

Clear Sign



Midstream Pregnancy Test

Clear Sign is more than 99% accurate from the day your period is due.

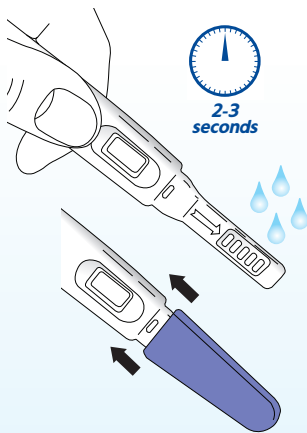
Clear Sign can be used up to 7 days before your period is due.

Please read this leaflet carefully before carrying out a test.

Carrying out a test

If testing from the day your period is due, you can test any time of the day. If testing early, use the first morning urine.

- Collect your urine sample in a clean, dry container.
- When you are ready to carry out the test, open the foil pouch, take out the Midstream test stick and remove the cap.
- Hold the test stick with the absorbent tip downwards and place in your urine stream for 2-3 seconds taking care NOT to let your urine stream pass above the narrow end of the test stick. Alternatively you can collect your urine in a clean, dry container and dip half of the absorbent tip into the urine for 2-3 seconds again taking care NOT to immerse the test stick above the absorbent tip.
- Re-cap the test stick and either hold point downwards or lie the test stick on a flat surface.
- Wait for colored band(s) to appear in the window and read results.



Reading your result

You can read your result as early as 1 minute.

A negative result can be read in 3-5 minutes.

IMPORTANT! Read your result within 5 minutes of doing a test. Disregard any changes after this time.



Early as
1 minute



Negative
result
3-5 mins



DO NOT
read after
5 mins

Negative

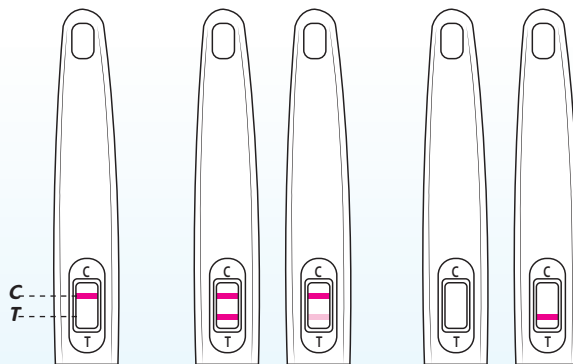
A pink coloured band appears at the control region only.

Positive

A clear pink control band and a detectable test band indicates your result is "pregnant".

Invalid

If no pink control band appears within 5 minutes, the test has not worked. Refer to the questions overleaf.



Negative

Positive

Invalid

Questions & Answers

1. How does Clear Sign work?

- a. When you are pregnant, your body produces the pregnancy hormone hCG (human Chorionic Gonadotrophin). The amount of hCG in your body increases rapidly in the early stages of pregnancy, and Clear Sign due to its high sensitivity can detect tiny amounts of this hormone in your urine up to 7 days before your period is due.

2. How accurate is Clear Sign?

- a. Clear Sign is more than 99% accurate in laboratory tests when used from the day your period is due.

3. When can I test with Clear Sign?

- a. Clear Sign can be used up to 7 days before your period is due. If you test before your period is due and you get a negative "not pregnant" result, there is still a chance you may be pregnant.
- i. If you have irregular cycles, you should allow for your longest cycle in recent months before testing.
- ii. If you do not know when your period is due, it is recommended that you test not less than 19 days after the last time you had unprotected sex.
- iii. If testing from the day your period is due, you can test any time of the day. If you are testing early, use the first morning urine and avoid excessive fluid intake before testing.

4. Can medication or medical conditions affect the result?

- a. Always refer to the manufacturers' instructions for any medication you are taking before conducting a pregnancy test.
- b. Some treatments / disease conditions such as ectopic pregnancy (which cannot be distinguished from normal pregnancy from hCG measurements alone), ovarian cysts and menopause may result in elevated hCG levels giving misleading results. All diagnoses should be considered if appropriate to the clinical evidence.
- c. Fertility drugs containing hCG may give misleading results if testing occurs too soon after administration.
- d. If you have recently stopped using hormonal contraception your periods may be irregular leading you to test too soon.
- e. You may show a "pregnant" result and later find that you are not pregnant due to natural loss of the pregnancy which can occur in the early stages.
- f. Any unexpected results should be discussed with your doctor.

5. No Pink line has appeared in the control region, what should I do?

- a. If there is no pink line in the control region within 5 minutes of performing the test, the test has not worked properly. This may be because:
- i. The test stick was not laid down on a flat surface after dipping in the urine.
- ii. Too much or too little urine was used.
- b. You should test again using a new test taking care to follow exactly the instructions as directed.
6. I am unsure of my result?
- a. For your result to be positive - "pregnant", there must be a visible pink band in the control region AND a pink band in the test region. The test band may be a slighter lighter pink colour, this still indicates a positive "pregnant" result.

- b. For your result to be negative "not pregnant", there must be a pink line in the control region only within 5 minutes of performing the test. If your result is negative and you still suspect you are pregnant, refer to point 8.

7. My test says I'm pregnant, what should I do?

- a. Please consult your doctor who will advise on the next steps.

8. My test says I'm not pregnant, what should I do?

- a. You may not be pregnant, the level of hCG hormone may not yet be high enough to be detected, or you may have miscalculated the date your period was due.
- b. If you tested early, test again when your period is due.
- c. If your period is overdue, test again in 3 days time. If this test gives a negative "not pregnant" result, but you have not had your period or suspect you may be pregnant, consult your doctor.
- d. If you suspect you are pregnant you should not undergo any form of X-ray or invasive treatment until you have consulted your doctor.

QUALITY CONTROL

The Clear Sign, hCG Midstream test has included a process control in the test. If a test stick is valid and the test was performed properly, a pink coloured band will always appear in the control region regardless of positive or negative results.

STORAGE AND STABILITY

Store at room temperature (2 to 30°C) in the sealed pouch to the date of expiration. Keep the test kit away from direct sunlight, moisture and heat. Do not use the test kit beyond the expiration date or if the pouch is damaged. Use once only. Do not open the pouch or remove the test device more than a couple of minutes before you are ready to do the test. Dispose of with normal household waste.

LIMITATIONS

The Clear Sign hCG Midstream test is for in vitro diagnostic use only (for external use only)

As with all diagnostic tests, a final clinical diagnosis should not be based on the results of a single test, but should only be made by a doctor.

A negative result may be obtained by a mother in the very early stages of pregnancy due to extremely low concentration of hCG. In such cases, the test should be repeated on a fresh sample of urine obtained three days later.

If a urine sample is too dilute, it may not contain a representative hCG concentration. If a negative result is obtained and pregnancy is still suspected, obtain a first morning urine sample and retest.

Test instructions must be followed precisely to ensure accurate results. Please read the instructions carefully and follow the exact test procedure.

Please check with your doctor to verify diagnostic results – or if you receive unexpected or inconsistent test results.



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