Clearblue Digital Pregnancy Test

with Conception Indicator

There are some factors which might affect the result of the test, and the following considerations should be made:

- If a woman tests before the date of her expected period and gets a ‘Not Pregnant’ result, it is possible that the level of pregnancy hormone may not be high enough to be detected. She should test again when her period is due.
- If a woman is testing early, she should use the first sample of the day (if testing from the day the period is due, she can test any time of the day for an accurate Conception Indicator result, she must use the first urine of the day).
- The manufacturer’s instructions for any medication being taken should be read before conducting the test.
- Forbidly 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 outside the uterus, most commonly 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, immediate medical advice must be sought.
- If a woman tests before the date of her expected period and gets a ‘Not Pregnant’ result, it is possible that the level of pregnancy hormone may not be high enough to be detected. She should test again when her period is due.
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- A recent pregnancy, miscarriage or termination can give misleading results. hCG may be found in the body for up to 3 weeks after birth, and can remain in the body for up to 9 weeks after a miscarriage or termination. whilst hCG remains in the body, it is possible for a pregnancy test to detect it and show a false ‘Pregnant’ result.
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- It is possible to obtain a false positive result when a woman is in or approaching the menopause. In a study of non-pregnant, premenopausal and menopausal women tested with different lots (batches) of Clearblue Digital Pregnancy Test with Conception Indicator, an average of 0.2% of results were positive, with a range from 0% to 0.5% for different lots. All false results were from women aged over 55 years.
- If a ‘Pregnant’ result is obtained and the woman later finds out that she is not pregnant, then it is possible that this is due to natural loss of the pregnancy which can occur in the early stages.
- None of the following should affect the result of the test: common illnesses, common painkillers (ibuprofen, paracetamol and aspirin), hormonal contraceptives including pills, implants, intrauterine devices (IUDs) and injections, fertility drugs that do not contain hCG, hormone replacement therapy (HRT), antibiotics, skin or eye infections, diabetes, urinary tract infections, alcohol or coffee.
- Unexpected results should be discussed with a doctor.

References
4. SPD laboratory testing
5. SPD laboratory testing

SPD Swiss Precision Diagnostics GmbH,
Route de St Georges 47, 1213 Petit-Lancy, Geneva, Switzerland.

www.Clearblue.info
www.swissprecisiondiagnostics.com

Clearblue

Clearblue is a trademark
Background Facts about Pregnancy Testing

A woman generally produces a single egg each cycle, which is released from the ovary in a process known as ovulation. Once ovulation has occurred, the egg travels down the Fallopian tube towards the uterus. Within 24 hours of ovulation, it is possible for the egg to be fertilised by a sperm.

The fertilised egg then continues to move down the Fallopian tube into the uterus, where it becomes attached to the lining of the uterus. This is known as implantation and generally happens during the week after ovulation.

The pregnancy hormone, human Chorionic Gonadotrophin (hCG), starts to be produced around the time of implantation. The role of hCG is to maintain production of the hormones progesterone and estrogen. These in turn maintain the uterine lining and prevent menstruation, so allowing the pregnancy to continue.

The level of hCG increases rapidly during early pregnancy, doubling every 2 – 3 days, soon reaching a level that can be detected in urine.

Reassurance and certainty - over 99% accurate and now tells women when they conceived

Women know they can trust Clearblue pregnancy tests. Women can feel confident in using a test which is over 99% accurate with an unmistakably clear digital result, ‘Pregnant’ or ‘Not Pregnant’.

Driven by a real consumer demand, the new Clearblue Digital Pregnancy Test with Conception Indicator now has the additional benefit of estimating when a woman conceived. If the woman is pregnant, the test will show how many weeks since conception occurred: 1-2 weeks, 2-3 weeks or 3+ weeks.

The average age of women having children is increasing, many women are delaying starting a family until they are established in their careers, or more financially secure. When they make the decision to try for a baby, they want as much information about their pregnancy as possible. In recent consumer research of over 1,000 women, the new Clearblue Digital Pregnancy Test with Conception Indicator was found to be considerably more appealing than existing pregnancy tests available, and the likelihood to purchase this new product was significantly higher. The additional information offered by the Conception Indicator was found to be reassuring for the women, and would help them in their planning. The women in the research study described how this new test made the pregnancy seem more real and gave them the confidence to really believe they were pregnant.

Clearblue Digital Pregnancy Test with Conception Indicator can be used up to 4 days before the woman’s period is due, giving early reassurance and allowing the woman to plan accordingly.

Research carried out in the UK shows that more women get a correct reading with Clearblue Digital Pregnancy Tests than with other pregnancy tests when testing before their period is due.

New Clearblue Digital Pregnancy Test with Conception Indicator

- Over 99% accurate*
- Tells a women when she conceived
- Unmistakably clear digital result
- Results up to 4 days before her period is due
- Most accurate reading in early pregnancy**

The only test that answers the first two questions women ask when they think they might be pregnant

* Over 99% accurate when used from the day the period is due.
** Research carried out in the UK. More women get a correct reading with Clearblue Digital Pregnancy Tests than with other pregnancy tests when testing before period is due.
Conception Indicator

The Clearblue Digital Pregnancy Test with Conception Indicator works by detecting the pregnancy hormone Human Chorionic Gonadotrophin (hCG). Once a fertilised egg has implanted in the uterus wall, hCG is produced and can be detected at a low level in urine. This level reaches at least 50mIU/ml on the day the period is due and continues to rise during the early weeks of pregnancy. Clearblue Digital Pregnancy Test with Conception Indicator has a sensitivity of 25mIU/ml allowing it to be used by women as early as 4 days before their period is due.

