Procedure to Quality Control Urine Dipsticks CAPT_URI_0100

I. Purpose:

This procedure provides instructions on how and when to perform Quality Control (QC) on the urine dipsticks.

qUAntify Advance Control is intended for the use as an assayed quality control to monitor the precision of urinalysis test procedures for the analytes listed in the insert package.

QC is performed in the same manner as patient samples and rotated among all operators who perform the examination; nursing staff.

In the event of a QC failure, do not proceed with patient testing, and do not report any patient results in the patient medical record.

Frequency of QC:

Once within a 24 hour period before patient testing.
When starting a new vial of test strips.
When starting a new lot number of test strips.

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Locations: 6th Floor (6E), 5th (5E) Floor, 2nd (Radiation Support) Floor and 3rd Floor Labs (Research Purposes Only)

NOTE:

The BCCA clinical nurse educator is responsible for the training of staff for urine dipstick testing.

QC is performed in the same manner as patient samples and rotated among all operators who perform the examination.

II. Samples: N/A

III. Materials:

A. Reagents: Bio-Rad qUAntify Advance Control; Level 1 (normal) & Level 2 (abnormal). Provided by the lab. Replaced monthly. Lab will print labels from date opened to date expired.

1. Is prepared from a liquid base matrix with human urine and added constituents of human and animal origin, chemicals and preservatives.
2. Stable until the expiration date when stored unopened at 2 – 8'C. Once opened, the product is stable for 31 days when stored tightly between 2 – 25'C.

3. Do not freeze.

B. Supplies:

a. Urine testing dipsticks:
   i. Roche Chemstrip 10A
b. Gloves
c. Absorbent towel/pad for blotting
d. QC Record Sheet
   i. CAPT_URI_0100cl2 Roche Chemstrip Urine Dipstick QC Testing Log

C. Equipment:

a. Timer
b. Pen

IV. Procedure:

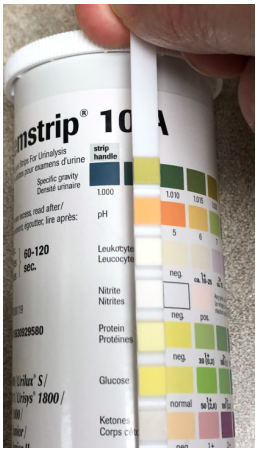
1. The product should be treated in the same as patient specimens.
2. Before sampling allow the control to reach room temperature (18 – 25'C)
3. Place gloves on.
4. Record date of QC, urine dipstick lot number and expiry date on QC log sheet.

   Note: if expiry date is the same month, inform appropriate personnel that new strips need to be ordered.
5. Remove test strip from vial. Immediately replace the cap for a tight seal.

   Note: Discard strip vial and contents if found with cap removed.
6. Invert the bottle several times to ensure homogeneity.
7. Add a couple of drops onto the test strip from the Quality Control vial.
8. Gently touch the long edge of the test strip to a piece of absorbent paper to remove any excess urine.

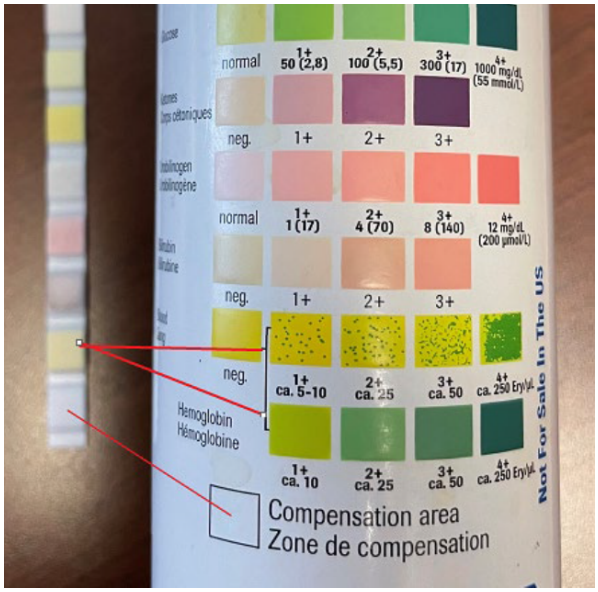
   Caution: Do not blot urine test strip onto pad with color pads facing down onto the absorbent material.
9. Place the test strip, pads facing up, onto paper towel or absorbent pad.
10. Set timer
11. Urine Quality Control Results:
    i. Hold the container upright and test the strip vertically.
    ii. Compare the test pad to the corresponding row of color blocks on the label.

