

HEALTH-CHEM DIAGNOSTICS, LLC

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ONESTEP™ PREGNANCY TEST SLIDE

Read all instructions before performing the test. If you have any questions, call 1-800-482-2907 and speak with a medical professional.

For *in vitro* Diagnostic Use only.
Do not take any part of this kit internally.
Keep out of the reach of children.

In just one step, OneStep™ Pregnancy Slide Test provides the results you need:

- **Easy:** Just add 3-4 drops of urine to the sample well and read in 5 minutes.
- **Convenient:** You can test any time of the day.
- **Accurate:** >99% accurate in laboratory studies and 99% accurate in consumer use.
- **Fast:** Provides results in as little as 5 minutes.
- **Early:** Can be used as early as the first day of the missed period.
- **Clear:** Provides easy-to-read results: two (2) lines you are pregnant, one (1) line you are not pregnant.

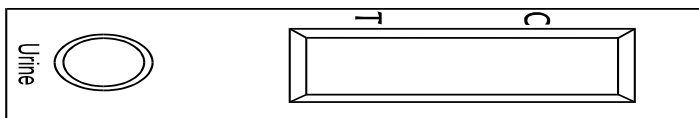
OneStep™ Pregnancy Slide Test

This pregnancy test kit contains everything you need to simply and accurately find out if you are pregnant or not in the privacy of your home. All you need to do is put 3-4 drops of your urine in the sample well of the Slide and wait for five (5) minutes. The test result in the form of red to magenta (reddish purple) lines or bars will appear in the Result Area of the slide. But before you begin, familiarize yourself with the test components.

Important:

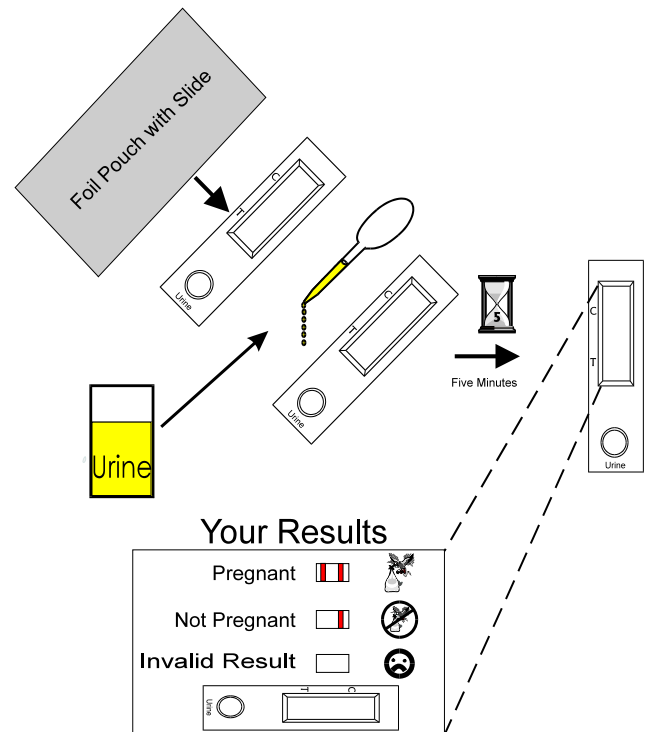
- Do not open the foil packet until you are ready to do the test.
- The OneStep™ Pregnancy Slide Test is not reusable.

OneStep™ Pregnancy Slide Test



Before You Begin

1. Read this entire pamphlet carefully. Do not open the foil packet until you are ready to perform the test.
2. Select a well-lighted room with a clean, flat surface for performing the test. Make sure you have a timer or clock within view.
3. Collect your urine in a clean glass container. Use the transfer pipette to place 3-4 drops of urine in the sample well of the slide. Stored urine needs to be at room temperature (68-85°F) for testing.
4. Do not use the test Slide beyond the expiration date printed on the package or on the foil pouch.
5. **IMPORTANT:** When placing the 3-4 drops of urine in the sample well of the Slide to perform the test, be sure to place the Slide flat and level so that the urine does not spill out of the sample area on the Slide. The test will not work properly if too much urine is used. It is better to use a smaller volume of urine than a larger volume of urine. If you exceed the maximum sample size, the test will not work. Overview of how to test using OneStep™ Pregnancy Slide Test



KIT CONTENTS:

- Test Device (Slide) in foil pouch
- Sampling device (Transfer Pipette)

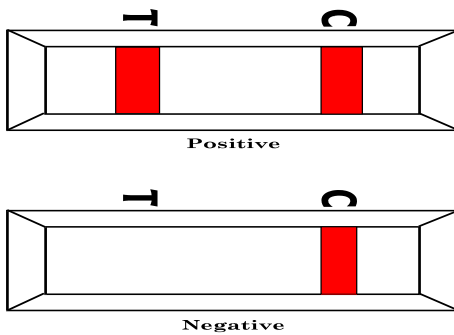
- Instructions

How OneStep™ Pregnancy Slide Test Works

When a woman is pregnant, her body produces a special pregnancy hormone known as hCG (human chorionic gonadotropin). This hormone appears in the urine. This test will detect the presence of hCG in the urine as early as the first day of a missed period.

