hCG Early Pregnancy Rapid Test

User instruction

For Self-testing

REF IDH-MS-HCG-1	English

【INTENDED USE】

The Identify Health hCG Early Pregnancy Rapid Test is intended for the qualitative detection of human chorionic gonadotropin (hCG) in urine, as an aid in early detection of pregnancy, in some cases as early as five (5) days before the expected period, i.e., as early as six (6) days before the day of the missed period.

Important note regarding positive results:

Because this test detects low levels of hCG, it is possible that this test may give positive results even if you are not pregnant. All results should be confirmed by your healthcare provider, especially when making decisions about future medical care.

This device is intended for home-use only.

【PRECAUTIONS】

Please read all the information in this user instruction before performing the test.

- Do not use after the expiration date on the foil pouch.
- Store in a dry place at 2-30°C or 35.6-86°F. Do not freeze.
- Do not use if pouch is torn or damaged.
- Keep out of reach of children.
- The desiccant in the foil pouch is for storage purposes only. **DO NOT** swallow.
- Do not open the test device foil pouch until you are ready to start the test.
- The used test device should be discarded according to local regulations.

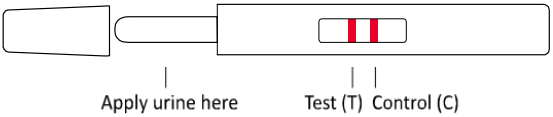
【MATERIALS PROVIDED】

- Pregnancy Test (with desiccant)
- User Instruction

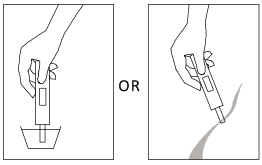
【MATERIALS NEEDED BUT NOT PROVIDED】

- A clean, dry cup to collect urine
- Timer (Watch or clock)

【INSTRUCTIONS】



1. Remove the device from the foil pouch and use test immediately.
2. Remove the cap of the device, then urinate on the device sponge for at least 10 seconds or place the head of sponge (greater than two-thirds) into urine in a clean cup for at least 10 seconds.



3. Replace the cap, then lay down the test on a clean flat surface, start the timer immediately.
4. The result should be read within 3~10 minutes. Do not read result after 10 minutes as results may be wrong.

【READING THE RESULTS】

POSITIVE

Two colored lines, one in the control line region (C) and the other line in the test line region (T), is a positive result. This double line test result indicates that you are pregnant.

NEGATIVE

One colored line in the control line region (C), but no visible line in the result region (T), is a negative result. This single line test result indicates that you are not pregnant.

INVALID

If there is no visible line in the control region(C), the test is not valid. This indicates an error in testing procedure or deterioration of reagents. If you obtain an invalid result, repeat the test with a new kit.

INVALID POSITIVE NEGATIVE

【LIMITATIONS】

1. Low levels of hCG may be present in non-pregnant people. Because this test detects low levels of hCG, positive results may occur even if you are not pregnant. All results should be confirmed by your healthcare provider, especially when making decisions about future medical care
2. Medications containing hCG can affect the result. A number of conditions other than pregnancy cause elevated levels of hCG and could cause misleading results. All results should be confirmed by your healthcare provider.
3. Very diluted urine samples may not contain representative levels of hCG. If pregnancy is still suspected after a negative result, a first morning urine sample should be obtained 48 hours later and tested.
4. This test may produce false negative results. 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 should be collected 48 hours later and tested. In case pregnancy is suspected and the test continues to produce negative results, see a physician for further diagnosis.
5. A confirmed pregnancy diagnosis should only be made by a doctor.
6. This device is intended for home-use only and not intended for clinical-care settings.

【QUESTIONS AND ANSWERS】

Q. Is it important to follow the instructions exactly?

A. Yes. Accurate results depend upon correct testing procedure.

Q. How does the test work?

A. The hCG Early Pregnancy Rapid Test detects a very small concentration of the HCG in your urine, your body produces hCG during pregnancy. The amount of hCG increases as pregnancy progresses.

Q. How soon after I suspect that I am pregnant can I take the test?

A. You can test your urine as early as 6 days before the day of the missed period.

Q. Do I have to test with first morning urine?

A. You can test at any time of the day, your first morning urine is recommended. First morning urine is usually the most concentrated of the day, it would have the most hCG in it.

Q. How accurate is the test?

A. The hCG Early Pregnancy Rapid Test was compared with another commercially urine hCG test with clinical samples. The results indicated the same accuracy.

Q. What should I do if the result is positive?

A. All results should be confirmed by your healthcare provider, especially when making decisions about future medical care.

Q. What should I do if the result is negative?

A. It means you are probably not pregnant, or it may be too early to tell. If you do not get your period within a week of its due date, you should retest with a new hCG Early Pregnancy Rapid Test. If you receive the same result, discuss them with your doctor.

Q. How do I know that the test was run properly?

A. A colored line in the control line region (C) tells you that you followed the test procedure properly and the test has worked.

Index of Symbols

	Consult instructions for use	Σ	Contains sufficient for <n> tests	86°F 30°C 35.6°F 2°C	Store between 35.6-86°F (2-30°C)
IVD	*In vitro* diagnostic medical device	LOT	Batch code	REF	Catalogue number
	Manufacturer		Use-by date		Do not re-use
	Do not use if package is damaged and consult instructions for use	UDI	Unique device identifier		

Manufactured for:

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