

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

INTENDED USE

The **ultimed hCG Dipstick 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 indicates if the defined cut-off value has been exceeded or not. The ulti med pregnancy test is determined for the in vitro diagnostic use in laboratories or physicians' offices.

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.^{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 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 **ultimed hCG Dipstick Pregnancy Test** 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 **ultimed hCG Dipstick Pregnancy Test** shows no cross-reactivity interference from the structurally related glycoprotein hormones hFSH, hLH and hTSH at high physiological levels.

PRINCIPLE

The **ultimed hCG Dipstick 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 immersing the test strip 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.

REAGENTS

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

PRECAUTIONS

- For in vitro diagnostic use only
- Do not use after expiry date
- The test device should remain in sealed foil pouch until use.
- Do not moisten nitrocellulose membrane with urine.
- For single use only. Do not reuse.
- Do not use if protective pouch is damaged. Testkit must reach room temperature in order to avoid deactivation of special membrane by condensation from air humidity.
- Use a new urine cup for each specimen in order to avoid cross contaminations.
- Urine specimens are to be considered infectious material and to be treated as such with respective precautions.
- The used test has to be disposed off according to local regulations.
- Immerse test strip at most until maximum line.
- Interpret test results in 3-5 minutes. Do not interpret after more than 10 minutes.
- If no C-line, repeat test with a new test strip.

STORAGE AND STABILITY

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

- Do not freeze.
- Do not use beyond the expiration date.

MATERIALS**MATERIALS PROVIDED**

- Test strips with coated special membrane (monoclonale and polyclonal antibodies) and colour reagent (colloidal gold coated with monoclonal antibodies) and dessicant in foil pouch.
- Package insert

REQUIRED BUT NOT PROVIDED MATERIAL

- 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. 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.

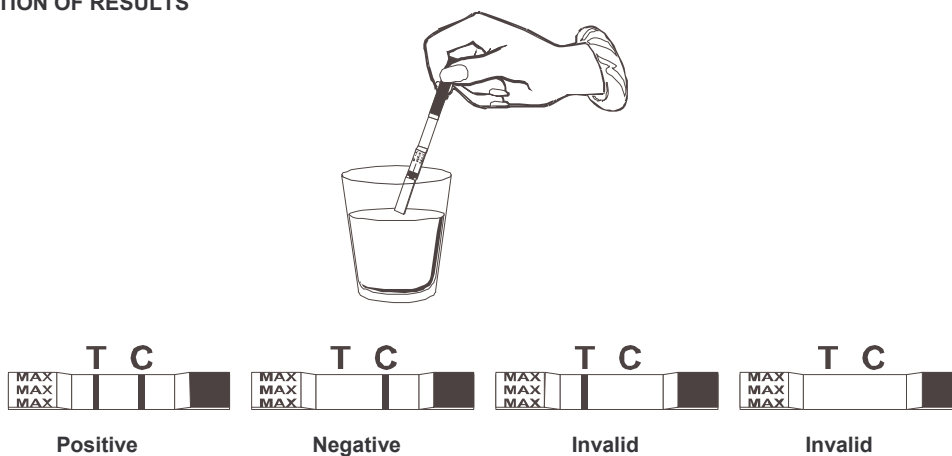
Note: urine specimens and all materials that have been in contact with urine should be considered, treated and disposed off as infectious material. A contact with the skin is to be avoided by wearing protective gloves and proper laboratory clothing.

DIRECTIONS FOR USE

The above instructions for specimen collection are to be followed. The specimen, test strip and / or controls should be brought to room temperature. Open the protective pouch only shortly before performing the test, as the special membrane is sensitive to humidity.

