

# Rapid Response® Pregnancy Test Cassette

## Product Insert

### Before Using

The Rapid Response® Pregnancy Test Cassette 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 is capable of detecting pregnancy as early as 1 day after the first missed period. **Read these instructions carefully before taking a test.**

### Contents of the Box

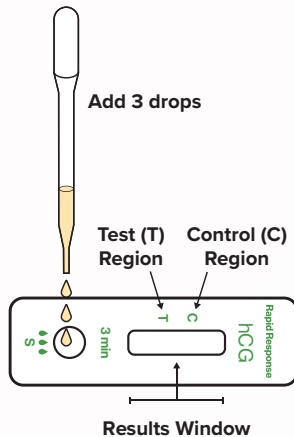
Contains materials for 1 to 100 tests.

**Provided:**  
Test cassette(s), Dropper(s), Urine sample collector(s)

**Not provided:**  
Timer

### 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.



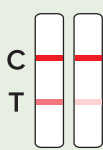
1. Use a clean, dry container to collect the urine.
2. Open the pouch and take out the cassette and dropper. Place the test cassette on a non-absorbent clean, flat surface.
3. Using the provided dropper, add 3 drops of urine into the sample well (S). Avoid dropping air bubbles onto the sample well (S) and do not touch or put any liquid on the results window in the center of the cassette.

### 2 Wait for Results

Start the timer. 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



#### PREGNANT (Positive)

Two lines appear. One in the **Test Region (T)** and one in the **Control Region (C)**. It does not matter how faint or dark the lines are. Speak to your doctor to confirm that you are pregnant.



#### NOT PREGNANT (Negative)

Only one line appears in the Control Region (C). No line appears in the Test Region (T).



#### INVALID

Do not interpret the results if there is **no** line in the **Control Region (C)**. If no control line appears, discard the test, review the procedure and test again.

### Questions

1. **The test shows I am not pregnant but I think I might be. What should I do?**  
You may not be pregnant, or the level of hCG might not be high enough to be detected by the test. If you test negative but think you may still be pregnant, re-test with first morning urine 2-3 days later, after your missed period. If you continue to test negative but think you are pregnant, see your doctor.
2. **Can other medical conditions affect the results?**  
Some trophoblastic diseases and non-trophoblastic neoplasms or cancers can cause elevated levels of hCG. These conditions must be ruled out before the test can be used to diagnose pregnancy.
3. **What if the test says I'm pregnant but I think I'm not?**  
You may get a pregnant result and find out that you are not pregnant. This may be due to natural loss of pregnancy early in the first trimester, which is extremely common. If you get unexpected results, speak to your doctor.
4. **The test result shows I am pregnant, what should I do?**  
Contact your doctor for the next steps and arrange a laboratory pregnancy test to confirm your result.

### Performance

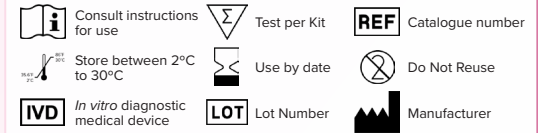
**Accuracy:** When compared against laboratory methods, the Rapid Response® Pregnancy Test Cassette is shown to be 99.9% effective at detecting pregnancy one day after a missed period.

**Sensitivity:** The Rapid Response® Pregnancy Test Cassette has a sensitivity of 20 mIU/mL for urine and is capable of detecting pregnancy as early as 1 day after the first missed period. Reportedly, a level of 20 mIU/mL or more is present 7-10 days after conception or 4-5 days prior to the first missed period.

### 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 test cassette membrane to avoid contamination. Do not immerse, soak or dip the test cassette. 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.

**BTNX, Inc.**  
722 Rosebank Road,  
Pickering, ON L1W 4B2, Canada  
Technical Support: 1-888-339-9964



Effective date: 2024-03-26  
Insert document #