

D.15 POCT URINE PREGNANCY PROCEDURE SURE-VUE HCG STAT

- I. **PRINCIPLE:** Sure-Vue™ hCG-STAT is a rapid test that qualitatively detects the presence of hCG at the sensitivity of 20 mIU/mL in urine. The test utilizes a combination of monoclonal and polyclonal antibody reagents to selectively detect elevated levels of hCG in urine. The assay is conducted by the addition of a urine specimen into the test device sample well and observing for the formation of colored lines. The specimen migrates via capillary action along the membrane and reacts with the colored conjugate. A positive specimen reacts with the hCG-specific antibody colored conjugate and forms a colored line in the T (test) window. Absence of this colored line suggests a negative result. To serve as a control for the procedure, a colored line in the C (control) window will always appear regardless of the presence or absence of hCG.
- II. **SCOPE/RELATED POLICIES:**
- Ancillary Testing Policy (113-05)
 - Urine Pregnancy CBOC Patient Result Entry
- III. **SPECIMEN:**
- First morning voided urine (preferred) or random urine specimen collected in a clean, dry urine container.
 - Urine samples may be stored at (2-8 °C) for up to 48 hours prior to testing.
 - **CBOCS run only Urine samples on test packs.**
 - Serum HCG CBOC samples are sent to the main hospital lab for processing.
 - Allow urine specimen, test device, controls, and /or Proficiency samples to equilibrate to room temperature (15-30 °C) prior to testing.
 - Urine samples with visible precipitate should be centrifuged 1500 rpms for 5 minutes OR allow precipitate to settle in cup to facilitate a clear specimen for testing.
- IV. **MATERIALS:**
- Sure-Vue Serum/Urine HCG-STAT test Packs: Store 2-30°C.
 - Stable: through the expiration date printed on the back of the sealed pouch.
 - *Do not use test packs beyond the printed expiration date.*
 - The test device must remain in the sealed pouch until use.
 - CBOCS under the VA Albany will be supplied Sure-Vue HCG kits from the main lab.
 - Urine Pregnancy Controls Positive and Negative: Store 2-8°C.
 - Controls are stable until expiration date printed on the QC label when stored at 2-8°C.
 - CBOCS under the VA Albany will have controls supplied by the lab.
 - **ALL reagents and controls are to be used only within their indicated expiration date.**
 - **ALL reagents and controls must be stored and handled as recommended by the manufacturer.**
 - Permanent Marker
 - Disposable gloves
 - Biohazard Container or Biohazard Bag
- V. **INSTRUMENTATION:**
- Centrifuge
- VI. **SAFETY:**
- Universal blood and body fluid precautions
- VII. **DOCUMENTS:**
- Urine CBOC Pregnancy HCG Test QC Worksheet

VIII. QUALITY CONTROL

- Internal procedural controls are included within each test device pack.
- A red line appearing in the control region (C) is the internal procedural control.
 - Confirms sufficient specimen volume and correct procedural technique.
- A colorless test device background is an internal negative control.
- Main hospital Lab:
 - External quality control is performed on each new lot and/or shipment of test packs in the microbiology department.
 - If QC is acceptable, label test kits with green “Lot ready for use” stickers.
 - Current HCG lots are re-checked every 30 days with external quality controls by the microbiology department.
 - HCG test kits are sent out to the CBOCS by the Ancillary Testing Coordinator as needed.
- CBOC Quality Controls:
 - CBOCS are required to run a Positive and Negative external quality controls minimum **every 30 days** at the CBOC to check HCG test pack stability at the CBOC.
 - CBOC are required to run both Positive and Negative controls **on the day** of patient and/or Proficiency sample testing.
 - CBOCS are required to purchase their own quality control materials.
- **Technical problems should be directed to the Ancillary Testing Coordinator @ # 518-626-5771.**

IX. PROCEDURE:

- Employees MUST wash their hands and wear gloves per the facilities Infection Control policy.
- Due to the hazardous nature of handling urine and control reagents, disposable gloves must be used when performing any type of urine pregnancy testing (Patient samples, Controls, Proficiency samples).
- Gloves are to be removed and hands washed thoroughly with soap and water or antibacterial hand gel (as appropriate) both before and after completing the test procedure.
- Gloves MUST be changed between patients.

A. Running HCG Sample:

1. Allow the test device, patient urine sample, controls, and/or Proficiency samples to equilibrate to room temperature (15-30°C) prior to testing.
2. Remove the test device from the protective pouch and place it on a flat surface.
3. Label the device with patient, control, or Proficiency sample identification.
4. Hold the provided pipette vertically and transfer 3 drops of specimen into the round sample well of the test device and then start the timer.
5. A colorless test device background is an internal negative control.
6. **Wait for colored lines to appear → Read results at 3-4 minutes for urine.**
7. **Do not read test pack results later the 3-4 minutes time frame.**

X. INTERPRETATION OF RESULTS:

A. Positive Results: The test is positive if two distinct red lines appear.

One colored line appears in the T (test) window and one colored line appears in the C (control) window.



B. Negative Results: The test is negative if a colored line only appears in the C (control) window.



C. Invalid Results: **The test is invalid if no colored line appears in the C (control) window even if a colored line appears in the T (test) window.**

- Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure.
- Check that the lot of test packs has not expired and repeat the test with a new test device.
- **If the test comes up as INVALID again→ DO NOT report out the test pack result.**
- **Notify the Ancillary Testing Coordinator @ # 518-626- 5771 for assistance.**

XI. RESULTS REPORTING:

- All patient HCG results are entered into the patient's medical record in VISTA using the bypass data entry.
- Negative: Report negative results as NEG in VistA.
- Positive: Report positive result as POS in VistA.
- For detailed entry instructions click on hyperlink: [Urine Pregnancy CBOC Patient Result Entry](#)

XII. LIMITATIONS OF THE PROCEDURE

- False negative results may occur with very dilute urine samples, as indicated by a low specific gravity. If pregnancy is still suspected, a first morning urine specimen should be collected 48 hours later and tested or order a quantitative serum B-HCG.
- False negative results may occur when the levels of hCG are below the sensitivity of the test. If pregnancy is still suspected, a first morning urine specimen should be collected 48 hours later and tested.
- Very low levels of hCG (less than 50 mIU/mL) are present in urine specimens shortly after implantation. However, because a significant number of first trimester pregnancies terminate for natural reasons, a test result that is weakly positive should be confirmed by retesting with serum or first morning urine specimen collected 48 hours later.
- Elevated levels of hCG may be found in trophoblastic disease, choriocarcinoma, and embryonal cell carcinoma. Islet cell tumors may also produce hCG as well as other carcinomas. Therefore, the presence of hCG in urine should not be used to diagnose pregnancy unless these conditions have been ruled out.
- As with any assay employing mouse antibodies, the possibility exists for interference by human anti-mouse antibodies in the specimen. Specimens from patients who have received preparations of monoclonal antibodies for diagnosis or therapy may contain these antibodies. These specimens may cause false positive or false negative results.
- Interfering Substances: Refer to package insert for listing of potential substances and concentrations tested.

XIII. REFERENCE

- Sure-Vue Serum/Urine hCG-STAT Package Insert. DN: 1155810102, 2007.
- CAP POCT Checklist, 2015.