

Contents of Package

- Foil Package (Contains: Test Device)

Self Test Device
FOR IN-VITRO DIAGNOSTIC USE
NOT FOR INTERNAL USE

Materials required but not provided:

- Clock with second hand or timer

PLEASE READ CAREFULLY BEFORE BEGINNING TEST

Before You Begin the Test

Do not open the foil wrapper until you are ready to perform the test.

Store at 3°-30°C.

Keep out of reach of children.

Do not use the test after the expiration date printed on the package.

Allow to reach room temperature (15°-30°C) for 30 minutes prior to testing.

If you have any questions regarding the instructions or your results, please refer to the Question and Answer section on reverse side or call our Technical Support department at 800-854-3002 (USA Only).

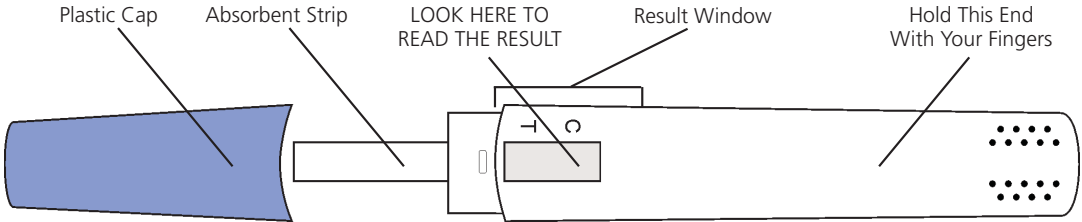


Figure 1: Top View showing Result Window where you will read your results

Intended Use

The Fortel® Midstream Pregnancy Test is designed to detect a very small amount of the pregnancy hormone hCG (human Chorionic Gonadotropin) in your urine. The cut-off of this test is 25 mIU/ml with an accuracy of >99% in laboratory studies. The Fortel® pregnancy test is ultra-sensitive; studies have shown this test can detect as low as 10 mIU/ml of hCG. It is designed to detect the pregnancy hormone (hCG) as early as 2-3 days from the rise of hCG levels.

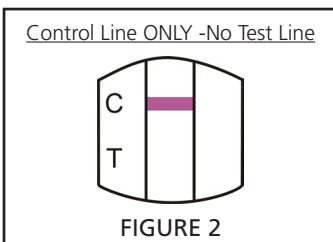
Instructions for Use

1. Remove the test device from its wrapper. Remove the purple plastic cap to expose the absorbent strip. The test device must be handled by the end opposite to the absorbent strip. Do not touch the absorbent strip with your fingers.
2. With the Result Window side of the test device facing you, place the absorbent strip of the test device in your urine stream for 5 seconds so that adequate urine will be absorbed.
If you cannot maintain a urine stream for 5 seconds, urinate into a clean, dry cup; immerse the absorbent strip of the device into the urine for 10 seconds, making sure to immerse only two-thirds to three quarters of the absorbent strip into the urine sample; continue with step #3 below.
3. After holding the device in your urine stream for 5 seconds, replace the plastic cap. Place the test device on a level surface, with the Result Window side facing up.
4. Start a timer at this point. As the urine is absorbed, you should see a pink color moving across the Result Window.
5. At exactly 5 minutes, read the result in the Result Window (see Figures 2, 3, & 4). A positive result could appear in the Result Window in less than 5 minutes, but the full 5 minutes is required to confirm a negative result. Do not read the result after 5 minutes.

NOTE: Regardless of whether you are pregnant or not, a Control band should appear in the Result Window (see Figure 2). This indicates that the test is working properly. If a Test Band also appears in the Result Window, this means that you are pregnant (FIGURE 3).

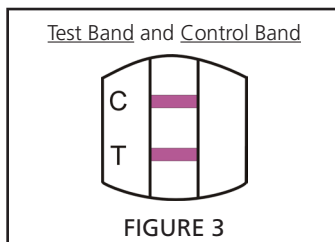
Reading and Interpretation of Test Results

6. In the Results Window there is a Control Area marked with a "C" and a Test Area marked with a "T".



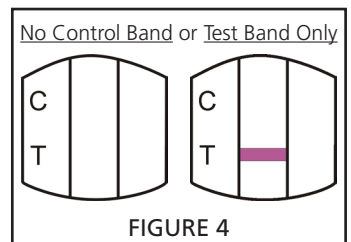
NOT PREGNANT

If only the Control Band appears in the Result Window, this indicates that you are **NOT pregnant**.



