



Weekly®

• Rapid semi-quantitative Pregnancy test with week of conception

Test for self-diagnostic

EN

Exacto®

**COMPONENTS OF THE BOX**

- 1 test device and a silica gel bag in a sealed foil pouch
- 1 Instruction for use leaflet.

Desiccant bag assures low humidity rate to preserve functionality of the test and should be discarded after opening the foil pouch.

**DEFINITION AND PRINCIPLE OF THE TEST**

Weekly test is an immunological test for the detection of the human chorionic gonadotropin (hCG) in urine. This rapid, easy-to-use pregnancy test is intended for home use. The number of weeks of pregnancy can be estimated by visual reading of the test. Weekly is a semi-quantitative test with a sensitivity of 10 mIU/mL. Anti-hCG antibody (mouse monoclonal) is immobilized in the test zones 1, 2 and 3 on the nitrocellulose membrane, and a goat anti-mouse antibody (polyclonal) on the control zone C. During the running of the test, the hCG containing sample reacts with an anti-β-hCG antibody (mouse monoclonal), conjugated to colloidal gold label to produce to the naked eye visible colored signal in the test zones 1, 2 and 3 (depending on the concentration of hCG). Excess of conjugate continues to migrate across the membrane and interacts with the reagents present in the control zone «C» to create a visible colored line.

**PRECAUTIONS**

**Read the leaflet carefully before using the test.**

- The test is only to be used once. Do not use it again.
- Do not use the test if the pouch is torn or damaged.
- Keep the test out of the reach of children.
- Check the expiry date. Do not use the test if it has passed the expiry date.
- Store the test kits between 4°C and 30°C. Do not freeze.

Weekly test is intended for use with urine samples only.

- The test is functional within 24 hours after opening the foil pouch. Testing after that time may yield erroneous results.

Excess of conjugate continue to migrate across the membrane and interacts with the reagents present in the control zone “C” to create a visible colored line.

**RECOMMENDATIONS**

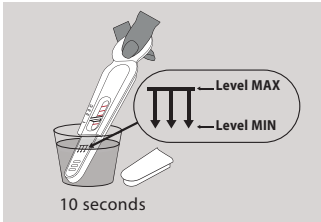
- A urine sample taken at any time during the day may be used, however due to the variation of hCG (depending of the activities of the patient) the first morning specimen of urine is recommended since it contains an highest concentration of hCG.
- The test must be used one from the expected date of the next period.
- The test is semi-quantitative and provides an estimate number of weeks of pregnancy for a positive result.

**HOW TO CARRY OUT THE TEST?**

- Remove the test from its aluminum pouch packaging.
- Remove the cap and carry out the test immediately.

**Carry out the test using a collected urine sample**

- Collect the urine sample in a clean and dry the cup.
- Dip vertically the tip of the test into the urine container until the reference line.
- Ensure that the level of urine is sufficient to dip 2,5cm of the test.
- Dip for 10 seconds and pull out the test.
- Replace the cap and place the test on a flat surface.



**HOW LONG DO I NEED TO WAIT BEFORE READING THE TEST?**

- You need to wait for at least 5 minutes before reading a result. Sometimes the results can show after 2 minutes.
- Do not read after 10 minutes.

**NOTE : It is essential to comply with these time limits in order to avoid errors in interpreting the result, and to obtain the most accurate estimate of pregnancy weeks.**

**HOW SHOULD I INTERPRET THE TEST?**

- The interpretation of the test can only be validated if a pink-colored line is identified in position “C” of the reading window.
- The presence of this control line means that the test has worked properly.
- The intensity of the control line does not vary whatever the concentration of hormone.
- If the control line is not present, the test should be repeated.
- The week of pregnancy is indicated by the presence of pink-colored lines in position “1”, “2” and “3” on the test stick.
- The intensity of the color in the test lines 1, 2, 3 may vary depending on the hCG concentration present in the specimen.

Therefore, any shade of color visible in the test region 1, 2, 3, should be considered as a positive result.

1 2 3 C

«NOT PREGNANT»

A negative result is shown by the appearance of a single pink line in the control zone (C). No other coloured lines appear in positions “1”, “2” and “3”.

1 2 3 C

«PREGNANT 1 TO 2 WEEKS»

Presence of a pink line in position “1” reveals the presence of hCG at a concentration corresponding to one to two weeks of pregnancy.

1 2 3 C

«PREGNANT 2 TO 3 WEEKS»

Presence of 2 pink lines in position “1” and “2” reveals the presence of hCG at a concentration corresponding to two to three weeks of pregnancy.

1 2 3 C

«PREGNANT 3 WEEKS OR MORE»

Presence of 3 pink lines at “1”, “2” and “3” reveals the presence of hCG at a concentration corresponding to three weeks of pregnancy or longer.

