Clearblue®

Rapid Detection
Pregnancy Test

Result as fast as
1 minute[a]

reddot design award
winner 2012

Professional Series
Pregnancy

About Clearblue®

Clearblue is the world's number one selling brand in home pregnancy and fertility tests.[b] 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.

If you are a healthcare professional and wish to contact a member of the Clearblue support team about any product in the Clearblue range, please send an email to **spdproductsupport@spdspark.com**

Clearblue Rapid Detection Pregnancy Test

Result as fast as 1 minute[a]

The innovative Clearblue Rapid Detection Pregnancy Test represents the next step in visual home pregnancy tests. It provides women with five important benefits:

- It is over 99% accurate at detecting pregnancy from the day of the expected period
- It provides an easy-to-read ⊞ or ⊖ result in just 1–3 minutes[a]
- It has an award-winning, ergonomically designed handle, and was shown in a study to be the easiest home pregnancy test to use[1,c]
- Its colour change tip helps women to perform the test more easily
- Its integrated Floodguard™ Technology helps women to use the test correctly

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

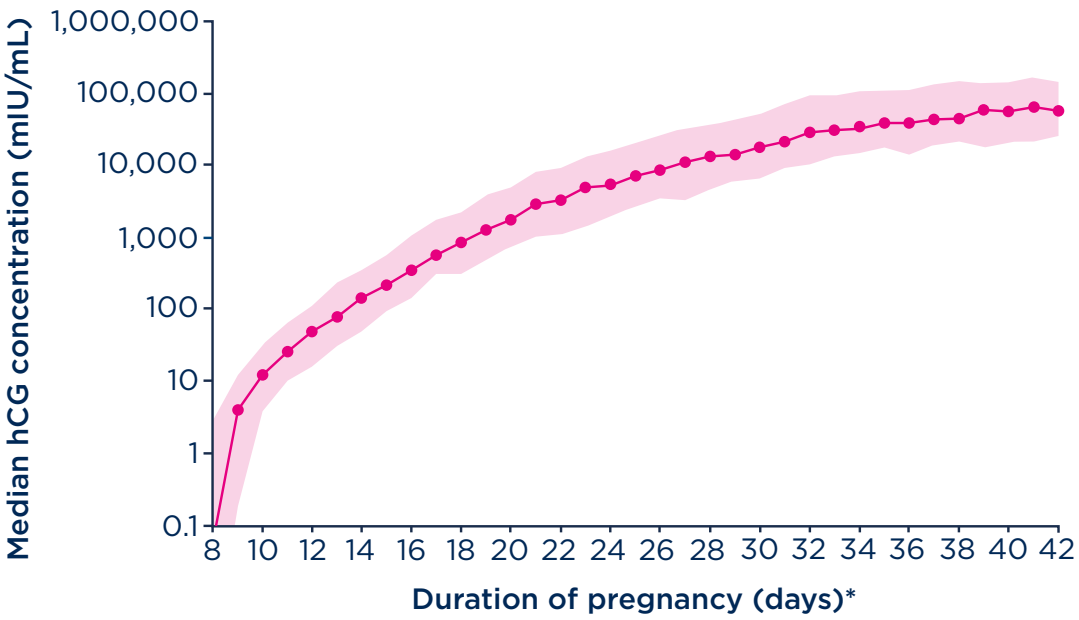
The Clearblue Rapid Detection Pregnancy Test detects the presence of urinary levels of human chorionic gonadotrophin (hCG), a clinically accurate marker of pregnancy. The production of hCG occurs in the earliest stages of pregnancy, where it plays a role in the survival of the corpus luteum, implantation of the blastocyst and protection of the embryo against immune attack at the foetal/maternal boundary.[2] The hormone is initially produced by the embryo and therefore also acts as a marker for its presence.[3]

Levels of hCG in serum and urine rise rapidly during the first days of pregnancy,[4–8] by approximately 50% per day.[9] Thus, hCG is the earliest accurate marker of gestational age; estimates of gestational age are highly comparable between hCG concentrations and ultrasound-dated pregnancy.[10] The rise in hCG levels is also consistent between different ethnicities, making it an ideal urinary marker for quickly and accurately assessing whether a woman is pregnant or not.[3–9]

The published literature shows that the level of hCG reaches at least 50mIU/mL on the day of the expected period.[5,10,11] If the Clearblue Rapid Detection Pregnancy Test is used on or after the day of the expected period, it is more than 99% accurate.

Figure One shows a typical rise in urinary hCG from the first detection of pregnancy.[9]

Figure One: Reference ranges for urinary intact hCG for each day of pregnancy (median, 10th and 90th centiles; data from 109 UK volunteers)[9]



*from calculated day of ovulation (luteinising hormone surge +1 day).

If testing after they expect their period, most women will have sufficient urinary hCG to provide a positive result if they are pregnant.

If a woman receives a negative result when her period is overdue, she should test again in 3 days' time. If this test gives a 'Not Pregnant' ⊖ result and the woman has still not had her period, she should consult a healthcare professional.

