

### INTENDED USE

The EasyCheck<sup>®</sup> Ovulation Test (LH Test) is a rapid, one step test for qualitative detection of luteinizing hormone (LH) in urine, as an aid to predict time of ovulation. The test is intended for in vitro diagnostic self-testing.

### HOW DOES IT WORK

Luteinizing hormone (LH) in elevated quantities causes ovulation (the release of the egg from the ovary). Throughout the menstrual cycle, a small amount of LH is produced, but during the middle of the cycle LH briefly and dramatically increases. This increase is called the "LH Surge" and precedes ovulation. Conception is most likely to occur within 24-48 hours following the LH Surge. This is the most fertile time of your cycle.

A positive result with EasyCheck<sup>®</sup> Ovulation Test (LH Test) tells you that you are about to ovulate (release an egg), if you have intercourse within the next 24-48 hours you will maximize your chance of becoming pregnant.

### ADDITIONAL EQUIPMENT REQUIRED

1. Timing Mechanism (such as a watch or clock).

### WHEN TO BEGIN TESTING

To find out when to begin testing, determine the length of your normal menstrual cycle. The length of your menstrual cycle is the number of days from the beginning of one period to the beginning of the next period. Work this out by counting the days from the first menstrual bleeding to the day before the next bleeding begins.

Use the chart below to determine when you should start testing.

NOTE: IF your cycle is irregular, that is, it varies by more than a few days each month; take the average number of days for the last 3 months. IF your cycle is shorter than 21 days or longer than 40 days, consult your doctor. IF you do not know your cycle length, you may begin testing 12 days after your first menstrual bleeding since the average cycle length is 28 days.

Perform one test each day over a 5-day period or until the LH Surge has been detected.

### CYCLE CHART

Length of normal cycle (total days)	Day of cycle to begin testing	Length of normal cycle (total days)	Day of cycle to begin testing
21	Day 5	31	Day 15
22	Day 6	32	Day 16
23	Day 7	33	Day 17
24	Day 8	34	Day 18
25	Day 9	35	Day 19
26	Day 10	36	Day 20
27	Day 11	37	Day 21
28	Day 12	38	Day 22
29	Day 13	39	Day 23
30	Day 14	40	Day 24

For example, if your period normally begins every 28 days, you should begin testing twelve (12) days after the beginning of your last period.

SUN	MON	TUES	WED	THU	FRI	SAT
1	2	3	4	5	6	7
8	9*	10	11	12	13	14
15	16	17	18	19	20 (s)	21
22	23	24	25	26	27	28
29	30	31				

NOTE: If the ninth (9th) day in the calendar above is the first day (day one\*) of menstrual bleeding, the 20th, or day twelve (12), of your cycle is the day to begin testing (s).

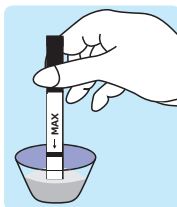
### SPECIMEN COLLECTION

- Do not use first morning urine. Urine at any other time of the day is suitable.
- For best results, try to collect urine at approximately the same time each day between 11am and 8pm.
- Reduce your liquid intake for 2 hours before testing.
- Collect your urine in a clean, dry cup (either plastic or glass) and test at room temperature (15-30°C).

### TEST PROCEDURE

Read the entire procedure carefully before performing any test. The test pouch and urine sample should be brought to room temperature (15-30°C) prior to testing. Do not open the pouch until you are ready to perform the test.

1. Urinate into a clean, dry cup (Sample Collection Cup enclosed)
2. Remove the test strip from the sealed pouch by tearing at the notch.
3. To perform the test, hold the test strip by the blue handle, with the arrow end pointing downwards towards the urine, dip the test into the urine sample. NOTE: do not immerse the test strip past the Max Line.
4. Remove the test strip after 10 seconds. Lay the strip flat on a clean, dry, non-absorbent surface, and begin timing. Do not move the test strip while results are developing.
5. Wait for coloured lines to appear. The test should be read (interpreted) at 3-5 minutes. Do not interpret results after 10 minutes.



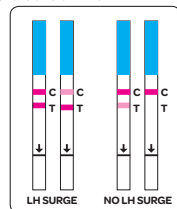
### INTERPRETATION OF RESULTS

To determine your result, compare the colour intensity, i.e. shade of colour, lightness or darkness of colour, of the Test Line to the Control Line.

**LH Surge (Positive):** Two coloured lines will appear, and the colour intensity of the Test (T) Line is darker or equal to the Control (C) Line. You are experiencing a hormone surge that indicates you will ovulate soon, usually within 24-48 hours of the surge. If you have intercourse after 24 hours but before 48 hours you maximize your chance of becoming pregnant.

