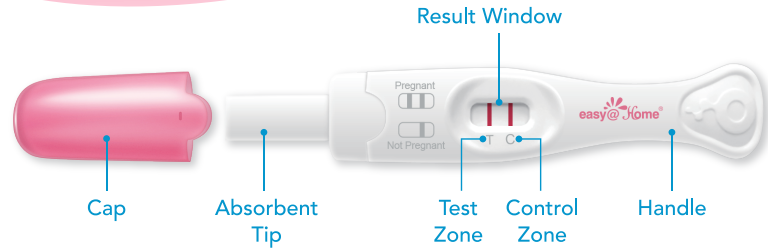


easy@Home[®]

PREGNANCY TEST

Cat.# EZW1-MA



Please read all of the information in the insert before performing the test.

INTENDED USE

Easy@Home Pregnancy Test is a rapid pregnancy test, which you can easily carry out yourself. It is used for qualitative detection of Human Chorionic Gonadotropin (hCG) in human urine, as an aid in early detection of pregnancy. It is intended for use by people who would like to find out whether they are pregnant in a home environment.

For *in vitro* self-testing use only.

It is intended for over-the-counter use.

HOW DOES IT WORK?

Human chorionic gonadotropin (hCG) is a hormone produced by the developing placenta shortly after the conception and secreted into the urine. The pregnancy test contains antibodies which specifically react with this hormone.

When the test is contacted with urine specimen, capillary action carries the specimen to migrate along the membrane. When hCG in the sample reaches the Test Zone of the membrane, it will form a colored line. The absence of this colored line suggests a negative result.

To serve as a procedure control, a colored line will appear at the control zone if the test has been performed properly.

PRECAUTIONS

1. This device is for external testing of human urine only. Not for internal use.
2. DO NOT make any decision of medical relevance without first consulting your physician.
3. Discard after first use. The test device cannot be used more than once.
4. Keep out of the reach of children.
5. The desiccant in the foil pouch is for storage purposes only. DO NOT swallow.
6. Do not use test device beyond expiry date.
7. Do not use the device if the pouch is punctured or not well sealed.
8. Please follow local regulations to discard used device.

STORAGE AND STABILITY

1. Store at 35.6°F to 86°F (2°C to 30°C) in the sealed pouch up to the expiration date. If stored refrigerated, allow to warm to room temp before performing the test.
2. Keep away from direct sunlight, moisture and heat.
3. DO NOT FREEZE.
4. The test should be used immediately after opening.

COLLECTION AND STORAGE OF SPECIMENS

WHEN TO COLLECT URINE FOR THE TEST?

Any urine specimen is appropriate for pregnancy testing. However, the first morning urine specimen is preferred because of its highest concentration of hCG.

HOW TO COLLECT THE URINE SAMPLE?

Directly urinate on the absorbent tip of the test to collect the urine sample. Or, have urine collected in a clean, dry plastic or glass container just prior to testing.

CONTENTS OF THE TEST KIT

1. One pouch containing a midstream and a desiccant. The desiccant is for storage purpose only and is not used in the test procedures.
2. Instructions for use.

ADDITIONAL ITEMS NEEDED

1. A clean, dry, plastic or glass container to collect the urine
2. Timer (watch, clock or smartphone)

HOW TO PERFORM THE TEST?

Step 1. Remove the test device from the pouch.

Step 2. Remove the cap of the test device and expose the absorbent (Save the cap nearby, you will use it again soon).

Step 3.

Test in urine stream:

Hold the test device with the absorbent tip pointing downwards in urine stream for 5-10 seconds to be thoroughly wet.



OR

Test in a urine collection cup:
Collect your urine into a clean, dry urine collection cup and dip the entire absorbent tip into the urine for 5-10 seconds.



Make sure that only the absorbent tip is wet during sampling and that other parts of the test remain dry.

Step 4. Re-cap the device and lay it flat with the result window facing upwards. Wait for color lines to appear. Never hold the test with the absorbent tip pointing upwards during testing.

