

Instructions

Pregnancy Test Strips

Intended use

Ovry Pregnancy Test Strips are rapid and convenient pregnancy tests. Each strip detects the presence of the pregnancy hormone called Human Chorionic Gonadotropin (HCG), which appears in urine very early during pregnancy. The test is designed for people with uteruses and is intended for at-home use. Each test provides a visual, qualitative result.

How do Ovry Pregnancy Test Strips detect pregnancy?

Ovry Pregnancy Test Strips detect the presence of HCG, which in normal female urine samples provides an early indication of pregnancy.

Ovry Pregnancy Test Strips can detect pregnancy up to 6 days before your missed period. In a 28-day menstrual cycle this would occur approximately 23 days after the beginning of your last period. In the early weeks of a normal pregnancy, the concentration of HCG doubles approximately every 2 days. For this reason, if you take a test and the result is negative, you should repeat the test in 48 hours with a new strip and a new urine sample. If your results are negative again and you still think you might be pregnant, you should seek medical advice.

The detection limit for these HCG test kits is 10 mIU/ml. Urine samples containing HCG levels equal to or greater than the detection limit will test positive. Samples containing HCG at levels less than the detection limit may still produce a positive result indicated by the appearance of a very faint line in the test region (T). Elevated HCG levels are also associated with trophoblastic diseases and certain nontrophoblastic neoplasms. Thus, the possibility of such diseases or other health concerns must be excluded by a physician before a diagnosis of pregnancy can be made.

Package contents

- Pouches (contain: test strip, desiccant)
- A clean, dry plastic container to collect the urine sample
- Test instructions

Limitations

- As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by a physician after all clinical and laboratory findings have been evaluated.
- Low concentrations of HCG in very early pregnancy can give a negative result. If pregnancy is suspected, repeat the test two days later.
- If a urine sample is too diluted, it may not contain enough HCG to reach the cutoff level. If pregnancy is suspected, repeat the test two days later.
- Aside from pregnancy, a number of conditions such as trophoblastic diseases, proteinuria, hematuria, choriocarcinoma, ovarian teratomas can cause elevated levels of HCG. Therefore, a positive HCG test should not be used alone to diagnose pregnancy, unless all other possible conditions have been ruled out by a physician.
- Immunologically interfering substances such as those used in antibody therapy treatments may invalidate this pregnancy test.
- Ectopic pregnancy cannot be distinguished from normal pregnancy using HCG measurements alone. Only a physician can diagnose an ectopic pregnancy.
- Patients on chemotherapy for cancer who suspect they might be pregnant should seek the advice of a physician who will administer a pregnancy test.
- Positive HCG levels may be detectable for several weeks following delivery, abortion, or miscarriage.
- If you are testing before the date of your expected period, faint positives early on may become negative later due to a natural termination of the pregnancy. This is often referred to as a chemical pregnancy. For those with a history of loss and/or who might be struggling to conceive, it is recommended to wait until the date of your expected period to avoid the heart-break that can come from detecting a chemical pregnancy with an ultra-sensitive test.
- Treatments affecting HCG levels (such as IVF trigger shots), may cause false results. Consult a doctor for how to complete the test properly if you are taking any hormone medication or undergoing any hormonal treatments.

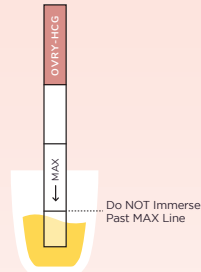
How to perform the test

1

Remove the strip from the foil pouch by tearing at the notch. Hold the strip at the colored end.

2

Holding the strip vertically, immerse the end of the strip with the arrows into the urine. Do not immerse past the MAX line.

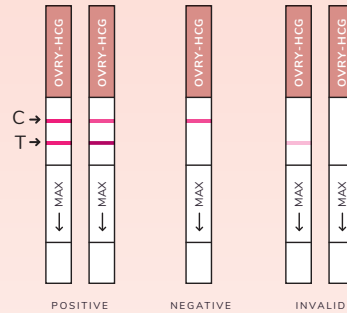


3

Take the strip out when the urine has migrated to the test window (about 5-10 seconds). Lay the strip (MAX side facing up) flat on a clean, dry, and non-absorbent surface.

4

Read the results in 5 minutes, following instructions under the “Reading the Results” section.



NOTE: Strong positive urine may produce positive results in as little as 1 minute. Confirm negatives in 10-15 minutes.

Do not interpret results after 15 minutes. Results read after 15 minutes are not accurate because as the urine evaporates, it can sometimes reveal a faint colorless ‘evaporation line’. This evaporation line is not an indication of pregnancy. To avoid any confusion, do not interpret results after 15 minutes.

Reading the Results

Positive Two lines appear: A clear pink-colored band appears in the control region (C) and another detectable test line, the intensity of which can vary, appears in the test region (T) below the first line, indicating a positive result for pregnancy.

NOTE: If the color in the test zone (T) is very faint, it is recommended to repeat the test two days later with a new strip and a fresh urine sample, or to seek medical advice.

Negative One clear pink-colored line appears only in the control region (C) and no line appears in the test region (T), indicating a negative result for pregnancy. If the result is negative, you should repeat the test in 48 hours with a new strip and a new urine sample. If your results are again negative and you still think you might be pregnant, you should seek medical advice.

NOTE: The clear pink-colored line in the control region (C) should always appear whether your test is negative or positive. It indicates that you performed the test correctly.

Invalid No visible lines appear in the control region (C) after use. Repeat with a new test strip. If the next test is also invalid, please take note of the lot number on the packaging and contact us through our website (www.myovry.ca).

Other Required Materials (Not Provided)

- Timer (watch, clock or smart phone)

Precautions

- Do not swallow. This test is for external use only.
- Do not use after the expiration date shown on the pouch.
- Do not reuse. Strips are for single use only.
- Do not use if the pouch seal or its packaging is compromised.
- Keep out of children’s reach.

For in vitro diagnostics use.
Not to be taken internally.

When and How to Collect Urine for the Test

- Urine may be collected at any time of day. However, urine collected in early morning is most desirable as the HCG concentration is the highest at that time.
- Urine may be collected in any clean and dry plastic or glass container.

Storage and Stability

- Sealed pouches can be stored between 2-30 °C (36-86 °F) up to the expiration date.
- Sealed pouches should be kept away from direct sunlight, moisture, heat and freezing conditions.
- Each test should be used immediately after opening the aluminum pouch.