A positive result indicates that your urine contains hCG and you can assume you are pregnant.

A negative result means that no hCG has been detected and you can assume you are not pregnant.



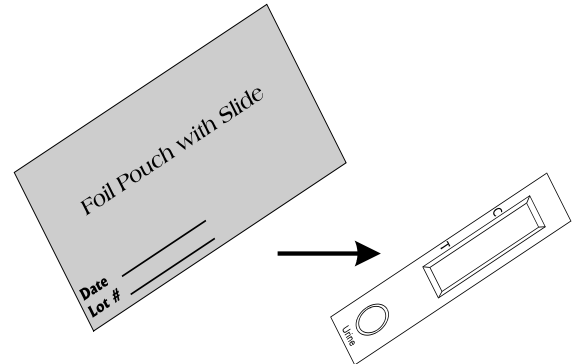
Urine Collection

You can collect your urine in any clean glass container. Your test can be performed any time of the day. You do not need to use first morning urine. However, if you are pregnant, first morning urine does have the most pregnancy hormone, since the amount of hormone has had a chance to build up in your urine overnight. You can test for pregnancy from the first day of a missed period and onward.

If you don't have time to perform the test immediately you can collect your urine in a clean glass container. After collecting your urine, cover and store your urine specimen in the refrigerator (40-50°F). Do not freeze. Do not

store for more than 12 hours after collection. If the urine has been refrigerated, let it warm to room temperature (68-85°F) before using. This should take 15-20 minutes.

Instructions For Testing



1. Open and remove the Slide from the Foil pouch. Lay the Slide Test Device down on a flat surface so that the sample and results windows are up.

NOTE: Both the Slide (Test Device) and the urine must be at room temperature before use

2. From the collection container draw up a volume of urine in the plastic pipette provided. **Remember that the urine must be brought to room temperature if it has been stored in the refrigerator.**

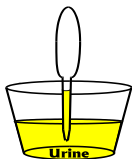
3. Dispense 3-4 drops from the plastic pipette into the sample well (the round opening on the slide. Do not use more than 4 (four) drops.

4. After 5 minutes read the results of your test in the test window per the illustrations in the **Reading Your Results** section of this package insert.

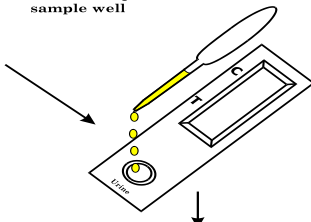
Reading Your Results

When a red line appears in the Control Area and you see a line in the Test Area, you can assume you are pregnant and should consult your doctor. **IMPORTANT:** Sometimes one line is darker than the other. The darkness of the reaction line has no meaning in the interpretation of the test results. Even if one line is very light, you can assume you are pregnant and should consult your doctor. When one red line appears in the Control Area and you do not see any lines in the Test Area, you can assume you are not pregnant.

1. Collect Urine



2. Put 3-4 Drops in sample well

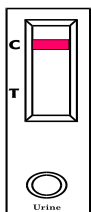


3. Wait 5 minutes Before Reading



Five Minutes

4. Read Results



Note: Do Not Read Results after 10 Minute

IMPORTANT: Any trace of a light red line in the Test Area is a positive result and you can assume you are pregnant (see above).

If You Have a Question

If you see a reddish purple line in the Control Area, you know the test system is working. If you do not see one line in the Control Area, please call our toll-free number for assistance.

If you have a question about the instructions or your test results, please call our toll-free number for assistance (1-800-xxx TBA) between XXX a.m. and XXX p.m. Eastern Time, Monday through Friday. **Please have the Product Lot Number, which appears on the outer package, and on the foil pouch, available when you call the toll-free number. Our technical staff will gladly answer your questions.**

Storage

The contents of the test kit should be stored at room temperature (68-85°F). The kit and its contents should be kept out of the reach of children.

What The Results Mean

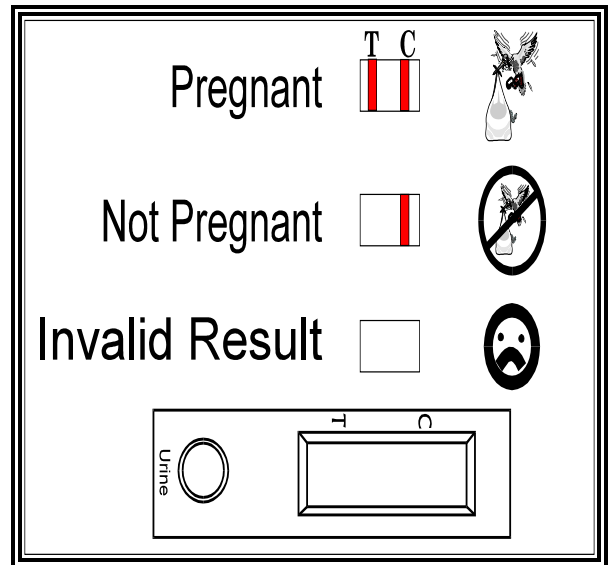
A positive result indicates that your urine contains hCG and you can assume you are pregnant. You should consult your doctor who is best able to further advise you on proper prenatal care. If you are taking any medication, telephone your doctor immediately and make sure it is safe for your baby. A negative result means that no hCG has been detected and you can assume you are not pregnant. If a week passes and you still have not started menstruating, you should do another OneStep™ Pregnancy Slide Test. If the result is still negative in this later test, there is little chance that you are pregnant. However, because there could be health-related reasons why you are not menstruating, you should see your doctor without delay.

