**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.

 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 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 timing device wait 3 minutes and read. Do not handle or

 move the cassette until test is complete and ready for reading.

**Interpretation:** **Positive:** Red T line with a red C line

 **Negative:** No red T line with a red C line

 **Invalid:**  No red C line with or without a red 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 three times a year.

This will be rotated among the providers performing the tests.