PREGNANT

You are pregnant if **TWO** pink-purple color bands (Test Band and Control Band) appear in the Result Window. Even if the Test Line is a very faint color at 5 minutes, the result is positive & you are **pregnant**. The color of the test band need not match with the control band color.



INVALID RESULT

If the Control Band does not appear in Result Window in 5 minutes, the result is **Invalid**. If only a Test Band appears in the Result Window, the result is also **Invalid**. A fresh test should be repeated if either condition occurs.

Commonly Asked Questions

How does the test work?

The Fortel® Pregnancy Test is designed to detect a very small amount of the pregnancy hormone hCG (human Chorionic Gonadotropin) in your urine. The cut-off of this test is 25 mIU/ml with an accuracy of >99% in laboratory studies. This hormone is produced soon after conception, and progressively increases during the first three months of pregnancy. The Fortel® pregnancy test is ultra-sensitive; studies have shown this test can detect as low as 10 mIU/ml of hCG. It is designed to detect the pregnancy hormone (hCG) as early as 2-3 days from the rise of hCG levels.

When can I do the test?

Allow 7 days after the date of intercourse before testing. You need not wait until you have missed your period to complete the test, but when testing before your period is due, it is recommended to use your first morning urine. An early positive result means you are pregnant, but a negative result should be retested once your period is due. You do not need to use your first morning urine if you have missed your period.

Can I collect a urine sample in a cup instead?

Yes, as long as the urine sample is collected in a clean, dry container and tested immediately. Remove the test device from its wrapper. Immerse only the absorbent strip of the test device in the urine for at least 10 seconds. Make sure to immerse two-thirds to three-quarters of the absorbent strip into the urine sample. Remove the test device, replace the plastic cap, then read the result at exactly 5 minutes.

Does breast feeding or drinking alcohol affect the test? No.

What do I do if I get a positive result?

If the test result is positive, you should consult a doctor to discuss your pregnancy and what steps and precautions you should take next. In addition, you may want to confirm your test by re-testing with another Fortel® test three days later. Remember, early pregnancy care is very important to ensure a healthy baby and mother.

What do I do if I get a negative result?

A negative result means that no hCG hormone has been detected and you are probably not pregnant. If your period does not start within a week, you may have miscalculated the day your period was due. Repeat the test using another Fortel® test. If the second test still gives you a negative result and you still have not menstruated, you should see your doctor.

What factors can affect the result?

If you follow the instructions carefully, you should not get a false result. However, certain drugs and rare medical conditions may give a false result. Injected medicines containing the pregnancy hormone hCG may cause a false result. These include, but are not limited to: A.P.L.®, Pregnyl®, Follutein®, and Profasi®.

What if I am unsure about the intensity of the color band in the test result?

If the test is positive, the Result Window will show TWO pink-purple colored bands at five minutes after the absorbent strip is exposed to the urine. The result is positive regardless of how faint or strong the colored bands are. However, if you are unsure of the result, you can confirm the result by repeating the Fortel® test after 3-4 days when rising hCG levels will produce a darker band and confirmation of pregnancy. If the repeat test fails to produce a darker test band, then please call our help-line for further interpretation of the result.

What is the clinical performance of the test?

Clinical studies for the test were performed using 100 confirmed samples. The test showed accuracy greater than 99%, specificity greater than 99%, and sensitivity greater than 99%.

Can the result change after a certain length of time?

A positive (pregnant) result will not change several days after the test is completed. However, some reddish background might be noticeable several hours after the test has been performed.

A negative (not pregnant) result should not be read in the Result Window after the five minute test waiting period. After 30 minutes some negative results might appear to be weakly positive. This happens because the test chemicals continue to react even after the five minute waiting time.

Who can I call if I have any other questions?

If you have further questions about the Fortel® test or your results call toll free 800-854-3002 weekdays 8 am - 5 pm PST (USA). Our specially trained staff will be delighted to answer any questions you have about the test.

Trying to have a baby?

The Fortel® Ovulation Test predicts the most likely day that you can become pregnant. Buy one today!

IMPORTANT MESSAGE FROM BIOMERICA

To increase your chances of a healthy pregnancy for you and your baby, you should consider the following:

- Maintain a well-balanced diet
- Stop smoking and alcohol consumption

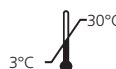
From conception through the first three months of pregnancy is the most critical time for fetal development. You need to see your doctor immediately for proper care and nutrition counseling.



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