If your menstrual cycle is irregular, it can be difficult to know the day you've missed your period. If your test indicates you are not pregnant and your period does not begin within a few days, you may have miscalculated your cycle and should use a second test.

Warning: According to the Surgeon General, women should not drink alcoholic beverages during pregnancy because of the risk of birth defects.

Limits of The Test

OneStep™ Pregnancy Slide Test is not reusable. The test works only if instructions are followed precisely. Although OneStep™



Pregnancy Slide Test is highly accurate in detecting pregnancy, a low incidence of false results (positive when no pregnancy exists or negative when pregnancy is present) can occur. Check with your doctor if you get unexpected or inconsistent test results. Certain health conditions such as an ovarian cyst or an ectopic pregnancy (a pregnancy outside the uterus) can cause a false or irregular result with your test. Oral contraceptives, pain killers, antibiotics and other common drugs do not affect the result of the test. Do not use after the expiration date shown on the package.

For In Vitro Diagnostic Use Only (Not for Internal Use).

Additional Reading on Home Pregnancy Testing:

"A Faster Home Pregnancy Test," Changing Times, April 1985, p. 14.

"Take Two Tests and Call Me in the Morning," Health Care, March 1985, pp 173-174

Commonly asked Questions with their Answers About your One Step™ Pregnancy Slide Test

Q. If I see a line in both the Test and Control areas, but one line is darker than the other, am I pregnant?

A. Yes. Even if one line is darker than the other, this should be interpreted as a positive result, and you should assume you are

pregnant. The color intensity of the line has no meaning to the results of the test.

Q. I am not sure I used enough urine in the Slide well. Will I still get an accurate result?

A. Your result will be accurate if you observe the control bar in the control window. If the control bar is present the entire test has worked as it should. If you fail to observe the development of the control bar in the control window you should call the user help line at 1-800-482-2907.

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

A. A positive test result (pregnant) will not change after the test is completed. However, some fading of the result might be noticed several days after the test is performed. The reddish purple line in the Result Area might fade to a reddish pink after several hours. If your period does not start within a week, you may have miscalculated the day your period was due. Repeat the test using another One Step™ Pregnancy Slide Test. If the second test still gives a negative result and you still have not menstruated, you should see your doctor.

Q. Do I have to wait the full five minutes before reading my results?

A. It is important that you wait for the formation of the line in the Test Area furthest from the urine sample well before reading your result. This should take approximately 5 minutes. One line may become visible quickly, but you must wait for the line furthest from the urine sample well in the Results Area to turn red (about 5 minutes) to see if the second (Control) line is going to appear.

Q. Are the reaction colors permanent?

A. Yes, the reaction colors are permanent. The test Slide when dry can be taken to your physician for confirmation of the reading.

Q. How will I know the test worked?

A. There will be the formation of a single line or bar furthest from the urine sample well. If after five (5) minutes you do not observe any lines or bars the test did not work. If the control band is not visible in the control window you should call the help line at 800-482-2907. Of course, if there are two lines or bars (one in the test window and one in the control window) you have a positive test and can assume you are pregnant.

TECHNICAL INFORMATION

SENSITIVITY AND REACTION TIME

The control line will be visible within three (3) minutes. The positive line will appear within three (3) minutes when hCG is present in the urine at a concentration equal or higher than

25mIU/ml. The urine sample should be in contact with the test strip for at least 5 minutes. There is no interference with the performance of the test, nor Prozone Effect, up to and including levels of 600,000 mIU/hCG/ml.

Positive standard solutions used: 25 IU/1 (WHO 3rd International Standard)

SPECIFICITY

No cross reactivity has been observed with the following:

LH: up to 500 mIU/ml

FSH: up to 1000 mIU/ml

TSH: up to 1000 mIU/ml

No interference has been observed with the following:

Acetaminophen – up to 20 mg/dl

Acetylsalicylic acid – up to 20 mg/dl

Albumin – up to 2 g/dl

Ampicillin – up to 20 mg/dl

Ascorbic acid – up to 20 mg/dl

Atropine – up to 20 mg/dl

Caffeine – up to 20 mg/dl

Gentisic acid – up to 20 mg/dl

Glucose – up to 2 g/dl

Hemoglobin – up to 1 mg/dl

Additional Reading on Home Pregnancy Testing

- “A Faster Home Pregnancy Test,” Changing Times, April 1985, p. 14.
- “Take Two Tests and Call Me in the Morning,” Health Care, March 1985, pp. 173-174.

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CUSTOMER HOT-LINE: 1-800-482-2907

