The hCG One Step Pregnancy Test Device (Urine) is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin in urine to aid in the early detection of pregnancy.

**INTENDED USE**

The hCG One Step Pregnancy Test Device (Urine) is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin in urine to aid in the early detection of pregnancy.

**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.1,2,3 hCG levels continue to rise very rapidly, frequently exceeding 100 mIU/mL by the first missed menstrual period and peaking in the 100,000-200,000 mIU/mL range about 10-12 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 hCG One Step Pregnancy Test Device (Urine) is a rapid test that qualitatively detects the presence of hCG in urine at the sensitivity of 25 mIU/mL. The test utilizes a combination of monoclonal and polyclonal antibodies to selectively detect elevated levels of hCG in urine. At the level of claimed sensitivity, the hCG One Step Pregnancy Test Device (Urine) shows no cross-reactivity from the structurally related glycoprotein hormones fSH, fLH and fTSH at high physiological levels.

**PRINCIPLE**

The hCG One Step Pregnancy Test Device (Urine) is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin in urine to aid in the early detection of pregnancy. The test uses two lines to indicate results. The test line utilizes a combination of antibodies including a monoclonal hCG antibody to selectively detect elevated levels of hCG. The control line is composed of goat polyclonal antibodies and colloidal gold particles. The assay is conducted by adding a urine specimen to the specimen well of the test device and observing the formation of colored lines. The specimen migrates via capillary action along the membrane to react with the colored conjugate.

Positive specimens react with the specific antibody-hCG-colored conjugate to form a colored line at the test line region of the membrane. Absence of this colored line suggests a negative result. To serve as a procedural control, a colored line will always appear in the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

**REAGENTs**

The test contains anti-hCG particles and anti-hCG coated on the membrane.

**PRECAUTIONS**

- For professional in vitro diagnostic use only. Do not use after the expiration date.
- The test should remain in the sealed pouch until use.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The used test should be discarded according to local regulations.

**STORAGE AND STABILITY**

Store as packaged in the sealed pouch at room temperature or refrigerated (2-30°C). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

**SPECIMEN COLLECTION AND PREPARATION**

**Urine Assay**

A urine specimen must be collected in a clean and dry container. A first morning urine specimen is preferred since it will contain 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.

**Specimen Storage**

Urine specimens may be stored at 2-8°C for up to 48 hours prior to testing. For prolonged storage, specimens may be frozen and stored below -20°C. Frozen specimens should be thawed and mixed before testing.

**MATERIALS**

- **Test devices**
- **Materials Provided**
- **Materials Required But Not Provided**
- **Specimen collection container**
- **Droppers**
- **Package insert**
- **Timer**

**INTERPRETATION OF RESULTS**

(Refer to the illustration above)

**POSITIVE:** Two distinct colored lines appear. One line should be in the control line region (C) and another line should be in the test line region (T).

**NEGATIVE:** One colored line appears in the control line region (C). No apparent colored line appears in the test line region (T).

**INVALID:** Control line fails to appear. Insufficient specimen volume or incorrect procedure techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

**QUALITY CONTROL**

A procedural control is included in the test. A colored line appearing in the control line region (C) is considered an internal procedural control. It confirms sufficient specimen volume and correct procedural technique. A clear background is an internal negative procedural control. If a background color appears in the result window and interferes with the ability to read the test result, the result may be invalid.

It is recommended that a positive hCG control (containing 25-250 mIU/mL hCG) and a negative hCG control (containing 0 mIU/mL hCG) be evaluated to verify proper test performance when a new shipment of tests are received.

**LITERATURE**


**EXPECTED VALUES**

Negative results are expected in healthy non-pregnant women and healthy men. Healthy pregnant women have hCG present in their urine and serum specimens. The amount of hCG will vary greatly with gestational age and between individuals. The hCG One Step Pregnancy Test Device (Urine) has a sensitivity of 25 mIU/mL, and is capable of detecting pregnancy as early as 1 day after the first missed menses.

**BIBLIOGRAPHY**