

Ultra One Step Pregnancy Test Strip (Urine/Serum)

A rapid, one step test for the qualitative detection of human chorionic gonadotropin (hCG) in urine or serum.

For professional in vitro diagnostic use only.

INTENDED USE

Atlas hCG One Step Pregnancy Test Strip (Urine/Serum) is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine or serum 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⁽¹⁻⁴⁾. hCG levels continue to rise very rapidly, frequently exceeding 100 mIU/mL by the first missed menstrual period⁽²⁻⁴⁾, 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.

Atlas hCG One Step Pregnancy Test Strip (Urine/Serum) is a rapid test that qualitatively detects the presence of hCG in urine or serum specimen at the sensitivity of 10 mIU/mL. The test utilizes a combination of monoclonal and polyclonal antibodies to selectively detect elevated levels of hCG in urine or serum. At the level of claimed sensitivity, Atlas hCG One Step Pregnancy Test Strip (Urine/Serum) shows no cross-reactivity interference from the structurally related glycoprotein hormones hFSH, hLH and hTSH at high physiological levels.

PRINCIPLE

Atlas hCG One Step Pregnancy Test Strip (Urine/Serum) is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine or serum 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 or serum 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 and 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 at the control line region if the test has been performed properly.

REAGENTS

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

PRECAUTIONS

- For professional *in vitro* diagnostic use only. Do not use after the expiration date.
- The test strip should remain in the closed pouch until use.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The test strip should be discarded in a proper biohazard container after testing.

STORAGE AND STABILITY

Store as packaged in the closed pouch at 4-30°C. The test strip is stable through the expiration date printed on the sealed pouch. The test strip must remain in the closed 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.

Serum Assay

Blood should be collected aseptically into a clean tube without anticoagulants. Separate the serum from blood as soon as possible to avoid hemolysis. Use clear non-hemolyzed specimens when possible.

Specimen Storage

Urine or serum specimen 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.

PROCEDURE

Materials Provided

- Test strips
- Package insert

Materials Required but not Provided

- Specimen collection container

- Timer

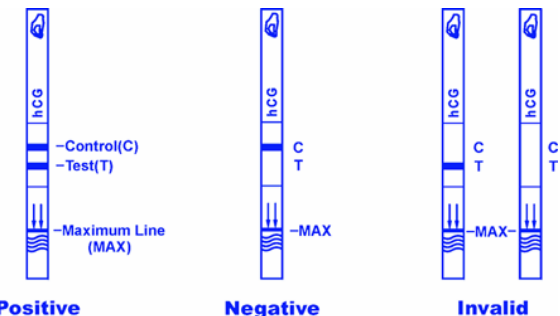
PROCEDURES FOR USE

Allow the test strip, urine or serum specimen and/or controls to equilibrate to room temperature (15-30°C) prior to testing.

1. Bring the pouch to room temperature before opening it. Remove the test strip from the sealed pouch and use it as soon as possible.
2. With arrows pointing toward the urine or serum specimen, immerse the test strip vertically in the urine or serum specimen for at least 5 seconds. Do not pass the maximum line (MAX) on the test strip when immersing the strip. See the illustration below.
3. Place the test strip on a non-absorbent flat surface, start the timer and wait for the red line(s) to appear. **Read the result at 3 minutes when testing a urine specimen, or at 5 minutes when testing a serum specimen.** It is important that the background is clear before the result is read.

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 10 minutes.

INTERPRETATION OF RESULTS



(Please refer to the illustration above)

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).

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

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.

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. However, neither the quantitative value nor the rate of increase in hCG can be determined by this qualitative test.

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. A clear background is also required.

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. 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.
2. 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 or serum specimen should be collected 48 hours later and tested.
3. Very low levels of hCG (less than 50 mIU/mL) are present in urine or serum specimen shortly after implantation. However, because a significant number of first trimester pregnancies terminate for natural reasons⁵⁾, a test result that is weakly positive should be confirmed by retesting with a first morning urine or serum specimen collected 48 hours later.
4. 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 or serum specimen should not be used to diagnose pregnancy unless these conditions have been ruled out.
5. 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.

Atlas hCG One Step Pregnancy Test Strip (Urine/Serum) has a sensitivity of 10 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 Atlas hCG One Step Pregnancy Test Strip (Urine/Serum) to another commercially available urine/serum membrane hCG test. The urine study included 155 specimens and both assay identified 76 negative and 79 positive results. The serum study included 57 specimens and both assays identified 38 negative and 19 positive results. The results demonstrated a 100% overall agreement (for an accuracy of $\geq 99\%$) of Atlas hCG One Step Pregnancy Test Strip (Urine/Serum) in comparison to the other serum/urine membrane hCG test.

SENSITIVITY AND SPECIFICITY

Atlas hCG One Step Pregnancy Test Strip (Urine/Serum) detects hCG at a concentration of 10 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 (10 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 ,
Hemoglobin	1 mg/dL
Bilirubin (serum)	40 mg/dL,
Bilirubin (urine)	2 mg/dL
Thiglycerides (serum)	1200 mg/dL

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

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