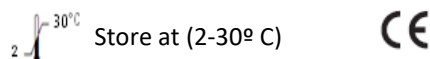


hCG Pregnancy Test Device (Urine/Serum)

IVD For *in vitro* diagnostic and professional use only



INTENDED USE

ATLAS hCG One Step Pregnancy Test Device (Urine/Serum) is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine or serum aiding to the early detection of pregnancy.

INTRODUCTION

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. hCG levels continue to rise very rapidly, frequently exceeding 100 mIU/mL by the first missed menstrual period, 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 Device (Urine/Serum) is a rapid test that qualitatively detects the presence of hCG in urine or serum 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 or serum. At the level of claimed sensitivity, ATLAS hCG One Step Pregnancy Test Device (Urine/Serum) shows no cross-reactivity interference from the structurally related glycoprotein hormones hFSH, hLH and hTSH at high physiological levels.

PRINCIPLE

The One Step HCG Pregnancy Rapid Test Kit is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin (HCG) in (urine/serum) to aid in the early detection of pregnancy. The test utilizes antibodies including a monoclonal HCG-β antibody and goat anti-mouse IgG on the nitrocellulose membrane with colloidal gold marked anti-HCG-α monoclonal antibody as a marker. The reagent is used to detect the HCG in (urine/serum) according to the principle of double antibody sandwich method and gold immunochromatography assay.

There is a control line (C) controlling the reaction process shown on the coated film. Based on test line's (T) appearance to determine whether the tested sample contains HCG (Human Chorionic Gonadotrophin) or not.

MATERIALS

MATERIALS PROVIDED

- Test devices (The test device contains anti-hCG particles and anti-hCG coated on the membrane).
- Disposable specimen droppers.
- Package insert.

MATERIALS REQUIRED BUT NOT PROVIDED

- Specimen collection container.
- Timer.

PRECAUTIONS

- For professional *in vitro* diagnostic use only, Do not use after the expiration date.
- The test device should remain in the sealed pouches until use.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The test device should be discarded in a proper biohazard container after testing.
- Reagents should be used as soon as possible after opened. This reagent cannot be reused for disposable.
- The test device should remain in the sealed pouches until use. If sealing problem happens, do not test, do not use after the expiration date.
- A small bag of desiccant is in the aluminum foil bag, do not eat.

STORAGE AND STABILITY

- Store as packaged in the closed pouch at 2-30°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.
- Some protective measures should be taken in hot summer and cold winter to avoid high temperature or freeze-thaw.

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.

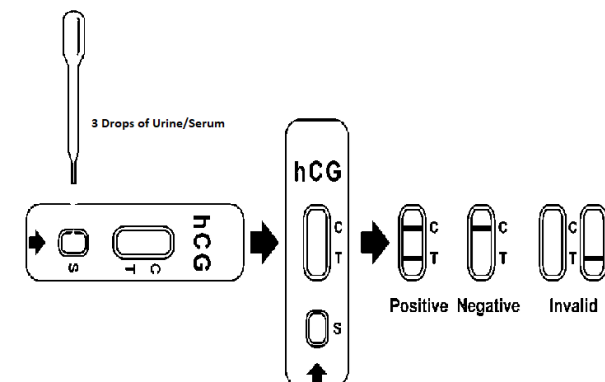
PROCEDURE

Allow the test device, 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.
2. 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.

4. Hold the dropper vertically and transfer **3 full drops of urine or serum** to the specimen well (S) of the test device avoiding the formation of bubbles and then start the timer.
5. Wait for the red line(s) to appear.
 - Read the result within **5 minutes**, the result is invalid over 5 minutes for urine specimen.
 - Read the result within **5-7 minutes**, the result is invalid over 7 minutes for serum specimen.

Note: It is important that the background is clear before the result is read.



INTERPRETATION OF RESULT

(PLEASE REFER TO THE ILLUSTRATION ABOVE)

1. **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).
2. **NEGATIVE:** One red line appears in the control region (C). No apparent red or pink line appears in the test region (T).
3. **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.

NOTE:

If the result is still suspected, a first morning urine specimen should be collected 24 to 72 hours later and test again.

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 Device (Urine/Serum)** 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 positive 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

- 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.
- 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.
- Very low levels of hCG (less than 50 mIU/mL) are present in urine and serum specimen shortly after implantation. However, because a significant number of first trimester pregnancies terminate for natural reasons, a test result that is weakly positive should be confirmed by retesting with first morning urine or serum specimen collected 48 hours later.
- 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. Therefore, the presence of hCG in urine or serum specimen should not be used to diagnose pregnancy unless these conditions have been ruled out.
- 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.
- False Negative results may occur to samples of women who are pregnant for more than 5 weeks. This is due to excess hCG variants in the urine that had been noticed in some uncommon cases of 10 weeks of pregnancy. If such cases are suspected, a dilution of 1:10 of the samples needs to be retested to confirm the negative results.

PERFORMANCE CHARACTERISTICS

1. Limit of detection:

The limit of detection concentration of HCG test is not higher than 25mIU/ml.

2. Specificity

2.1 Negative specificity:

Samples	500 mIU/mL hLH 0 mIU/mL HCG	1000 mIU/mL hFSH 0 mIU/mL HCG	1000 µIU/mL hTSH 0 mIU/mL HCG
Results	Negative	Negative	Negative

2.2 Positive specificity:

Samples	500 mIU/mL hLH 25 mIU/mL HCG	1000 mIU/mL hFSH 25 mIU/mL HCG	1000 µIU/mL hTSH 25 mIU/mL HCG
Results	Positive	Positive	Positive

3. Diagnostic specificity and sensitivity

A clinical evaluation was conducted on 230 specimens (including 80 positive specimens and 150 negative specimens) comparing the results obtained using HCG test kits of Atlas and other commercially available HCG tests. The results are as follows:

Positive Specimens	80	HCG test Kits of Atlas	HCG test Kits of control group
		80/80 (100 %)	80/80 (100 %)
Negative Specimens	150	HCG test Kits of Atlas	HCG test Kits of control group
		150/150 (100 %)	150/150 (100 %)

4. Repeatability:

The results should be consistent and the coloration degree should be consistent when detecting the 25mIU/mL of HCG standards by 10 kits of the same batch.

5. Lot tolerance:

Detecting with three different batches HCG test kits, the results should all meet the requirements of repeatability.

6. Analytical sensitivity:

Chyluria proteinuria, hematuria, bilirubinuria and proteinuria has no effect on the detection results, however injection or oral administration of human chorionic gonadotropin may affect the detection results.

7. Hook effect:

When the concentration of HCG exceeds 50000mIU/ml, the detection result may be negative due to the hook effect and should be diluted and test again.

NOTES

- The test line is significant when the concentration of HCG is high, and the control line maybe weak. It is a normal phenomenon.
- A number of conditions other than pregnancy, including uterine cancer, hydatidiform mole or menopause, cause elevated levels of HCG and positive result.
- If ectopic or abnormal pregnancy is still suspected, a confirmed pregnancy diagnosis should be made by other methods,
- If pregnancy is still suspected, a first morning urine specimen should be collected 48 to 72 hours later and tested.

















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	Catalogue Number		Temperature limit
	In Vitro diagnostic medical device		Caution
	Contains sufficient for <n> tests and Relative size		Consult instructions for use (IFU)
	Batch code		Manufacturer
	Do not re-use		Use-by date
	Manufacturer fax number		Do not use if package is damaged
	Manufacturer telephone number		Date of Manufacture
	Keep away from sunlight		Keep dry