




Home Pregnancy Test Midstream (Urine) For In-Vitro and self-testing use

 Store at 2 to 30°C

INTENDED USE

Home Pregnancy Test, Midstream (Urine) is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine to aid in the early detection of pregnancy.

MATERIALS

- Test Device
- Desiccant
- Package Insert

PRECAUTIONS & WARNINGS

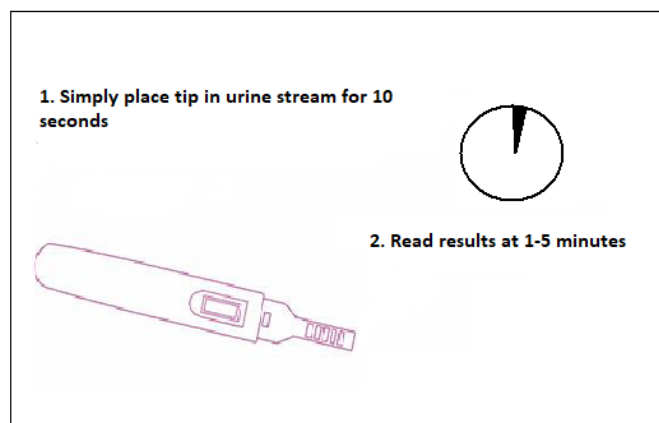
- Do not use the test after the expiration date.
- If the package is not completely sealed do not use the test.
- If the test is stored in the refrigerator, bring it out of the refrigerator and keep it at room temperature for 30 minutes to reach the room temperature.
- The test should be performed in a well-lit area.
- Use the test device immediately after opening it.
- Do not touch the test window. This could affect results and may also impose personal hazards.
- The pouch contains a Silica gel pack to absorb humidity. Do not open the pack. Throw it away with the remaining of the test.
- At the end of the test, wrap everything you have used in a plastic bag and throw away in the bin. Do not forget to wash your hands and test tabletop with soap properly.
- In the unlikely event of a test component being swallowed, medical aid should be sought immediately.
- Keep away from children reach.
- Do not keep the test, sample or any component related to the test unattended.
- Do not eat, chew or swallow the test.

PROCEDURE

Refer to the illustration below

- Step 1:**
- Read instructions carefully before use.
 - It is preferred to perform the test on the first morning void because the first thing morning urine contains the highest amount of hCG.
 - Check that the test is completely sealed then open the pouch.
- Step 2:**
- Remove the cap from the device.
- Step 3:**
- Hold the device by the handle with the exposed absorbing tip pointing downwards.
 - Place the wick into the urine stream for at least 10 seconds; making sure that the entire tip is wet.
(Note: Do not urinate on the result window of the device. If you prefer, you can urinate into a clean and dry container, then dip only the absorbent tip of the midstream test into the urine for at least 10 seconds.)
 - Remove the device from the urine stream (if you like, you may replace the cap - replacing the cap will not affect the results).
- Step 4:**
- Place the device on a flat surface with the window facing up. You will notice a pink color moving across the result window indicating that the test reaction is taking place.
- Step 5:**
- Read results at 1-5 minutes. Look for colored bands (lines) to appear in result window.
 - Test results should not be read after 5 minutes.

Refer to the illustration below



HOW TO READ THE RESULTS



PREGNANT: Positive results: 2 bands

The presence of two red lines in the result window means you are probably pregnant. One line may be lighter than the other; they do not have to match. Check with your doctor to confirm pregnancy.



NOT PREGNANT: Negative results = one band in the (C) area

The presence of one red line in the control area (C) means you are probably not pregnant.



INVALID RESULT: Invalid results = no bands or 1 band in the (T) area.

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

WHAT THE RESULTS MEAN?

A positive result indicates that your urine contains hCG (the pregnancy hormone) **at a concentration more than or equal to 25mIU/ml which is our device sensitivity** and you can assume you are pregnant. You should consult your doctor who is best able to further advise you on proper prenatal care. If you are taking medication, inform your doctor immediately and make sure it is safe for your baby.

A negative result means that no hCG has been detected and you can assume you are not pregnant. If a week passes and your menstrual period is still delayed, you should do another test after two days. If the result is still negative in the second test, there is little chance that you are pregnant and there could be other health-related reasons why you are not menstruating. In this case you should see your doctor without delay.

If your menstrual cycle is irregular, it can be difficult to know the day you have missed your period. If your test indicated you are not pregnant and your menstrual cycle does not begin within a few days, you may have miscalculated your cycle and should use a second test after two days.

LIMITATION OF THE TEST

The test is not reusable and works only if the instructions are followed precisely. Although the test is highly accurate in detecting pregnancy, a low incidence of false results can occur. Check with your doctor if you get unexpected or inconsistent test results. Certain health conditions can also cause a false or irregular test result.

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. Interfering substances:

None of the substances mentioned below at the concentration tested interfered with the expected test results of the Atlas Home Pregnancy Test Midstream.

Analyte	Concentration	Analyte	Concentration
Acetaminophen	20 mg/mL	Atropine	20 mg/mL
Acetylsalicylic Acid	20 mg/mL	Bilirubin	2 mg/dL
Ascorbic Acid	20 mg/mL	Caffeine	20 mg/mL
Gentisic Acid	20 mg/mL	Glucose	2 g/dL
Hemoglobin	10 mg/dL	Ampicillin	20 mg/mL
Tetracycline	20 mg/mL		



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REF	Product No.	Reference		Single use. Do not re-use.
IVD	For in-vitro diagnostic use.			Do not use if the pouch is damaged.
ST	For Self-Testing use.			Store at
	Caution.			Number of tests in the pack.
	Read product insert before use.			Manufacturer.
LOT	Lot (batch) number.			Expiry date.
	Manufacturer telephone number.			Manufacturer fax number.

QUESTIONS & ANSWERS**Q. How does the test work?**

A. When a woman is pregnant; her body produces a special pregnancy hormone known as hCG (human Chorionic Gonadotropin). This hormone appears in the urine as early as the first day of a missed menstrual cycle. A positive result indicates that your urine contains hCG and you can assume you are pregnant. A negative result means that no hCG has been detected and you can assume you are not pregnant.

Q. What if the two pink lines appear, but one is much lighter than the other, am I pregnant?

A. Yes. You should assume you are pregnant.

Q. What if I am uncertain about the pink line in the "T" area?

A. It is recommended that you retest three days later using other tests.

Q. Can the result change after a certain length of times?

A. A positive test result might not change after the test is completed and several hours thereafter. However, a negative test result should not be read after 5 minutes.

Q. What should I do if the test result is negative and I still suspect that I am pregnant?

A. You may have miscalculated when your period was due. If your period does not start within a week, repeat the test. If you still get a negative result and your period has not started, you should see your doctor.

Q. What if I am uncertain about the other pink line in the "T" area?

A. It is recommended that you retest three days later using another tests.