The new Test also monitors the concentration of hCG in the urine within certain thresholds, thereby indicating how many weeks since conception occurred – 1-2 weeks, 2-3 weeks or 3+ weeks. This information is shown clearly on the liquid crystal display of the test.

In order to calculate the thresholds, hCG levels in over 3000 urine samples from pregnant women were analysed. The data generated established the likely hCG concentration in each of these time bands, and thresholds were set.

The Conception Indicator result is 92% accurate when testing with the first urine of the day.

If testing more than 6 weeks after conception, the Conception Indicator may give unexpected results. Once hCG levels have peaked they will begin to decrease, but will remain too high for the test to provide an accurate estimate of the time since conception.

In multiple pregnancies, the rise in hCG is more rapid than in single pregnancies. In these circumstances, the test will display an accurate ‘Pregnant’ result, but can give misleading Conception Indicator results.

HCG levels and Early Pregnancy Testing

The ability of the Test to detect hCG levels up to and including the day of the expected period was investigated in a group of women trying to conceive. Urine was collected daily during conception cycles from the first day of that cycle. Detection rates from 4 days before the period was due, to 1 day before the period was due were as follows:

<table>
<thead>
<tr>
<th>Number of days before the period is due</th>
<th>% of samples from pregnant women giving a ‘Pregnant’ result</th>
</tr>
</thead>
<tbody>
<tr>
<td>-1</td>
<td>98%</td>
</tr>
<tr>
<td>-2</td>
<td>97%</td>
</tr>
<tr>
<td>-3</td>
<td>86%</td>
</tr>
<tr>
<td>-4</td>
<td>55%</td>
</tr>
</tbody>
</table>

The day of the luteinising hormone (LH) surge was used as a reference, and the day of the expected period was determined for each cycle as 15 days after this detection. This is based on previous studies which have shown a low variability in the duration of the luteal phase, and a typical length of 14.1±1.4 days.

Whilst hCG levels in early pregnancy vary between women, the results demonstrate that the Clearblue Digital Pregnancy Test with Conception Indicator is sensitive enough to detect pregnancy before the day of the expected period.

The Conception Indicator result is 92% accurate when testing with the first urine of the day.


Simple and easy to use

The Clearblue Digital Pregnancy Test with Conception Indicator is an integrated one-step test. Each Test Stick incorporates a liquid crystal display (LCD) that shows the results in words – ‘Pregnant’ or ‘Not Pregnant’. The test result is displayed on the screen within 3 minutes of use.

To perform a Clearblue Digital Pregnancy Test with Conception Indicator, the user simply removes the one-piece Test Stick from its individual foil wrapper, takes off the cap and places the Absorbent Sampler in her urine stream for 5 seconds. Alternatively she can place the Sampler into a container of collected urine for 20 seconds.

Application of the urine sample to the Absorbent sampler triggers start up of the device, which then automatically calibrates itself. The ‘Wait’ symbol on the Display begins to flash to show that the Test is working.

Within 3 minutes the Display will show a ‘Pregnant’ or ‘Not Pregnant’ result. A ‘Pregnant’ result may appear on the Display before the Conception Indicator result. The ‘Wait’ symbol will continue to flash until this appears. Where a high level of hCG is present, the result may be shown in as little as 1 minute. The result will continue to be shown on the Display for approximately 24 hours.

How the test works

Unlike the traditional Clearblue Pregnancy test, the new Clearblue Digital Pregnancy Test with Conception Indicator contains two test strips – a low sensitivity strip and a high sensitivity strip.

Inside a Clearblue Digital Pregnancy Test with Conception Indicator

Urine travels up the Absorbent Sampler and flows through the pad. If hCG is present in the urine it will bind to anti-αhCG antibodies attached to blue dye in the pad. The urine moves along both test strips. As the hCG and anti-αhCG antibodies pass through the result line zone, they bind to anti-βhCG antibodies to form blue result lines.

Both strips contain a ‘result’ line; the low sensitivity strip also contains a ‘control’ line. The Test monitors the control line on the low sensitivity strip and only when a valid control line has been detected will the result lines on both the strips be determined.

At low concentrations, hCG binds on the high sensitivity strip. At higher concentrations, hCG will also bind to the low sensitivity strip. The concentration of hCG detected in the results lines of the two strips determines the result of the Conception Indicator: 1-2 weeks since conception occurred; 2-3 weeks since conception; more than 3 weeks since conception. If no hCG is present, the anti-αhCG antibodies attached to blue dye flow past the result zones on both strips, and no lines will be formed giving a ‘Not Pregnant’ result. If insufficient hCG is present, result lines may form but will be below the lowest thresholds set, and a ‘Not Pregnant’ result will be displayed.

The test has inbuilt control features, and if any errors occur a book symbol will be displayed on the screen, or the Display will remain blank. These are explained in the instruction leaflet accompanying the Test.

<table>
<thead>
<tr>
<th>Results</th>
<th>Time since conception</th>
<th>How the doctor will date pregnancy (assuming a 28 day cycle)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not Pregnant</td>
<td></td>
<td>The result is Not Pregnant</td>
</tr>
<tr>
<td>Pregnant 1-2</td>
<td></td>
<td>The result is ‘Pregnant’ and conception occurred approximately 1-2 weeks ago 3-4 weeks</td>
</tr>
<tr>
<td>Pregnant 2-3</td>
<td></td>
<td>The result is ‘Pregnant’ and conception occurred approximately 2-3 weeks ago 4-5 weeks</td>
</tr>
<tr>
<td>Pregnant 3+</td>
<td></td>
<td>The result is ‘Pregnant’ and conception occurred more than 3 weeks ago 5+ weeks</td>
</tr>
</tbody>
</table>

* Doctors will date the pregnancy based on the date of the last period, not from conception.