

hCG Dipstick for the Detection of Pregnancy 001L023



**A rapid test for the qualitative detection of human chorionic gonadotropin (hCG) in urine.
For professional in vitro diagnostic use only.**

INTENDED USE

The ulti med hCG Dipstick 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 indicates if the defined cut-off value has been exceeded.

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 or plasma as early as 7 to 10 days after conception.^{1,2,3,4} hCG levels continue to rise very rapidly, frequently exceeding 100 mIU/mL by the first missed menstrual period^{2,3,4} 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 or plasma 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 Dipstick is a rapid test that qualitatively detects the presence 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 Dipstick shows no cross-reactivity interference from the structurally related glycoprotein hormones hFSH, hLH and hTSH at high physiological levels.

TEST PRINCIPLE

The ulti med hCG Dipstick 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 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 immersing the test dipstick in a urine specimen 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.

PRECAUTIONS

- For professional in vitro diagnostic use only.
- For single use only. Do not reuse.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- Do not use if protective pouch is damaged.
- Immerse test strip at most until maximum line.
- Do not use after the expiration date.
- The used test should be discarded according to local regulations.
- Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
- The Test Dipstick must reach room temperature in order to avoid deactivation of special membrane by condensation from air humidity.

STORAGE AND STABILITY

Store as packaged 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.**

MATERIALS PROVIDED

- Test Dipsticks
- Package insert

MATERIALS REQUIRED, BUT NOT PROVIDED

- Specimen collection container
- Timer

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.

Note: urine specimens and all materials that have been in contact with urine should be considered, treated and disposed off as infectious material. A contact with the skin is to be avoided by wearing protective gloves and proper laboratory clothing.

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.

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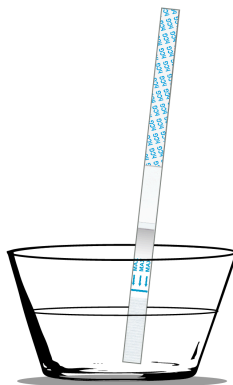


DIRECTIONS FOR USE

Bring pouch to room temperature before opening it. Remove the test from the sealed pouch and use it within one hour.

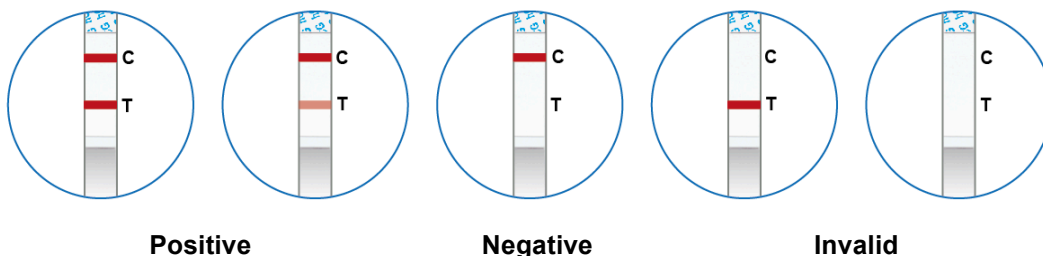
1. Label the test strip immediately after removing it with the individual patient number.
2. With arrows pointing toward the urine specimen, immerse the test dipstick vertically in urine for at least 15 seconds.
3. **Do not exceed the maximum line (MAX)** when immersing the test strips in urine specimen.
4. Place the test dipstick on a non-absorbent flat surface, start the timer and wait for the colored line(s) to appear.
5. **The result should be read at 3 minutes.**

Note: A low hCG concentration might result in a weak line appearing in the test line region (T) after an extended period of time. Do not interpret the result after 10 minutes.



Reproductions may vary from original!

INTERPRETATION OF RESULTS



Positive

Negative

Invalid

Positive (hCG > 25 mIU/mL)

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). One line may be lighter than the other; they do not have to match. **Probably pregnant.**

Negative (hCG < 25 mIU/mL)

One colored line appears in the control line region (C). No line appears in the test line region (T). **Probably not pregnant.**

Invalid

The result is invalid if no colored line appears in the control line region (C), even if a line appears in the test line region (T). You should repeat the test with a new test dipstick.