**No LH Surge (Negative):** Only one coloured line appears in the Control (C) region, or the Test (T) Line appears but is lighter than the Control (C) Line. This means there is no LH Surge.

Invalid: Control (C) Line fails to appear. The result is invalid if no coloured line appears in the Control (C) region, even if a line appears in the Test (T)



region. NOTE: Insufficient specimen volume or incorrect testing procedural techniques are the most likely reasons for a control-line failure. Review the procedure and test with a new LH Test. If the problem persists please contact your local distributor.

### LIMITATION AND POSSIBLE ERRORS

The test works only if the instructions are followed precisely. Although the EasyCheck<sup>®</sup> Ovulation Test (LH Test) is highly accurate and sensitive in detecting ovulation, an extremely low incidence of false results (positive when no ovulation exists or negative when ovulation exists) can occur.

The EasyCheck<sup>®</sup> Ovulation Test should not be used for contraception.

Some prescription drugs, such as menotropins may affect the test result. Certain rare medical conditions or the onset of menopause can cause elevated levels of LH. Some women do not ovulate every cycle and they will not see any increase in the level of LH hormone during these non-ovulating cycles. Women with Poly Cystic Ovary Syndrome (PCOS) may not get reliable results from ovulation tests. Please check with your doctor if you are unsure.

Medications containing LH or hCG may affect the test and should not be taken while using this test. In addition, the results of the test may not be valid if you are taking oral contraceptives.

The EasyCheck<sup>®</sup> Ovulation Test Strips only detect the hormone surge that precedes ovulation; they can't tell you if you will actually release an egg during your cycle.

### QUESTIONS AND ANSWERS

**Q: How accurate is the EasyCheck<sup>®</sup> Ovulation Test (LH Test)?**

A: In clinical trials, the EasyCheck<sup>®</sup> Ovulation Test (LH Test) has shown to be over 99% accurate in detecting the LH Surge.

**Q: Once I detect my LH Surge, when is the best time to have intercourse?**

A: Your two most fertile days begin with the LH Surge. You are most likely to get pregnant if you have intercourse within 24-48 hours after you detect your LH Surge.

**Q: Does this test replace the basal body temperature method (BBT)?**

A: The shift in basal body temperature primarily indicates that ovulation has already occurred. The EasyCheck<sup>®</sup> Ovulation Test (LH Test) indicates that ovulation is about to occur.

**Q: Will alcohol or common medicines affect the results?**

A: No. Alcohol, commonly used painkillers, antibiotics, or drugs should not affect test results.

**Q: Why is first morning urine not recommended?**

A: First morning urine is not recommended as most women experience a blood LH surge in early morning but this does not show up in urine until later in the day.

**Q: Can test results be interpreted after 5 minutes?**

A: No. The test should be read at 3-5 minutes for best results. Though a positive result should not change for several days, a negative result may change to a false-positive result within minutes after the end of the testing period, which would not be an accurate reading.

**Q: Today's Control Line is a different shade of red than yesterday's Control Line. Is this a concern?**

A: No. Variations in the colour of the Control Line will not affect the test result. Always compare the colour of the Test Line to that of the Control Line of the same device on the days the test is performed. Do not compare bands from different devices.

**Q: A pink-rose background colour and vertical streaking appeared in the result area during the testing period. Is this a concern?**

A: No. Each urine sample will vary in chemical makeup, as well as the humidity of the air in the room. As long as a control band appears within five minutes, the test is working properly.

**Q: How long should I continue to use the tests for?**

A: Unless otherwise advised by your doctor, stop testing once the LH Surge is detected. Five to Ten days of testing may be needed to detect the LH Surge, although additional testing may be required.

**Q: If I am still uncertain when the test kit is showing positive, what should I do?**

A: You may try this activity: During one cycle, have intercourse when you think your kit shows you are ovulating, and then continue to test your urine even though ovulation has passed. This will help you understand your maximum darkness of your Test Line. Knowing that the ovulation signal (LH Surge) only lasts 48-60 hours, your Test Line will start to fade away if you test after your ovulation. Seeing this line fade will help you now your peak darkness of your Test Line and give you more confidence in pinpointing your most fertile time.

**Q: I have received a positive test result and had intercourse during these fertile days. I have not become pregnant. What shall I do?**

A: There are many factors that can affect the ability to become pregnant. Often it may be necessary to use the test kit for 3-4 months before achieving pregnancy. A doctor should be consulted if pregnancy is not achieved after 3-4 months.

### STORAGE AND STABILITY

1. Store as packaged in the sealed pouch at room temperature (4-30°C).

The kit is stable within the expiry date printed on the labeling.

2. Once the sealed pouch is opened, the test strip should be used within one hour.

Prolonged exposure to ambient humidity will cause product deterioration.

