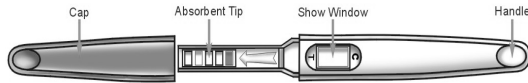


Pregnancy Test

Information Leaflet

Please read all the information in this package insert before performing the test.



- Fast, easy to read result.
- Accurate Result: 99% accurate at first day of missed period.
- Convenient: You can test at any time of the day but the test is most sensitive with first morning urine.
- Can be used as early as 4 days before a period is due. Most accurate on the first day of the missed period.

Kit Contents

- Either 1 or 2 Pregnancy Tests (each in foil pouch)
- Package Insert

How to Use

Allow Pregnancy Test to reach room temperature (15-30°C).

- Remove the Pregnancy Test from the foil pouch. Hold the test by the thumb grip and remove the cap but do not discard it.

RECOMMENDED USE

Urinate into a clean, dry glass container, then, holding the test upright; dip **only** the Absorbent Tip into the urine for at least **10 seconds**.

ALTERNATIVE USE

Hold the test by the thumb grip with the exposed Absorbent Tip pointing downwards directly into your urine stream for at least **2-3 seconds** until thoroughly wet.

NOTE: Do not allow urine to come into contact with the Test and Control windows.

- After removing the test from your urine, immediately replace the cap over the absorbent tip, lay the test on a flat surface with the test and control windows facing upwards, and then begin timing.
Note: As the test begins to work, you will see the formation of a reddish-purple line in the Control (C) indicating the test is working properly.

- Some positive results may be observed after 1 minute depending on the concentration of hCG but leave for **up to 3 minutes** for a line to appear in the Test region.

- IMPORTANT! Read results within 15 minutes. Discard the test stick after this time.** After 15 minutes you should disregard any change in the result or any lines that appear after this time.

- If no coloured line appears in the Control region (C) within 5 minutes the test has not worked properly.

Reading the Results

PREGNANT– Two distinct coloured lines appear. One line should be in the Control Region (C) and another line should be in the Test Region (T). One line may be lighter than the other; they do not have to match. This means you are probably pregnant.

NOT PREGNANT– One coloured line appears in the Control Region (C). No line appears in the Test Region (T). This means that you are probably not pregnant.

INVALID– The result is invalid if no coloured line appears in the Control Region (C), even if a line appears in the Test Region (T). Insufficient volume of urine or incorrect procedure are the most likely reasons for an invalid result. You should repeat the test with a new Pregnancy Test.

Questions and Answers

Q: How does the Test work?

A: The Pregnancy Test detects a hormone in your urine that your body produces during pregnancy (hCG-human chorionic gonadotropin). The amount of pregnancy hormone increases as pregnancy progresses.

Q: How soon after I suspect that I am pregnant can I take the test?

A: You can test your urine as early as four days before your period is due. However, the test is over 99% accurate on the first day of your missed period.

Q: Do you have to test with first morning urine?

A: Although you can test at any time of the day, your first morning urine is usually the most concentrated of the day and would have the most hCG in it. Do not drink excessively before taking the test.

Q: How will I know the test has worked?

A: The appearance of a coloured line in the Control Region (C) tells you that you followed the test procedure properly and the test has worked.

Q: Do I have to wait the full 3 minutes before reading my results?

A: Yes. It is important that you wait to see if a line appears in the Test region (T) before reading the result. Although the line in the Control Region (C) may appear quickly, a line in the Test Region (T) may take up to 3 minutes to become visible.

Q: If I see a line in both the Test and Control Regions, but one line is darker than the other, am I pregnant?

A: Yes. Even if one line is darker than the other, the result indicates that you are pregnant.

Q: I am not sure I held the test in my urine stream for long enough. Will I still get an accurate result?

A: To achieve accurate results, you should hold the test in your urine stream for at least 2-3 seconds, then wait at least 1 minute and up to 3 minutes to read the results. If a coloured line appears in the Control Region (C), the test has worked properly.

