



# hCG Pregnancy Test Midstream

Instruction for Use

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

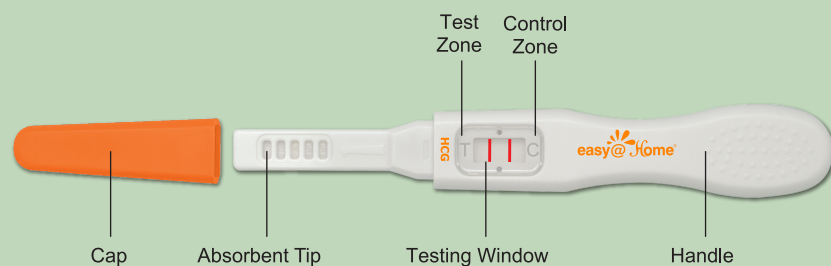
## INTENDED USE

Easy@Home hCG Pregnancy Test Midstream is an in vitro diagnostic visual qualitative immunochromatographic assay designed for the rapid determination of human chorionic gonadotropin (hCG) in urine to aid in the early detection of pregnancy.

For *in vitro* diagnostic 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 conception and secreted into the midstream test. The midstream test is designed to be used during urination stream. Start new sentence from Capillary. Action carries the specimen to migrate along the membrane. When hCG in the sample reaches the Test Zone region of the membrane, it will form a colored line.



## CONTENTS OF THE TEST KIT

1. One pouch containing a test midstream and a desiccant. The desiccant is for storage purposes only and is not used in the test.
2. Instruction for Use.

## ADDITIONAL ITEMS NEEDED

Timer (watch, clock or smartphone)

## PRECAUTIONS

1. This kit is for external use only and for *in vitro* diagnostic use only. Do not swallow.
2. Do not use the test kit beyond expiration date.
3. Do not use the kit if the test pouch is punctured or not fully sealed.
4. Keep out of the reach of children.
5. Discard after first use. The test midstream cannot be used more than once.
6. Urine specimens may be infectious. Ensure proper handling and discard all used devices according to the local regulations.

## STORAGE AND STABILITY

1. Store at 2°C to 30°C (35 - 86°F) performing the test. Open the pouch just a few minutes before running the test.
2. The test should be used immediately after opening.
3. Keep away from sunlight, moisture and heat.
4. DO NOT FREEZE

## 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?

There is no need to use a urine cup for collection. The midstream test is used directly during urination.

## HOW TO PERFORM THE TEST?

The test material should be at room temperature (59-86°F or 15-30°C) before performing the test to ensure accurate result.

1. Remove the test midstream from the sealed pouch.
2. Hold the round end of cover with one hand. Use the other hand to pull out the midstream cap and expose the absorbent. (Save the cap nearby, you will use it again.)
3. Point the absorbent tip downward and place the absorbent tip in urine stream for at least 3 seconds to be thoroughly wet. Do not urinate past the arrow mark. Note: Do not urinate past the arrow mark. (See the illustration below.)
4. Re-cap the device and wait for color bands to appear.
5. Read the results between 5 and 10 minutes. Do not read results before 5 minutes or after 10 minutes.



## HOW TO READ THE RESULTS?

### Positive (Pregnant)

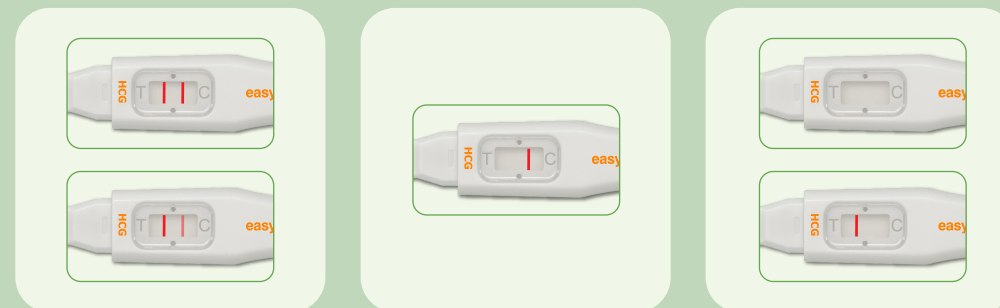
Two distinct color bands appear in the Control and Test Zones. One band should be in the control region (C) and another band should be in the test region (T).

### Negative (Not pregnant)

Only one color band appears in the control region (C). No apparent Rosy Pink band in the test region (T).

### Invalid

The result is invalid if no visible band appears in the control region (C), even if a line appears in the test region (T). You should repeat the test with a new test midstream.



