Clearblue®

Pregnancy Test with
Weeks Indicator

The only test that tells her
how many weeks

About Clearblue®

Clearblue is the world's number one selling brand in home pregnancy and fertility tests.[a] 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 Pregnancy Test with Weeks Indicator

The only test that tells her how many weeks

Revolutionising home pregnancy testing

The Clearblue Pregnancy Test with Weeks Indicator is the latest innovation in pregnancy testing. It is an over-the-counter semi-quantitative urine test for human chorionic gonadotrophin (hCG), which is intended for the detection of pregnancy. It is a simple-to-use product that is unique because it not only informs the user whether she is pregnant or not, but also indicates the time since conception occurred, shown on screen as 1–2, 2–3 and 3+, indicating weeks since conception.

• The Clearblue Pregnancy Test with Weeks Indicator is over 99% accurate at detecting pregnancy from the day of the expected period[1,b]

• The Weeks Indicator feature uses known levels of hCG in urine relative to the day of the luteinising hormone (LH) surge to estimate time since conception

• Agreement between Clearblue Pregnancy Test with Weeks Indicator results and time since conception by LH surge detection (± 1 day) is 93%[2]

• It is also sensitive enough to be used up to 5 days before the missed period (which corresponds to 4 days before the expected period)[1,c]

Innovation using established technology

• As with other home pregnancy tests, the Clearblue Pregnancy Test with Weeks Indicator detects hCG, the hormone produced early in pregnancy and excreted in urine[3]

• The hormone hCG is the marker of choice for detecting pregnancy and has a long and proven history in pregnancy testing[4]

• Uniquely, in addition to detecting the presence of hCG, the Clearblue Pregnancy Test with Weeks Indicator also measures the level of hCG, which indicates the time since conception occurred, shown on screen as 1–2, 2–3 and 3+, indicating weeks since conception

• The Weeks Indicator feature assumes that conception occurs on the day after the urinary LH surge (which stimulates ovulation)[5,6] and works by measuring threshold levels of urinary hCG (Table One).[2] These thresholds are based on extensive research of the urinary hCG rise in early pregnancy[7,8]

Table One: Urinary hCG threshold levels used in the Clearblue Pregnancy Test with Weeks Indicator to determine time since conception

Weeks since conception	Urinary hCG threshold (mIU/mL)
1–2	10
2–3	153
3+	2,753

The Clearblue Pregnancy Test with Weeks Indicator

A semi-quantitative assay
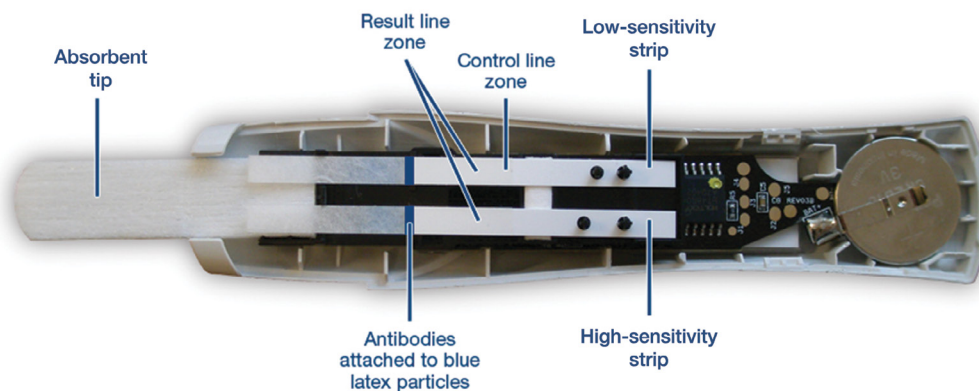
- The Clearblue Pregnancy Test with Weeks Indicator uses a pioneering new approach and novel algorithm for measuring urinary hCG

- It contains two hCG measurement strips, a low-sensitivity strip and a high-sensitivity strip, to enable the device to detect and analyse the wide dynamic range of hCG concentrations found in urine during pregnancy. The high-sensitivity strip detects low levels of hCG, expected in early pregnancy, and the low-sensitivity strip detects higher levels of hCG, typical in pregnancies over 3 weeks since conception

