HACKETTSTOWN REGIONAL MEDICAL CENTER
LABORATORY POLICY MANUAL
QUALITY CONTROL FOR N-MULTISTIX 10G

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PRINCIPLE: Proper performance of urine reagent strips must be confirmed by testing with a control known to produce a positive reaction with each area of the test strip. Use of the control also confirms the user/s ability to properly perform and reliably interpret the reagent strip tests.

REAGENTS AND EQUIPMENT:

1. N-Multistix: firm plastic strip to which are affixed eight separate reagent areas which test for pH protein, glucose, ketones, bilirubin, blood nitrite, and urobilinogen in the urine.
   The N-Multistix can be stored in its original container at $15^{o} – 30^{o}$ C till the expiration date on the container.
2. qUAntify Controls Levels 1 and 2. Level 1 is the negative control and Level 2 is the positive control. The product will be stable until the expiration date when stored unopened at 2 to8°C. Once opened, this product will be stable for 31 days when stored tightly capped at 2 to 25°C.

PROCEDURE:

1. This product should be treated the same as patient specimens and run in accordance with the instructions accompanying the instrument, kit, or reagent being used.
2. Before sampling, allow the control to reach room temperature (18 to 25◦C) and invert the bottle several times to ensure homogeneity**.**
3. Remove the dropper tip cap.
4. Holding the dipstick reagent strip in one hand, invert the control bottle and apply control material directly across each pad by gently squeezing the bottle.
5. Remove excess control by tilting the dipstick on its edge and blotting on an absorbent towel.
6. Scan the appropriate barcode on the Clinitek for the control being run and place dipstick on analyzer.
7. Wipe the tip of the control bottle, recap, and return, to appropriate storage conditions.
8. Check results against expected QC criteria that is posted above the Clinitek and in the computer. Take corrective action if necessary and document corrective action in the computer.
9. Document QC on maintenance log sheet with a check or “CA” for corrective action.
10. If QC is out of tolerance limits, repeat test, if still out, than make up new control.
11. Document action on Corrective Action Log and notify supervisor if necessary.

QUALITY CONTROL:

Level 1 (neg) 903403122
Level 2 (pos) 903403121
Level 1 is the negative control and all results should be negative with a specific gravity of 1.105 – 1.030
Level 2 is the positive control and values should be as follows:

Glucose	Trace - ≥1000mg/dl
Bilirubin	Small - Large
Ketone	Trace - ≥ 80 mg/dl
Specific Grav.	≤ 1.005 – 1.020
Blood	Mod-Large
pH	6.5 – 8.0
Protein	30 - ≥300 mg/dl
Urobilinogen	1 - ≥ 8EU/dl
Nitrite	Positive
Leukocytes	Trace-Moderate

REPORTING RESULTS
The Bio-Rad qUAntify control solutions will react with N-Multistix Reagent Strips to yield the results listed in the Table of Values found on the back side of each package insert.

REFERENCES
BioRad qUAntify Product Insert, Bio-Rad Laboratories, Inc., Irvine, CA.