**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 levels of hCG.
- It is important that the dipstick must remain in the sealed pouch until use.

**STORAGE AND STABILITY**

- Frozen specimens should be thawed and mixed before testing.
- Urine specimens may be stored at 36-46°F/2-8°C for up to 48 hours prior to testing.
- Urine specimens exhibiting visible precipitates should be added to hCG negative and positive specimens.

**PRECAUTIONS**

- None of the substances at the concentration tested interfered in the assay.

**INTERPRETATION OF RESULTS**

- The intensity of the red color in the test line region (T) will vary with the concentration of hCG present in the specimen and observing the formation of colored lines. The specimen migrates via capillary action along the membrane to react with the combination of antibodies including mouse monoclonal anti-hCG antibodies and goat anti-alpha hCG antibody coated on the membrane.

**LIMITATIONS**

- 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 McKesson Consult® Diagnostics hCG Dipstick shows no cross-reactivity interference from the structurally related glycoprotein hormones hFSH, hLH, and hTSH at high physiological levels.

**REFERENCE**


**DISTRIBUTED BY**

McKesson Medical-Surgical Inc.

**MADE IN CHINA**

PVN B0218

**GENERAL QUESTIONS CALL**

1-800-777-4308

**TECHNICAL SUPPORT CALL**

1-866-216-0094

**SATISFACTION GUARANTEED**

If you are not completely satisfied with any McKesson Brands product, you may return it for a full refund or credit.

**MKesson Consult® Diagnostics hCG Dipstick**

A rapid test for the qualitative detection of human chorionic gonadotropin (hCG) in urine. For professional use only. For in vitro diagnostic use only. Rx Only. For use with IMR® 5000.

**CLIA Category:** Waived

**INTENDED USE**

The McKesson Consult® Diagnostics hCG Dipstick is a rapid chromatographic immunomassay for the qualitative detection of human chorionic gonadotropin (hCG) 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 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 McKesson Consult® Diagnostics hCG Dipstick 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 McKesson Consult® Diagnostics hCG Dipstick shows no cross-reactivity interference from the structurally related glycoprotein hormones hFSH, hLH, and hTSH at high physiological levels.

**PRINCIPLE**

The McKesson Consult® Diagnostics hCG Dipstick is a rapid chromatographic immunomassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine to aid in the early detection of pregnancy. The test utilizes a
**MATERIALS**

Materials provided: 25 Test dipsticks, and 1 Package insert.

Materials required but not provided: Specimen collection container, timer.

**DIRECTIONS FOR USE**

1. Read the expiration date on the sealed pouch. The test dipstick is stable through the expiration date printed on the sealed pouch. The test dipstick is not required by your lab internal quality system procedures.

2. Place the test dipstick on a non-absorbent, flat surface, start the timer and vertically in the urine specimen for at least 5 seconds. Do not pass the dipstick horizontally. The background is clear before the result is read.

3. Read the result at 3-4 minutes. Do not interpret results after the appropriate read time. *NOTE: the background is clear before the result is read.*

4. If the problem persists, discontinue using the test kit immediately and contact Technical Support at (866) 216-0094.

5. If pregnancy is still suspected, a first morning urine specimen should be collected 48 hours later and tested.

6. A number of conditions other than pregnancy, including trophoblastic disease and certain non-trophoblastic neoplasms including testicular tumors, prostate cancer, breast cancer, and lung cancer, cause elevated levels of hCG in urine specimens. It is recommended that these specimens not be used to diagnose pregnancy unless these conditions have been ruled out.

7. This test provides a presumptive diagnosis for pregnancy. A confirmed pregnancy diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.

**EXPECTED VALUES**

Negative results are expected in healthy non-pregnant women and healthy non-pregnant women who have not been pregnant in the three months preceding the test. The amount of hCG will vary greatly with gestational age and between individuals.

The McKesson Consult ® Diagnostics hCG Dipstick has a sensitivity of 25 mIU/mL, and is capable of detecting pregnancy as early as 1 day after the first missed menses.

**PERFORMANCE CHARACTERISTICS**

Method Comparison: A multi-center clinical evaluation was conducted comparing the results obtained using the McKesson Consult ® Diagnosis hCG Dipstick to another commercially available urine hormone hCG test. The study included 500 urine specimens: both assays identified 72 negative and 78 positive results.

**SUMMARY**

The McKesson Consult ® Diagnostics hCG Dipstick is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine to aid in the early detection of pregnancy.

**INTENDED USE**

The McKesson Consult ® Diagnostics hCG Dipstick is for professional diagnostic use only. Do not use after the expiration date. Do not use for professional diagnostic use only. Do not use after the expiration date.

For professional in vitro diagnostic use only. Do not use after the expiration date.

**STORAGE AND STABILITY**

Store as packaged in the sealed pouch at 36-86°F/2-30°C. The test dipstick is stable through the expiration date printed on the sealed pouch. Store as packaged in the sealed pouch at 36-86°F/2-30°C. The test dipstick must remain in the sealed pouch until use. Do not remove 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 discarded in a proper biohazard container the same manner as an infectious agent.

**SPECIMEN STORAGE**

Urine specimens may be stored at 36-46°F/2-8°C for up to 68 hours prior to testing. For prolonged storage, specimens may be frozen and stored between -4°F/-20°C. Frozen specimens should be thawed and mixed before testing.

**NOTE:** A sample hCG concentration below the cut-off level of this test might result in a weak line appearing in the test region (T) after an extended period of time. A line in the test region (T) seen after the read time could be indicative of a line on the control (C) region with a much lower concentration. The test dipstick should be re-tested with a new sample in 48-72 hours or that an alternative hCG detection method is used. If the problem persists, discontinue using the test kit immediately and contact Technical Support at (866) 216-0094.

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

**INVALID:** One red line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control (C) line failure. The test dipstick should be re-tested with a new test dipstick. If the problem persists, discontinue using the test kit immediately and contact Technical Support at (866) 216-0094.

**PVN B0218**

Richmond, VA 23233

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