sQuality Control Pregnancy Tests Procedure

CAPT_PRG_0200

I. Purpose:

This procedure provides instructions on how and when to perform Quality Control (QC) on the Technologist Choice, One Step Pregnancy Test.

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.

Controls are prepared from a liquid base matrix with human urine and added constituents of human and animal origin, chemicals and preservatives

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:

- Weekly – before patient testing.
- When opening a new box/ or new lot of kits
- Used for troubleshooting.

Locations: 2nd Floor surgical suite

NOTE:

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

II. Samples: N/A

III. Materials:

A. Reagents: Bio-Rad qUAntify Advance Control; Level 1 (Negative) & Level 2 (Positive).

1. Provided by the lab.
2. Replaced monthly. Lab will print labels from date opened to date expired.
3. Is prepared from a liquid base matrix with human urine and added constituents of human and animal origin, chemicals and preservatives.

4. 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.
5. Do not freeze.

B. Supplies:

a. One Step hCG Pregnancy Test Kit – 2 kits
b. Gloves
c. Absorbent towel/pad for blotting
d. QC Record Sheet
   i. CAPT_PRG_0200F1 POCT Urine Pregnancy: Quality Control Record Form

C. Equipment:

a. Timer
b. Pen

IV. Procedure:

1. **Built In Quality Control**

- The pregnancy test has a built-in procedural control that checks:
  - Test procedure is performed properly.
  - Adequate sample volume was used.
  - Sample and reagent are wicking on the membrane.
  - Test reagents at the control line and conjugate color indicator are reactive.
- After the sample is applied, a reddish-purple line will develop at the Control © region and the background will become clear.
- ***If there is no line at the control © region, the test is INVALID and MUST BE REPEATED.***

2. **External Quality Control**

i. The product should be treated in the same as patient specimens.

ii. Before sampling allow the control to reach room temperature (18 – 25'C) if not already.

iii. Place gloves on.

iv. Record on log sheet:

1. Date of QC

2. Operator ID or Initials
3. Pregnancy Test lot number

Note: if expiry date is the same month, inform appropriate personnel that new kits need to be ordered.

v. Remove pregnancy kit from foil pouch.

vi. Invert the bottles several times to ensure homogeneity.

vii. Add 3 drops into the sample well of kit.

viii. Set the timer for 5 minutes up to 10 minutes. DO NOT EXCEED 10 MINUTES.

ix. Report the results on the POCT Pregnancy QC Log.

CAPT_PRG_0200F1 POCT Urine Pregnancy: Quality Control Record Form

x. Repeat for Level 2

xi. Expected Results:

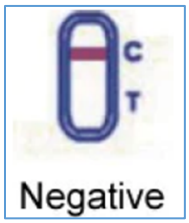
a. Vial 1 – Blue Cap – Negative
b. Vial 2 – Red Cap – Positive

Normal Reference Values: Negative (for male or non-pregnant female)

3. **Results**:

i. If all levels within QC acceptable limits, proceed to patient testing.

- Negative



- Positive

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.***

- **One or more levels of quality control fail – Repeat all levels with new kit.**
- **Quality control continues to fail – Obtain fresh controls from the laboratory.**
- **Quality control continues to fail after new controls – Suspend testing and contact the laboratory for further instructions.**
- **When QC is unacceptable, the laboratory evaluates results from patient samples that were examined after the last successful QC event.**

4. ***Possible cause:***
    a. Expired test kit.
    b. Expired Quality Control samples.
    c. Inadequate sampling – not enough sample added to the sample well.
    d. Inadequate mixing of QC solutions.
    e. QC lid left off vial.
    f. QC solutions not stored properly.
5. ***Action:***
    a. Access test kit that are not expired
    b. Access new QC material from the lab that is not expired..
    c. Make sure adding 3 full drops to sample well.
    d. Make sure adequate mixing of QC solutions.
    e. Discard QC solutions if cap left off or not stored according to instructions. Obtain new ones.
    f. Notify POCT department if Quality Control issue unresolved.

4. Dispose of pregnancy tests in appropriate waste as per established procedure. Routine garbage is acceptable.

5. 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:

VI. Method Limitations:

VII. Reference(s):

1. Laboratory – PHC - Point of Care Pregnancy Test Competency Assessment
2. PHSA - LABS - CW - POCT - Urine Pregnancy Assessment
3. 8700 Pregnancy Test in Urine Using the NCS HCG Device for POCT
4. Quick Reference Guide for Pregnancy Test in Urine using the NCS HCG Device POCT

VIII. Appendix(es): N/A