leak-proof outer container. The shipping container must be rigid, such as a Styrofoam cooler, and labeled with the UN 3373 Biological Substance Category B marking. Close securely.
8. **Commercial carrier by ground/air transport.** Place the specimen(s) inside a biohazard labeled bag and seal securely. Place the test requisition(s) on the outside of the biohazard labeled bag. Place the sealed bag and completed test requisitions(s) inside the outer shipping container. Place cold packs, which have been frozen for at least 24 hours, in the leak-proof outer container. Label the outer shipping container with Reditus Laboratories address listed below. Complete the return address section to include the name of the person shipping the package, business name and address, and a business phone number. The shipping container must include the UN3373 Biological Substance Category B marking.
9. *Ship specimens by overnight delivery* to the attention of Molecular Diagnostics at Reditus laboratories. This can be accomplished by use of local courier, shipping corporations or U.S. Postal Service.

- a. **If specimens are shipped on a Friday for Saturday delivery, you must include/indicate *Saturday delivery*** during shipment or the specimens will not be received until the following non-holiday business day. Failure to receive specimens within 24 hours of shipment will result in specimens being rejected from testing.
10. The specimen(s) must be received at the laboratory **no later than** 24 hours *from the time of collection* and 24 hours from the time of shipment. Do not ship specimens over weekends or holidays as they will not be received, and cold-packs will not maintain the required 2-8°C (36-46°F) specimen temperature.

NOTE: Testing may be delayed, or specimens may be considered UNSATISFACTORY if the above instructions are not followed or the requisition form is not filled out completely. If there are any questions about specimen collection, handling, or shipping please contact the Reditus Laboratories to speak with laboratory personnel.

Ship specimens by a local courier or overnight by commercial carrier to the designated laboratories indicated below.

Send to: Reditus Laboratories
200 Enterprise Drive
Pekin, IL 61554

Phone: (469) 498-0222

Website: <https://www.redituslabs.com/>