INSTRUCTIONS FOR USE

# EasyCheck®

# Ovulation Kit LH Ovulation Rapid Test Strip

**Over 99% Accurate***

Sensitivity of 25mIU/mL

CE 0197

## INTENDED USE

The EasyCheck® LH Ovulation Rapid Test Strip is a rapid one step assay designed for qualitative detection of human luteinizing hormone (LH) in urine to predict time of ovulation. For self-testing and in vitro diagnostic use only.

## HOW DOES IT WORK

Luteinizing hormone (LH) in elevated quantities causes ovulation (the release of the egg from the ovarian follicle). 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 to 48 hours following the LH surge. The LH Ovulation Rapid Test Strip is specifically designed to detect your LH surge - the time when you are likely to ovulate. If you receive a positive on an LH test, you are in your most fertile phase of your menstrual cycle.

The test reagent is exposed to urine, allowing urine to migrate through the absorbent test strip. The labelled antibody-dye conjugate binds to the LH in the specimen forming an antibody-antigen complex. This complex binds to the anti-LH antibody in the test region (T) and produces a colour line. In the absence of LH, there is no colour line in the test region (T). The reaction mixture continues flowing through the absorbent device past the test region (T) and control region (C). Unbound conjugate binds to the reagents in the control region (C), producing a colour line, demonstrating that the test strip is functioning correctly. The test strip can accurately detect your LH surge when the concentration of LH is equal to or greater than 25mIU/ml.

## WARNINGS AND PRECAUTIONS ⚠

- For in vitro diagnostic use only.
- Please read all the information in this leaflet before performing the test.
- Do not use the kit beyond the labelled expiry date.
- Do not open the sealed foil pouch until you are ready to start the test.
- Do not touch the membrane located within the Result Region.
- As with all diagnostic tests, a final clinical diagnosis should not be based on the results of a single test, but should only be made by a physician after all clinical and lab findings have been evaluated.
- Do not reuse the test strip. Discard it in the dustbin after testing.
- All urine specimens and used strip should be considered potentially infectious and avoided contact with skin.

## COMPOSITION

The test strip consists of colloidal gold-monoclonal antibody against LH coated on polyester membrane, and monoclonal antibody against LH and goat-anti- mouse IgG coated on cellulose nitrate membrane. Each pouch contains one test strip and one desiccant. Each box contains 10 pouches and one instruction for use.

## STORAGE AND STABILITY

- Store as packaged in the sealed pouch at room temperature (4-30˚C or 40-86). The kit is stable within the expiry date printed on the labelling.
- Once open the pouch, the test strip should be used within one hour. Prolonged exposure to hot and humid environment will cause product deterioration.

## WHAT ELSE YOU NEED

• Specimen collection container • Timer

## SPECIMEN

First morning urine is not recommended, but any other time of day is suitable. For best results, try to collect urine at approximately the same time between 10:00 A.M. and 8:00 P.M. each day. The urine specimen must be collected in a clean, dry container either plastic or glass.

## WHEN TO START TESTING

The length of the menstrual cycle is the duration from your first menstrual bleeding day to the day before the next bleeding begins. Determine the length of menstrual cycle before test. Please refer to the chart below to determine when you should start testing. If your cycle length is irregular, that is, if 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 a physician. If you do not know your cycle length, you may begin the test 12 days after your first period since the average cycle length is 28 days. Perform one test each day over a 5 days period, or until the LH surge has been detected.

## CYCLE CHART

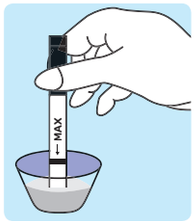
| Length of normal cycle (total days) | Day of cycle to begin testing | Length of normal cycle (total days) | Day of cycle to begin testing |
|---|---|---|---|
| 21 | Day 5 | 31 | Day 15 |
| 22 | Day 6 | 32 | Day 16 |
| 23 | Day 7 | 33 | Day 17 |
| 24 | Day 8 | 34 | Day 18 |
| 25 | Day 9 | 35 | Day 19 |
| 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) in the calendar above is the first day (day one *) of menstrual bleeding, then the 20th, or day twelve, of your cycle is the day to begin testing (s).*

## TEST PROCEDURE




- Read the entire procedure carefully before performing any tests. Allow test strip and urine specimen to equilibrate to room temperature (20-30˚C or 68-86˚F) prior to testing.

