

**Urine Dipstick Medical Mobile Unit: Appendix B - Quality Control Solution****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:**

- Once every 24 hours 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 – HYCOR KOVA TROL HUMAN URINALYSIS CONTROL**

- Normal Control – HYCOR KOVA® Trol III Human Urinalysis Control.
- Abnormal Control – HYCOR KOVA® Trol I Human Urinalysis Control.
- KOVA-Trol is prepared from normal human urine to which is added predetermined amounts of chemicals, stabilized human red cells and organic particles to simulate leukocytes.
- Lyophilized preparation is reconstituted in the Chemistry laboratory weekly for use with the Chemistry Urisys 1800 analyzer and in the Children's Emergency.
- Seven 1 mL aliquots of a normal and abnormal urine control material packaged and stored at 4°C in the Chemistry laboratory.
- Children's Emergency Porter delivers aliquot each day.

**STORAGE**

- Urine Quality Control (QC) 1 mL aliquots are stored at 20 to 80C.
- Stock supply is in the walk-in fridge Room 2F50 in the Division of General Laboratory Services

**STABILITY**

- 1 mL aliquot is stable for 7 days at 2° to 8°C – Chemistry.
- 1 mL aliquot is stable for 24 hours at room temperature.
- Warm to room temperature for daily use.
- Do not return to refrigerated storage. Discard next day.

**MEDICAL MOBILE UNIT- BIO-RAD 975X qUAntify Urine Control**

- Control Solution 1 (blue cap) – Normal Control
- Control Solution 2 (red cap) – Abnormal Control

<b>STORAGE</b>
<ul style="list-style-type: none"> <li>BIO-RAD qUAntify Solution is stored at room temperature 2° to 30° C.</li> <li>Stock supply is available in the Children’s Hospital Laboratory – Point of Care Testing – Rm. 2J8.</li> </ul>
<b>STABILITY</b>
<ul style="list-style-type: none"> <li>The Quality Control material is stable 2° to 30° C to the expiry date given.</li> <li>QC bottles are dated when opening the bottle for the first time.</li> <li>Open bottle stability is 2 months, but not longer than the expiry date on the bottle once opened.</li> </ul> <p><i>Note: Store UQC solutions tightly capped.  Mix UQC well before use, dispense first drop and wipe tip before replacing the cap.</i></p>

**REFERENCES**

KOVA-Trol™ Directional Insert, HYCOR BIOMEDICAL LTD., Pentlands Science Park, Bush Loan, Penicuik EH26 OPL, UNITED KINGDOM, May, 2004. www.hycorbiomedical.com

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

**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

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