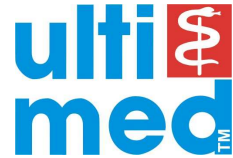


**ulti med hCG Card Test  
001C040**



**FOR PROFESSIONAL USE ONLY  
FOR IN-VITRO DIAGNOSTIC USE ONLY  
A rapid, one step test for the qualitative detection of  
human chorionic gonadotropin (hCG) in urine**

**INTENDED USE**

The *ulti med* hCG Card Pregnancy Test 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 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.<sup>1,2,3,4</sup> hCG levels continue to rise very rapidly, frequently exceeding 100 mIU/mL by the first missed menstrual period,<sup>2,3,4</sup> 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 *ulti med* hCG Card Pregnancy Test is a rapid test that qualitatively detects the presences of hCG in urine specimen 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 *ulti med* hCG Card Pregnancy Test shows no cross-reactivity interference from the structurally related glycoprotein hormones hFSH, hLH and hTSH at high physiological levels.

**PRINCIPLE**

The *ulti med* hCG Card Pregnancy Test 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 utilizes a combination of antibodies including a monoclonal hCG antibody to selectively detect elevated levels of hCG. 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 card contains anti-hCG particles and anti-hCG coated on the membrane.

**PRECAUTIONS**

- For in vitro diagnostic use only.
- Do not use after the expiration date.
- The test device 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 device should be discarded according to federal state and local regulations.

**STORAGE AND STABILITY**

The kit can be stored at room temperature or refrigerated (2-30°C). The test card is stable through the expiration date printed on the sealed pouch. The test card 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 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.

### 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

#### MATERIALS PROVIDED

- Test devices
- Disposable specimen droppers
- Package insert

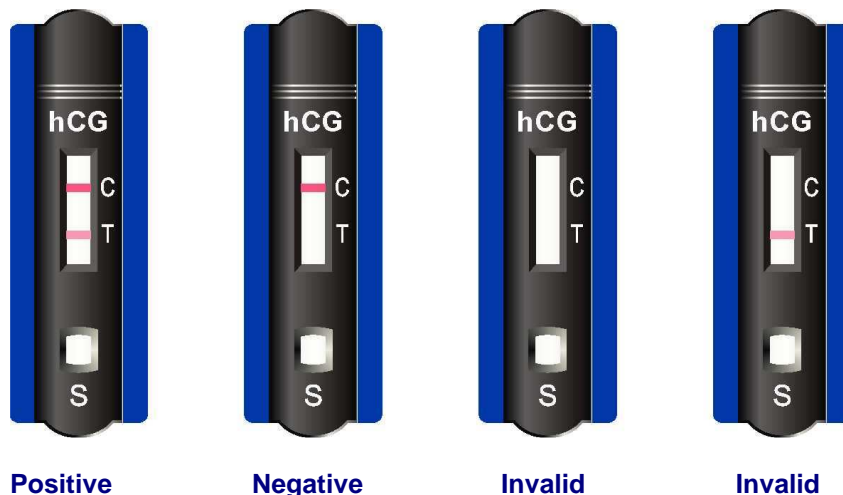
#### MATERIALS REQUIRED BUT NOT PROVIDED

- Specimen collection container
- Timer

### DIRECTIONS FOR USE

- 1 Allow the test device, urine specimen and/or controls to equilibrate to room temperature (15-30°C) prior to testing.
- 2 Bring the pouch to room temperature before opening it. Remove the test device from the sealed pouch and use it as soon as possible.
- 3 Place the test device on a clean and level surface. Hold the dropper vertically and transfer 3 full drops of urine (approx. 180 µl) to the specimen well (S) of the test device, and then start the timer. Avoid trapping air bubbles in the specimen well (S). See the illustration below.
- 4 Wait for the red line(s) to appear. The result should be read at 3 minutes.

**Note:** A low hCG concentration might result in a weak line appearing in the test region (T) after an extended period of time; therefore, do not interpret the result after more than 10 minutes.



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**INTERPRETATION OF RESULTS**

(Please refer to the illustration on previous page)

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

**\*NOTE:** The intensity of the red color in the test line region (T) will vary depending on the concentration of hCG present in the specimen. Therefore, any shade of red in the test region (T) should be considered positive.

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

**INVALID: Control line fails to appear.** Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test device. 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 red line appearing in the control region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique.

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 test devices are received.

**LIMITATIONS**

1. The *ulti med* hCG Card Pregnancy Test is a qualitative test, therefore, neither the quantitative value nor the rate of increase in hCG can be determined by this test.
2. Very dilute urine specimens, as indicated by a low specific gravity, may not contain representative levels of hCG. If pregnancy is still suspected, a first morning urine specimen should be collected 48 hours later and tested.
3. False negative results may occur when the levels of hCG are below the sensitivity level of the test. When pregnancy is still suspected, a first morning urine specimen should be collected 48 hours later and tested.
4. Very low levels of hCG (less than 50 mIU/mL) are present in urine specimen shortly after implantation. However, because a significant number of first trimester pregnancies terminate for natural reasons,<sup>5</sup> a test result that is weakly positive should be confirmed by retesting with a first morning urine specimen collected 48 hours later.
5. 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.<sup>6,7</sup> Therefore, the presence of hCG in urine specimen should not be used to diagnose pregnancy unless these conditions have been ruled out.
6. 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 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 *ulti med* hCG Card Pregnancy Test has a sensitivity of 25 mIU/mL, and is capable of detecting pregnancy as early as 10 days after a possible conception.

**PERFORMANCE CHARACTERISTICS**

**ACCURACY**

A multi-centre clinical evaluation was conducted comparing the results obtained using the *ulti med* hCG Card Pregnancy Test to another commercially available urine membrane hCG test. The study included 159 urine specimens: both assays identified 88 negative and 71 positive results. The results demonstrated a 100% overall accuracy of the *ulti med* hCG Card Pregnancy Test when compared to the other urine membrane hCG test.

### hCG Reference Method

| Method                                  | Other hCG Rapid Test |          |          | Total Results |
|---|----------------------|----------|----------|---------------|
| <i>ulti med</i> hCG Card Pregnancy Test | Results              | Positive | Negative |               |
|   | Positive             | 71       | 0        | 71            |
|   | Negative             | 0        | 88       | 88            |
| <b>Total Results</b>                    |                      | 71       | 88       | 159           |

Relative Sensitivity: 100%

Relative Specificity: 100%

Accuracy: 100%

### SENSITIVITY AND SPECIFICITY

The *ulti med* hCG Card Pregnancy Test detects hCG at a concentration of 25 mIU/mL or greater. The test has been standardized to the W.H.O. Third International Standard. The addition of LH (300 mIU/mL), FSH (1,000 mIU/mL), and TSH (1,000 mIU/mL) to negative (0 mIU/mL hCG) and positive (25 mIU/mL hCG) specimens showed no cross-reactivity.

### INTERFERING SUBSTANCES

The following potentially interfering substances were added to hCG negative and positive specimens.

|                      |          |               |          |
|----------------------|----------|---------------|----------|
| Acetaminophen        | 20 mg/mL | Caffeine      | 20 mg/mL |
| Acetylsalicylic Acid | 20 mg/mL | Gentisic Acid | 20 mg/mL |
| Ascorbic Acid        | 20 mg/mL | Glucose       | 2 g/dL   |
| Atropine             | 20 mg/mL | Haemoglobin   | 1 mg/dL  |
| Bilirubin            | 2 mg/dL  |               |          |

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

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