**PREGNANCY TESTING INSERVICE (SureVue Urine hCG test)**

**CLIA complexity:** Waived

**Intended use:**  The qualitative detection of human Chorionic Gonadotropin (hCG)

 in urine for the early detection of presumptively diagnosis pregnancy.

**Principle:** Test uses a monoclonal ab specific to the beta subunit of hCG in a

 single-step technology to detect hCG.

**Sensitivity:** 25 mIU/mL or greater

**Specimen:** First morning urine samples generally contain the highest concentrations of hCG but any urine sample may be used. Testing should be performed immediately after collection for patient testing to be entered timely. Specimen can be stored up to 8 hrs at room temp or up to 72 hrs refrigerated.

**Quality Control:** **External:** Each shipment must be tested with external controls

 prior to use. Date QC’d will be placed on the outside of the test kit box.

 **Internal:** Each test cassette contains an internal control. The

appearance of the blue procedural control line the indicates the

 cassette is functioning properly.

**Test procedure:** 1. Obtain urine sample.

 2. Check SureVue Urine hCG test kit for expiration date.

 3. Remove test cassette from foil pouch and label with patient

identifiers (i.e.…use the patient’s sticker) and place on a clean,

dry level surface.

 4. Using one of the disposable pipettes supplied, add 3 drops of

 urine to the round sample well on the cassette.

5. Using a certified timing monitor, set and wait 3 minutes and read. Do not handle or move the cassette until test is complete and ready for reading 3-4 minutes. Document result and Discard testing materials in hazardous waste.

**Interpretation:** **Positive:** Red/Pink T line with a Red/Pink C line

 **Negative:** No Red/Pink T line with a Red/Pink C line

 **Invalid:**  No Red/Pink C line with or without a Red/Pink T line

**Recording Results:** The patient result along with the kit lot number and expiration date, and the internal control result must be recorded in a note in the patients CPRS record. Results along with the patient’s name and last 4 of their SS# must be recorded on the Women’s Lab Testing Log on the Primary Care share drive. I perform monthly chart review to make sure all the required information is recorded in the patients record.

**Proficiency Testing:** Proficiency samples will be sent to the facility 2-3 times a year.

This will be rotated among the providers performing the tests.

**TEST PROCEDURE is located on the P&LMS SharePoint, Ancillary Testing.**

**CHECKLIST: POC Urine Pregnancy Test**

1. Gloves should always be worn when performing this test.

2. A first morning voided sample is best due to the greatest concentration of hCG.

3. Pregnancy test results are considered presumptively diagnostic of early detection of hCG.

 4. Questionable results should be confirmed by laboratory testing.

5. A positive result is indicated by colored lines appearing in the TEST & Control region.

6. An invalid result is indicated by NO colored lines appearing in the CONTROL region.

7. Patient results are to be entered into patient’s CPRS record as soon as possible.

8. Supplies can be obtained from the Clinical Lab at Overton Brooks VAMC.

9. There is a procedure manual for this test available on the hospital intra-net.

10. Two levels of liquid control material must be performed and documented on the UPT Control

 Log each month and glucose meter.

11. Proficiency test must be performed and rotated among trained staff.

12. Testing personnel must complete Training and Competency occurs initially and annually.

13. The spreadsheet on the PC S: Drive→ Women’s Health→ CBOC Lab Logs

 must be completed for all patient testing.

14. The Providers must document the LAB Testing CBOC WOMEN excel spreadsheet includes Patient ID,

 Patient’s Result, Internal Control, Lot # and Expiration, and Testing Person.

*Complete two levels of controls and document in glucose meter or test log.*