

Rapid Response® Pregnancy Test

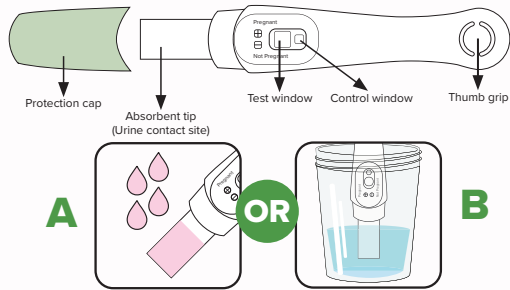
Product Insert

Before Using

The Rapid Response® Pregnancy Test is a rapid home test to aid in the early detection of pregnancy. The device is a chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine. This test can help detect pregnancy as early as 6 days before the day of the missed period (5 days before the day of the expected period). **Read these instructions carefully before taking a test.**

1 Take the Test

If you are testing before your expected period, use first morning urine, as it contains the most pregnancy hormone. If testing on the day of or any day after your expected period, you can test any time of the day. You can test directly in your urine stream (Option A), or by collecting your urine in a clean, dry container (Option B).



Do not touch the absorbent tip!

1. After reading the instructions, when you are ready to use the test, take the test out of the protective foil and remove the protective cap (do not discard).

Option A: Test directly in urine stream: Hold the test by the thumb grip with the absorbent tip pointed down and the result windows facing away from you while you pee. Urine should only touch the absorbent tip, do not urinate on the test window. Place the tip in the urine stream for 5-10 seconds.

Option B: Test in collected urine sample: Collect fresh urine in a clean, dry container. Collect enough urine to submerge the entire absorbent tip, but do not submerge the plastic. Hold in the collected urine for 5-10 seconds.

2. After sampling, immediately replace the cap over the absorbent tip and lay the test on a flat, non-absorbent surface with the test window facing up.

2 Wait for Results

Wait for the coloured lines to appear. Read the results at 3 minutes. Do not interpret the results after 10 minutes.



3 Reading The Results

Hold the test horizontal with the writing upright and facing you.

PREGNANT (Positive +)



A vertical and a horizontal line is present in the **Test Window**, forming a plus (+) sign. It does not matter how faint or dark the lines are. A vertical line must be present in the **Control Window**. Speak to your doctor to confirm that you are pregnant.

NOT PREGNANT (Negative -)



A vertical line is present in the **Control Window** and a blue horizontal line is present in the **Test Window**.

INVALID



Do not interpret the results if there is **no** vertical line in the **Control Window** or no horizontal line in the **Test Window**. If these lines fail to appear, discard the test, review the procedure and test again.

Questions

1. How does the test work?

Rapid Response® Pregnancy Test detects a hormone in your urine that your body produces during pregnancy (hCG - human Chorionic Gonadotropin). The amount of this hormone in your body increases as pregnancy progresses.

2. How soon after I think that I am pregnant can I take the test?

You can take the test up to 6 days before your missed period (5 days before the day of your expected period). If you test before your expected period and get a "Not Pregnant" result, there is still a chance that you may be pregnant. See the chart below for results from clinical testing of the Rapid Response® Pregnancy Test with early pregnancy samples.

Testing Early

Number of days before the expected period	0	1	2	3	4	5
% of samples from pregnant women giving a "pregnant" result	>99%	>99%	>99%	97%	94%	75%

3. Do I have to test with my first morning urine?

If you are testing before your expected period, we recommend that you test with your first morning urine as it is usually the most concentrated of the day and would have the most pregnancy hormone (hCG) in it. If you are testing on the day of, or after your missed period, you can test at any time of the day. Avoid excessive fluid intake before testing.

4. Can other medical conditions affect the results?

Medications containing hCG can affect the result. Ectopic pregnancy and recent pregnancy even if not carried to full term can cause misleading results. If you are in or approaching the menopause you may obtain a false pregnant result even though you are not pregnant. These conditions must be ruled out before the test can be used to diagnose pregnancy.

5. What if the test result shows I am pregnant but I think I am not?

If you received a "Pregnant" result but believe that you are not pregnant, schedule an appointment with your doctor. You may have a health condition, not pregnancy, that is raising your hCG level.

6. The tests result shows I am not pregnant but I think I might be. What should I do?

- The test may indicate "Not Pregnant" for a few different reasons. Your hCG levels may not be developed enough to be detected yet. If you tested early, you should test again in 3 days with another Rapid Response® Pregnancy Test.

- If you do not get your period within 7 days, you should retest with another Rapid Response® Pregnancy Test. If this second test also indicates "Not Pregnant" and you still have not had your period, see your doctor.

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

The appearance of a blue vertical line in the Control Window indicates that the correct amount of urine was applied to the absorbent tip and the test was performed properly. If there is no blue vertical line in the Control Window and/or no blue horizontal line or "-" (minus) symbol in the Test Window, the test was not performed properly and the result is invalid. Please repeat the test with a new test. Make sure the absorbent tip is dipped in the urine or placed in the urine stream for at least 5 seconds, but no more than 10 seconds.

Performance

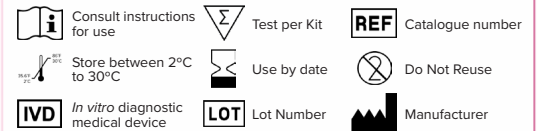
Accuracy: A clinical evaluation was conducted comparing the Rapid Response® Pregnancy Test to a market leading pregnancy test. The clinical trial included 205 urine samples: both assays identified 103 positive and 102 negative results. The results showed the test is over 99% accurate.

Sensitivity: The Rapid Response® Pregnancy Test detects hCG in urine at a concentration of 10 mIU/mL or greater. The test has been standardized to the W.H.O. International Standard. The addition of LH (1,000 mIU/mL), FSH (1,000 mIU/mL), and TSH (1,000 µIU/mL) to negative (0 mIU/mL hCG, 3mIU/mL hCG) and positive (10 mIU/mL hCG) samples showed no false positives.

Warnings

For *in vitro* diagnostic use. For self-testing at home. This is a single use device, do not reuse. Not for internal use. Keep out of reach of children. Contains small parts. Do not eat the components of the test. If accidentally swallowed, seek medical attention. Store between 2-30°C (36-86°F). Limit exposing the test to humid conditions, as humidity and high temperature may adversely affect results. Do not freeze. Allow the test to reach room temperature before use, leaving it to sit for at least 30 minutes at room temperature if it is being stored refrigerated. Keep in sealed pouch until use. Do not use if the wrapper is damaged. Do not use past 'use by' date (indicated by the hourglass symbol on the packaging). Use the test immediately after removing it from the pouch. Do not touch the absorbent tip to avoid contamination. Do not immerse, soak or dip the test above the absorbent tip. Use the test immediately after sample collection. Use fresh urine, do not allow urine to sit for a prolonged period at room temperature before using the test. If the urine sample is cloudy, allow it to settle until it is clear. Urine samples may be infectious, use care when handling. Do not use urine containing excessive bacterial contamination. Use a clean, dry collection container for each urine sample. Protect the test from contamination. This test is for human urine only. Dispose of with normal household waste.

Glossary of Symbols



Contact

If you have questions, reach out to our Technical Support:
support@btnx.com
1-888-339-9964
Monday-Friday 9:00AM-5:30PM EST.

