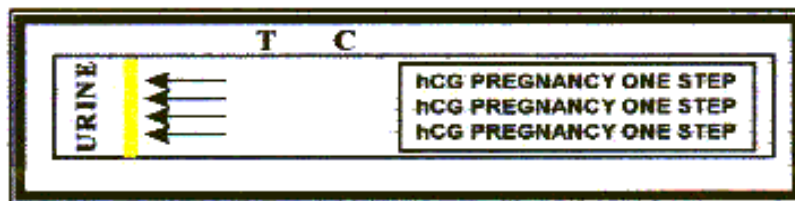


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hCG PREGNANCY ONE STEP® TEST STRIP



DESCRIPTION OF THE TEST

The hCG Pregnancy One Step® Test Strip 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. Simply place the Test Strip into the performance cup filled with urine and wait five (5) minutes. The results will appear in the form of a reddish purple line in the middle of the Test Strip.

INSTRUCTIONS FOR USE

- Read all Instructions before performing the test.
- **Convenient Result:** You can test any time of the day.
- **Accurate Result:** 99% accurate in laboratory studies; 99% accurate in consumer use.
- **Unmistakable Result:** Provides an easy-to-read, yes (II) or no (I) result as well as an indicator to tell you the test has worked.
- **Early Result:** Can be used as early as the first day of the missed period.
- **For in vitro** diagnostic use only.
- Do not take any part of this kit internally.
- Keep out of reach of children.

Important

Do not open the foil packet until you are ready to use the test. Do not use the Test Strip beyond the expiration date printed on the foil pouch. Before you begin, familiarize yourself with the kit contents.

Kit Contents – Each test kit contains:

- 1 individually packaged Test strip
- Product instruction sheet
- 1 Performance Cup

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 hCG Pregnancy One Step™ Test Strip Works

When a woman is pregnant, her body produces a pregnancy hormone known as hCG (human Chorionic Gonadotropin). This hormone appears in urine. **The hCG Pregnancy One Step™ Test Strip** can detect hCG as early as one (1) day after a missed period.

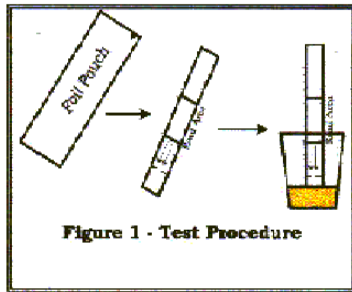
Positive Result: Indicates that your urine contains hCG and you can assume you are pregnant. **Negative Result:** Indicates that no hCG has been detected and you can assume you are not pregnant.

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.

TEST PROCEDURE

Collect the urine sample in a sample container. Remove the test strip from its foil pouch (Figure 1) holding the test strip vertically. Place in the collection vessel so that it remains vertical. The test strip should remain in the urine for a period of 5 minutes.



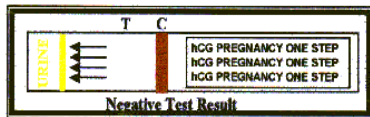
Instructions For Testing

1. Collect your urine in a cup
2. Remove the **hCG Pregnancy One Step™** Test from the foil packet.
3. Holding the Test Strip with the arrows pointing down, place the Test Strip in the cup. Do not allow the urine to exceed the line below the arrows. The Test Strip should remain in the urine for a period of five (5) minutes.

Reading Your Results

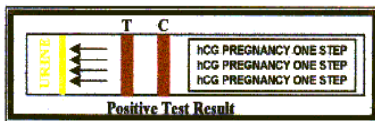
While you are waiting for your results, one (1) line will become visible quickly. However, you need to wait five (5) minutes to see if the second line is going to appear.

Negative Result: One (1) line in the Result Area means you can assume you are not pregnant.



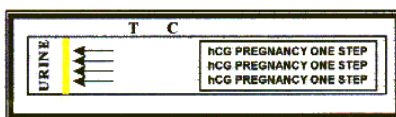
Negative Result

Positive Result: If you see two (2) lines in the Result Area, you can assume you are pregnant and should consult your physician.



Positive Result

Invalid Result: No line appear in the Result Area



Invalid Result

Important:

Sometimes one (1) line is darker than the other. The darkness of the reaction line has no meaning in the reading of the test results. Even if one (1) line is very light, you can assume you are pregnant and should consult your physician. When a red line appears in the Results Area and you see only one (1) line in the Result Area, you can assume you are not pregnant. If you do not see a reddish purple line in the Result Area the test did not work properly and this is considered an invalid result.

Limits of the Test

hCG Pregnancy One Step™ Test is not reusable. The test works only if instructions are followed precisely. Although **hCG Pregnancy One Step™ Test** is highly accurate in detecting pregnancy, a low incidence of false results 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 result. Oral contraceptives, pain killers, antibiotics and other common drugs do not affect the result.

Answers to some commonly asked questions

- Q. If I see two (2) lines appear, but one (1) line is darker than the other, can I assume I am pregnant?
- A. *Yes, even if one (1) 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. 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 hCG Pregnancy One Step™ Test. If the second test still gives a negative result and you still have not menstruated, you should see your physician.*
- Q. Do I have to wait the full five (5) minutes before reading my results?
- A. *It is important that you wait for the formation of the line in the Test Area before reading your result. This should take approximately five (5) minutes. One (1) line may become visible quickly, but you must wait for the appearance of the second line in the Test Area to see if you are pregnant.*

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.

TECHNICAL INFORMATION

SENSITIVITY AND REACTION TIME

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

SPECIFICITY

No cross reactivity has been observed with the following:

LH: upto500mIU/ml
FSH: up to1000 mIU/ml
TSH: up to 1000mIU/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

STORAGE CONDITIONS AND SHELF LIFE

The test should be stored at +5°C +30°C.

Shelf life of hCG Pregnancy One Step® Test Strip

is twenty four (24) months from production date.

Do not use after expiration date.

Manufactured in the USA by:
HEALTH-CHEM DIAGNOSTICS LLC,
POMPANO BEACH, FLORIDA
Website: www.healthchemdiagnostics.com
ISO 13485 & US FDA Certified Facility
FDA – Establishment Registration No.: 1048532

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The control line will be visible within five (5) minutes. The positive line will appear within five (5) minutes when hCG is present in the urine at a concentration equal or higher than 25 mIU/ml. The urine sample should be in contact with the test strip for at least five (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.