Q: How accurate is the test?

A: Clinical evaluations have shown that the Pregnancy Test is more than 99% accurate from the day your period is due.

Q: How sensitive is the test?

A: The Pregnancy Test detects hCG in urine at a concentration of 15mIU/mL or greater. The presence in the urine sample of LH (500mIU/mL), FSH (1,000mIU/mL), and TSH (1,000µIU/mL) did not interfere with the expected result.

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

A: It means that your urine contains hCG and you are probably pregnant. See your doctor to confirm that you are pregnant and to discuss the steps you should take.

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

A: It means that no hCG has been detected in your urine and you are probably not pregnant. If you do not start your period within a week of its due date, repeat the test with a

new Pregnancy Test. If you obtain a negative result after repeating the test and you still do not start your period, you should see your doctor.

Q: Do common medications affect the test?

A: At the concentrations shown, none of the following substances affected the test results: Acetaminophen (Paracetamol 20mg/dL), Acetylsalicylic acid (Aspirin 20mg/dL), Ascorbic acid (Vitamin C 20mg/dL), Atropine (20mg/dL), Caffeine (20mg/dL), Gentamic acid (20mg/dL), Glucose (2g/dL), Haemoglobin (20mg/dL), Ampicillin (20mg/dL) and Tetracycline (20mg/dL).

☎ If you have questions about the instructions or your results, call our Helpline 0800 0430318.

The Pregnancy Test is a rapid lateral flow immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine to aid in the detection of pregnancy. The test utilizes a combination of antibodies including a monoclonal hCG antibody to selectively detect elevated levels of hCG. The assay is conducted by urinating on the Absorbent Tip of the Pregnancy Test or immersing the Absorbent tip in urine and obtaining the result from the coloured lines in the result window.

Limitations

- Alcohol may interfere with the test result. Do not use the test after drinking alcohol.
- If a woman has recently been pregnant, (even if not carried to full term), a false “Pregnant” result may be obtained. Occasionally, urine specimens containing less than 15mIU/mL hCG also give a positive result.
- Ectopic pregnancy, ovarian cysts, menopause and some very rare medical conditions can give misleading results.
- In cases where very high levels of hCG are present (>500000mIU/mL), a false negative result can occur due to a “prozone” effect.
- Excessive fluid intake should be avoided before testing, as a “Not Pregnant” result may be obtained if the urine sample is too dilute.
- Fertility drugs containing hCG can give misleading results. These fertility drugs are usually given by injection and testing too soon after administration may give a false “Pregnant” result.
- Other fertility therapies (e.g. clomiphene citrate), painkillers and hormonal contraceptives (e.g. contraceptive pill) should not affect the results.
- A false positive test result can be caused by a number of conditions other than pregnancy which produce raised levels of hCG (e.g. Breast and lung cancer, or trophoblastic disease).
- A diagnosis of pregnancy by this test should be confirmed by a physician who will evaluate all clinical and laboratory findings.
- Do NOT take any medical decision based on the results of this test without consulting your doctor.

Warnings

- Keep out of reach of children.
- For in vitro diagnostic use.
- Not to be taken internally.
- Do not eat the desiccant in the package.
- The Pregnancy Test is not reusable.
- Do not open the test foil pouch until you are ready to start the test.
- Do not use if pouch is torn or damaged.
- Dispose of the used test hygienically in domestic

Storage

- This device is for self testing.
- Do not use after the expiration date printed on the foil pouch.
- Store in a dry place at 4-30°C.
- Do not freeze.

	Attention see instructions for use		Store between 2-30°C		Use by		Lot Number
	For in vitro use only		Tests per Kit		Do not reuse		Catalogue #

REF R5FRHC 103-1-15 (1 Test)
R5FRHC 103-2-15 (2 Tests)

CE 0843

Manufacturer

CIGA Healthcare Ltd.
Kilcran House, Kildowney Road
Ballymena U.K. BT44 9EY