NOTE ON INTERPRETATION OF THE TEST RESULTS

In case of an expected pregnancy, a negative result should be repeated 2-3 days later with a new urine specimen or checked with a quantitative test.

Border line cases in that only a weak test line (T-line) appears, should be repeated 2-3 days later with a new specimen. If the on the repeated testing you receive a definite negative result, this could indicate a miscarriage. A natural termination of pregnancy has been observed in 22% of not diagnosed pregnancies.⁵

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 is received.

LIMITATIONS

1. The ulti med hCG Dipstick is a preliminary 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.

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3. Very low levels of hCG (less than 50mIU/mL) are present in urine specimens shortly after implantation. However, because a significant number of first trimester pregnancies terminate for natural reasons,⁵ a test result that is weakly positive should be confirmed by retesting with a first morning urine specimen collected 48 hours later.
4. This test may produce false positive results. 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.^{6,7} Therefore, the presence of hCG in urine should not be used to diagnose pregnancy unless these conditions have been ruled out.
5. This test may produce false negative results. 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. In case pregnancy is suspected and the test continues to produce negative results, see a physician for further diagnosis.
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.
7. Medication taken in the course of antibody therapy can falsify the result.
8. At very high hCG concentrations (~ 200000 mIU/mL) the free hCG can block the formation of a red line in the T area. In such cases, repeat the test with a diluted sample (1:10 or 1:20).

EXPECT VALUE

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 Dipstick for urine 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

Accuracy

A multi-center clinical evaluation was conducted comparing the results obtained using the ulti med hCG Dipstick to another commercially available urine hCG Rapid test. The study included 608 urine specimens, and both assays identified 231 positive and 377 negative results. The results demonstrated >99% overall accuracy of the ulti med hCG Dipstick when compared to the other hCG Rapid Test.

Method		Other hCG Rapid Test		Total Results
ulti med hCG Test	Results	Positive	Negative	
	Positive	231	0	231
	Negative	0	377	377
Total Results		231	377	608

Accuracy: >99% (99.1%~100%) *

Specificity: >99% (98.8%~100%) *

Sensitivity: >99% (96.9%~100%)*

* 97.5% Confidence Intervals

Sensitivity and Cross-Reactivity

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

PRECISION

Intra-Assay

Within-run precision has been determined by using 10 replicates of four specimens containing 25 mIU/mL, 100 mIU/mL, 250 mIU/mL and 0 mIU/mL of hCG. The negative and positive values were correctly identified 100% of the time.

Inter-Assay

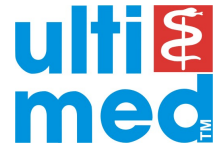
Between-run precision has been determined by using the same four specimens of 25 mIU/ml, 100 mIU/ml, 250 mIU/ml and 0 mIU/ml of hCG in 10 independent assays. Three different lots of the hCG Dipstick have been tested. The specimens were correctly identified 100% of the time.

Interfering Substance

The following potentially interfering substances were added to hCG negative and positive specimens. None of the substances at the concentration tested interfered in the assay.












Acetaminophene	20mg/dL	Atropine	20mg/dL	Gentesin acid	20mg/dL
Acetylsalicylic acid	20mg/dL	Bilirubine	2mg/dL	Glucose	2g/dL
Ascorbic acid	20mg/dL	Caffeine	20mg/dL	Hemoglobine	1mg/dL

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 Manufacturer	 Contents sufficient for <n> tests
 For in vitro diagnostic use only	 Lot. no.
 For single use only	 Expiration date
 Read instructions for use	 Store at
 Keep away from direct sunlight	 Ordering number
 Keep dry	

This operating manual conforms to the latest technology / revision. Subject to change without prior notice!



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