- The test monitors the 'control' line, which is present on the low-sensitivity strip, and the 'result' lines, which are present on both strips. Only when a valid control line is detected will the result be determined

- The control and result lines cannot be read by eye. Instead, the test uses an optical system to measure the density of the lines – a red light shines onto the control and result line zones, a photodiode detects reflected light and a micro-processor converts the light signal into clear results, visible on a liquid crystal display

Over 99% accurate from the day of the expected period[b]

The Clearblue Pregnancy Test with Weeks Indicator demonstrated over 99% accuracy in detecting pregnancy when compared with a laboratory method (quantitative AutoDELFIA).[1]

The study, using urine samples from 300 women aged 18–45 years across three batches, found 99.4% overall agreement in detecting pregnancy between the Clearblue Pregnancy Test with Weeks Indicator and quantitative hCG measurements.[1]

Can be used up to 5 days before the missed period[c]

The Clearblue Pregnancy Test with Weeks Indicator is highly sensitive and can be used up to 5 days before the missed period. In a study, 135 women provided their first morning urine samples every day during the cycle in which they became pregnant.

The Clearblue Pregnancy Test with Weeks Indicator detected 65% of pregnancies 5 days before the missed period (which corresponds to 4 days before the expected period) and 90% of pregnancies 4 days before the missed period (which corresponds to 3 days before the expected period) (Table Two).[1]

Table Two: Percentage of pregnancies detected 0–4 days before the expected period with the Clearblue Pregnancy Test with Weeks Indicator[1]

Days before the expected period	4	3	2	1	0
Percentage of pregnancies detected	65%	90%	97%	98%	99%

Has excellent specificity

Concentrations of hCG in non-pregnant women increase with age, which can potentially result in some peri- or post-menopausal women obtaining inaccurate false-positive results with some types of pregnancy tests. The Clearblue Pregnancy Test with Weeks Indicator is over 99% accurate from the day of the expected period, regardless of whether women are pre-, peri- or post-menopausal.[1]

A total of 301 individual female urine samples were collected from pre-menopausal (n=100), peri-menopausal (n=101) and post-menopausal (n=100) age groups. Qualitative hCG analysis was performed on all samples prior to conducting the study. In this non-pregnant population, all 301 urine samples were tested with three batches of the Clearblue Pregnancy Test with Weeks Indicator. All tests conducted on these samples were negative, with no false-positive results reported.[1]

Background on how the Clearblue Pregnancy Test with Weeks Indicator provides an estimate of time since conception

LH surge – An accurate method for referencing time since conception

Identifying the day of fertilisation is the most accurate method for dating pregnancy. It can be estimated from the day of ovulation, as studies have shown that the egg only survives for up to 24 hours[9] and a woman's fertile period ends on the day of ovulation.[10–12]

LH is a hormone produced by the anterior pituitary gland. A surge in LH triggers ovulation and initiates the conversion of the residual follicle into a corpus luteum that, in turn, produces progesterone to prepare the endometrium for a possible implantation. The World Health Organization has defined the rise in circulating LH as the best indicator for impending ovulation, and the day of ovulation is considered a surrogate marker for conception, as conception can only occur within 24 hours of egg release.[13–15] Levels of LH in urine correlate 100% with ultrasound detection of ovulation.[16]