    Do not touch the dipstick to the container as it may cause transference of fluid to subsequent dipsticks.



12. Document the UQC results onto the QC record sheet.

Note the last square on the strip is a compensation zone. Will not change color. Does not represent blood/hemoglobin.



13. Repeat for Level 2
14. Check the UQC results with the appropriate chart.
    i. Roche refer to: CAPT_URI_0100JA2 Expected QC Results Urine Dipsticks - Roche ChemStrip
15. Results: Refer to procedural notes for values
    i. If within QC acceptable limits, proceed to patient testing
    ii. Not within QC acceptable limits - Nonconformities:
        - ***Do not proceed with patient testing.***
            - ***When the quality control rules are violated and indicate that examination results are likely to contain clinically significant errors the results are rejected, and relevant patient samples re-examined after the error condition has been corrected and within-specification performance is verified.***
            - ***Repeated patient sample collection should be collected and sent to lab to confirm results.***
        - When QC is unacceptable, results are held until confirmed or invalidated by re-examination.
        - When QC is unacceptable, the laboratory evaluates results from patient samples that were examined after the last successful QC event.

1. *Possible cause:*

a. Lid off of Test Strip Vial?
b. Inadequate sampling – test strip not inserted into solution?
c. Inadequate mixing?
d. QC lid left off vial?
e. QC not within expiry date?
f. QC not within open vial expiry date?

2. *Action:*

a. Open new vial of Test Strips, and discard the vial with the lid left off.
b. Discard UQC if lid left off vial.
c. Discard UQC if not within expiry date.
d. Discard UQC if not within open expiry date.
e. Repeat UQC testing with new test strip – ensure full absorption of test pads. Mix UQC well before testing.
f. Notify POCT department if Quality Control issue unresolved.

16. Dispose of urine test strip in appropriate waste as per established procedure.

17. Manufacturer-issued defects, recalls and safety advisories are acted upon immediately. Remove affected products and follow up with supply chain instructions of how to proceed.

V. Procedure Notes:

ROCHE CHEMSTRIP 10 WITH SG / VISUAL (2)		
Specific Gravity	1.020 - 1.030	1.000 - 1.015
pH	5 - 6	7 - 9
Leukocytes	Negative	+ - ++
Nitrite	Negative	Positive
Protein, Total	Negative	30 - 500 mg/dL
Glucose	Normal	250 - 1000 mg/dL
Ketones	Negative	Small - Large (+ - +++)
Urobilinogen (1)	Normal	1 - 8 mg/dL
Bilirubin (1)	Negative	++ - +++
Blood / Hemoglobin	Negative	50 - 250 Ery/µL

VI. Method Limitations:

This method is not precise and is dependent on visual comparison to colored reference ranges. ***Individuals who are color blind must not conduct this QC.***

Endogenous crystalline sediment may be present and does not affect the performance of the product.

Colors produced by the Urobilinogen and/or Bilirubin test pads may not be characteristic of those shown on the manufacturer's color chart or label. Intensity of color may be correlated to concentration.

Values apply to all Chemstrip Reagent Strips.

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.

This product is not intended for use as a standard.

pH values may increase over time.

Ketone values may gradually decrease over product shelf life.

VII. Reference(s):

1. Bio-Rad: https://www.bio-rad.com/en-ca/product/quantify-advance-control?ID=PJY5N4TU86LJ
2. qUAntify Advance Control insert

VIII. Appendix(es): N/A