

Rapid Response™ Digital Pregnancy Test Package Insert

Intended Use

Rapid Response™ Digital Pregnancy Test is a pregnancy test. It is used for the qualitative detection of hCG in human urine as an aid in early detection of pregnancy. For in vitro diagnostic use, for over-the-counter use.

Storage Conditions

Store in dry places at 35.6-86 °F (2-30 °C). Do not freeze. Use the test within 1 hour after removing from the foil pouch. Do not use after the expiration date printed on the foil pouch.

Sample Requirements

The urine can be collected in a clean, dry cup, or by directly urinating on the absorbent tip of the test. The first morning urine specimen is preferred, however, urine specimen collected at any time of the day can be used. Please perform the test immediately after urine collection.

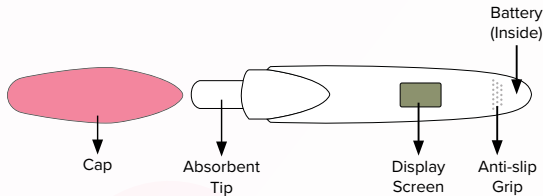
Materials

Materials Provided:

- Rapid Response™ Digital Pregnancy Test
- Package Insert

Materials Required but not Provided:

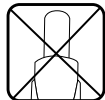
- Watch or Clock
- Clean, dry cup



Take The Test

The test should be performed at room temperature 59-86°F (15-30°C).

Important: Throughout testing never hold the test with the Absorbent Tip pointing upwards.



Step 1

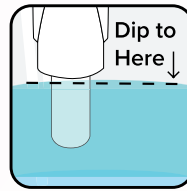
When you are ready, remove the test from the foil pouch and remove the cap. Hold Anti-slip Grip with the Absorbent Tip pointing downwards.



A

Keep the Display Screen facing upward, place the Absorbent Tip in your urine stream for 5 seconds. Be careful not to get the urine on the plastic holder.

OR

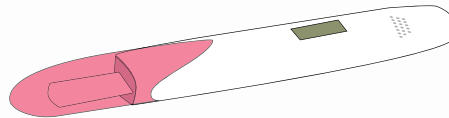


B

You may collect your urine in a clean, dry cup and immerse the entire Absorbent Tip in the urine for 10 seconds.

Step 2

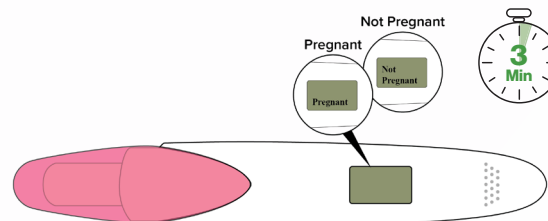
Replace the Cap and place the test on a flat surface with the Display Screen facing upwards.



The clock symbol ⌚ will appear and blink on the Display Screen after urine is applied, indicating the test is working.

Step 3

In approximately 3 minutes, the result "Pregnant" or "Not Pregnant" will appear on the Display Screen.



Reading The Results

Pregnant

PREGNANT (Positive)

Shows on the display, this means that you are probably pregnant.

Not Pregnant

NOT PREGNANT (Negative)

Shows on the display, this means that you are probably not pregnant.

INVALID

shows on the display, this means that your test is invalid.

Your result will remain on the display screen for about one hour.

If there are other results shown on the display screen, please read the section of Test Errors.

Test Errors



An error has occurred during test, it may be that:

- The absorbent tip did not keep pointing downward when applying urine.
- Too little urine was applied.
- Other instructions for use were not followed.



The test did not proceed as expected. It may be that:

- Urine sample was too little to start the test
- The test has reached the expiration date.
- Other instructions for use were not followed.

For both errors above, you should test with a new test following the instructions carefully.

Precautions

Please read all the information in this package insert before performing the test. Read the precautions listed below to ensure accurate results and proper operation of the test.

- For *in vitro* testing of human urine only. Not for internal use.
- Do not swallow any part of the test.
- Do not use after the expiration date printed on the foil pouch.

Rapid Response™

Digital Pregnancy Test

Package Insert

REF HCG-1DMAHU25

REF HCG-1DMAHU5

REF HCG-1DMAHU3

REF HCG-1DMAHU2

REF HCG-1DMAHU1

Precautions cont.

- Do not use if pouch is torn or damaged.
- Keep out of the reach of children.
- This product incorporates batteries, used test should be discarded according to local regulations.
- Do not reuse the test.

Limitations

There is the possibility that this test may produce false results. Consult your physician before making any medical decisions.

1. Medications containing hCG can affect the result. A number of conditions other than pregnancy cause elevated levels of hCG and could cause inaccurate results.
2. Very diluted urine specimens may not contain representative levels of hCG. If pregnancy is still suspected, a first morning urine specimen should be collected 48 hours later and tested.
3. 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 specimen 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.
4. This test provides a presumptive diagnosis for pregnancy. A confirmed pregnancy diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.

Extra Information

How does the test work?

It detects the pregnancy hormone hCG (human chorionic gonadotropin) in urine. When you are pregnant, your body produces the pregnancy hormone hCG (human chorionic gonadotropin), and the amount increases in the early stage of pregnancy.

Do I have to test with first morning urine?

Although you can test at any time of the day, your first morning urine is usually the most concentrated of the day and would contain the most hCG.

Extra Information cont.

What should I do if the result shows that I am pregnant?
You may be pregnant. See your doctor to confirm the result and get advice.

What should I do if the result shows that I am not pregnant?

You may not be pregnant, or your level of pregnancy hormone may not be high enough to be detected. If you do not start your period within a week of its due date, repeat the test with a new test. If you receive the same result after repeating the test and you still do not get your period, you should see your doctor.

There is an "?" displayed on the screen. What does it mean?

The "?" symbol indicates an error has occurred during test, you may read the instructions carefully and test again with a new test. See Test Errors.

I have used the test but no result has appeared on the display. What does it mean?













If no result appears, please see Test Errors.

Disposing of Your Test

The test contains batteries. Used test should be discarded according to local regulations.


Caution: Do not disassemble, recharge or dispose of batteries in fire.

Glossary of Symbols

 Consult instructions for use	 Test per kit	 Catalogue number
 Store between 35.6°F to 86°F (2°C - 30°C)	 Use by date	 Do not reuse
 In vitro diagnostic medical device	 Lot number	 Manufacturer
 Do not use if package is damaged	 Keep away from sunlight	 Keep dry

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.

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