CLEARBLUE RAPID DETECTION PREGNANCY TEST

Fast and accurate
Clearblue® is the world’s #1 selling brand in home pregnancy and fertility tests.* Consumers trust the Clearblue brand because it delivers the accurate information they want. The Clearblue product range is built on a strong foundation of peer-reviewed science and consumer understanding. Clearblue is supported by over 30 years of expertise, quality, and innovation in consumer diagnostics.

About Clearblue

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Clearblue Rapid Detection Pregnancy Test

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The innovative Clearblue Rapid Detection Pregnancy Test offers many important benefits:

• It provides an easy-to-read ‘Pregnant’ result from 1 minute when used from the day of the missed period (which is the day after the period was expected). The user should wait 3 minutes to confirm a ‘Not Pregnant’ result.

• It is over 99% accurate at detecting pregnancy from the day of the expected period.

• It has a number of features designed to make it the easiest home pregnancy test to use, such as an ergonomic handle, Color Change Tip and integrated Floodguard™ Technology.

Over 99% accurate at detecting pregnancy from the day of the expected period

The Clearblue Rapid Detection Pregnancy Test detects urinary levels of human chorionic gonadotropin (hCG), a clinically accurate marker of pregnancy. The hormone hCG is produced in the earliest stages of pregnancy, where it plays a role in the survival of the corpus luteum. Initially, hCG is produced by the embryo and therefore acts as a marker for its presence. Levels of hCG rise rapidly and predictably in the earliest days of pregnancy, and hCG usually first appears in urine 8–10 days (range 6–12 days) after conception, when it can be detected by the most sensitive laboratory analyzers. This makes it an ideal urinary marker for quickly and accurately assessing whether a woman is pregnant or not (Figure One).

* Based on international sales in nearly 20 countries compiled using independent market research data.
The Clearblue rapid Detection Pregnancy Test’s innovative technology means that, although it is highly sensitive, the proportion of false-positive results associated with the device is extremely low. It is over 99% accurate from the day of the expected period, regardless of whether women are pre-, peri-, or post-menopausal, so you can be confident that a woman who has received a ‘Pregnant’ result with the Clearblue rapid Detection Pregnancy Test really is pregnant.

Over 99% accuracy for all woman, regardless of age

The Clearblue Rapid Detection Pregnancy Test contains a number of innovative features that have been designed to make it the easiest home pregnancy test to use, including:

• A handle with an ergonomically designed stick and grip to help the user hold the device correctly in their urine stream
• A wide 18 mm sampler to help the user obtain an adequate sample from their urine stream with minimal mess
• A Color Change Tip (changes from white to pink when urine is applied) which lets the user know that urine has been absorbed
• Clear easy-to-read ‘Pregnant’ and ‘Not Pregnant’ results. Furthermore, the device is made from a white laminate reflective material, which provides a clear visual contrast against the blue lines in the Test and Control Windows
• Clearblue’s unique integrated Floodguard™ Technology, which helps reduce the #1 reported cause of user error, thereby increasing accuracy in consumers’ hands
• A large results window which is designed to be easy to read

Floodguard™ Technology helps women to use the test correctly

Occasionally, excess urine can enter a home pregnancy test: this usually happens because the user holds the stick incorrectly in her urine stream, or urinates for too long on the test stick. This can occasionally cause the test to run incorrectly, and will result in no control line being displayed. The Clearblue Rapid Detection Pregnancy Test has integrated Floodguard™ Technology, which collects excess urine and helps women to use the test correctly. Even though this is a problem for only a small number of women, Clearblue is committed to delivering products that meet the needs of all women, helping them test correctly and obtain the accurate information that they want.
The Color Change Tip helps women perform the test correctly

To perform a Clearblue Rapid Detection Pregnancy Test, the user simply removes the one-piece test stick from its individual foil wrapper, takes off the blue cap, and places the Color Change Tip into their urine stream or a container of their urine for 5 seconds. The Color Change Tip will instantly turn pink, showing that urine is being absorbed. Full instructions for users on how to perform the test correctly are provided in both English and Spanish.

Provides an easy-to-read 'Pregnant' or 'Not Pregnant' result

As the test begins to work, blue lines will start to develop in the device windows.

- The test is designed to be used from the day of the expected period
- It provides an easy-to-read 'Pregnant' result from 1 minute when used from the day of the expected period. The user should wait 3 minutes to confirm a 'Not Pregnant' result
- A 'Pregnant' result in the Test Window means that the user is pregnant. It does not matter if one of the lines that make up the symbol is lighter or darker than the other: the result is still 'Pregnant'
- A 'Not Pregnant' result in the Test Window means that the user is not pregnant

If no blue line has appeared in the Control Window after 10 minutes, the test has not worked. In a controlled study, the Clearblue Rapid Detection Pregnancy Test was scored highly by 88% of users for certainty of reading the result, and there was 97% agreement between the user and a trained technician’s interpretation of the result.

Additional points

- The manufacturer’s instructions regarding any medication being taken should be read before conducting the test
- When testing on or after the day the period is expected, it is not necessary to test with an early morning urine sample. Excessive fluid intake should be avoided before testing as a false ‘Not Pregnant’ result may be obtained if the urine sample is too dilute
- Fertility drugs containing hCG can affect the result. These are usually given by injection, and testing too soon (within 14 days) after administration can give a false ‘Pregnant’ result
- Ectopic pregnancy can result when the fertilized egg does not reach the uterus and continues to grow in the fallopian tube. The production of hCG in an ectopic pregnancy may be lower than in a normal pregnancy, and this may lead to a false ‘Not Pregnant’ result. However, other symptoms are likely to be experienced and if an ectopic pregnancy is suspected then immediate medical advice must be sought
- Ovarian cysts, menopause, and some very rare medical conditions can give misleading results
- A recent pregnancy, miscarriage, or termination can give misleading results. It is possible for hCG to be found in the body for up to 3 weeks after birth5,10 and it can remain in the body for up to 9 weeks after a miscarriage or termination. While hCG remains in the body, it is possible for a pregnancy test to detect it and show a false ‘Pregnant’ result
- If a ‘Pregnant’ result is obtained and the woman later finds out that she is not pregnant, it is possible that this is due to natural loss of the pregnancy. This is not uncommon in the early stages, affecting around one in four pregnancies11
- Women should be encouraged to discuss any unexpected pregnancy test results with a healthcare professional

References

1. Data on file. When compared with a laboratory reference method, Clearblue Rapid Detection Pregnancy Test has been shown to be over 99% accurate from the day of the expected period when using urine samples supplied for pregnancy testing. Reference method used: Perkin Elmer Delfia hCG.
8. Data on file. Study of 300 pre-, peri- and post-menopausal urine samples comparing the result from the Clearblue Rapid Detection Pregnancy Test with quantitative hCG levels measured using AutoDelfia (Perkin Elmer).
The Clearblue rapid Detection Pregnancy Test is:

**Fast** - pregnant result as fast as 1 minute from the day of the missed period\(^a\)

**Accurate** - over 99% accurate from the day of the expected period

**Easy** - Color Change Tip and ergonomic handle, designed to be the easiest to use

**Trustworthy** - from Clearblue, the world’s #1 selling brand in home pregnancy and fertility tests\(^b\)

\(^a\) A ‘Pregnant’ result may appear in 1 minute when testing from the day of the missed period. Wait 3 minutes to confirm a negative ‘Non pregnant’ result.

\(^b\) Based on international sales in nearly 20 countries compiled using independent market research data.