The McKesson Consult ® Diagnostics hCG Urine Cassette 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**

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**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 urine as early as 7 to 10 days after conception.1-5 hCG levels continue to rise very rapidly, frequently exceeding 100 mIU/mL by the first missed menstrual period,6-8 and peaking in the 100,000-200,000 mIU/mL range about 10-12 weeks into pregnancy. The appearance of hCG in urine 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 Urine Cassette is a rapid test that qualitatively detects the presence of hCG at the sensitivity of 20 mIU/mL in urine. 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 Urine Cassette 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 Urine Cassette is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine to aid in the early detection of pregnancy.
SPECIMEN STORAGE
Urine specimen may be stored at 36-46°F/2-8°C for up to 48 hours prior to testing. For prolonged storage, specimens may be frozen and stored below -4°F/-20°C. Frozen specimens should be thawed and mixed before testing.

MATERIALS
Materials provided: 25 Test cassettes, 25 disposable specimen pipettes and 1 Package insert.

Materials required but not provided: Specimen collection container, timer

DIRECTIONS FOR USE
1. Remove the test cassette from the sealed pouch and use it as soon as possible. Refrigerate unused cassettes in the sealed pouch at 36-46°F/2-8°C. Do not use after the expiration date.
2. Allow the test cassette, urine, and/or controls to equilibrate to room temperature (19-25°C/66.5-77°F) for 15 minutes in a clean environment, such as a lab fume hood or laminar flow hood, to prevent the access of contaminants.
3. Place the test cassette on a clean flat surface. Vertical and transfer 3 full drops of urine (approx. 100 μl) to the specimen well (S) of the test cassette, and then start the timer. Avoid trapping air bubbles in the specimen well. See illustration. Form a colored line at the test line region of the membrane to react with the colored conjugate. Absence of this colored line will always appear at the control line region if the test has been performed properly. The specimen migrates via capillary action along the membrane to react with the colored conjugate. A negative result appears as two distinct red lines appearing to the right of the control line. A positive result appears as a single red line appearing at the test line region to the right of the control line. A third red line appearing at the control line region indicates a problem with the test or a specimen that has been allowed to settle in the specimen well.

QUALITY CONTROL
Internal procedural controls are included in the test. A red line appearing in the internal procedural control line (P) verifies that the test has been performed properly. The intensity of the red color in the test line region (T) will vary depending on the concentration of hCG in the present sample. This should be noted when interpreting results. The intensity of the red color in the test line region (T) will vary depending on the concentration of hCG in the present sample. If the results are close to the claimed sensitivity level, it is recommended that the test be repeated with a new sample in 68-72 hours or that an alternate confirmation method be used.

PERFORMANCE CHARACTERISTICS
The McKesson Consult ® Diagnostics hCG Urine Cassette has a sensitivity of 20 mIU/mL in urine. It is capable of detecting pregnancy as early as 1 day after the first missed menses.