Biorad qUAntify

PRINCIPLE

qUAntify Advance Liquid Urine Controls are prepared from a liquid base matrix with human urine and added constituents of human and animal origin, chemicals, and preservatives. The control is provided in liquid form.

REAGENTS AND EQUIPMENT

Multistix 10 SG
QC Log Book
Bio Rad qUAntify Advance Liquid Urine Control Level 1 and 2

QUALITY CONTROL

Bio Rad qUAntify Advance Liquid Urine Control Level 1 and 2 are the control material for Multistix 10 SG strips
qUAntify Advance Liquid Urine Controls are prepared from a liquid base matrix with human urine and added constituents of human and animal origin, chemicals, and preservatives. The control is provided in liquid form.

Step	Action
1.	Before sampling, allow the control to reach room temperature (18 to 25°C) and invert the bottle several times to ensure homogeneity
2.	After each use, wipe the tip of the control bottle, recap, and return to appropriate storage conditions.

FREQUENCY

Controls must be performed once every 24 hours. Quality Controls must be within the acceptable range (See value assignment sheet for the lot number being run.) before processing and releasing any patient results.

STABILITY

Controls are stable until the expiration date when stored unopened at 2–8 degrees C. Once opened the controls are stable for 31 days when stored tightly capped at 2–25 degrees C.

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PROCEDURE Bio Rad qUAntify Advance Liquid Urine Control Level 1 is the NEGATIVE control; Level 2 is the POSITIVE control. Perform each test in the same manner as a patient specimen.

Step	Action- Dipstick
1.	Daily, remove 2-3 ml of each control and place them in labeled centrifuge tubes. Perform all the chemical checks on these aliquots.
2.	Dip a strip from the opened container of Multistix 10 SG. Run in Clinitek Advantus (refer to URN.MOB.03.0010) or manually (refer to URN.MOB.03.0020). Date and initial all reagent strip vials when opened. Record the results of each control on the appropriate sheets located in the Preventive Maintenance Book.
3.	Compare the test results with the lot-specific assigned values recorded on the QC sheets.

Step	Action- Microscopic QC
1.	Centrifuge 10-12 ml of each urine control for 5 minutes at 1500 RPM.
2.	Decant the supernatant completely and shake sediment into suspension.
3.	Place a drop of urine sediment on a slide and cover slip.
4.	Scan for casts with low power and subdued light before switching to high dry to read.

RESULTING Compare the test results with the lot-specific assigned values recorded on the QC sheets. Refer to www.qcnet.com for insert update information.
If the controls are not within the specified limits retest with new QC material. If the controls are still not within limits, retest with a new vial of Multistix. If QC results are still unacceptable, report situation to a supervisor. DO NOT PERFORM ANY PATIENT TESTING UNTIL QUALITY CONTROL IS ACCEPTABLE.

LIMITATIONS

- The assigned value charts are lot-specific for the Biorad Quantify Level I and Level 2. Lot numbers on the charts and vial labels must be the same.
- Reagents should be mixed prior to each use to ensure a uniform suspension.
- This product should not be used past the expiration date.
- If there is evidence of microbial contamination or excessive turbidity in the product, discard the controls.

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OUT OF CONTROL PROCEDURE

The following process is to be used if urine controls are outside of acceptable limits:

Step	Action
1.	Rerun Biorad qUAntify plus controls: a. If in control, record results. b. If out of control:
2.	Retest new bottle of Biorad qUAntify plus controls. a. If in control, use new bottle of Biorad qUAntify plus controls record result. b. If out of control:
3.	Use a new bottle or new lot number of test strips. a. If in control, use new bottle or new lot number of test strips. b. If out of control:
4.	Reorder new lot number of Biorad qUAntify plus controls or test strips.
5.	Report to a supervisor or a key operator: DO NOT REPORT PATIENT RESULTS.

REFERENCE

Bio-rad quantify product insert 2018
Multistix 10 SG: Siemens Product Insert 2008

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Document History Page

Change type: New, Major, Minor etc.	Changes Made to SOP – describe	Name of responsible person/date	Med. Dir. Reviewed/ Date	Dir. Lab Ops reviewed/ date	Date change Implemented
Minor	1. Format update 2. Replaced Count-10 control material with BioRad qUAntify Advance Control Level 1 and 2 3. Added microscopic QC procedure	Yvette Lingat 1/31/19			
Minor	1. Added out of control procedure 2. Revised index number	Yvette Lingat 8/20/20			