CLEARBLUE DIGITAL PREGNANCY TEST WITH SMART COUNTDOWN

The only test that counts down to the result
Clearblue DIGITAL Pregnancy Test with Smart Countdown

The Clearblue DIGITAL Pregnancy Test with Smart Countdown is an easy-to-use pregnancy test that is over 99% accurate from the day of the expected period. It gives a digital result in words – ‘Pregnant’ or ‘Not Pregnant’ – and is the only pregnancy test with a Smart Countdown to reassure women every step of the way until their result is displayed.

The Clearblue DIGITAL Pregnancy Test with Smart Countdown has the following innovative features:

- Smart Countdown – a unique progression indicator that reassures the user that the test is working, and provides a countdown to the result
- A ‘no mess’ 18 mm wide absorbent tip, for easy sampling
- Integrated Floodguard™ Technology to help reduce the #1 reported cause of user error during testing
- Highly sensitive – can be used up to 5 days before the missed period

About Clearblue

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.

*Based on international sales in nearly 20 countries compiled using independent market research data.
The Clearblue DIGITAL Pregnancy Test with Smart Countdown displays a clear result in words within 3 minutes. This eliminates any uncertainty the user may have about their result. It has been shown that one in four women can misread traditional line pregnancy test results. The Clearblue DIGITAL Pregnancy Test with Smart Countdown contains an optical reader and software which converts the test signal into a clear digital result in words and eliminates this human error. In a study of 120 female volunteers comparing home pregnancy tests, 100% of volunteers said they were ‘certain’ or ‘very certain’ about the result of the Clearblue DIGITAL test.

A ‘Pregnant’ result will be shown on the display for up to 6 months, enabling users to keep the test to show to their healthcare professional or friends and family if they wish. A ‘Not Pregnant’ result will be shown for approximately 24 hours.

The hormone human chorionic gonadotropin (hCG) is a clinically accurate marker of pregnancy, and 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 (Figure One), and hCG usually first appears in urine 8–10 days (range 6–12 days) after conception. The levels of hCG in early pregnancy have also been found to be highly similar between women, making it an ideal urinary marker for quickly and accurately assessing whether a woman is pregnant or not.

The Clearblue DIGITAL Pregnancy Test with Smart Countdown detects increased urinary levels of hCG. The test is over 99% accurate in detecting pregnancy when used from the day of the expected period.

Reassuring accuracy in a home-based test

Figure One: Reference ranges for urinary intact hCG for each day of pregnancy (median, 10th and 90th centiles; data from 109 UK volunteers)
Highly sensitive: Can be used up to 5 days before the missed period

It is important for women to know that they are pregnant as early as possible in order that they can seek early healthcare advice and make lifestyle changes, such as ceasing to smoke. Published literature shows that the level of hCG reaches at least 50 mIU/mL on the day of the expected period in pregnant women. As the rise in hCG can vary between women, not all women who test before the day of their missed period will get a ‘Pregnant’ result.

The Clearblue DIGITAL Pregnancy Test with Smart Countdown is sensitive enough to be used up to 5 days before the missed period. Table One shows the results of clinical testing on early pregnancy daily urine samples taken from 100 pregnant women.

### Table One: Results from clinical testing of the Clearblue DIGITAL Pregnancy Test with early pregnancy urine samples

<table>
<thead>
<tr>
<th>Days before the missed period</th>
<th>5</th>
<th>4</th>
<th>3</th>
<th>2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pregnancy detection rate (%)</td>
<td>51</td>
<td>82</td>
<td>90</td>
<td>95</td>
</tr>
</tbody>
</table>

Highly accurate for all women, regardless of age

Importantly, although the Clearblue DIGITAL Pregnancy Test with Smart Countdown is sensitive enough to be used up to 5 days before the missed period, the proportion of false-positive results associated with the device is extremely low.

Concentrations of hCG in non-pregnant women increase with age such that in non-pregnant, peri-, or post-menopausal women, some ‘ultra-sensitive’ pregnancy tests could provide a false-positive result. In a study of non-pregnant, peri-menopausal, and menopausal women tested with different batches of Clearblue DIGITAL Pregnancy Test, an average of 0.3% of results were positive, with a range from 0% to 1% for different batches. All false results were from women aged over 50 years.

### Additional points

- The manufacturer’s instructions for 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. When testing before the period is expected, an early morning urine sample should always be used. Regardless of when the test is performed, excessive fluid intake should be avoided before testing as a false ‘Not Pregnant’ result may be obtained if the urine sample is too dilute.
- If a woman receives a negative ‘Not Pregnant’ result and she has tested before her period is expected, she is advised to test again from the day her period is expected. There is clear information provided on the pack and an instruction leaflet about early testing, including guidance on the proportion of pregnant women that can expect a ‘Pregnant’ result. This allows women to make an informed decision about whether or not early testing would be the best choice for them.
- 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 immediate medical advice must be sought if an ectopic pregnancy is suspected.
- 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 birth 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 pregnancies.
- Women should be encouraged to discuss any unexpected pregnancy test results with a healthcare professional.

### References

1. Data on file. When compared to a laboratory reference method, Clearblue DIGITAL Pregnancy Test has been shown to be over 99% accurate from the day the period is expected when using urine samples supplied for pregnancy testing. Reference method used: PerkinElmer DELFIA hCG.
2. Data on file. The pregnancy hormone increases rapidly in early pregnancy and Clearblue DIGITAL Pregnancy Test can be used as early as 4 days before the expected period, which is 5 days sooner than waiting for the missed period. In clinical testing, Clearblue DIGITAL Pregnancy Test detected the pregnancy hormone in 51% of women when testing 4 days before their expected period, 82% at 3 days before their expected period, 90% at 2 days before their expected period and 95% at 1 day before their expected period.
13. Data on file. Study of 281 pee- (n=60), peri- (n=101) and post-menopausal (n=120) urine samples comparing the result from the Clearblue DIGITAL Pregnancy Test with quantitative hCG levels measured using AutoDELFIA (PerkinElmer).
The Clearblue DIGITAL Pregnancy Test with Smart Countdown is:

- **Unique** - the only pregnancy test that counts down to the result
- **Accurate** - over 99% accurate from the day the period is expected\(^1\)
- **Easy to use** - a quick and easy urine test, with a ‘no mess’ wide absorbent tip and integrated Floodguard™ Technology to help reduce the #1 reported cause of user error\(^a\)
- **Sensitive** - can be used up to 5 days before the missed period\(^2\)
- **Unmistakably clear** - digital results in words for greater accuracy in consumers’ hands\(^3\)

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\(^a\) Based on calls to Helpline throughout 2010 and 2014.

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For more information about the Clearblue DIGITAL Pregnancy Test with Smart Countdown, please visit our website: www.clearblueeasy.com

www.swissprecisiondiagnostics.com

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