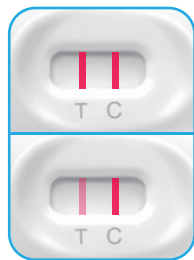
• Positive results may be observed in as soon as 3 minutes. However, the complete reaction time of 5 minutes is required.

• Do not read results after 10 minutes.



Replace the cap when waiting the test result.

HOW TO READ THE RESULTS?



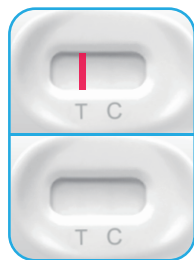
Positive (Pregnant) :

Two distinct color lines appear in the Control and Test Zones. It indicates that you are pregnant. The color intensity of the test lines may vary since different stages of pregnancy have different concentrations of hCG hormone.



Negative (Not Pregnant) :

Only one color line appears in the Control Zone. No apparent line in the Test Zone. It indicates that no pregnancy has been detected.



Invalid:

No visible line at all, or there is a visible line only in the Test Zone and not in the Control Zone. Repeat with a new midstream. If test still fails, please contact the distributor or the store, where you bought the product, with the lot number.

NOTE: If the color of the test line is faint, it is recommended that the test be repeated in 48 hours.

LIMITATIONS

1. Like any diagnostic procedure, a confirmed pregnancy diagnosis should only be made by a physician after evaluating all clinical and laboratory findings.
2. If a urine sample is too dilute (ie, low specific gravity) it may not contain a representative level of hCG. If pregnancy is still suspected, another urine specimen should be collected 48 hours later and tested.
3. Low concentration of hCG in a very early pregnancy can give a negative result. In this case, another specimen should be obtained at least 48 hours later and tested.

4. Elevated levels of hCG can be caused by a few conditions other than pregnancy. Therefore, the presence of hCG in urine specimen should not be used to diagnose pregnancy unless these conditions have been ruled out.
5. A normal pregnancy can not be distinguished from an ectopic pregnancy based on hCG levels alone. Also, spontaneous miscarriage may cause confusion in interpreting test results.
6. Sterility treatments, based on hCG, may cause false results. Consult your physician.

QUESTIONS AND ANSWERS

Q There is much difference between the control lines of two tests. Is this a concern?

A No. Variations in the color of the control line will not affect the test result.

Q Can test results be interpreted after more than 10 minutes?

A No. Test results must be read in 10 minutes. Though a positive result should not change for several days, a negative result may change to a false positive within minutes after the end of the testing period, which would not be an accurate reading. It is always best to read the results at the 5 minutes and then discard the test to avoid confusion.

Q I have waited longer than 10 minutes, and still there are no lines in the result window. What does this mean?

A There should always be at least one pink line in the Control Zone of result window at 10 minutes. If not, the test is invalid. The invalid results are normally caused by 3 major reasons: not placing absorbent tip in urine for enough 10 seconds, urine is insufficient or the urine permeates through the inner part of the test device. You should retest with another test and make sure place the absorbent tip in urine for 10 seconds meantime make sure urine is sufficient and avoid urinating or dipping beyond the scope of absorbent pad. If you still see the invalid result, contact the vendor.

Q What factors may affect the test result?

A Medications containing hCG can affect the result. A number of conditions other than pregnancy cause elevated levels of hCG and could cause misleading results.
Unclean urine collection containers or improper operation will also produce incorrect results.

Q What should I do if the result shows that I am pregnant?

A Consult your physician. They should confirm your pregnancy after evaluating all clinical and laboratory findings. Indeed, in some rare conditions, the test may give a false positive result. They will also give you further information and advise on your pregnancy.

Q What should I do if the result shows that I am not pregnant?

A If you have reasons to believe that you are pregnant (e.g. no menstrual bleeding), you can repeat the test a few days later. If the test is still negative, consult your physician.

MEANING OF SYMBOLS ON PACKAGE

	Keep away from sunlight		Temperature limit		Keep dry
	Do not re-use		For <i>in vitro</i> diagnostic use only		Contains sufficient for <n> tests
	Consult instructions for use		Unique device identifier		

QUESTIONS OR COMMENTS

Please call toll-free: 1-855-822-6999 M-F 9a.m.-5p.m. CST

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