TECHNOLOGIST CHOICE ONE STEP hCG PREGNANCY TEST PROCEDURE CAPT_PRG_0100

I. Purpose:

This procedure provides instructions on how to perform and interpret urine to determine pregnancy.

- The Technologist Choice – One Step hCG pregnancy test uses a combination of monoclonal dye conjugate and polyclonal solid phase antibodies to identify hCG in urine samples.
- hCG is present usually, but not always, about 6 days after fertilization. If woman is pregnant, levels continue to rise rapidly, doubling every 2 – 3 days.
- Human chorionic gonadotropin (hCG) is a hormone that's produced by the placenta during pregnancy.
- hCG is known as the pregnancy hormone.
- Screen for pregnancy prior to surgical procedure or treatment.

NOTE: POCT is performed by personnel who have completed training and demonstrated competence. Ensure that POCT is performed by personnel who have completed training and demonstrated competence. Personnel must complete the online training course & in person competency before performing procedure on patient samples. Refer to Learning Hub: **PHSA - BCC - VAN - Point of Care Test - hCG One Step Pregnancy Test**

Locations: 2nd floor surgical suite

NOTE:

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

PURPOSE OF THE TEST:

- To detect pregnancy.
- To verify there is no pregnancy before certain procedures or prescribing medications.

II. Sample:

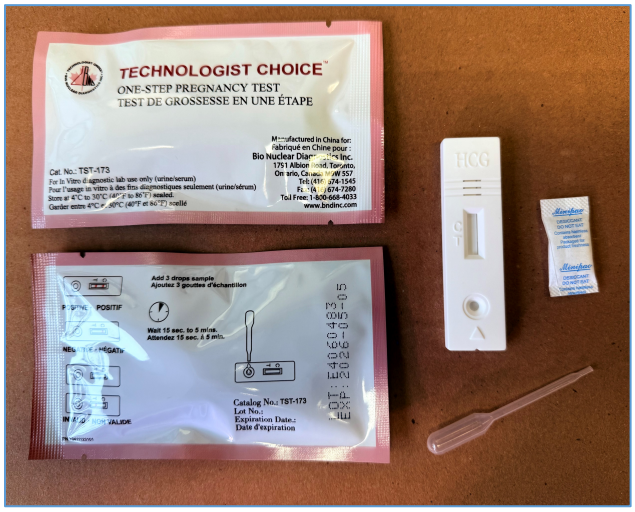
1. Urine Sample.
2. Patient samples must be treated as potentially infectious.

III. Materials:

A. Supplies: Test Kit

Technologist Choice – One Step hCG Pregnancy Test kit consists of:

- 40 kits per box
- Each kit consists of:
    - Test kit
    - Sample pipette
    - Silica desiccant – discard
- Store at 4°C - 30°C (room temperature) – Do Not Freeze
- Store in original sealed pouch until ready to use.
- Stable until expiration date on foil pouch.
- Epro number: 00025349



B. Equipment:

a. Timer

b. Pen

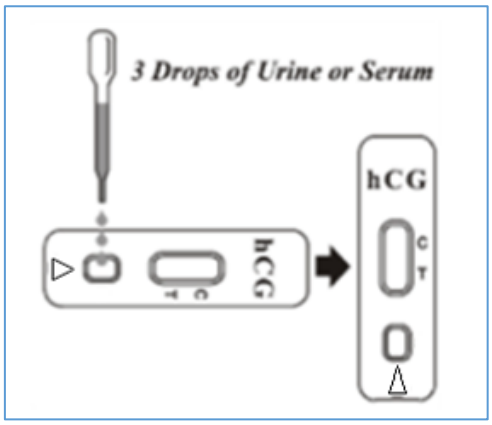
IV. Procedure:

1. **Ordering The Test:**
    i. Specific order by physician, eg via electronic ordering system, Cerner.
    ii. Order sets or pre-printed order set (PPO)
    iii. As per clinical area protocols and standard practice.
2. **Obtain Sample.**
    i. Provide patient with a clean collection container.
        1. Confirm patient identification using at least 2 patient identifiers. Urine collection container needs to be labelled with 2 patient identifiers and date and time of collection before giving it to patient for self-collection.
    ii. Random urine, but first morning specimen is preferred as it contains the highest concentration of hCG.
    iii. Minimum volume 1mL
    iv. Room temperature urine must be sampled immediately. Refrigerated sample (2-8°C) up to 48 hours (must come to room temperature for testing)

    * A low hCG concentration might result in a weak line appearing in the test region after an extended period of time: therefore, do not interpret the result after 10 minutes.

**avoid testing urine sample with visible particulates. Sample can be sent to lab for centrifugation.

3. **Test Procedure:**
   i. Use gloves. Wear a new pair of clean gloves for testing each patient.
   ii. Wash hands thoroughly with soap and water before putting on a new pair of gloves and performing the next patient test.
   iii. Ensure kit is within expiry date before testing.
   iv. Gather supplies and the sample. Sample test kit must be at room temperature.
   v. Label the test kit with the patient ID and place on a clean level surface.
   vi. Dispense **3 full drops** of urine in the Δ well and start the timer.



   vii. Read the results after 3 minutes. Background must be clear before interpreting results.
   viii. It is recommended that a negative result be read again at 5 minutes to 10 minutes. **DO NOT INTERPRET RESULTS AFTER 10 MINUTES.**

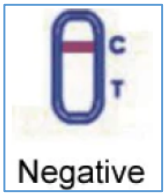
Note: The intensity of the red line in the test region (T) will vary depending on the concentration of hCG in the specimen. However, neither the quantitative value nor the rate of increase in hCG can be determined by this qualitative test.