3. DO NOT FREEZE.

### WARNINGS AND PRECAUTIONS

1. For in-vitro diagnostic use only.
2. Read all the information in this leaflet before performing the test.
3. Do not use the kit beyond the expiration date.
4. The test strip should remain in the sealed foil pouch until use. Do not use if the pouch is damaged or open.
5. Do not touch the membrane located within the results region.
6. As with all diagnostic tests, a confirmed diagnosis should only be made by a doctor after all clinical and laboratory findings have been evaluated.
7. Do not reuse the test strip. Discard in the dustbin after single use.
8. All urine specimens and used strips should be considered potentially infectious. Avoid contact with skin.

**EASYCHECK<sup>®</sup> is a trade mark.**

Distributed by: Phoenix MedCare Ltd, Auckland, New Zealand.

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Made in China

Manufactured by: Hangzhou Clongene Biotech Co, Ltd. No.1 Yichuang Road, Yuhang Sub-district, Yuhang District, Hangzhou 311121, China

\*In laboratory tests

## INTENDED USE

The hCG Pregnancy Test Midstream is a rapid, one step test for the qualitative detection of human chorionic gonadotropin (hCG) in urine, as an aid for the early detection of pregnancy. The test is intended for in vitro diagnostic self-testing.

## SUMMARY

Human chorionic gonadotropin (hCG) is a glycoprotein hormone secreted by the developing placenta shortly after fertilization. Healthy men and healthy non-pregnant woman do not have detectable hCG by the hCG Pregnancy Test Midstream. However, healthy pregnant woman have hCG in their urine and serum specimens. The amount of hCG will vary greatly with gestational age and between individuals. In normal pregnancy, hCG can be detected in serum as early as 7 days following conception. The concentration of hCG continues to rise rapidly, frequently exceeding 100 mIU/mL by the first missed menstrual period and peaking in the 100,000 – 200,000 mIU/mL range by 10 – 12 weeks into pregnancy. The appearance of hCG soon after conception and its subsequent rise in concentration during early gestational growth make it an excellent marker for the early detection of pregnancy. The hCG Pregnancy Test Midstream has a sensitivity of 25 mIU/mL, and is capable of detecting pregnancy as early as 1 day after the first missed period.

## WARNINGS AND PRECAUTIONS

1. Read all the information in this leaflet before performing the test.
2. Do not use the kit beyond the expiration date.
3. The test stick should remain in the sealed foil pouch until use. Do not use if pouch is damaged or opened.
4. Do not touch the membrane located within the result window.
5. As with all diagnostic tests, a confirmed pregnancy diagnosis should only be made by a doctor after all clinical and laboratory findings have been evaluated.
6. Do not reuse the test midstream. Discard it in the dustbin after single use.
7. All urine specimens and used midstream should be considered potentially infectious. Avoid contact with skin.

## STORAGE AND STABILITY

1. Store as packaged in the sealed pouch at room temperature (4-30 °C or 40-86 °F). The kit is stable within the expiry date printed on the labelling.
2. Once the sealed pouch is opened, the test midstream should be used within one hour. Prolonged exposure to ambient humidity will cause product deterioration.
3. DO NOT FREEZE.

## ADDITIONAL EQUIPMENT REQUIRED

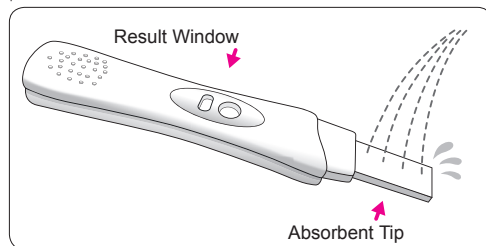
1. Timing Mechanism (such as a watch or clock).

## SPECIMEN COLLECTION

The first morning urine is preferred since it generally contains the highest concentration of hCG. However, urine at any time of the day may be used.

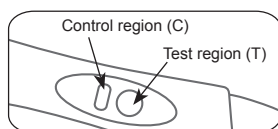
## TEST PROCEDURE

Read the entire procedure carefully before performing any tests. The midstream test pouch should be brought to room temperature (15-30 °C) prior to testing. Do not open the pouches until ready to perform the test.

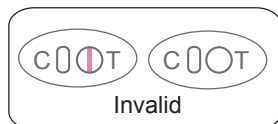


1. Remove the test midstream from its foil pouch by tearing at the notch and take the cap off the test stick.
2. To perform the test, turn the test stick so the absorbent tip is pointing in a downward direction and hold the test stick in your stream of urine so the urine makes contact with the absorbent area. Hold it for at least ten seconds so that adequate urine goes into the absorbent part of the tip. Do not allow urine to splash into the result window. NOTE: If you prefer, you can urinate into a clean and dry container, then dip only the Absorbent Tip of the midstream into the urine for at least 10 seconds.
3. Re-cap the pregnancy test stick and lay the test stick flat on a horizontal surface with the result window facing upwards.
4. Wait for red-colored lines to appear. The test should be read in approximately 3-5 minutes. Do not interpret results after 5 minutes.