A prospective study using the Clearblue Fertility Monitor found that the LH surge preceded the day of ovulation in 76% of cycles where there was a surge, and was within ±1 day of agreement for 97% of these cycles. Therefore, ovulation can be presumed to occur on the day of the LH surge +1 (with a ±1 day range).[17]
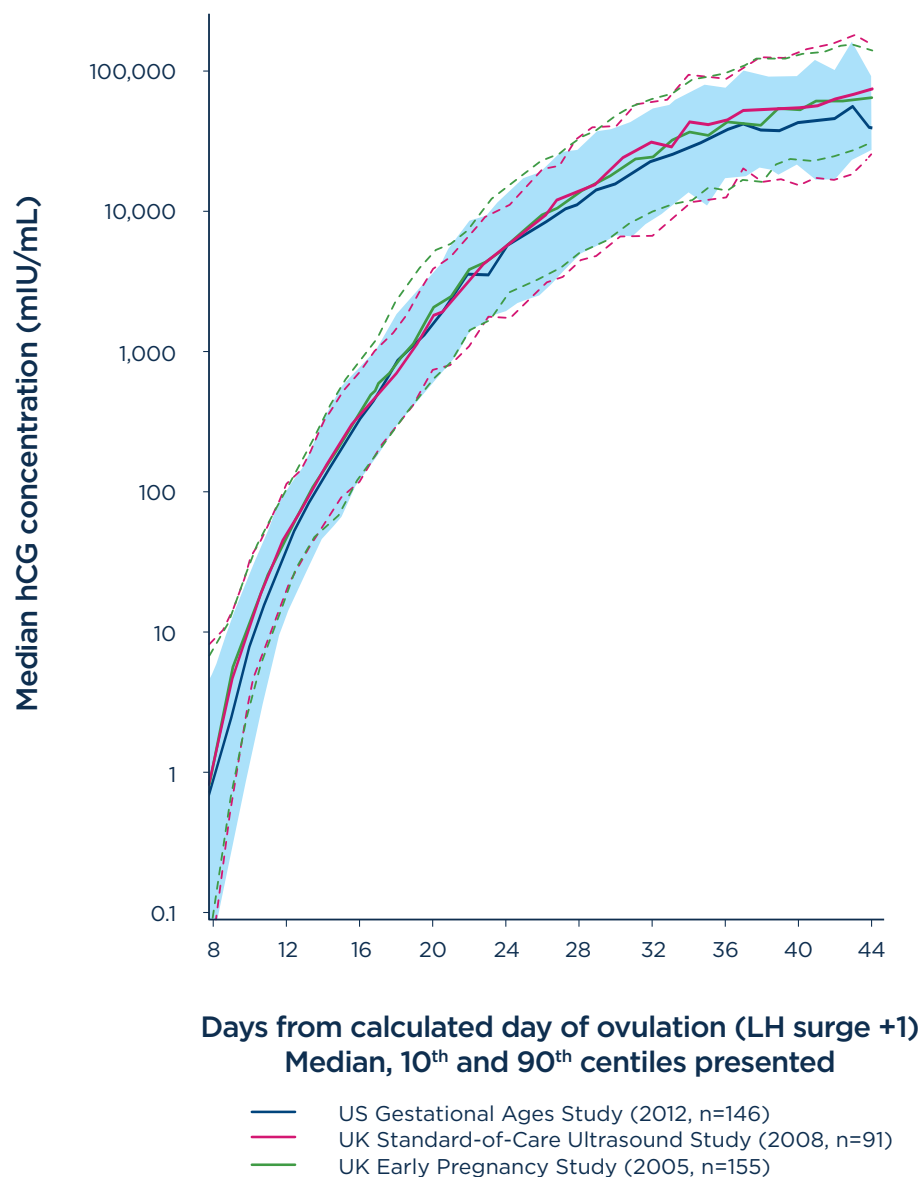
hCG – An accurate scientific marker of time since conception

The peptide hormone hCG is produced by the embryo soon after conception, and later by the syncytiotrophoblast (part of the placenta). An important role of hCG is to prevent the disintegration of the corpus luteum and thereby maintain progesterone production, which is critical for pregnancy in humans.

The Weeks Indicator uses urinary hCG levels to estimate the time since conception, as hCG levels change predictably with pregnancy duration.

