



hCG One Step Pregnancy Test Midstream

REF GAHCG-103a

Familiarize yourself with this test and read the Instructions For Use carefully before testing.

Instructions For Use

IVD For Over-the-Counter Use

INTENDED USE

The hCG One Step Pregnancy Test Midstream is an *in vitro* diagnostic visual qualitative immunochromatographic assay designed for the rapid determination of human chorionic gonadotropin (hCG) in urine to aid in the early detection of pregnancy. For OTC self-testing use.

PRECAUTIONS

- This test is designed for *in vitro* diagnostic use only.
- This kit is for external use only. Do not put in mouth.
- Do not use the test kit beyond the expiry date.
- Do not use the kit if the pouch is punctured or not sealed properly.
- Keep out of the reach of children.
- Urine specimens may be infectious; ensure proper handling and discard all used device according to the local regulations.
- The test is for single use. Do not reuse it.

STORAGE AND STABILITY

- Store at 2-30°C (36-86°F) in the sealed pouch up to the expiration date. If stored in the refrigerator 2-8°C (36-46°F), allow to warm to room temperature 15-30°C (59-86°F) before performing the test.
- Keep away from sunlight, moisture, and heat.
- DO NOT FREEZE (temperature below 0°C or 32 °F).

MATERIALS

- Midstream Test Device
 - Instructions For Use
- Materials Required but not Provided:**
- Timer, clock, or watch
 - Urine collection container (if applicable)

RECOMMENDED TIME OF USE

- Use the test after a missed period.
- The device can detect pregnancy starting at one day after the missed period.

SPECIMEN COLLECTION AND PREPARATION

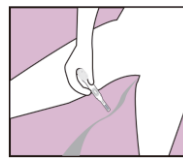
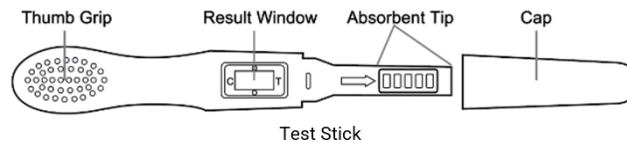
Any urine specimen is appropriate for pregnancy testing, but the first-morning urine specimen is optimal because of its highest concentration of hCG. The midstream test is designed to be used during urination or with urine collected in a cup.

DIRECTIONS FOR USE

1. Open the pouch just a **few** minutes before performing the test by tearing along the notch.
2. Remove the test device from the pouch and use it as soon as possible.
3. Hold the thumb grip with one hand and pull off the cap with the other hand to expose the absorbent tip. (See illustration below)
4. Point the absorbent tip downward; place the absorbent tip in the urine stream for at least 3 seconds to be thoroughly wet. **Do not urinate above the arrow mark.**

OR

- You can collect your urine in a clean, dry cup and dip half of the absorbent pad into the urine for at least 3 seconds.
5. Recap the device and set a timer for 5 minutes. Read the result after 5 minutes. **Do not interpret the result after 10 minutes.**



Midstream (3 seconds)

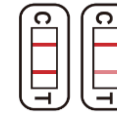
OR



Urine Cup (3 seconds)



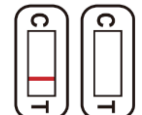
INTERPRETATION OF RESULTS



Positive



Negative



Invalid

Positive (Pregnant)

Two distinct red lines appear. One line should be in the control region (C) and another line should be in the test region (T). This suggests you are probably pregnant. **Note:** One line may be lighter than the other; they do not have to match.

NOTE: If the test line is weak, it is recommended the test be repeated in 48 hours.

Negative (Not pregnant)

One red line appears in the control region (C). No apparent red or pink line appears in the test region (T). This suggests you are probably not pregnant or the level of hCG is too low for the test to detect.

Invalid

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

EXPECTED RESULTS

Negative results are expected in healthy, non-pregnant women. Healthy pregnant women have hCG present in their urine specimens. The amount of hCG will vary greatly with gestational age and between individuals. The One Step Pregnancy Test can be used as early as the first day of the missed period. The One Step Pregnancy Test has a sensitivity of 25 mIU/mL.

QUALITY CONTROL

A procedural control is included in the test. A red line appearing in the control line region (C) is considered an internal procedural control. It confirms the reagents are working properly, sufficient specimen volume was used, and correct procedural technique was used. 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. If the test does not show any Control or Test line in the window or a smudged or partial line, the test should be discarded. Do not use the results. Run the test again with a

new midstream device and follow the procedure exactly. If the second test does not show lines, please contact Technical Service.

LIMITATIONS

- If the result is positive, please follow up with your doctor.
- If pregnancy is still suspected after getting a negative result, test yourself again in 2 days or a later time.
- Low concentration of hCG in a very early pregnancy can give a negative result. In this case, another specimen should be obtained at least 2 days later and tested.
- Besides being pregnant, some other conditions can also lead to high levels of hCG. So, a positive result cannot be used to diagnose pregnancy unless these reasons have been ruled out by a doctor.
- A normal pregnancy cannot be distinguished from an ectopic pregnancy based on hCG levels alone. Also, spontaneous miscarriage may cause confusion in interpreting test results.
- If you are on any medications containing hCG, such as for weight loss, to trigger ovulation or treat infertility (e.g., Pregnyl, Profasi, Pergonal, APL, Clomid® or Serophene®), you may get an inaccurate test result. Check with your doctor to follow up.












QUESTIONS & ANSWERS

- Q:** How soon after I suspect I am pregnant can I take the test?
A: You can test your urine as early as the first day you miss your period. You can perform the test any time of the day; however, if you are pregnant, first-morning urine contains the most pregnancy hormone.
- Q:** Do I have to test with first-morning urine?
A: Although you can test any time of the day your first morning urine specimen is usually the most concentrated of the day and would contain the highest concentration of hCG.
- Q:** Which factors may affect the test result?
A: Medications that contain hCG, such as Pregnyl, Profasi, Pergonal, APL, Clomid® or Serophene®, can give a false positive result. Alcohol, oral contraceptives, painkillers, antibiotics, or hormone therapies that do not contain hCG should not affect the test result.
- Q:** Does a positive result mean anything other than normal pregnancy if it shows that I am pregnant?
A: Yes, there are other medical conditions or medications

that can cause positive results. Consult your physician for any positive pregnancy result.

- Q:** How do I know that the test was performed properly?
A: The appearance of a red line in the control window (C) tells you that you followed the test procedure properly and the proper amount of urine was absorbed.
- Q:** What should I do if the result shows that I am not pregnant?
A: hCG concentrations vary greatly in early pregnancy. If you do not start your period within a week of its due date, repeat the test with a new midstream test. If you receive the same result after repeating the test and you still do not get your period, you should see your doctor.

SYMBOL INDEX

	Do not reuse		See Instruction for Use		Expiration Date
	Tests per Kit		Store Between 2-30°C (36-86°F)		Keep Dry
	Batch Number		Catalog#		Keep Away from Sunlight
	Unique Device Identifier		For <i>in vitro</i> diagnostic use only		

ASSISTANCE

If you have any questions regarding the use of this product, please call the Technical Support Number 1-888-982-3818 (8:30 a.m. to 5:00 p.m. CDT).