Award-winning, easy-to-use design[1,c]

The Clearblue Rapid Detection Pregnancy Test contains a number of innovative features that make it easy to use:

- A long handle with an ergonomically designed stick and grip to help women to hold the device correctly in the urine stream
- A wide 18mm tip to help obtain an adequate sample from the urine stream
- A colour change tip which lets the user know that urine has been absorbed
- A unique integrated Floodguard™ Technology feature which helps women use the test correctly
- A clear and easy-to-read ⊕ or ⊖ test result. Furthermore, the device is made from white laminate reflective material, which provides a clear visual contrast against the blue lines in the test and control windows
- A large result window which is easy to read

The colour change tip helps women perform the test correctly

To perform a test, the user simply removes the one-piece test stick from its individual foil wrapper, takes off the blue cap, and either places the colour change tip in her urine stream for 5 seconds, or into a container of her urine for 5 seconds. The colour change tip will instantly turn pink showing that urine is being absorbed. Throughout testing, the test stick should be held with the colour change tip pointing downwards, or laid flat until the user is ready to read the results.

Provides an easy-to-read ⊞ or ⊖ result in just 1–3 minutes[a]

As the test begins to work, blue lines will start to develop in the device windows. If testing from the day of the missed period, a 'Pregnant' ⊞ result may appear within 1 minute. If testing early, the user should wait 3 minutes to confirm a 'Not Pregnant' ⊖ result.

- A ⊞ 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 ⊖ result in the test window means that the user is not pregnant, unless she is testing before the day of her expected period and there is insufficient hCG to generate a 'Pregnant' ⊞ result

The test window must be read between 3 and 10 minutes after completing the test. If no blue line has appeared in the control window after 10 minutes, the test has not worked.

Helps women to use the test correctly

- Occasionally, excess urine can enter a home pregnancy test. This usually happens because the woman holds the stick incorrectly in her urine stream, or urinates for too long on the test stick tip. This can occasionally cause the test to run incorrectly. In cases where the test has not worked, no control line will be present on the test stick
- The Clearblue Rapid Detection Pregnancy Test is equipped with unique integrated Floodguard™ Technology, which collects excess urine and helps women to use the test correctly. Although this problem exists for only a small number of users, Clearblue aims to provide all women with the best products to help them test correctly and obtain the accurate information that they want

Easy to use and read

- Women prefer the midstream test stick format of the Clearblue Rapid Detection Pregnancy Test over other formats, such as strip- or cassette-based pregnancy tests. In a study, more than 95% of women prefer the midstream test stick format, stating hygiene and ease of use as key reasons for this preference[12]
- The result is displayed clearly as a ⊞ or ⊖, providing reassurance, confidence and trust in the accuracy of the result. Over 98% of women are confident of the results of a pregnancy test when the results are displayed visually as ⊞ or ⊖, compared with less than 50% for some traditional line-based tests. Furthermore, less than 30% of women are confident reading the results of strip- or cassette-based tests[12]

Women using the Clearblue Rapid Detection Pregnancy Test can be confident that they are pregnant if they receive a 'Pregnant' ⊕ result

- Consistent regulatory standards for the performance of home-based pregnancy tests are needed in Europe to enable healthcare professionals and women to have confidence in:
  - The result obtained with home-based pregnancy tests
  - The ability to test in the days before the next expected period[9]
- Many home pregnancy tests claim to be highly accurate and capable of detecting pregnancy before the missed period; however, certain available pregnancy tests may give women misleading results:[9]
  - One study tested nine over-the-counter pregnancy tests to evaluate the respective manufacturers' claimed sensitivities. Only four of the nine pregnancy tests (including the Clearblue Rapid Detection Pregnancy Test) were able to detect 25mIU/mL of hCG[9]
  - Another study evaluated the performance of eight home pregnancy tests using hCG standards. The test was performed by a technician and the results were read by a technician and a panel of volunteers; agreement between the technician/volunteer reading and the expected result based on the hCG concentration tested was greater than 90% for the Clearblue Rapid Detection Pregnancy Test. It was lower than 80% for the other pregnancy tests evaluated[13]

Limitations

- The manufacturer's instructions regarding any medication being taken should be read before conducting the test
- 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. Other fertility therapies (such as clomiphene citrate), painkillers and hormonal contraceptives (such as the contraceptive pill) should not affect the result
- Excessive fluid intake should be avoided before testing, as a urine sample that is too dilute may give a false-negative 'Not Pregnant' ⊟ result
- Ectopic pregnancy,[14] ovarian cysts, menopause and some very rare medical conditions can give misleading results
- Elevated levels of hCG that are caused by an increase of pituitary hCG production in peri-menopause and chemotherapy-induced suppression of gonadal function, or gestational trophoblastic disease, can give misleading results[14]
- A recent pregnancy, miscarriage or termination can give misleading results, as hCG can be found in the body for several weeks after giving birth[15] and after a miscarriage or termination[16]
- If a positive 'Pregnant' ⊞ result is obtained and the woman later obtains a 'Not Pregnant' ⊟ result, or her period starts, it may be due to natural loss during the early stage of pregnancy, which is not uncommon, as around one in four pregnancies end in early pregnancy loss[17,18]
- Women should discuss any unexpected results with a healthcare professional

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Clearblue Rapid Detection Pregnancy Test is:

Accurate – over 99% accurate from the day of the expected period

Fast – easy-to-read ⊞ or ⊖ result in just 1–3 minutes[a]

Easy – award-winning ergonomic design[c]

[a] A 'Pregnant' ⊞ result may appear within 1 minute when testing from the day of the missed period. Wait 3 minutes to confirm a 'Not Pregnant' ⊖ result.

[b] Based on international sales compiled using independent market research data (data on file).

[c] Red Dot Design Award winner 2012.

Clearblue®

For more information about the Clearblue Rapid Detection Pregnancy Test, please visit our websites:

www.clearblue.com
www.swissprecisiondiagnostics.com

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