

HEALTH-CHEM DIAGNOSTICS, LLC

One-Step One Minute Pregnancy Test Wand

DESCRIPTION OF THE TEST

The Midstream Pregnancy Test Wand is a rapid qualitative test for the determination of human Chorionic Gonadotropin (hCG) in urine. With this highly sensitive test, pregnancy can be determined as early as the first day of the missed period. This pregnancy test kit contains everything **YOU** need to simply and accurately find out if you are pregnant or not.

In just one step and in just one minute, One-Step One Minute Pregnancy Test provides the results you need:

- **Easy Use:** Just dip the Test Wand into urine or hold in urine stream for at least 6 seconds.
- **Convenient:** You can test any time of the day.
- **Accurate Result:** >99% accurate in laboratory studies and 99% accurate in consumer use.
- **Fast Result:** Provides result in as little as 1 minute.
- **Unmistakable Result:** Provides an easy-to-read, Yes (II) or No (I) result.
- **Early Result:** Can be used as early as the first day of the missed period.
- **Technical Assistance:** You can call our toll-free number and talk to a Technical Professional for information about your test or result by calling our Help Line at 1-800-482-2907 Monday-Friday, 9:00 am to 5:00 pm Eastern Time.
- **For in vitro diagnostic use only.**
- **Do not take any part of this kit internally.**
- **Keep out of the reach of children.**
- **Read all instructions before performing the test.**

One-Step One Minute Pregnancy Test Wand

This pregnancy test kit contains everything you need to quickly and accurately find out if you are pregnant or not, in the privacy of your home. Simply dip the Test Wand into your urine stream or a small container of urine. An unmistakable result of either two lines (II) pregnant or one line (I) not pregnant will appear. The result in the form of a reddish purple line will appear in the Result Area within 1 minute. But before you begin, familiarize yourself with the test components shown below. Important: Do not open the packet until you are ready to do the test. The **One-Step One Minute Pregnancy Test** is not reusable.

One-Step One Minute Pregnancy Test Contents

One Pregnancy Test Wand in a packet.

Reagent and Material

This package contains one reaction strip, which in turn contains a polyclonal antibody coated membrane and a pad containing mouse monoclonal IgG (antibody) dye conjugate in a protein matrix.

How The One-Step One Minute Pregnancy Test Works

When a woman is pregnant, her body produces a special hormone known as human Chorionic Gonadotropin (hCG). 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

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 (4-9°C). 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 (18-25°C) before using. This should take 15-20 minutes.

Before You Begin

1. Read this entire pamphlet carefully. Do not open 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. Hold the Test Wand in your urine stream for at least 6 seconds or collect your urine in a clean glass container. Then dip the Test Wand into the urine container for at least 6 seconds.
4. Do not use the Test Wand beyond the expiration date printed on the package or on the foil packet.
5. **IMPORTANT:** When dipping the Test Wand into your urine to perform the test, be sure to hold the wand so that the urine level does not exceed the wick (the area that was covered by the cap on the Test Wand). The test will not work properly if the urine level exceeds the wick area.

Instructions For Testing

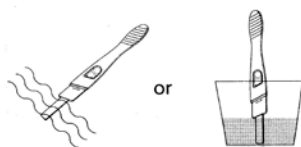
1. Remove the One-Step One Minute Pregnancy Test from the packet.



2. Pull the protective cap off the Test Wand, but do not discard it.



3. Hold the wick in your urine stream or place in collection container so that it remains upright. The Test Wand should remain in urine for a period of at least 6 seconds. Note: No urine should come in contact with the results window area.



4. Replace the protective cap and place the Test Wand on a flat surface with the Result Windows facing up.



5. As the test begins to work, you will see the formation of a reddish purple line in the Round Control Window (the window furthest from the end dipped into the urine) indicating the test is working properly. As soon as one minute, and within 5 minutes, read final results. Do not read your results after 10 minutes.



Reading Your Results

Pregnant (II): When a reddish purple line appears in both the Round Control Window and the Square Test Window, you can assume you are pregnant and should consult your physician. **IMPORTANT:** Sometimes one line is darker than the other. The color intensity has no meaning to the results of the test. Even if one line is very light, you can assume you are pregnant and should consult a physician.

Not Pregnant (I): When a reddish purple line appears in the Round Control Window and you do not see a line in the Square Test Window, you can assume you are not pregnant.

If you see a line in the Round Control Window the test has worked properly. If you do not see a line in the Round Control Window the test is invalid, please call our Help Line 9:00am - 5:00 p.m. Monday-Friday Eastern Time at 1-800-482-2907.



If You Have A Question

If you have a question about the instructions or your test results, please call our Help Line at 1-800-XXX (TBA). Our technical staff will gladly answer your questions.

Storage conditions and shelf life

The contents of the test kit should be stored at room temperature 5°C–30°C (68–85°F). The test kit and its contents should be kept out of reach of children. The shelf life of the test is 24 months from production date. An opened product stored at room temperature (5–30°C) is stable for at least 18 months (and as much as 24 months) Do Not use after the expiration date.

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What The Results Mean

A positive result indicates that your urine contains hCG and you can assume you are pregnant. You should consult your physician who is best able to further advise you on proper prenatal care. If you are taking any medication, telephone your physician 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 perform another **One-Step One Minute Pregnancy Test**. If the result is still negative the second time, there is little chance that you are pregnant. However, because there could be health-related reasons why you are not menstruating, you should contact your physician without delay.

If your menstrual cycle is irregular, it can be difficult to know the day you have 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 **One-Step One Minute Pregnancy Test**.

Accuracy

In laboratory studies, **One-Step One Minute Pregnancy Test** was shown to be **99% accurate overall**. **One-Step One Minute Pregnancy Test** was also shown to be 99% accurate when used by consumers.

Limits of the Test

One-Step One Minute Pregnancy Test is not reusable. The test works only if instructions are followed precisely. Although **One-Step One Minute Pregnancy 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 physician 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).

Question and Answer Section

- Q. If I see a line in both the Test and Control Windows, 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 held the Test Wand in my urine stream long enough. Will I still get an accurate result?

A. In order to receive an accurate results you should hold the Test Wand in your urine stream for at least 6 seconds and wait as soon as one minute but up to five minutes to read the results. If you see a reddish purple line in the Control Window, the test has worked properly. If you fail to observe the development of the line in the Control Window you should call the Help Line at 1-800-482-2907.

Q. Can the test result on the Test Wand change after a certain length of time?

A. A positive result (two lines (II) = pregnant) will not change after 5 minutes. However, some fading of the results might be noticed several hours after the test is performed. In addition, if your result was negative with only one line visible (One line (I) = not pregnant), the appearance of a faint line may appear in the test window after 30 minutes. This does not mean you are pregnant! A woman's body normally contains a small amount of hCG, this may cause a second line to appear after 30 minutes. Do not interpret your results after 10 minutes.

Q. Do I have to wait the full 5 minutes before reading my results?

A. Yes. It is important that you wait to see if a line in the Test Window (The window closest to the end dipped into the urine) appears before reading your result. This might take as soon as one minute but up to 5 minutes. The line in the Control Window may become visible quickly, but it might take up to 5 minutes for the Test Window line to appear.

Q. How will I know the test worked?

A. There must be the formation of a single line in the Control Window. If after 5 minutes you do not observe any line the test did not work properly. If the Control Line is not visible in the Control Window you should call the Help Line at 1-800-482-2907

Of course, if there are two lines (one in the Test Window and one in the Control Window) you have a positive test result and you 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.

PIN# 450612/R3-03/01/05

Positive standard solutions used: 25 IU/l (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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