SURE-VUE™ hCG Triage

**SUMMARY**

Human chorionic gonadotropin (hCG) is a glycoprotein hormone produced by the developing placenta shortly after fertilization. In normal pregnancy, hCG can be detected in both urine and serum as early as 7 to 10 days after conception. hCG levels continue to rise very rapidly, frequently exceeding 100 mIU/mL in the first trimester, and peak in the 100,000-200,000 mIU/mL range about 12-14 weeks into pregnancy. The appearance of hCG in both the urine and serum soon after conception, and its subsequent rapid rise in concentration during early gestational growth, make it an excellent marker for the early detection of pregnancy. The SURE-VUE™ Urine hCG is a rapid test that qualitatively detects the presence of hCG in urine using a monoclonal anti-hCG antibody and a polyclonal anti-βhCG antibody to selectively detect elevated levels of hCG in urine. The assay is conducted by adding a urine specimen to the well of the test device and observing the formation of color. If the specimen migrates via capillary action along the reagent pad, a positive result will be indicated.

**REAGENTS**

- The test device contains mouse anti-βhCG antibody conjugated to colloidal gold and goat anti-mouse-βhCG antibody coated on the membrane.

**PRECAUTIONS**

- It is recommended that a positive hCG test result be confirmed by re-testing with a new reagent bottle.

**STORAGE AND STABILITY**

Store as packaged in the sealed pouch at 2-30°C. The test device is stable through the expiration date printed on the sealed pouch. The test device must not be sealed in the pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

**SPECIMEN COLLECTION AND PREPARATION**

- A urine specimen must be collected in a clean and dry container. A first morning urine specimen is preferred since it generally contains the highest concentration of hCG; however, urine specimens collected at any time of the day may be used. Urine specimens exhibiting visible precipitates should be centrifuged, filtered, or allowed to settle to obtain a clear specimen for testing.

**DIRECTIONS FOR USE**

- Allow the test device, urine specimen, and controls to equilibrate to room temperature (15-30°C) prior to testing.
- Remove the test device from the sealed pouch and use as soon as possible.