## READING THE RESULT WINDOW



NOTE: One line may be lighter than the other



## INTERPRETATION OF RESULTS

**PREGNANT:** Two distinct red-coloured lines will appear, one in the test region (T) and one in the control region (C). You can assume that you are pregnant. You should consult your doctor.

**NOTE:** The intensity of the red-coloured line in the test-region (T) may vary depending on the concentration of hCG present in the specimen. Therefore, any shade of red colour in the test region should be considered positive.

**NOT PREGNANT:** Only one red-coloured line appears in the control region (C). No apparent red or pink line appears in the test region (T). You can assume that you are not pregnant.

**INVALID:** Control band fails to appear. The result is invalid if no red-coloured line appears in the control region (C), even if a line appears in the test region (T).

**NOTE:** Insufficient specimen volume or incorrect testing procedural techniques are the most likely reasons for control-line failure. Review the procedure and repeat the test with a new midstream test. If the problem persists, please contact your local distributor.

## QUALITY CONTROL

A procedural control is included in the test. A coloured line appearing in the control region (C) is considered an internal positive procedural control, indicating proper performance and reactive agents. A clear background in the Result Window can be seen as a basis for effective testing, and is considered an internal negative procedural control. If the test has been performed correctly and reagents are working properly, the background will be clear to give a discernable result. If the test line is weak, it is recommended that the test be repeated with the first morning specimen obtained 48-72 hours later.

## LIMITATION

1. Drinking too much fluid before taking the test may cause a false-negative result. For the most accurate results, take the test first thing in the morning when your urine is the most concentrated.
2. Very low levels of hCG (less than 50mIU/mL) are present in urine specimens shortly after implantation. A test result that is weakly positive should be confirmed by re-testing with a first morning urine specimen collected 48 hours later.
3. Certain fertility medications which contain hCG (such as Pregnyl, Profasi, Novare) can give a false-positive result. Alcohol, oral contraceptives, birth control pills, analgesics (pain killers), antibiotics or hormone therapies that do not contain hCG should not affect the test result.
4. A number of medical conditions other than pregnancy, including ovarian cyst, choriocarcinoma or ectopic pregnancy (pregnancy outside the uterus) can cause elevated levels of hCG.
5. Using the test midstream within 8 weeks of giving birth or having a miscarriage may also cause a positive result. You should ask your doctor for help in interpreting your test result if you have had the experience of pregnancy as described above recently.

## QUESTIONS AND ANSWERS

### 1. Q: How soon after I suspect that I am pregnant can I take the test?

A: You can test your urine as early as the first day you miss your period.

### 2. Q: Do I have to test with first morning urine?

A: You can perform the test at any time of the day. However, your first morning urine is usually the most concentrated of the day and would have the most hCG in it.

### 3. Q: How do I know the test was run properly?

A: The appearance of a coloured line in the control region (C) tells you that you followed the test procedure properly and the proper amount of urine was absorbed.

### 4. Q: Can test results be interpreted after more than 5 minutes?

A: No. Test results must be read within 5 minutes. Though a positive result should not change for several days, a negative result may change to a false positive within minutes after the end of the testing period, which would not be an accurate reading.

### 5. Q: What should I do if the test result shows that I am pregnant?

A: Consult your doctor to confirm the result and for advice on pregnancy.

### 6. Q: What should I do if the test result shows I am not pregnant?

A: It means no hCG has been detected in your urine and you are probably not pregnant, if you do not start your period within a week of its due date, repeat the test with a new test stick. If you receive the same result after repeating the test and you do still not get your period, you should see your doctor.

### 7. Q: How accurate is the test?

A: The test has shown to be over 99% accurate in laboratory tests when the hCG level is 25mIU/mL or greater. This level is normally reached by the first day of the missed period.

## INDEX OF SYMBOLS

	Consult instructions for use		Do not reuse		Manufacturer
	For in vitro diagnostic use		Use by		Authorized representative
	Store between 4-30 °C		Lot number		

### EASYCHECK<sup>®</sup> is a trade mark.

Distributed by: Phoenix MedCare Ltd, Auckland, New Zealand.

Email: enquiries@phoenixmedcare.co.nz  
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### Made in China

Manufactured by: Hangzhou Clongene Biotech Co, Ltd. No.1 Yichuang Road, Yuhang Sub-district, Yuhang District, Hangzhou 311121, China

\* In laboratory tests