1 2 3 C

1 2 3 C

1 2 3 C

1 2 3 C

1 2 3 C

“INVALID RESULT”

If control line fails to appear in the control zone “C”. The obtained results are invalid and must not be interpreted.

**Note : An insufficient sample volume, incorrect procedural technique or out-of-date tests sticks are the most likely reasons for the control line failure.**

**The test specificity (95% confidence interval) to 5 to 10 minutes after contact with sample is equal to 100% (95.9% - 100%) The test sensitivity (95% confidence interval) is equal to 98.3% (97.6% - 98.8%) to 5 minutes and to 99.8% (99.5% - 99.9%) to 10 minutes after contact with sample.**

**LIMITATIONS OF THE TEST**

1. Highly diluted urine specimens, as indicated by a low specific gravity, may not contain significant hCG concentrations. If pregnancy is still suspected after a negative result is obtained, a first morning urine specimen should be collected 48 to 72 hours later and tested.
2. Very low levels of hCG (less than 10mIU/mL) are found in urine shortly after conception. However, owing to the large number of pregnancies ending naturally in the first trimester, a weak positive result should be interpreted with other clinical data.

3. Trophoblastic and non-trophoblastic diseases, such as breast cancer and lung cancer, may cause elevated hCG levels (above 10 mIU/mL). The clinical practitioner will take care to exclude these clinical situations.
4. As for all other rapid diagnostic tests, further confirmation tests must be performed to confirm a positive result. The final diagnosis by a specialist should take additional clinical results into account.

**RELIABILITY OF THE TEST**

Weekly test with conception estimation is more than 99% reliable from the expected date of your next period, and indicates whether you are pregnant or not.

**FREQUENTLY ASKED QUESTIONS**

**1- How reliable is the test?**

You need to make a distinction between using the test:

- Before the date on which your period is expected to start.
- At the expected date of your period.
- After the expected date of your period.

The test is sensitive for minimum detection of 10 mIU/ml at the expected date of your period.

If you use the test before the expected date of your period, you may obtain a negative result as the hCG level cannot yet be detected by the test.

If you carry out a test more than six weeks after conception, you might obtain abnormal results due to very high hCG concentrations in the urine.

**2- What is the maximal sensitivity of your test?**

The test sensitivity is 10 mIU/ml of hCG. The test with conception estimation shall be used the 1<sup>st</sup> day expected date of your period.

**3- The test tells me I am not pregnant, but I am not convinced**

If you have performed the test before the expected date of your period, repeat the test 48 hours later.

Possible error in calculating the expected date of your next period.

(You should base this on the usual length of your menstrual cycle by counting the number of days between the first day of your period and the day before the first day of your next cycle. If your cycles are irregular, take the longest cycle in the past few months and if you do not know what the expected date of your next period is, count at least 19 days since your last unprotected intercourse.

If the test is still negative three days after the expected date of your next period, and if your period has not started, **contact your doctor.**

**4- I did the tests a few days ago, and the results are inconsistent**

If the estimation of the week of pregnancy decreases or gives unexpected results when carrying out several tests over several days, **contact your doctor.**

**5- Which conditions can interfere with the results?**

Normal diet, drinks (Alcohol, coffee) does not interfere with the results. Some medications, treatments and disorders can affect the result by yielding false-positive and disrupted results.

Carefully read through the instructions for prescribed medications, together with any contraindications.

**The following are likely to yield false-positive results:**

- Fertility drugs containing hCG administered by injection. Other fertility treatments such as clomifene citrate, analgesics and hormone contraceptives do not affect the results. If you were recently pregnant, the test may detect residual hCG in the urine.
- If you are in the menopause or pre-menopause.

**The following are likely to yield erroneous results:**

- Tests carried out too soon after recently stopping hormonal contraception (irregular cycles).
- In the presence of ovarian cysts.
- In the event of multiple or ectopic pregnancies.

**6- The test did not work properly**

- You did not hold the test in the correct position under the stream of urine or in the collected urine container.
- You did not place the test stick on a flat stick afterwards.
- You did not wait for the minimum amount of time before reading the result.
- You did not sufficiently immerse the test stick in urine.
- In all cases, you should repeat the test.

**7- Can I re-use a test?**

No, the test is for single use only.

**8- How should I dispose the test?**

The test may be disposed normally with household wastes.

**PATENED WO2013/140089**

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IVD

For In-Vitro Diagnostic

Σ

Content

LOT

Batch number

i

Consult Package insert

Manufacturer

Single use

Expiration Date

Storage temperature

Catalogue number

+4°C

+30°C

CE 0483

NG BIOTECH

ZA Courbouton

Atelier relais le Tremplin

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