- Levels of hCG in serum and urine rise rapidly during the first days of pregnancy[18,19] and are first detectable by sensitive laboratory assays 7 days before the missed period (which corresponds to 6 days before the expected period), when the day of the missed period is estimated using the day of ovulation[10]
- In studies, absolute levels of hCG have been used to estimate gestational age[20,21]
- Rigorous trials on approximately 3,000 individual samples show there is a consistent pattern to urinary hCG levels during early pregnancy[9]
- Three separate studies conducted in the UK and US over several years have each provided identical evidence that hCG rises consistently in early pregnancy (Figure One)[7]
- No differences in the daily rise in urinary hCG concentration in early pregnancy are observed between different ethnicities or races[7,8]

Figure One: The daily rise in urinary hCG detected in early pregnancy in three different studies[7]

Days from calculated day of ovulation (LH surge +1)
Median, 10th and 90th centiles presented

——— US Gestational Ages Study (2012, n=146)
——— UK Standard-of-Care Ultrasound Study (2008, n=91)
——— UK Early Pregnancy Study (2005, n=155)

- Pregnancy duration has been shown to be related to rising hCG levels in urine, and urinary hCG can be used to estimate time since ovulation in weeks, relative to the LH surge (Figure Two).[7,8,18,20] Studies have shown that gestational age estimated by hCG concentration (measured by automated immunoassay) agrees with gestational age estimated using the day of ovulation by 96% for 1–2 weeks gestation, 93% for 2–3 weeks and 95% for more than 3 weeks[8]

Figure Two: Derivation of the weeks since conception indications based on hCG levels relative to the day of ovulation (day following LH surge), in comparison to dating of pregnancy by LMP

LMP, last menstrual period
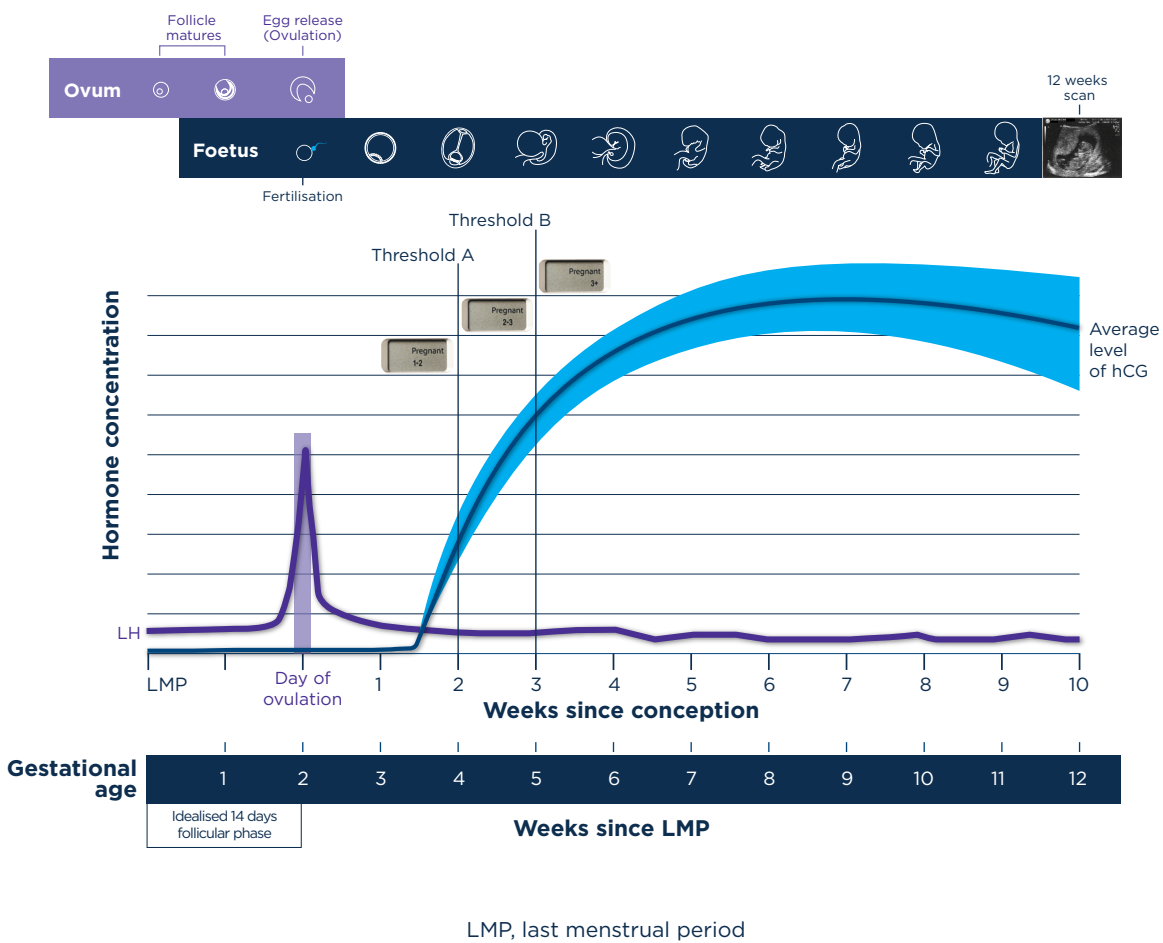
Comparison of the Clearblue Pregnancy Test with Weeks Indicator to standard methods of dating pregnancy

