

**One Step hCG Panel Test Kit**  
For OTC

(Revised 2018-11-27)

**INTENDED USE**

The One Step hCG Panel test is a simple one-step rapid detection of the hormone hCG for use in early pregnancy.

**EXPLANATION OF THE TEST**

The hormone hCG is produced during pregnancy. hCG can first be detected by a urine test about 12 – 14 days after conception. In general, during the first several weeks of a normal pregnancy, the hCG level will double every 48-72 hours. The levels reach their peak at about 8 to 11 weeks from the LMP (Last Menstrual Period) and then will decline and to a constant level for the remainder of the pregnancy.

**MATERIALS PROVIDED**

The One Step hCG Panel test kit contains the following items to perform the test:

1. One Step hCG midstream test device
2. Instructions for use

**PRECAUTIONS**

1. Do not remove the One Step hCG Panel test device from its original sealed pouch until ready for use.
2. Do not use the test if the pouch is damaged or the seal is broken.
3. Do not use the test kit after the expiration date.

**STORAGE AND STABILITY**

Store the One Step hCG Panel test kit at room temperature in the original sealed pouch.

**PROCEDURE OF THE TEST**

1. Remove the test stick from the foil pouch, and remove the cap from the midstream.
2. Submerge the tip of the test device into at least 3cm deep of urine sample in a urine cup. Otherwise, it may cause wicking problems.
3. Hold the Test Stick vertically, carefully dip it into the urine for at least 15 seconds.
4. Then carefully remove the Test Stick vertically from the urine specimen and hold the test stick vertically for about 10 seconds to let extra urine samples to flow out from the tip of test stick.
5. Finally carefully lay the Test Stick on a flat surface (without tilting) with the Result Window facing up. Note: failing to do this could result in erroneous results. Read test results at 5 minutes after the “C” Lines appear.

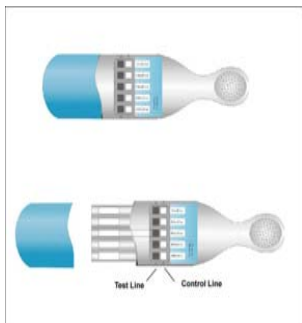


Fig 1



**INTERPRETATION OF RESULTS**

As the test kit begins to work, a **purple** line (Control Line indicated as letter “C” on the cassette) will appear in the result window to show that is working properly. If the “C” line appears as expected it means that there sufficient urine was present to activate the test, that it is working properly and that the reaction is beginning to take place in the test-chambers of the kit.

The result window in 25, 100, 500, 2000, 10000 mIU/ml columns indicates the test results. If another purple line appears at the result window, this band is the Test Line (indicated as letter “T” on the cassette).

**POSITIVE:**

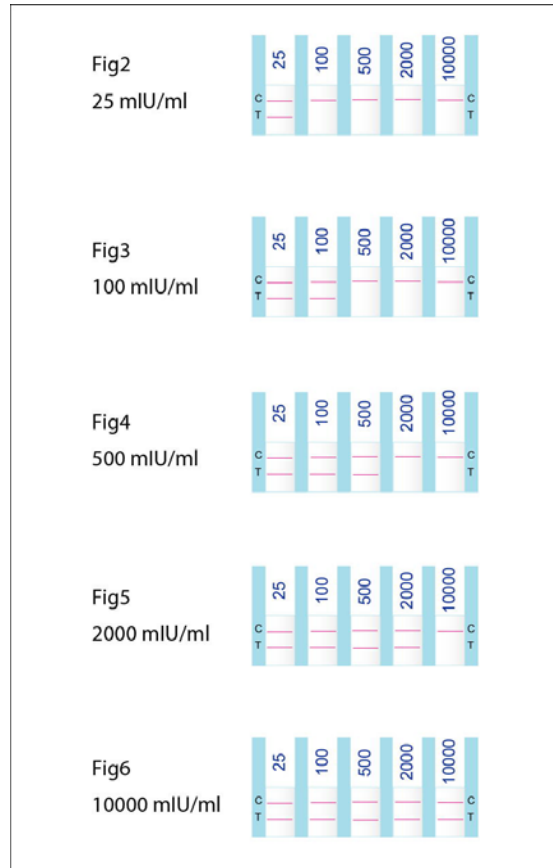
**25mIU/ml Zone:** Two purple color lines in the 25 mIU/ml Column of the Result Window, regardless of what the other columns show, indicate that the specimen contains about 25 mIU/ml of hCG. See Fig. 2

