## TITLE: Quality Control in Urinalysis

PRINCIPLE:

Running Quality Controls serve to verify the accuracy and precision of reported test values by checking instrument performance, reagent performance and human performance. Negative and positive controls must be run every 24 hours or more frequently if recommended by the manufacturer on days when patient specimens are being tested. Quality controls must be performed in the same manner and by the same personnel who are reporting patient results.

 Testing controls provides confidence that the reagent strips are reacting and being read properly. Errors resulting from user techniques can also be detected. It is suggested that controls be run under the following conditions:

* Every 24 hours preferably at the start of the day’s run
* Whenever test results are in doubt
* After major maintenance and/or component replacement

**CLINICAL SIGNIFICANCE:**

The use of quality control materials is indicated as an objective assessment of the precision of methods and techniques in use and is an integral part of good laboratory practices. Two levels of control are available to allow performance monitoring within the clinical range.

### PERSONNEL:

Medical Technologists.

**SPECIMEN COLLECTION/TREATMENT**:

Patient Preparation: No patient preparation necessary.

Type of Specimen: Aution Check Plus 1 and 2 for Arkray

 iQ Control/Focus for Iris

Liquid Urine Dipstick Control

 Alta Diagnostics Inc for u411

Handling Precautions: Handle the same as clinical specimens

## REAGENTS AND EQUIPMENT:

Arkray/Iris and/or Cobas u 411

Refractometer

Transfer pipettes

Kova urine centrifuge tubes and caps

Kova slides

Aution Sticks

Roche Chemstrips 10 UA

## REAGENT PREPARATION:

1. Aution Check Plus Controls (Low and High)

Store at 2-8ºC, stable until expiration date on the package when unopened, expire 30 days after opening, product must be brought to room temperature before use.

1. iQ Focus/Control set

Store at 2-8ºC, stable until expiration date on the package when unopened, expire 30 days after opening, product must be brought to room temperature before use.

1. Liquid Urine Dipstick Control (Positive & Negative) Alta Diagnostics, Inc.

Unopened product is stable up to the expiration date printed on the label when kept at 2 – 8 C and used as directed. Once the control is opened, it will be stable for up to 8 weeks at room temperature when stored away from ultraviolet light, 30 days if using a DIP method. Do not store the control material in direct light.

**CALIBRATION:**

See Procedure no. 4840-UA-30, Iris iQ200 Elite/Arkray AX-4030 Automated Urinalysis System Procedure for Calibration.

## See Procedure No. 4840-UA-1014A, Cobas u 411 Operation Procedure for Calibration

## QUALITY CONTROL:

Running Quality Control:

**Arkray/Iris**

Control specimens will be run once a day by the 1st shift technologist in the same manner as a patient sample. All QC results will be entered into the TQC program..

**Cobas u411**

Control specimens will be run by the 3rd shift technologist in the same manner as a patient sample. Alta Diagnostics Urine Controls will be run once a day on the cobas u 411. It is also recommended to run controls when a new bottle of strips is opened (this only applies to the u411). All QC results will be entered into the TQC program.

Refractometer controls will be run only on days of patient testing.

## STEPWISE PROCEDURE:

1. Performing Quality Control

 i. AUTION Check Plus Control

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

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

 c. Invert bottle several times to ensure homogency

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

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

f. Return bottles to the refrigerator immediately.

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

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

ii. iQ Positive, iQ Negative and Focus

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

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

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

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

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

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

c. Load iQ200 QC rack as follows:

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

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

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

f. If QC fails repeat process

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

h. Collate results through the LIS, adding corrective action if result is unacceptable.

 See Urinalysis Quality Control Entry sheet at the end of this procedure.

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

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

a. Do not report patient test results.

b. Rerun the QC material that failed

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

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

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

f. No patient results can be reported until all QC issues are resolved and in the acceptable range.