Day of LMP – A frequently inaccurate method

Traditionally, the date of the first day of a woman's LMP is used to date pregnancy, as this is often the only information available in early pregnancy upon which to base an estimate. However, LMP is frequently inaccurate due to a variety of reasons:

- Many women do not know or are uncertain of their LMP:
  - Examination of US birth records found that 16–20% of women have no recorded LMP,[22,23] and another study found that 16% of women had an unknown LMP[24]
  - Only 32% of women are truly certain of their LMP[25]
  - The high incidence of 'round number' preference observed when women are asked to recall their LMP supports the uncertainty of many women; 2.5 times more women than would be expected chose the 15th day of the month as their LMP[26]
- Bleeding in early pregnancy can be mistaken for the LMP
- Recent contraceptive use or underlying endocrine problems can lead to an inaccurate estimate of the LMP
- For those women whose LMP is certain, there is an assumption that the follicular phase is 14 days long; however, the follicular phase can range from 5–24 days[27] resulting in as many as 10% of women who are certain of their LMP date being more than 7 days inaccurate in their estimation of gestational age[28]
- LMP provides a value to the same week in only 46% of women (within +1 week in 78%, within +2 weeks in 87%)[29]

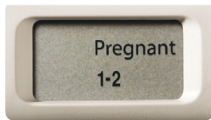### Ultrasound – Standard of care for dating pregnancy in many countries

First-trimester ultrasound is a more accurate method for dating pregnancy than LMP. Ultrasound at approximately 11^{+0} to 13^{+6} weeks after LMP is the standard of care for dating pregnancy in many countries. This method estimates gestational age based on crown rump length (CRL) converted using validated formulae,[30–32] which include an idealised 14-day follicular phase, to align the result to LMP dating. Dating using ultrasound CRL is typically quoted as providing an accurate estimation of gestational age ±5 days.[33–36]

How the Clearblue Pregnancy Test with Weeks Indicator results relate to clinical care

The test is not intended to be a replacement for clinical care, but rather provides information that a woman is immediately interested in once she has received a pregnant result, i.e. "How long is it since I conceived?" Knowing the answer to this question can help women when speaking with healthcare professionals (HCPs). The instruction leaflet makes it clear that the woman should seek guidance from an HCP on receipt of a pregnant result and also helps her to put the results into context with other methods of pregnancy dating: i.e. this test estimates time since conception, which can be related to the way a doctor dates pregnancy if an idealised follicular phase (14 days) is added to the Weeks Indicator result.

The table below is included in the instruction leaflet to help women understand how the result from the Weeks Indicator relates to pregnancy dating by HCPs (Table Three).

Table Three: How the Clearblue Pregnancy Test with Weeks Indicator result relates to pregnancy dating by HCPs using LMP

Result	Pregnant 1–2	Pregnant 2–3	Pregnant 3+
What does this mean?	Pregnant and conceived approximately 1–2 weeks ago	Pregnant and conceived approximately 2–3 weeks ago	Pregnant and conceived more than 3 weeks ago
Pregnancy dating by HCP (weeks pregnant)*	3–4 weeks	4–5 weeks	5+ weeks

* Based on date of LMP

Clearblue Pregnancy Test with Weeks Indicator compared with reference methods for determining gestational age

A multi-centre, prospective study was conducted to compare the Weeks Indicator results with reference methods for determining gestational age. Women were recruited pre-conception, providing 153 pregnancies for analysis. Urine samples were collected by participants throughout their cycle and for 4 weeks from the date their period was due if pregnancy occurred. Quantitative measurement of urinary LH was used to determine the LH surge (with LH surge +1 day defined as the day of ovulation), and ultrasound dating scans were conducted at 11^{+0}–13^{+6} weeks' gestation following Fetal Medical Foundation guidelines.[37] The Clearblue Pregnancy Test with Weeks Indicator was tested on a random set of urine samples, from 4 days prior to the day the period was due until 4 weeks later, ensuring equal representation per volunteer and per week, and ensuring analysis accounted for inter-cycle variation.

In this study, agreement between Clearblue Pregnancy Test with Weeks Indicator results and time since conception (ovulation) by LH surge (±1 day) was 93%. If the ±1 day variation in timing of ovulation from LH surge is not accounted for, agreement was 87%. The breakdown by weeks category is shown in Table Four.[2]

Table Four: Accuracy of the Clearblue Pregnancy Test with Weeks Indicator compared with ovulation day[2]

Time since ovulation	Accuracy allowing for measurement error (without allowance for measurement error)
1–2 weeks	96.0% (92.0%)
2–3 weeks	84.0% (72.0%)
3+ weeks	97.0% (94.0%)
Overall	93.0% (87.0%)

When comparing Clearblue Pregnancy Test with Weeks Indicator results with the CRL measurement taken later in the same pregnancy, consideration has to be given to the formula used to convert this CRL measurement into gestational age. Formula choice can have a profound influence on agreement analysis due to the systematic bias evident with some formulae. In addition, CRL measurement has a measurement error associated within it; therefore, in cases of disagreement between methods, it can be unclear whether this is due to the CRL measurement or the Clearblue Pregnancy Test with Weeks Indicator. Typically, for scans conducted in early pregnancy, a ±5-day range is applied to any measurement. Therefore, analysis of the multi-centre prospective study results was conducted applying this clinical practice. Table Five summarises the agreements found between the Clearblue Pregnancy Test with Weeks Indicator and ultrasound using different formulae and allowing or not allowing for ultrasound measurement error.

Table Five: Agreement between Clearblue Pregnancy Test with Weeks Indicator result and ultrasound estimate using different methods with or without allowing for ultrasound error[35–39]

Reference method and method of comparison	Clearblue Pregnancy Test with Weeks Indicator result			
	1–2	**2–3**	**3+**	**Overall**
Robinson[30] with adjustment for ultrasound error (without adjustment), %	95.5 (49.5)[38]	94.6 (63.7)[38]	100.0 (98.8)[38]	98.0 (82.5)[38]
Hadlock[31] with Pexsters[39] adjustment for bias with adjustment for ultrasound error (without adjustment), %	99.1 (76.5)	97.4 (71.1)	99.9 (96.2)	98.9 (86.0)

Notes on formulae: The Hadlock formula is frequently used in clinical care and is a preset formula for most ultrasound equipment. Evidence shows that this formula has a systematic bias of +2 days,[39] which has no consequence in clinical practice, but when used as a reference method can provide a low agreement. The Pexsters adjustment removes this bias, indicating that the low level of agreement at 1–2 weeks was algorithm dependent.

When gestational age estimated by LMP was compared in this study with gestational age estimates based on ultrasound and day of ovulation, it was found to agree in 78% and 82% of cases, respectively (when CRL was converted using the Hadlock formula, with bias adjustment). This is significantly lower than the agreements observed between the Clearblue Pregnancy Test with Weeks Indicator and these reference methods (P<0.05).[2]

Comparison with standard-of-care ultrasound

In a study conducted in the UK, the Clearblue Pregnancy Test with Weeks Indicator was compared with standard-of-care ultrasound for assessing pregnancy duration in a real-life observational setting. Data were available from 52 pregnant women and this study reported an 82% agreement between the two methods. However, when a ±5-day range was applied to the ultrasound reading (as per routine UK clinical practice), the level of agreement increased to 98%.[40]

Comparison with ultrasound assessment in combined data from the US Gestational Ages[41] and UK Standard-of-Care Ultrasound[40] studies

Two separate studies have examined the agreement between the Clearblue Pregnancy Test with Weeks Indicator and ultrasound; both studies found a high level of agreement (98%) despite being conducted in different geographies and using slightly different analysis methods.[40,41] To provide a consistent, consolidated agreement figure between the Clearblue Pregnancy Test with Weeks Indicator and ultrasound, a new analysis on all the available ultrasound data was conducted using the same methodology. Data from 143 women from the US Gestational Ages study[41] and 44 women from the UK Standard-of-Care Ultrasound[40] study were combined. Analysis of this combined dataset confirmed a high level of agreement (97%) between the Clearblue Pregnancy Test with Weeks Indicator result and gestational age based on estimates using an ultrasound dating scan, thus indicating that the Clearblue Pregnancy Test with Weeks Indicator results are comparable to an ultrasound dating scan.[42,d]

Comparison with delivery date

A prospective study was conducted to compare the Clearblue Pregnancy Test with Weeks Indicator results with the ultrasound CRL measurement for the prediction of final delivery date. Urine samples were collected pre-conception until approximately 8 weeks' gestational age from 46 women with a natural delivery from the US Gestational Ages[41] and UK Standard-of-Care Ultrasound[40] studies. The mean time from the Weeks Indicator result (time since ovulation) to delivery was 37.47 weeks, while the mean time from ovulation to delivery date based on ultrasound CRL measurement was 37.40 weeks. The Clearblue Pregnancy Test with Weeks Indicator provides a prediction of delivery date comparable to ultrasound CRL measurement, and the mean duration of time from ovulation to delivery is also consistent with the typically reported 38 weeks.[43]

Comparison with serum levels of hCG

Results of the Clearblue Pregnancy Test with Weeks Indicator have also been compared with serum levels of hCG (Figure Three). It can be seen that there is little overlap between the Clearblue Pregnancy Test with Weeks Indicator result and the serum hCG concentrations.[44]

Figure Three: Comparison of Clearblue Pregnancy Test with Weeks Indicator result with serum beta hCG concentration in 500 urine samples from 200 pregnant women[44]
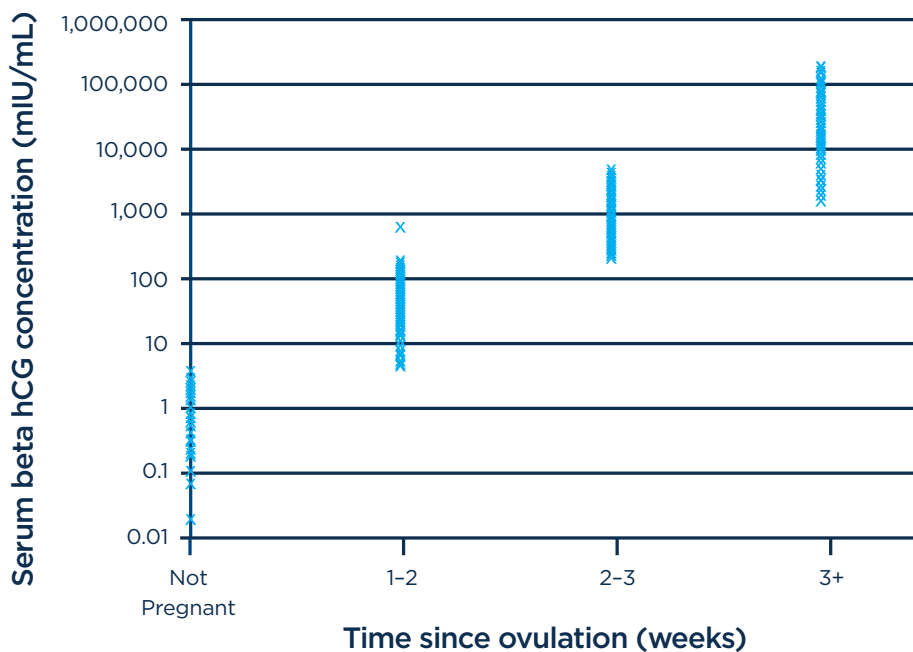
What do consumers think of the Clearblue Pregnancy Test with Weeks Indicator?

- **Easy to use** – Women prefer its midstream test stick format over other formats such as cassette or strip-based pregnancy tests. In a study, more than 95% of women stated that they preferred the midstream test stick format, stating hygiene and ease of use as some of the reasons for this preference[45]

- **Trusted by women** – Women feel great confidence in the digital results which are easy to read, giving women reassurance, confidence and trust in the accuracy of the result.[46] In studies, 98% of women were confident of the results of a pregnancy test when the results were displayed in words, compared with less than 50% for some traditional line-based tests, and less than 30% for strip- or cassette-based tests.[45] Furthermore, it has been shown that one in four women can misread traditional line pregnancy test results[47]

- **Women favour a Weeks Indicator feature** – A pregnancy test with a Weeks Indicator feature is preferred over a standard pregnancy test[48]

Limitations

- The manufacturer's instructions regarding any medication being taken should be read before conducting the test

- When testing before the day of the expected period, the first morning urine sample should always be used. This is not necessary when testing on or after the day of the expected period

- Testing within 14 days after administration of a fertility drug containing hCG can give a false pregnant result. Other fertility therapies (such as clomiphene citrate), painkillers and hormonal contraceptives (e.g. the contraceptive pill) should not affect the result. Recent cessation of hormonal contraceptives or use of fertility therapies like clomiphene citrate may cause irregular periods, in which case the user may test too soon

- Excessive fluid intake should be avoided before testing, as a urine sample that is too dilute may give a false-negative (non-pregnant) result

- Ectopic pregnancy and ovarian cysts can give misleading results.[49] Multiple pregnancies can also give misleading results

- Elevated levels of hCG that are caused by an increase of pituitary hCG production in peri-menopause, chemotherapy-induced suppression of gonadal function or gestational trophoblastic disease can give misleading results[49]

- A recent pregnancy, miscarriage or termination can give misleading results, as hCG can be found in the body for several weeks after giving birth[50] and after a miscarriage or termination[51]

- If a positive (pregnant) result is obtained and the woman later obtains a non-pregnant result, or her period starts, it may be due to natural loss during the early stage of pregnancy. This is not uncommon, as around one in four pregnancies end in early pregnancy loss[52,53]

- Women should discuss any unexpected results with an HCP

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Clearblue Pregnancy Test with Weeks Indicator is:

Accurate – over 99% accurate from the day of the expected period[1,b]

Clinically proven – correlates with estimation of gestational aging by routine ultrasound[e]

Sensitive – can be used up to 5 days before the missed period[2,c]

Unmistakably clear – results displayed in words and numbers on a digital screen

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

[b] The Clearblue Pregnancy Test with Weeks Indicator has been shown to be over 99% accurate from the day of the expected period when compared with a reference method in laboratory studies using urine samples supplied for pregnancy testing.

[c] Five days before the missed period corresponds to 4 days before the expected period. In laboratory testing, 98% of pregnant results were detected on the day before the expected period, 97% were detected 2 days before, 90% were detected 3 days before and 65% were detected 4 days before the expected period (5 days before the missed period).

[d] The Clearblue Pregnancy Test with Weeks Indicator result does not replace the need for a pregnant woman to attend routine ultrasound examinations.

[e] Based on studies of 143 women comparing ultrasound dating to weeks result (up to 3+ weeks).[2]

Clearblue®

For more information about the Clearblue Pregnancy Test with Weeks Indicator, please visit our websites:
www.clearblue.com
www.swissprecisiondiagnostics.com

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Clearblue Professional Series: HCP-0018.5