- 1 Use for each test a new test strip.
- 2 Use only test strips whose foil pouch is not damaged.
- 3 Before performing the test, bring urine specimen, test strips and / or controls to room temperature. (15 – 30 °C).
- 4 Remove test strip from protective pouch from sealed pouch and use it as soon as possible.
- 5 Immediately after removing the test strip from the sealed pouch, mark the test strip with the corresponding patient number.
- 6 Perform the test on a clean an plain surface.
- 7 Immerse the tip vertically in urine for at least 10-15 seconds.
- 8 Do not exceed the maximum line (MAX) when immersing the test strips in urine specimen.
- 9 Wait until chromatography has finished, i. e. that the liquid has proceeded to the end of the result fields.
- 10 Perform the test on a non-absorbent surface, start timer and wait for red lines to appear.
- 11 Interpret the test results after 3-5 minutes. The confirmation of a negative result should be done after max. 10 minutes.

INTERPRETATION OF RESULTS



Negative:*	Only in the control region (C) appears a red line, i. e. hCG < 25 m I.U. / mL.
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).
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 strip. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

ADVICE REGARDING THE INTERPRETATION OF 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

LIMITATIONS

- 1 An increase of hCG levels is not always to due a pregnancy, because neoplastic processes can also cause an increase of hCG concentrations.
- 2 Urine specimens with low specific gravity may contain only low hormone levels. Therefore, it is recommended to repeat the test after 2-3 days with morning urine.
- 3 The **ultimed hCG Dipstick Pregnancy Test** results should be confirmed by further results of clinical evaluation by the physician in charge.
- 4 Drugs prescribed in an antibody therapy may influence the results.
- 5 At very high hCG concentrations (~ 200 000 m I.U. / mL) the free hCG can inhibit the development of a red line in the test region (T-line). The test is to be repeated with a diluted specimen (1:10 or 1:20).
- 6 Heterophilic antibodies or unspecific protein binding can cause false positive results. If the test result does not fit in the clinical report the test should be repeated with a different method.

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 **ultimed** hCG Dipstick Pregnancy Test has a sensitivity of 25 mIU/mL, and is capable of detecting pregnancy as early as 1 day after the first missed menses.

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 is received.

SENSITIVITY

The **ultimed hCG Dipstick Pregnancy Test** gives a red line in the test region if the hCG concentration exceeds 25 m I.U. / mL.

SPECIFICITY

The possible cross reactions have been checked with structurally similar hormones like human follicle-stimulating hormone (hFSH), human luteinizing hormone (hLH) and human thyroid-stimulating hormone (hTSH). At the below mentioned concentrations there was no discoloration observed at the indicated concentrations in the test region.

hLH	300	no
hFSH	1000	no
hTSH	1000	no

CROSS REACTIONS

Following substances were added to positive and negative urine:

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

There were no cross reactions found.

LITERATURE

1. Batzer FR. "Hormonal evaluation of early pregnancy", *Fertil. Steril.* 1980; 34(1): 1-13
2. Catt KJ, ML Dufau, JL Vaitukaitis "Appearance of hCG in pregnancy plasma following the initiation of implantation of the blastocyte", *J. Clin. Endocrinol. Metab.* 1975; 40(3): 537-540
3. Braunstein GD, J Rasor, H. Danzer, D Adler, ME Wade "Serum human chorionic gonadotropin levels throughout normal pregnancy", *Am. J. Obstet. Gynecol.* 1976; 126(6): 678-681
4. Lenton EA, LM Neal, R Sulaiman "Plasma concentration of human chorionic gonadotropin from the time of implantation until the second week of pregnancy", *Fertil. Steril.* 1982; 37(6): 773-778
5. Steier JA, P Bergsjö, OL Myking "Human chorionic gonadotropin in maternal plasma after induced abortion, spontaneous abortion and removed ectopic pregnancy", *Obstet. Gynecol.* 1984; 64(3): 391-394
6. Dawood MY, BB Saxena, R Landesman "Human chorionic gonadotropin and its subunits in hydatidiform mole and choriocarcinoma", *Obstet. Gynecol.* 1977; 50(2): 172-181
7. Braunstein GD, JL Vaitukaitis, PP Carbone, GT Ross "Ectopic production of human chorionic gonadotropin by neoplasms", *Ann. Intern Med.* 1973; 78(1): 39-45