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 2o to 8oC.
- 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 2o 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
**STORAGE**
- BIO-RAD qUAntify Solution is stored at room temperature 2° to 30° C.
- Stock supply is available in the Children’s Hospital Laboratory – Point of Care Testing – Rm. 2J8.

**STABILITY**
- The Quality Control material is stable 2° to 30° C to the expiry date given.
- QC bottles are dated when opening the bottle for the first time.
- Open bottle stability is 2 months, but not longer than the expiry date on the bottle once opened.

*Note: Store UQC solutions tightly capped. Mix UQC well before use, dispense first drop and wipe tip before replacing the cap.*

**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

**REVISION & APPROVAL LOG**

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<th>Version</th>
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<td>Elvira Kozak</td>
<td>Dr. Cathy Halstead</td>
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<td>Document title and number change. Upload to QMS document control</td>
<td>28 Dec 2016</td>
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