**NEGATIVE:**

If there is only one purple color line in the 25 mIU/ml Column, regardless of what the other columns show, this indicates that the hCG level in the urine is less than 25 mIU/ml.

**Note: The “T” line and the “C” line do not have to have the same color intensity. One may be fainter or darker than the other.**

You can also determine the approximate hCG level in your urine by comparing your test results to the diagrams below. This will be an estimate (depending on the concentration of your urine) of the amount of pregnancy hormone circulating in your blood stream.



**100mIU/ml Zone:** If there are **two purple** color lines of 100 mIU/ml Column of the Result Window, this indicates that the specimen contains about 100 mIU/ml of hCG. See Fig. 3.

**500mIU/ml Zone:** If there are **two purple color lines** of 500 Column in the Result Window, this indicates that the specimen contains about at 500mIU/ml. See Fig 4.

**2,000mIU/ml Zone:** If there is **two purple color line** of 2000 Column in the Result Window, this indicates that the specimen contains about 2000mIU/ml. See Fig. 5

**10,000 mIU/ml Zone:** If there is **two purple** color line of 10000 Column in the Result Window, this indicates that the specimen contains about at 10000 mIU/ml or higher. See Fig. 6

**INVALID:** The test is invalid if no color line appears in the “C” line area of the corresponding Result Window. A distinct purple line should always appear in the “C” line area of each Result Window.

**Limitations of the Test**

1. In addition to pregnancy, hCG has been found in patients with both gestation and non-gestation trophoblastic diseases.
2. Although the test can detect and indicate hCG levels at 25 mIU/ml and higher, a low incidence of false results can occur.

**QUESTIONS AND ANSWERS**

**Q: If I see two bands appear, but one band is much darker than the other, can I confirm that there are two lines?**

A: Yes. Even if the line is a slightly different color, the test should be interpreted as showing two lines.

**Q: Can the result change after standing for a certain length of time?**

A: A positive or negative result will not change after the test is completed at 5 minutes. However, in order to prevent any incorrect readings, the test result should not be interpreted after more 5 minutes.

**Q: If the test result is positive, what do I do?**

A: If the test result is positive at any zone, you should consult with your doctor. If you have already been given instructions from a doctor as to how to use this test, then follow those instructions. The earlier you see your doctor, the better it is for your health. You should also reduce alcohol intake as this may be harmful to the fetus.

**Q: If the test result is negative, what do I do?**

A: If the test is negative, you may not be pregnant or there may not be enough pregnancy hormone in your system to make the test positive. If you do not get your period in a few days, you should test again. It is possible that you miscalculated your cycle length.

**Q: If I run a second test 5 days after previous test and the result shows the concentration of hCG has dropped, what do I do?**

A: You should see your doctor and show him/her the test results of two tests.

**Q: Can I test urine at any time of a day?**

A: Yes, but the first morning urine is recommended, because it contains more hCG.

**Q: Can I get a false or misleading result?**

A: Normally this will not happen if you follow the instructions correctly. However, if you get the absorbent material wet before using the test, then you may not get a reliable result. Certain rare medical conditions can also cause a false result. If you repeatedly get unexpected results, you should check with your doctor.

**Q: Can drugs or medications affect the result?**

A: If you are taking any drugs that change the concentration of your urine, or increase the volume of your urine, the test result may not be reliable. For example, diuretic increase urine output might therefore change the concentration of the urine and the test read falsely low.

**Q: How accurate is the test?**

A: consumers' results agreed 98.75% of the time compared with professionals' results.