

Appendix B: Point of Care Urine Dipstick - Quality Control Solutions

Urine Quality Control (UQC) – Normal and Abnormal Levels Intended Use:

- To monitor the performance of the Chemstrip 10A for a standardized urinalysis.
- To check test strip reagent integrity, operator performance and result reporting.

Note: Quality Control testing is mandatory and is consistent with Point of Care Testing regulatory guidelines for patient sample testing at C&W.

Running Urine Quality Control:

- Warm QC vials to room temperature before use.
- Minimum weekly before patient testing.
- When troubleshooting the system.
- When starting a new vial of Chemstrip 10A test strips.
- When starting a new lot number of Chemstrip 10A test strips.
- Refer to Daily Quality Control Procedure.

Note: Both levels of QC results must be within the acceptable range before patient test is done.

Precautions And Warnings: For Invitro Diagnostic use only.

- Human serum source material used in the QC product is tested for the presence of antibody specific to HIV-1, HIV-2, HBsAg and HCV is found to be negative.
- No test method can offer complete assurance that infectious agents are absent.
- Use universal precautions in handling of all QC material.
- Do not use past expiry date. Recap reagents tightly after each use.

CHILDREN'S HOSPITAL ER BIO-RAD 975 qUAntify Urine Control and MEDICAL MOBILE UNIT- BIO-RAD 975X qUAntify Urine Control
<ul style="list-style-type: none"> • Control Solution 1 (blue cap) – Normal Control • Control Solution 2 (red cap) – Abnormal Control
STORAGE
<ul style="list-style-type: none"> • Store unopened vials in refrigerator. • Stock supply is available in the Children's Hospital Chemistry Laboratory walk-in fridge.
STABILITY
<ul style="list-style-type: none"> • The Quality Control material is stable to the expiry date on the vial when stored at 2°C to 8°C • QC bottles are dated when opening the bottle for the first time. • Open Vial expiry is 10 days at room temperature (18-25°C) or 31 days refrigerated, (Ketone stability at room temperature is 10 days, stability for all other analytes at room temperature is 31 days.) but not longer than the manufacture expiry date on the bottle.
<p>Note: Store UQC solutions tightly capped. Mix UQC well before use, dispense first drop and wipe tip before replacing the cap.</p>

References

BIO-RAD qUAntify Control Levels 1 and 2, United States, Bio-Rad laboratories, 9500 Jeronimo Road, Irvine, CA, 92618 August, 2010 [www.bio-rad.com/quality control](http://www.bio-rad.com/quality%20control)

REVISION & APPROVAL LOG

Version	Revision Type	Description of Change	Revision Date	Technical Approval	Medical Approval
1.0		New document		Elvira Kozak	Dr. Cathy Halstead
1.1	Minor	Document title and number change. Upload to QMS document control	28 Dec 2016		Dr. Benjamin Jung
1.2	Minor	Corrected BioRad QC stability	Apr 28, 2017	Calvin Lee	
1.3	Minor	Reformatted, removed reference to ER.	Mar 13, 2020	Calvin Lee	

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