 Cobas u411

1. Verify that the lot number indicated on each control bottle matches the assay sheet enclosed. Invert the bottle several times (DO NOT SHAKE) to ensure mixing of the contents.
2. Place expiration date on the bottle (expiration date is 8 weeks placing control in use when stored at room temperature and stored away from ultraviolet light.
3. Invert the tube several times to ensure the uniform mixing of the contents. DO NOT SHAKE.
4. Drop control material on each of the chemstrip pads.
5. Run dipstick through the Cobas u 411.

See Cobas u 411 Operation procedure number 4840-UA-1015 for more information.

1. Collate results through the LIS, adding corrective action if result is unacceptable.

g. If control is unacceptable, contact senior technologist. No patient results can be

 reported until all QC issues are resolved and in the acceptable range.

1. The quality control data will be reviewed by the Senior Technologist at least once a

 month.

1. The Urinalysis Department adheres to all Rush Copley Medical Center Hospital and Laboratory Department Quality Assurance Policies as outlined in section 300 of the Department of Pathology and Laboratory Medicine General Policies and Procedures Book.

**VALIDATION OF NEW LOTS OF QUALITY CONTROL:**

 New lots of quality control must be verified with the current lot before use.

This applies to the Aution Check plus controls (Low and High) and the Alta Diagnostics Liquid Urine Dipstick Control (Positive and Negative).

1. Run both levels of the control least 2 times on the analyzer which the controls are normally run.

 2. Complete a New lot of Quality Control Validation form.

 3. Compare values to make sure they match within one semi-quantitative grade.

 4. Notify Lead Tech or Designee if results do not match.

### PROCEDURAL NOTES:

1. The listed values and ranges were obtained using instruments, reagents and procedures available at the time of analysis. Any change in the reagents, methods or instrument

methodology by the manufacturer may result in different values. Consult manufacturer’s instructions for further information.

2. All control solutions should produce the values stated in the respective package insert. If the control results fall outside of these values, the following sources of error may have occurred:

1. Improper technique or instrument setup.
2. Deterioration of the Reagent Strip test areas due to exposure to light, ambient moisture or heat. Obtain a fresh bottle of the strips being used and repeat the control procedure. If fresh reagent strips fail to give results within the expected values, proceed to step c.
3. Deterioration of the control solution. Take out a fresh bottle of solution and repeat the control procedure. If fresh solution fails to give results within the expected values, proceed to step d.
4. If instrument malfunction is suspected :

 see TROUBLESHOOTING AND SERVICE section of the Operating Manual, or

 contact the Customer Service Department for assistance.

**REFERENCES:**

1. Isreal Davidsohn, M.D., F.A.C.P., and John Bernard Henry, editors. Todd- Sanford Clinical Diagnosis by Laboratory Methods - 15th edition, W.B. Saunder Company, (Philadelphia, 1974) pp 20-21.

2. Iris AX-4030 Operators Manual

3. Iris iQ200 Operators Manual

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

5. Alta Diagnostics Liquid Urine Dipstick Control Package Insert, Alta Diagnostics,

 Laboratories, Carson city NV

 SCC, Clearwater, Florida 33760

 Roche Diagnostics, Indianapolis, In, 46250-0457

**VALIDATION**

**NEW LOT OF QUALITY CONTROL**

**Control: (circle one): AUTION Check Plus Control OR Alta Urine Dipstick Control**

**Current Lot # of QC\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Exp. Date\_\_\_\_\_\_\_\_\_\_\_**

**New Lot # of QC \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Exp. Date\_\_\_\_\_\_\_\_\_\_\_**

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Sample ID**Low/Neg** | S.G. | pH | LEU | NIT | PRO | GLUC | KET | UROB | BIL | HGB | Acceptable?Yes or No |
| New LotOld Lot |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |
| New LotOld Lot |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |
|  | **High/Pos** |  |  |  |  |  |  |  |  |  |  |  |
| New LotOld Lot |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |
| New LotOld Lot |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |

**\*Tests strip results must match within one semi-quantitative grade**

**Corrective Action (if required):**

**The new lot quality control is acceptable for patient testing.**

**Technologist: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**