**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 device wait 3 minutes and read. Do not handle or move the cassette until test is complete and ready for reading 3-4 minutes.

**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

 **\*\*\*see the Kit’s Package Insert and individual pouch.**

**Recording Results:** The patient result along with the kit lot number and expiration date, and the internal control result must be recorded in at the glucose meter and downloaded in the patients CPRS record. Monthly chart reviews are performed to make sure all the required information is recorded in the patients record. Also, 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.

**Proficiency Testing:** Proficiency samples will be sent to the facility 2-3 times a year and will be rotated among the Certified Testing personnel performing the tests.