**1.** Remove the test strip from the sealed pouch.

**2.** Holding the strip vertically, carefully dip it into the specimen with the arrow end pointing towards the urine.

*NOTE: Do not immerse the strip past the Max Line.*

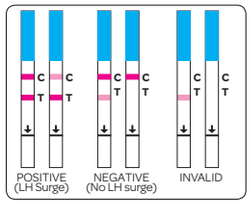
**3.** Remove the strip after 10 seconds and lay the strip flat on a clean, dry, non-absorbent surface, and then begin timing.

**4.** Wait for coloured lines to appear. Interpret the test results at 3-5 minutes.

*NOTE: Do not read 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. In determining a positive or negative result, it is important to compare the colour intensity, for this will indicate whether or not the LH surge (indicating ovulation) is in progress..




**Positive (LH Surge):** If the test line is equal to or darker than the control line, you are experiencing the hormone surge that indicates you will ovulate soon, usually within 24 to 48 hours of the surge. If you want to be pregnant, the best time to have intercourse is after 24 hours but before 48 hours.

**Negative (No LH Surge):** Only one colour line appears in the control region, or the test line appears but is lighter than the control line. This means there is no LH surge.

**Invalid:** The result is invalid if no colour line appears in the control region (C), even if a line appears in the test region (T). In any event, repeat the test. If the problem persists, discontinue using the lot immediately and contact your local distributor.

NOTE: A colour line appearing in the control region can be seen as a basis for effective testing.

## PERFORMANCE CHARACTERISTICS

**Sensitivity and Specificity**

The EasyCheck® LH Ovulation Rapid Test Strip will detect the concentration of LH is equal to or greater than 25mIU/ml (calibrated against WHO 2nd IS 80/552). The addition of Follicle Stimulating Hormone (FSH, 200mIU/ml, calibrated against WHO 1st IS 92/510) and Thyroid Stimulating Hormone (TSH, 250IU/ml, calibrated against WHO 3rd IS 81/565) to negative specimens (0mIU/ml LH) showed that these hormones do not impact the test results.

**Cross-Reactivity**: The following potentially interfering substances were added to either LH negative urine specimens or LH positive urine specimens, none of the substances at the concentration tested interfered in the assay.

| | | | |
|---|---|---|---|
| Acetaminophen | 20mg/dl | Glucose | 2g/dl |
| Acetosalicylic Acid | 20mg/dl | Haemoglobin | 10mg/dl |
| Ascorbic Acid | 20mg/dl | Ampicillin | 20mg/dl |
| Atropine | 20mg/dl | Tetracycline | 20mg/dl |
| Caffeine | 20mg/dl | Bilirubin | 2mg/dl |
| Gentisic Acid | 20mg/dl | | |

**Lay Person Study:** 60 native English-speaking females volunteers with age of 20~40, without any professional knowledge of rapid test, had participated in this experiment. They have different educational background. Questionnaire was also designed to assess the suitability of the IFU and the use of the device, concerning performing the test, reading the results, understanding the IFU, etc. The test results showed that all of the lay persons could detect the LH surge in their menstrual cycle.

## LIMITATIONS & POSSIBLE ERRORS

- The test works only if the instructions are followed precisely. Although the LH Ovulation Rapid Test Strip 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 LH Ovulation Rapid Test Strip 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.
- Reduce your liquid intake for 2 hours before testing, since drinking excessive amounts of liquids can dilute the LH in your urine yielding a negative result when it should be positive.
- The LH Ovulation Rapid Test Strip Strips only detect the hormone surge that precedes ovulation; they can't tell if you will actually release an egg during your cycle.

## QUESTIONS AND ANSWERS

***Q: How accurate is the LH Ovulation Rapid Test Strip?***

A: In clinical trials, the LH Ovulation Rapid Test Strip has been shown to be >99% accurate in detecting the LH surge.

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

A: Your 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 LH Ovulation Rapid Test Strip indicates that ovulation is about to occur.

***Q: Does alcohol, aspirin, paracetamol or any other common drug affect the test?***

A: No, but some hormonal medications can interfere with test results. If such medications are being taken or are suspected, seek professional advice from a physician to confirm the test results. