



About Clearblue

Clearblue® is the world's leading brand in home pregnancy and fertility testing. 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 products are also trusted and recommended by doctors, many of whom recognize that Clearblue is supported by 25 years of expertise, quality, and innovation in consumer diagnostics.

Clearblue Digital Ovulation Test

The Clearblue Digital Ovulation Test is an easy-to-use home ovulation test, which is over 99% accurate in detecting the LH surge,¹ and which provides an easier and more accurate reading in consumers' hands than traditional line tests.^{2,3}

Proven method of detecting peak fertility

There are only a few days per cycle when a woman is fertile and can conceive. Evidence shows that this time of high fertility usually spans six days, starting approximately five days prior to ovulation and ending on the day of ovulation itself.⁴ The two most fertile days of this six-day window are known as peak fertile days. These peak fertile days are one day prior to ovulation and the day on which ovulation takes place.⁵

Predicting when ovulation occurs can be beneficial for women who are actively trying to conceive. Data show that women who are aware of their peak fertile days have an increased likelihood of conceiving when compared to women who are unaware of their ovulatory pattern.^{6,7} The Clearblue Digital Ovulation Test helps women to pinpoint the two most fertile days in their cycle by measuring levels of luteinizing hormone (LH). LH levels rise rapidly 24-36 hours prior to ovulation (i.e. during the time of peak fertility – see Figure One),⁸ with various studies showing that this 'LH surge' is an accurate and reliable marker of impending ovulation.⁹⁻¹³ Extensive laboratory studies have shown that the Clearblue Digital Ovulation Test is over 99% accurate at detecting the pre-ovulatory LH surge.¹

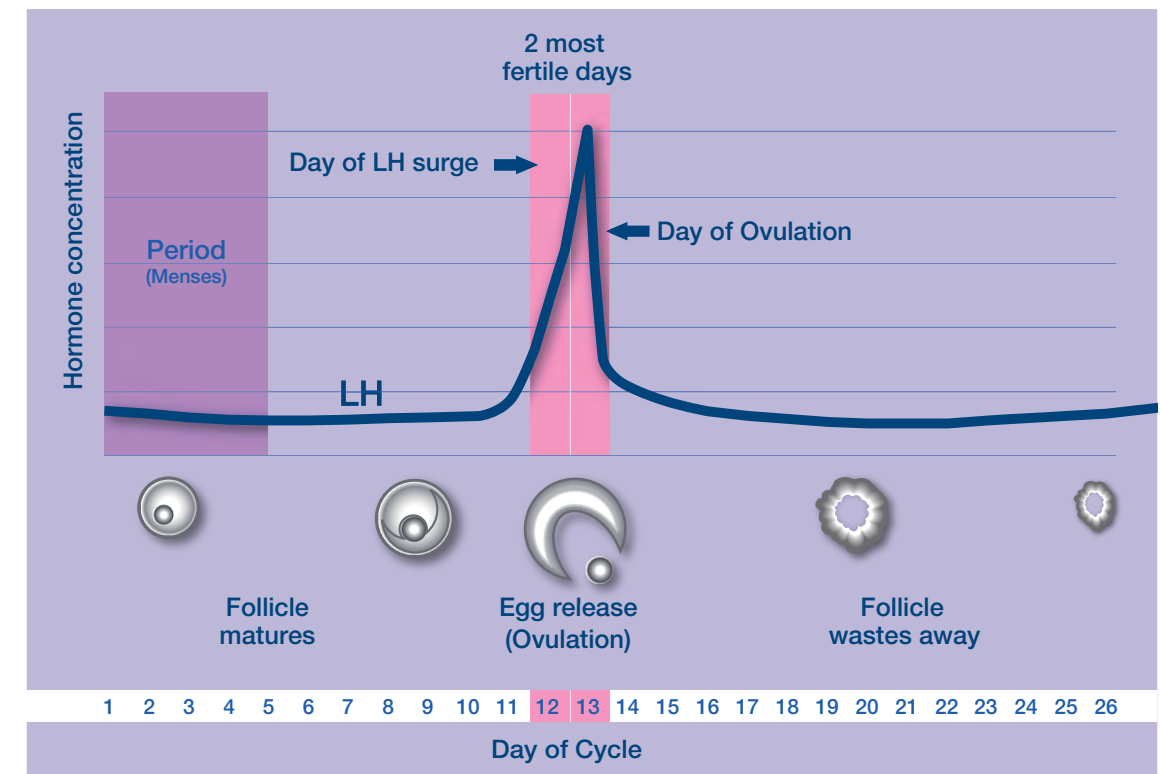


Figure One: An example of how the LH surge could appear during a menstrual cycle

Adapts to a woman's own LH surge threshold

As many women have low levels of LH present in their urine throughout their cycles, the Clearblue Digital Ovulation Test does not measure the LH surge to a constant uniform threshold. Instead, the Clearblue Digital Ovulation Test sets a personalized threshold level for each woman, by measuring their change in LH level from their personal baseline. This is an obvious advantage over visual tests which ignore the fact that different women have different baseline LH levels and that levels can even vary between cycles.

More effective than a five-stick test

The day the LH surge occurs varies from woman to woman and from cycle to cycle. Moreover, data show that cycle length itself varies by seven days or more in 46% of women aged 18-40 years.¹⁴ Therefore, compared with traditional home ovulation tests with only five Test Sticks, the two additional Test Sticks in the Clearblue Ovulation Test – 7 Test Pack gives women a greater chance of detecting their LH surge and time of peak fertility.¹⁵

Most accurate reading – easier to read than a 'line test'

It has been shown that 1 in 4 women can misread a line test.² However, the Clearblue Digital Ovulation Test has a clear, digital display that provides two simple results: a ☺ for a 'No LH surge' result and a ☹ for a positive 'LH surge' result. Indeed, a recent study which compared four leading ovulation test brands found that the Clearblue Digital Ovulation Test was the test that women read most accurately (see Figure Two).³

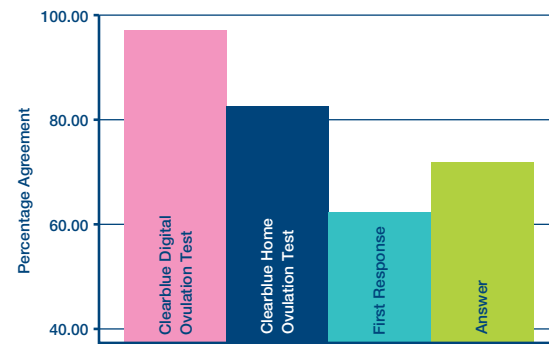


Figure Two: In a study of 72 women reading ovulation tests using urine samples from normal cycles, more women obtained the same result as a laboratory professional when reading the Clearblue Digital Ovulation Test than when reading three other leading Ovulation Test brands. The study was done on tests available in the UK and US markets.³

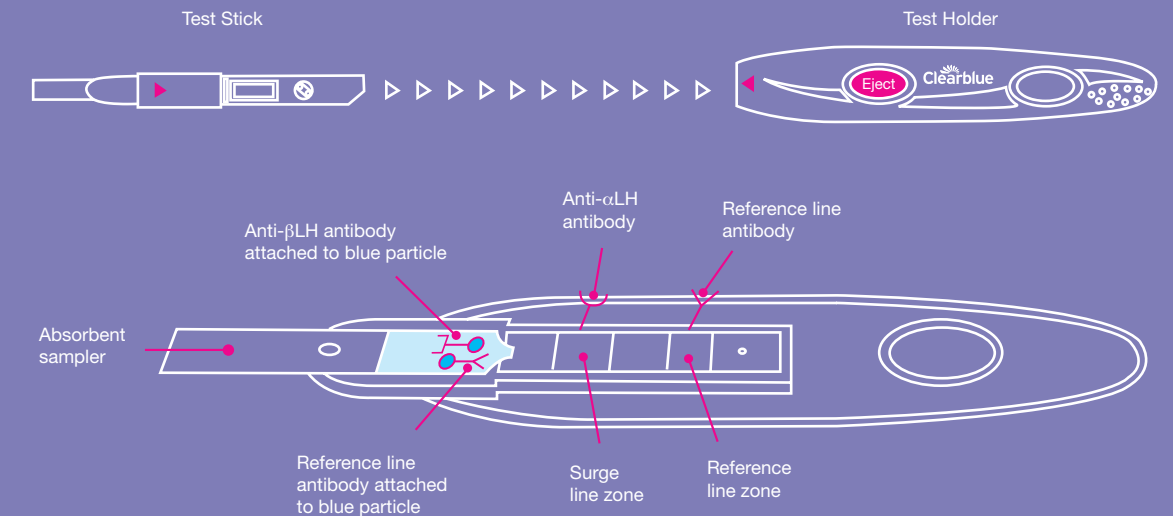
Additional points

- A woman who does not know her usual cycle length is advised to wait for at least one menstrual cycle, and note the length of this cycle, before using Clearblue Digital Ovulation Test. She can then refer to the chart supplied on the in-pack leaflet to determine when she should start testing.
- If a woman's cycle length is shorter than 21 days she should start testing on day 5. If her cycle is longer than 40 days, she should start testing 17 days before she expects her next period.
- Users should always read the manufacturer's instructions for any medication they are taking before conducting a test.
- Certain medical conditions and medications can adversely affect the performance of the Test; for example if a woman is pregnant or has recently been pregnant, has reached the menopause or has polycystic ovary syndrome this may produce a misleading result. This may also be true for a woman taking fertility drugs containing Luteinizing Hormone or human Chorionic Gonadotrophin. It is advised in these cases that she checks with her doctor.
- Clomiphene citrate does not affect the tests, but may affect the length of the cycle and, therefore, when to start testing. A user may need to start a new pack and use the new Test Holder and Test Sticks to continue testing.
- If a woman has recently stopped using hormonal contraception this will not affect results. However the natural hormone pattern is disrupted by hormonal contraception and her cycles may be temporarily irregular. Women in this position may therefore wish to wait until they have had two natural menstrual cycles, and should note the length of these cycles before using Clearblue Digital Ovulation Test.
- Clearblue Digital Ovulation Test should not be used as a method of contraception.

How does the Clearblue Digital Ovulation Test work?

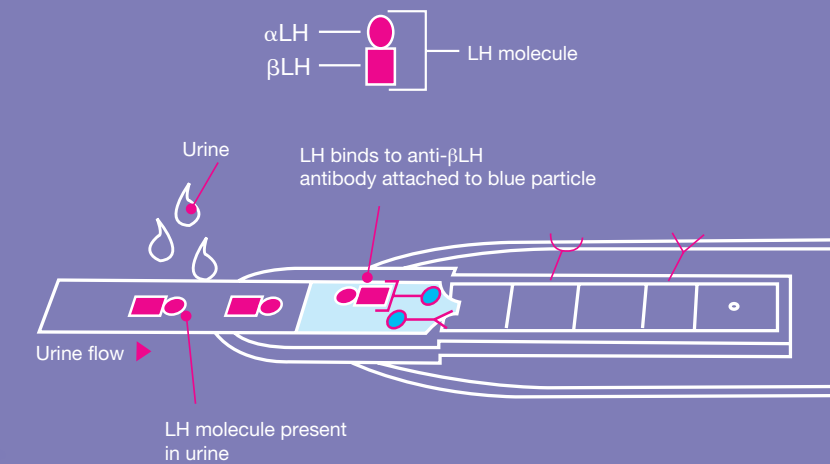
The Clearblue Ovulation Test is a rapid 'sandwich' assay which uses two distinct antibodies to detect two separate antigenic sites on the LH molecule: the α LH site and β LH site. The anti- β LH antibody is attached to blue latex particles that are dried onto the surface of the absorbent sampler. The anti- α LH antibody is immobilized in a line on the test strip known as the Surge line zone.

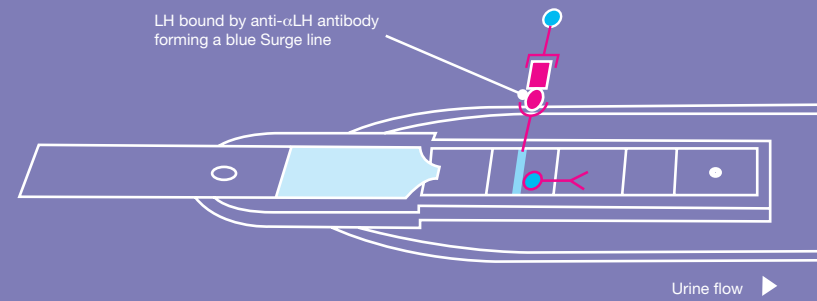
Reference antibodies are also present on the absorbent sampler. These are also attached to blue latex surface particles, but do not bind to LH.



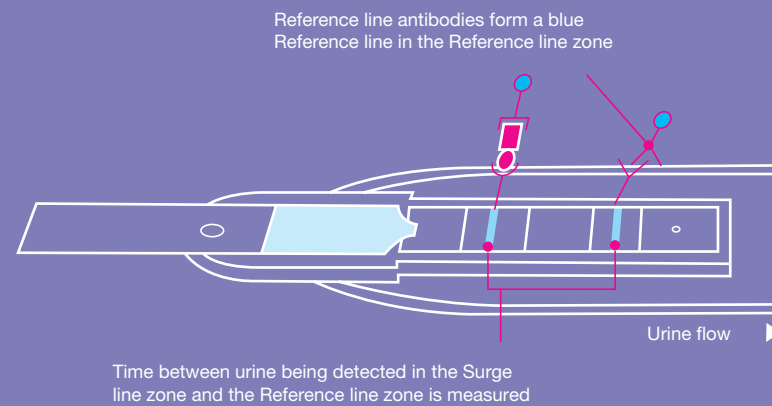
To begin the test the user inserts the stick into the reader, then urinates onto the test stick. If LH is present in the urine, its β LH antigenic site is bound by the anti- β LH antibody that is attached to a particle to form a complex. The urine flows along the test stick to the zones containing the Surge and Reference lines. As soon as the LH complex reaches the Surge line zone, the antigenic site on α LH is bound by the Surge line's immobilized anti- α LH antibodies. This means that the LH/blue particle complex cannot move any further down the test strip, resulting in an intense blue Surge line which is read by Clearblue's Digital Reader.

Test behaviour with urine sample on day of LH surge

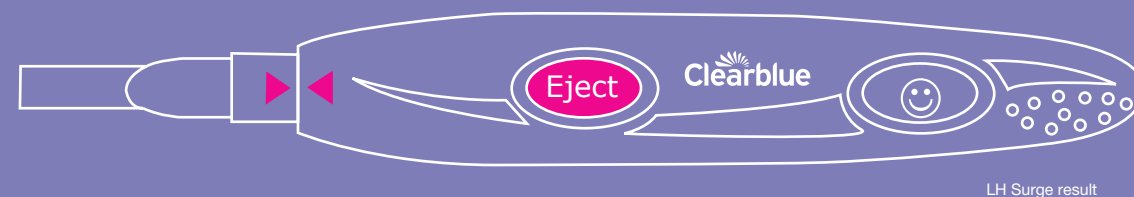




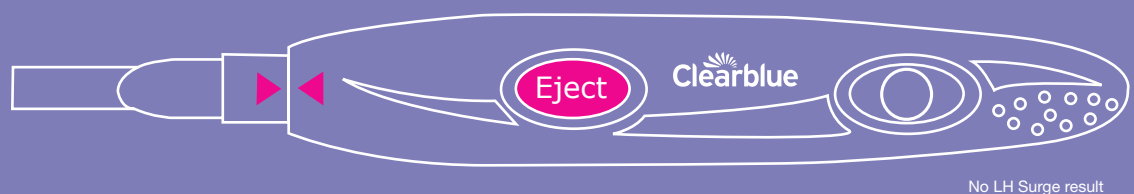
If no LH is contained in the urine sample, then the blue particles are not captured in the Surge zone and continue on to the end of the strip. No blue Surge line appears in the Surge zone. The flow of urine also facilitates the movement of the Reference antibody on blue particles. As the urine flows, reference blue particles are captured in a Reference line zone situated towards the end of the strip. This forms a blue line which is similar to that found in the Surge zone, and which occurs whether LH is present or not in order to show that the test has worked correctly. The addition of this Reference line enables the Digital Reader to check whether the test has completed successfully and ensures that the Surge line reading is only taken when the urine flow is completed (i.e. usually after three minutes have elapsed). Measurement of the flow of blue particles along the strip is also monitored to check there are no errors whilst the test is running.



If the Clearblue Digital Reader detects that the test has completed successfully and that the Surge line intensity is over a certain threshold, the display will show a 'Surge' result. This indicates that conception is most likely if intercourse occurs during the next 1-2 days.



If the Surge line fails to rise above this threshold within the three-minute testing period, a 'No Surge' result is displayed.



About SPD Swiss Precision Diagnostics GmbH

SPD Swiss Precision Diagnostics GmbH is a world leader in the research, design, production and supply of advanced consumer diagnostic products. Our brands, such as Clearblue®, FactPlus®, and Accu-Clear®, are familiar in many countries, and are trusted for their accuracy and simplicity by women keen to know more about their own reproductive health. SPD brands are acclaimed for their pioneering innovation: Clearblue was the first brand to introduce a one-step pregnancy test, a one-minute test, a urine sample indicator, and digitally displayed results.

At SPD, we are committed to helping people make informed decisions about their health and well-being, through a continuing flow of new and inventive developments. Our research centre is at the sharp edge of innovation, and is fully engaged in the development of reliable diagnostic products for better health and personal self-care.

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

Alternatively, you could write to us at:
 SPD Swiss Precision Diagnostics GmbH
 47 Route de Saint-Georges
 1213 Petit Lancy
 Geneva
 Switzerland
www.swissprecisiondiagnostics.com

References

1. SPD data on file. Clearblue Digital Ovulation Test has been shown to be 99% accurate when compared to a reference method in laboratory studies using urine samples from 123 cycles.
2. SPD data on file. DOT Consumer Study - one in four women can misread a line test.
3. SPD data on file. In a study of 72 women reading Ovulation Tests typical of normal cycle results, more women obtained the same result as a laboratory professional when reading Clearblue Digital Ovulation Test than when reading other Ovulation Tests.
4. Wilcox AJ, Weinberg CR, Baird DD. Timing of sexual intercourse in relation to ovulation. Effects on the probability of conception, survival of the pregnancy, and sex of the baby. *N Engl J Med* 1995 Dec 7;333(23):1517-21.
5. Ferreira-Poblete A. The probability of conception on different days of the cycle with respect to ovulation: an overview. *Adv Contracept* 1997 Jun;13(2-3):83-95.
6. Hilgers TW, Daly KD, Prebil AM, Hilgers SK. Cumulative pregnancy rates in patients with apparently normal fertility and fertility-focused intercourse. *J Reprod Med* 1992 Oct;37(10):864-6.
7. Stanford JB, Dunson DB. Effects of sexual intercourse patterns in time to pregnancy studies. *Am J Epidemiol* 2007 May 1;165(9):1088-95.
8. World Health Organisation. Temporal relationships between indices of the fertile period. *Fertil Steril* 1983 May;39(5):647-55.
9. Corson SL. Self-prediction of ovulation using a urinary luteinizing hormone test. *J Reprod Med* 1986 Aug;31(8 Suppl):760-3.
10. Guida M, Tommaselli GA, Palomba S, Pellicano M, Moccia G, Di Carlo C, et al. Efficacy of methods for determining ovulation in a natural family planning program. *Fertil Steril* 1999 Nov;72(5):900-4.
11. Behre HM, Kuhlage J, Gassner C, Sonntag B, Schem C, Schneider HP, et al. Prediction of ovulation by urinary hormone measurements with the home use ClearPlan Fertility Monitor: comparison with transvaginal ultrasound scans and serum hormone measurements. *Hum Reprod* 2000 Dec;15(12):2478-82.
12. Tanabe K, Susumu N, Hand K, Nishii K, Ishikawa I, Nozawa S. Prediction of the potentially fertile period by urinary hormone measurements using a new home-use monitor: comparison with laboratory hormone analyses. *Hum Reprod* 2001 Aug;16(8):1619-24.
13. Guermandi E, Vegetti W, Bianchi MM, Uglietti A, Ragni G, Crosignani P. Reliability of ovulation tests in infertile women. *Obstet Gynecol* 2001 Jan;97(1):92-6.
14. Creinin MD, Keveline S, Meyn LA. How regular is regular? An analysis of menstrual cycle regularity. *Contraception* 2004 Oct;70(4):289-92.
15. Johnson SR, Shaw R. Testing Strategies for the Home Detection of the LH surge. SPD data on file.

Clearblue

The Clearblue Digital Ovulation Test is:

Accurate - over 99% accurate in detecting the LH surge in urine

Unique - the only digital ovulation test

Reliable - uses innovation based on established technology

Unmistakable - clear digital results

Simple to use - convenient and easy to interpret

Recommended - number 1 OBGYN-recommended brand in the US

Trustworthy - from Clearblue, the world's leading brand in home pregnancy and fertility testing

Clearblue

For more information about the Clearblue Digital Ovulation Test, please visit our websites:

www.clearblue.com

www.swissprecisiondiagnostics.com



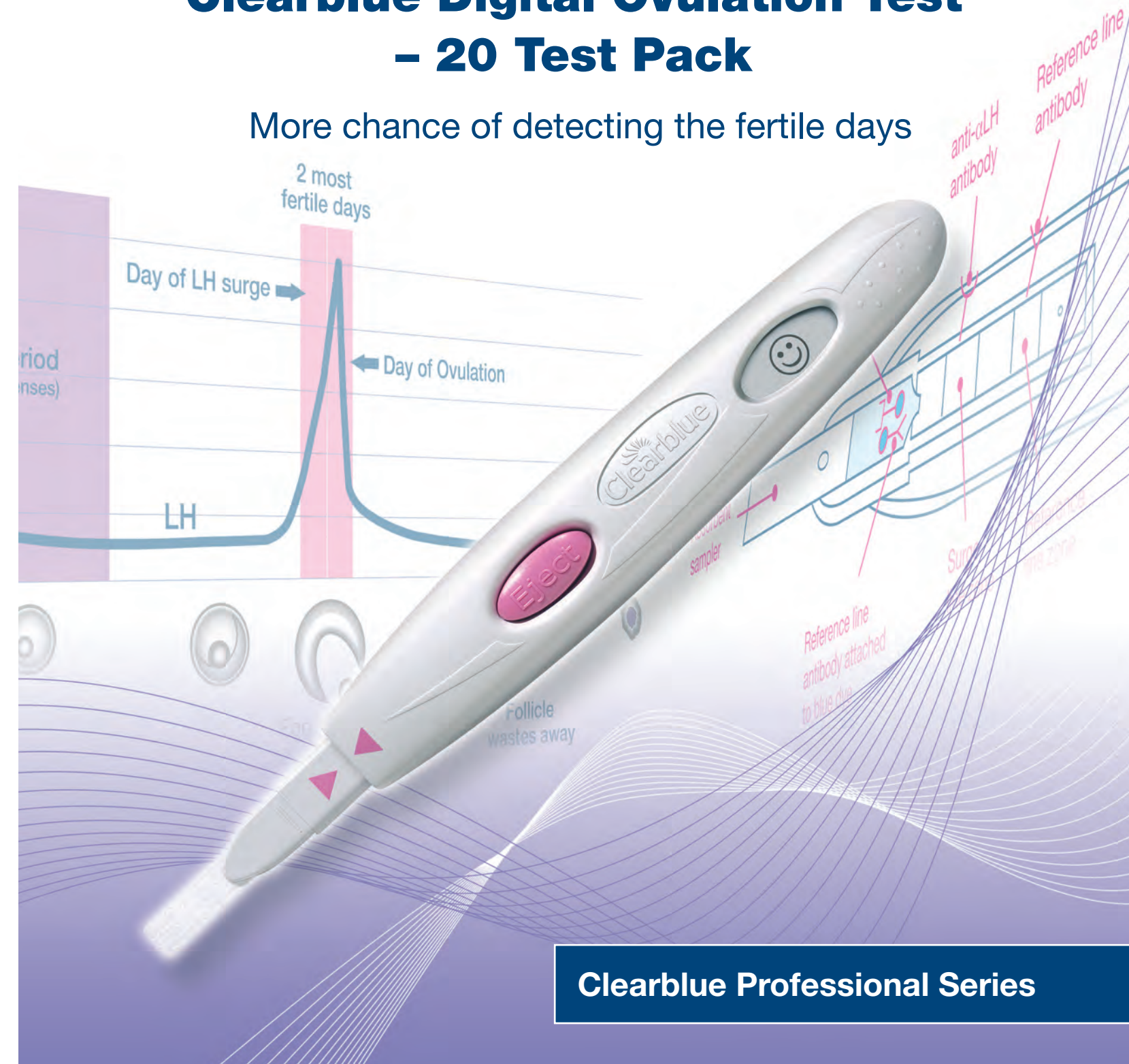
SPD Swiss Precision Diagnostics GmbH, 1213 Petit Lancy, Geneva, Switzerland

©2010 SPD Swiss Precision Diagnostics GmbH. All rights reserved.

Clearblue is a trademark

Clearblue Digital Ovulation Test - 20 Test Pack

More chance of detecting the fertile days



Clearblue Professional Series



About Clearblue

Clearblue® is the world's leading brand in home pregnancy and fertility testing. 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 products are also trusted and recommended by doctors, many of whom recognize that Clearblue is supported by 25 years of expertise, quality, and innovation in consumer diagnostics.

Clearblue Digital Ovulation Test – 20 Test Pack

The Clearblue Digital Ovulation Test – 20 Test Pack gives women more chance of detecting their fertile days.¹

Getting pregnant is something that most people believe should happen quickly and easily. However, because many women have a limited understanding of their own fertility,² getting pregnant can often take longer than expected.

A healthy couple in their 20s has just a one-in-three chance of conceiving in any one cycle, and for older women, the likelihood of conception is even less.³ As a result, an increasing number of couples now appreciate the benefits of using effective, easy-to-use, personalized ovulation tests, which inform them when their chance of achieving pregnancy is most likely.

The Clearblue Digital Ovulation Test – 20 Test Pack provides four important benefits for women who are trying to conceive; it is more than 99% accurate;⁴ it gives women a great chance of detecting their fertile days, even if their cycle lengths are variable;¹ it is extremely easy to use; and it provides clear, digital results.

More than 99% accurate

There are only a few days per cycle when a woman is fertile and can conceive. Evidence shows that this time of high fertility usually spans six days, starting approximately five days prior to ovulation and ending on the day of ovulation itself.⁵ The two most fertile days of this six-day window are known as peak fertile days. These peak fertile days are the one day prior to ovulation and the day on which ovulation takes place.⁶

The fertile period is affected by:

- The lifespan of the egg, which is up to 24 hours after ovulation
- The lifespan of sperm which is more variable, but is typically 3-5 days. Sperm survival is dependent on the type and quantity of the mucus within the cervix, and the quality of the sperm itself.

Predicting when ovulation may occur is critical for women who are actively trying to conceive. Data show that women who are aware of their peak fertile days have an increased likelihood of conceiving.^{7,8} The Clearblue Digital Ovulation Test – 20 Test Pack helps women to pinpoint the two most fertile days in their cycle by measuring daily levels of luteinizing hormone (LH). LH levels rise rapidly 24-36 hours prior to ovulation,⁹ with various studies showing that this 'LH surge' is an accurate and reliable marker of impending ovulation.¹⁰⁻¹⁴ Extensive laboratory studies have shown that the Clearblue Digital Ovulation Test – 20 Test Pack is over 99% accurate at detecting the pre-ovulatory LH surge.⁴

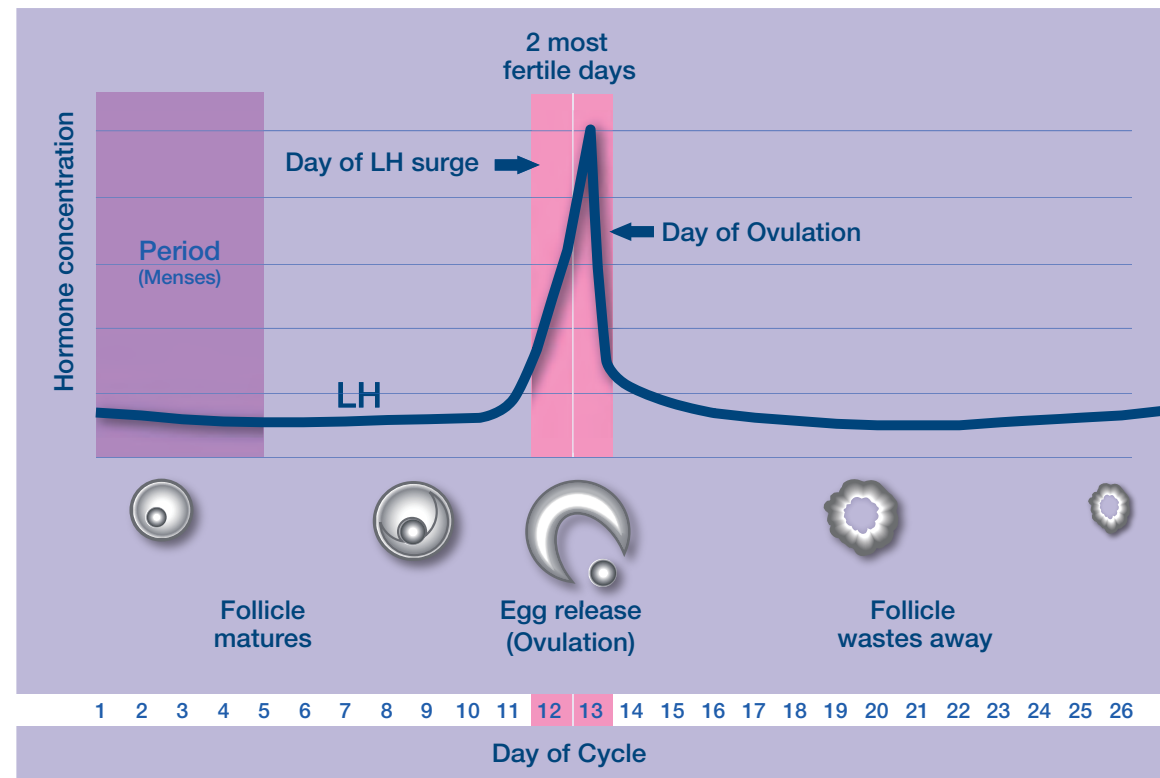


Figure One: An example of how the LH surge could appear during a menstrual cycle

Works for women with variable cycle lengths

The menstrual cycle begins and ends with the first day of menses (Day 1).¹⁵ It is generally assumed that the menstrual cycle lasts for 28 days. However, cycle length varies both between and within women. Indeed, data show that cycle length varies by seven days or more in 46% of women aged 18-40 years.¹⁶ Therefore, variations of fewer than eight days between the longest and shortest cycles are now considered normal; irregular cycles are defined as having 8-20 days variation in cycle length; and only variations of over 21 days are considered extremely irregular.¹⁶

The menstrual cycle is divided into two phases: follicular and luteal. The follicular phase commences at the onset of menses. This phase lasts until ovulation, which is triggered by the LH surge and marks the start of the luteal phase (see Figure One).

Many studies have been conducted to measure the lengths of the follicular and luteal phases. These reports have found that whilst variation exists with regard to total menstrual cycle duration between and within women, such variation appears to result from changes in the early, follicular phase of the cycle.¹⁷

Because of these differences in follicular phase length, the day of the LH surge varies from woman to woman and from cycle to cycle. Therefore, compared with traditional home ovulation tests with fewer Test Sticks, the additional Test Sticks in the Clearblue Digital Ovulation Test – 20 Test Pack gives women a greater chance of detecting their LH surge and time of peak fertility. The Clearblue Digital Ovulation Test – 20 Test Pack uses up to 20 Test Sticks per cycle, with measurements starting on day six (or day 12 if a typical cycle is longer than 40 days). When compared to a 7-Stick Test, the Clearblue Digital Ovulation Test – 20 Test Pack is significantly more likely to identify a woman's peak fertile days. Data show that a 7-Stick Test identifies the peak fertile days in 74-80% of cases, whereas the Clearblue Digital Ovulation Test 20 identifies the peak fertile period in more than 99% of cases.¹

Adapts to a woman's own LH surge threshold

As many women have small levels of LH present in their urine throughout their cycles, the Clearblue Digital Ovulation Test does not measure the LH surge to a constant uniform threshold. Instead, the Clearblue Digital Ovulation Test sets a personalized threshold level for each woman, by measuring their change in LH level from baseline. This is an obvious advantage over visual tests which ignore the fact that different women have different baseline LH levels and that levels can even vary between cycles.

Easy to use

The Clearblue Digital Ovulation Test – 20 Test Pack comprises 20 foil-wrapped Test Sticks and an electronic Test Holder. The pack also contains an instruction leaflet. An abbreviated version of these instructions is provided below:

Prior to using the Clearblue Digital Ovulation Test, the user must remove a Test Stick from its foil wrapper, take off the Test Stick cap, and insert the Test Stick into the Test Holder. The Test Stick and Test Holder are marked with pink arrows. The user must align these when inserting the Test Stick into the Test Holder. The Test Stick clicks into place when inserted and the 'Test Ready' symbol appears on the Display.

When the 'Test Ready' symbol appears, the user simply holds the Absorbent Sampler in her urine stream for 5-7 seconds. Alternatively, she can collect a sample of urine in a clean, dry container and immerse the sampler in the collected specimen for 15 seconds. After 20 to 40 seconds, the Test Ready symbol will flash to show that the Test is working.



Provides clear, digital results

It has been shown that 1 in 4 women can misread a traditional line test.¹⁸ However, the Clearblue Digital Ovulation Test has a clear, digital display that provides one of two simple results. Within three minutes, the Test Holder automatically reads and interprets the Test result and delivers a ☺ for a 'No LH surge' result and a ☺ for a positive 'LH surge' result. This gives consumers confidence that they have used the device correctly. Indeed, a recent study which compared four leading ovulation test brands found that the Clearblue Digital Ovulation Test was the test that women read most accurately (see Figure Two).¹⁹

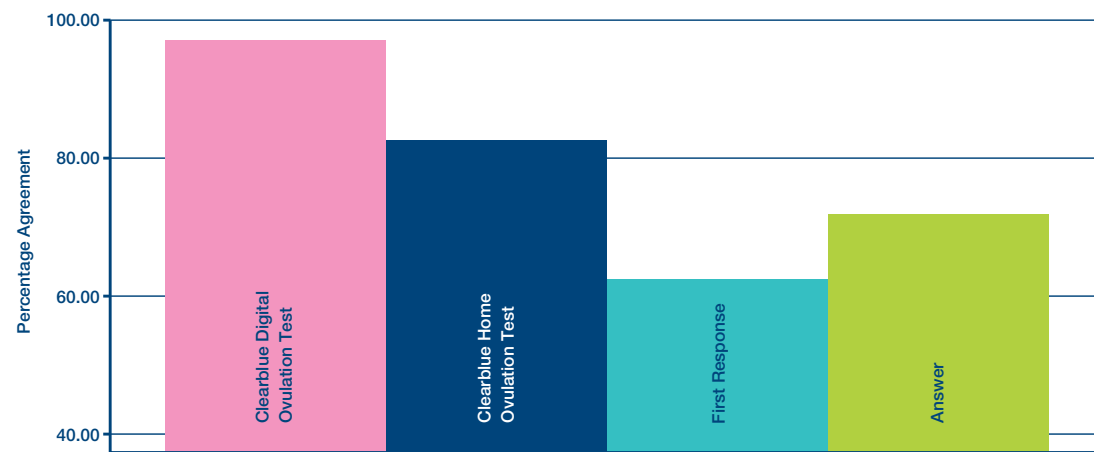


Figure Two: In a study of 72 women reading ovulation tests using urine samples from normal cycles, more women obtained the same result as a laboratory professional when reading the Clearblue Digital Ovulation Test than when reading three other leading Ovulation Test brands. The study was done on tests available in the UK and US markets.¹⁹

Additional points

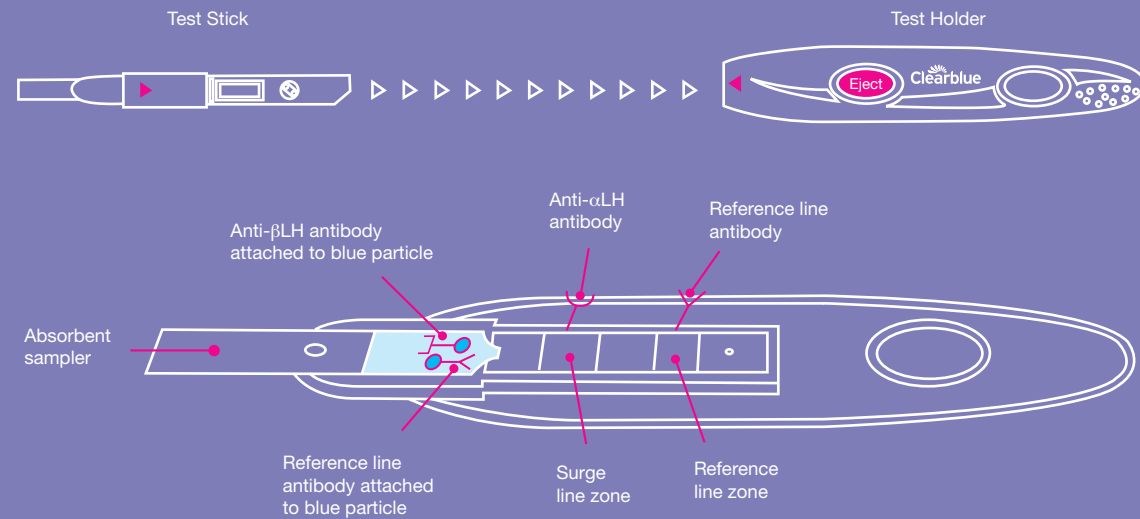
- Women should normally start testing on day six. However, women whose typical cycle lengths are 41 days or more should start testing on Day 12.
- Testing should take place at approximately the same time each day, but not within four hours of the last urination.
- Users should always read the manufacturer's instructions for any medication they are taking before conducting a test.
- Certain medical conditions and medications can adversely affect the performance of the Test; for example if a woman is pregnant or has recently been pregnant, has reached the menopause, or has polycystic ovary syndrome, this may produce a misleading result. This may also be true for a woman taking fertility drugs containing Luteinizing Hormone or human Chorionic Gonadotrophin. It is advised in these cases that she checks with her doctor.
- Clomiphene citrate does not affect the tests, but may affect the length of the cycle and, therefore, when to start testing. A user may need to start a new pack and use the new Test Holder and Test Sticks to continue testing.
- If a woman has recently stopped using hormonal contraception, this will not affect results. However the natural hormone pattern is disrupted by hormonal contraception and her cycles may be temporarily irregular. Women in this position may therefore wish to wait until they have had two natural menstrual cycles, and should note the length of these cycles before using Clearblue Digital Ovulation Test – 20 Test Pack.
- The Clearblue Digital Ovulation Test – 20 Test Pack should not be used as a method of contraception.



How does the Clearblue Digital Ovulation Test work?

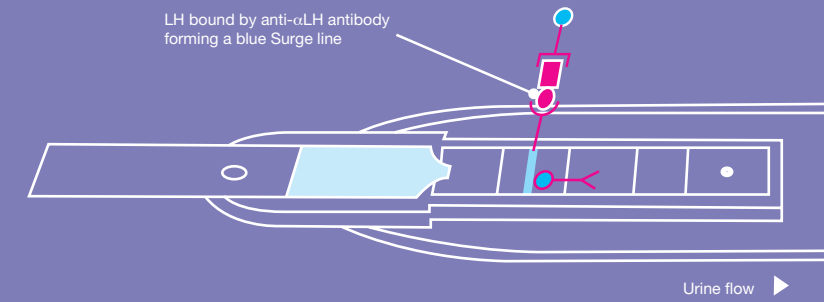
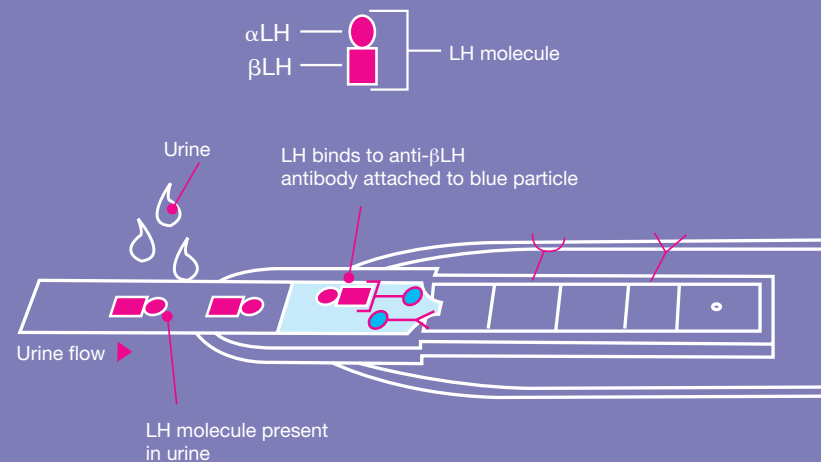
The Clearblue Ovulation Test is a rapid 'sandwich' assay which uses two distinct antibodies to detect two separate antigenic sites on the LH molecule: the α LH site and β LH site. The anti- β LH antibody is attached to blue latex particles that are dried onto the surface of the absorbent sampler. The anti- α LH antibody is immobilized in a line on the test strip known as the Surge line zone.

Reference antibodies are also present on the absorbent sampler. These are also attached to blue latex surface particles, but do not bind to LH.

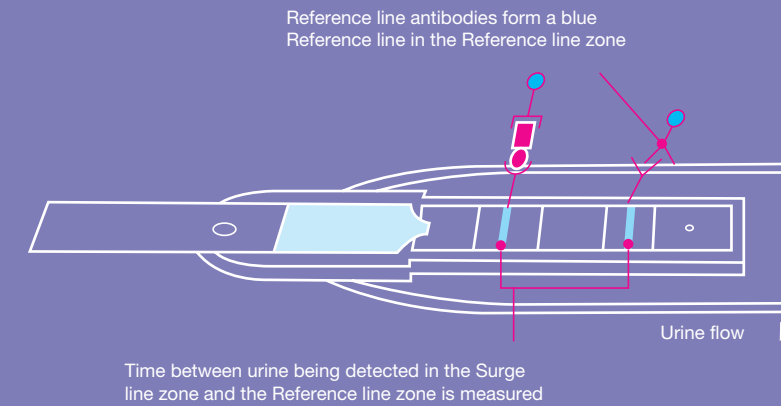


To begin the test the user inserts the stick into the reader, then urinates onto the test stick. If LH is present in the urine, its β LH antigenic site is bound by the anti- β LH antibody that is attached to a particle to form a complex. The urine flows along the test stick to the zones containing the Surge and Reference lines. As soon as the LH complex reaches the Surge line zone, the antigenic site on α LH is bound by the Surge line's immobilized anti- α LH antibodies. This means that the LH/blue particle complex cannot move any further down the test strip, resulting in an intense blue Surge line which is read by Clearblue's Digital Reader.

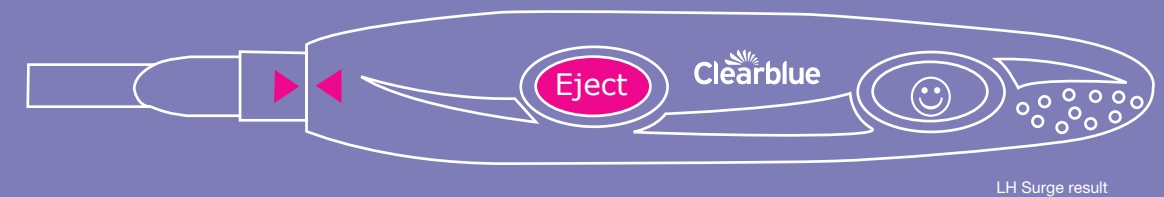
Test behaviour with urine sample on day of LH surge



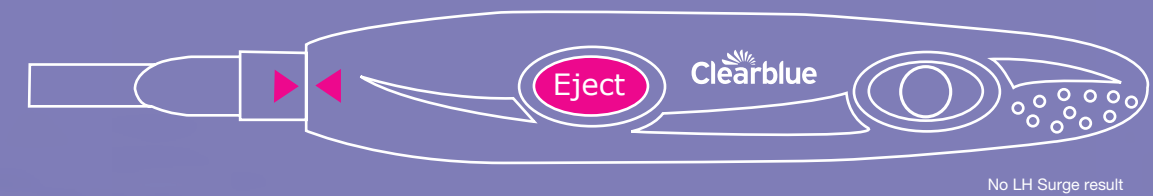
If no LH is contained in the urine sample, then the blue particles are not captured in the Surge zone and continue on to the end of the strip. No blue Surge line appears in the Surge zone. The flow of urine also facilitates the movement of the Reference antibody on blue particles. As the urine flows, reference blue particles are captured in a Reference line zone situated towards the end of the strip. This forms a blue line which is similar to that found in the Surge zone, and which occurs whether LH is present or not in order to show that the test has worked correctly. The addition of this Reference line enables the Digital Reader to check whether the test has completed successfully and ensures that the Surge line reading is only taken when the urine flow is completed (i.e. usually after three minutes have elapsed). Measurement of the flow of blue particles along the strip is also monitored to check there are no errors whilst the test is running.



If the Clearblue Digital Reader detects that the test has completed successfully and that the Surge line intensity is over a certain threshold, the display will show a 'Surge' result. This indicates that conception is most likely if intercourse occurs during the next 1-2 days.



If the Surge line fails to rise above this threshold within the three-minute testing period, a 'No Surge' result is displayed.



About SPD Swiss Precision Diagnostics GmbH

SPD Swiss Precision Diagnostics GmbH is a world leader in the research, design, production and supply of advanced consumer diagnostic products. Our brands, Clearblue®, FactPlus®, and Accu-Clear®, are familiar in many countries, and are trusted for their accuracy and simplicity by women keen to know more about their own reproductive health. SPD brands are acclaimed for their pioneering innovation: Clearblue was the first brand to introduce a one-step pregnancy test, a one-minute test, a urine sample indicator, and digitally displayed results.

At SPD, we are committed to helping people make informed decisions about their health and well-being, through a continuing flow of new and inventive developments. Our research centre is at the sharp edge of innovation, and is fully engaged in the development of reliable diagnostic products for better health and personal self-care.

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

Alternatively, you could write to us at:
SPD Swiss Precision Diagnostics GmbH
47 Route de Saint-Georges
1213 Petit Lancy
Geneva
Switzerland
www.swissprecisiondiagnostics.com

References

1. Johnson SR, Shaw R. Testing Strategies for the Home Detection of the LH surge. SPD data on file.
2. Small CM, Manatunga AK, Marcus M. Validity of self-reported menstrual cycle length. *Ann Epidemiol* 2007 Mar;17(3):163-70.
3. Barbieri RL. In: *Reproductive Endocrinology 6th Edition (2009) Chapter 21 - Female Infertility*. p518. Strauss JF and Barbieri, RL editors. Saunders Elsevier Philadelphia.
4. SPD data on file. Clearblue Digital Ovulation Test has been shown to be 99% accurate when compared to a reference method in laboratory studies using urine samples from 123 cycles.
5. Wilcox AJ, Weinberg CR, Baird DD. Timing of sexual intercourse in relation to ovulation. Effects on the probability of conception, survival of the pregnancy, and sex of the baby. *N Engl J Med* 1995 Dec 7;333(23):1517-21.
6. Ferreira-Poblete A. The probability of conception on different days of the cycle with respect to ovulation: an overview. *Adv Contracept* 1997 Jun;13(2-3):83-95.
7. Hilgers TW, Daly KD, Prebil AM, Hilgers SK. Cumulative pregnancy rates in patients with apparently normal fertility and fertility-focused intercourse. *J Reprod Med* 1992 Oct;37(10):864-6.
8. Stanford JB, Dunson DB. Effects of sexual intercourse patterns in time to pregnancy studies. *Am J Epidemiol* 2007 May 1;165(9):1088-95.
9. World Health Organisation. Temporal relationships between indices of the fertile period. *Fertil Steril* 1983 May;39(5):647-55.
10. Corson SL. Self-prediction of ovulation using a urinary luteinizing hormone test. *J Reprod Med* 1986 Aug;31(8 Suppl):760-3.
11. Guida M, Tommaselli GA, Palomba S, Pellicano M, Moccia G, Di Carlo C, et al. Efficacy of methods for determining ovulation in a natural family planning program. *Fertil Steril* 1999 Nov;72(5):900-4.
12. Behre HM, Kuhlage J, Gassner C, Sonntag B, Schem C, Schneider HP, et al. Prediction of ovulation by urinary hormone measurements with the home use ClearPlan Fertility Monitor: comparison with transvaginal ultrasound scans and serum hormone measurements. *Hum Reprod* 2000 Dec;15(12):2478-82.
13. Tanabe K, Susumu N, Hand K, Nishii K, Ishikawa I, Nozawa S. Prediction of the potentially fertile period by urinary hormone measurements using a new home-use monitor: comparison with laboratory hormone analyses. *Hum Reprod* 2001 Aug;16(8):1619-24.
14. Guermandi E, Vegetti W, Bianchi MM, Uglietti A, Ragni G, Crosignani P. Reliability of ovulation tests in infertile women. *Obstet Gynecol* 2001 Jan;97(1):92-6.
15. The Merck Manual for Healthcare Professionals. Female Reproductive Endocrinology – Introduction. Accessed on 07 October 2010. Available at: <http://www.merck.com/mmpe/sec18/ch243/ch243a.html>
16. Creinin MD, Keverline S, Meyn LA. How regular is regular? An analysis of menstrual cycle regularity. *Contraception* 2004 Oct;70(4):289-92.
17. Miller PB, Soules MR. The usefulness of a urinary LH kit for ovulation prediction during menstrual cycles of normal women. *Obstet Gynecol* 1996 Jan;87(1):13-7.
18. SPD data on file. DOT Consumer Study - one in four women can misread a line test.
19. SPD data on file. In a study of 72 women reading Ovulation Tests typical of normal cycle results, more women obtained the same result as a laboratory professional when reading Clearblue Digital Ovulation Test than when reading other Ovulation Tests.