Positive

Negative

Invalid

### NOTE:

The color intensity of the test lines may vary since different stages of pregnancy have different concentrations of hCG hormone. If the color of the test lines is faint, it is recommended to repeat the test in 48 hours.

## WHAT TO DO WHEN YOU KNOW THE RESULT?

### IF THE RESULT IS POSITIVE (TWO LINES)

Consult your physician to confirm your pregnancy after evaluating all clinical and laboratory findings. In certain conditions, the test may give a false positive result, and your physician will also give you further information and advise you on your pregnancy. See also "Limitations".

### IF THE RESULT IS NEGATIVE (ONE LINE)

If the result is negative and you still suspect you may be pregnant, you should wait a few more days and repeat the test. If you continue to have questions or concerns, you should contact your healthcare provider. See also "Limitations".

## QUALITY CONTROL

A procedural control is included in the test. A red line appearing in the control line region (C) is considered an internal procedural control. It confirms that the reagents are working properly, sufficient specimen volume is used, and correct procedure was used.

If the test does not show any Control or Test line in the testing window, the test should be discarded. Run the test again with a new midstream and follow the procedure exactly.

If the second test does not show lines, please contact Technical Services at 1-855-822-6999 (M-F 9 a.m.-5 p.m. CST).

## LIMITATIONS

1. A confirmed pregnancy diagnosis should only be made by a physician after evaluating all clinical and laboratory findings.
2. A low concentration of hCG in very early pregnancy can give a negative result. In this case, another test should be repeated at least 48 hours later.
3. Elevated levels of hCG can be caused by conditions other than pregnancy. Therefore, the presence of hCG in urine specimens should not be used alone to diagnose pregnancy unless these conditions have been ruled out.
4. Certain health conditions, such as an ovarian cyst or ectopic pregnancy, can cause false or irregular results.
5. The test is for early detection of pregnancy only.
6. Elevated levels of hCG have been found in patients with gestational and non-gestational trophoblastic disease. Where appropriate, these conditions should be ruled out before a diagnosis of pregnancy is reached.
7. Abnormal pregnancy cannot be distinguished from normal pregnancy based on hCG measurements alone.
8. If you are on any treatments containing hCG, such as for weight loss, to trigger ovulation or treat infertility, you may get an inaccurate test result. Check with your doctor to follow up.

## EXPECTED RESULTS

Negative results are expected in healthy non-pregnant women. Healthy pregnant women have hCG present in their urine specimens. The amount of hCG will vary greatly with gestational age and between individuals. The Easy@Home hCG Pregnancy Test Midstream can be used as early as the first day of the missed period.

## QUESTIONS AND ANSWERS

### 1. How soon after suspecting pregnancy can I take a test?

You can test your urine as early as the first day after you miss your period.

### 2. Do I need to use first morning urine for the test?

Although you can test at any time of the day, the first morning urine is typically the most concentrated of the day and may contain the highest level of hCG.

### 3. What factors may affect the test result?

Drugs containing hCG can give a false positive result. Alcohol, oral contraceptives, painkillers, antibiotics, or hormone therapies that do not contain hCG should not affect the test result.

### 4. Does a positive result always mean normal pregnancy?

No, other medical conditions or medications can cause positive results. Consult your physician for any positive pregnancy result.

### 5. How can I know if the test was conducted correctly?

The appearance of a red line in the control window (C) indicates that you followed the test procedure correctly and that the urine was properly absorbed.

### 6. What should I do if the result shows I am not pregnant?

hCG concentrations can vary greatly in early pregnancy. If you do not start your period within a week of its due date, repeat the test with a new one. If you receive the same result after repeating the test and you still do not get your period, see your doctor.

### 7. Is a significant difference between the control lines of two tests a concern?

No, variations in the color of the control line will not affect the test result.

### 8. Can test results be interpreted after more than Ten minutes?

No, test results must be read between 5 and 10 minutes. Although 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. Always read the results within the testing period to avoid confusion.

### 9. Is the appearance of a pink background color and vertical streaking during the testing period a concern?

No, variations in urine chemical makeup and testing conditions can cause the vertical streaking and pink-rose background color, but they will not affect the test results. As long as the control line appears within 5 minutes, the test is working correctly.

## MEANING OF SYMBOLS ON PACKAGE



Keep away from sunlight



Do not re-use



Keep dry



Store between 35°F and 86°F



Contains sufficient for <n> tests



Consult instructions for use

Distributed by **Easy Healthcare Corporation**  
360 Shore Dr., Unit B, Burr Ridge, IL 60527

**www.premom.com**  
Questions or Comments?  
Please call toll-free: +1-855-822-6999 M-F 9 a.m.-5 p.m. CST  
Email: support@premom.com

Made in China

V01: 20230329