4. **Interpretation Of Test Results:**
   i. POSITIVE
   1. Two coloured lines appear
   2. One line must be in the control region © and the other must be in the test region (T).

   3. Note the colour intensity of the test line may vary from pale pink to red-purple. The shade of the red line in the test region (T) may vary, but the test should be considered positive whenever there is a faint red line, see examples below.

ii. NEGATIVE

1. One coloured line in the © region and NO red/pink line appears in the test region (T)



iii. INVALID

1. Control line © fails to appear.
2. Insufficient specimen volume or incorrect technique is most common cause of control.
3. Review procedure, perform external quality control, make sure test kit is not expired and repeat test with new test device.

Additional Result Interpretation Notes

- If clinically indicated, patients with negative urine pregnancy results should be verified by serum hCG test or the urine test repeated in 48 hours.
- If you have a questionable result, confirm with a serum hCG. Send labelled patient sample to main lab to be sent to VGH chemistry department for investigation.

5. Discard the test device immediately after testing.
6. Enter patient results in patient's medical record or the electronic health record.
   i. Wash hands before charting.
   ii. *All orders must be recorded in the patient's medical record or the electronic health record.*
   iii. Enter results into Cerner as per nursing protocol
   iv. If result is negative, can order laboratory serum for hCG confirmation.
   v. Document all actions taken based on the results into the patient's medical record.

Normal Reference Values

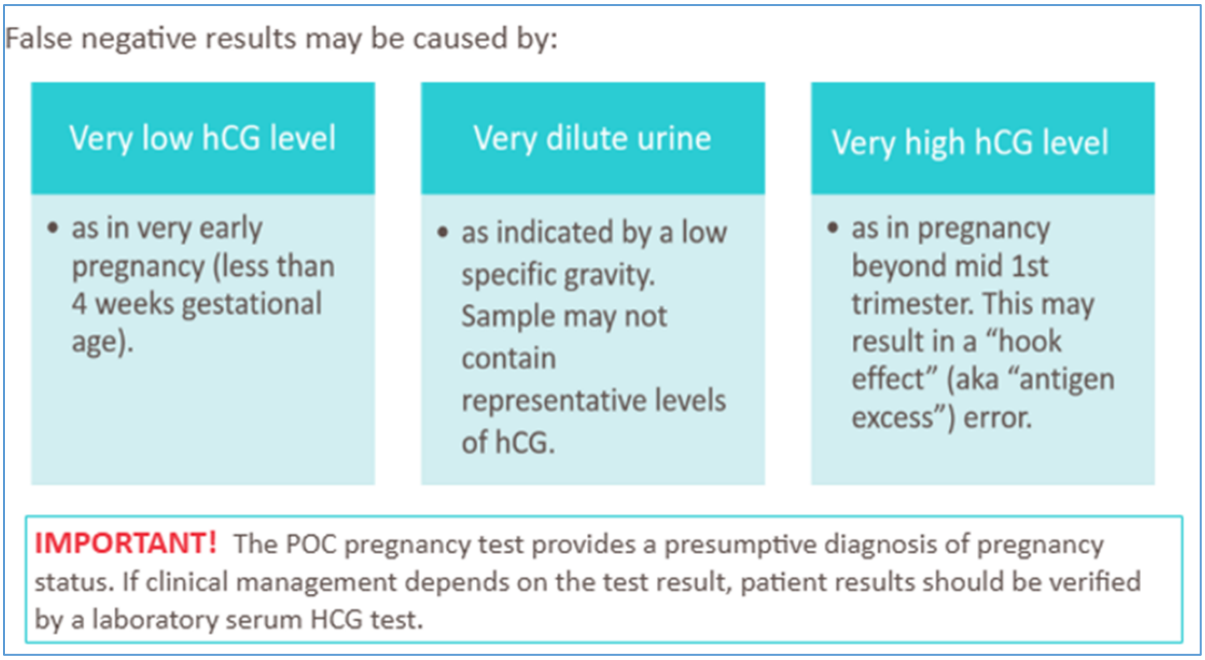
1. Negative (for male or non-pregnant female)

Critical Value

2. None

V. Procedure Notes:

VI. Method Limitations:



*One Step Pregnancy Test has a sensitivity of 25 miu/ml which means it can detect levels of hCG as low as that.

Other Factors Can Affect hCG Levels:

- Other conditions, such as bowel disease, stomach ulcers, and cirrhosis of the liver, can cause high hCG levels.
- Certain cancers, such as choriocarcinoma and extra-uterine malignancies.
- Dilute urine specimens, as indicated by a low specific gravity (≤1.015), may not contain representative levels of hCG. If pregnancy is still suspected, repeat test using first morning specimen or request serum quantitative hCG test.
- Elevated levels have been associated with some abnormal physiological states (e.g., trophoblastic and non-trophoblastic neoplasms) and should not be used in the diagnosis of these abnormal states that are not related to pregnancy.
- In the late first trimester, a hook-like effect from hCG beta core degradation product can result in a false negative urine hCG result. Any negative urine hCG result should be confirmed with a follow-up serum.
- hCG test if the urine hCG result is inconsistent with the clinical presentation (eg suspected pregnancy or ectopic pregnancy) and/or prior to any procedure which may pose a risk to a pregnant individual.

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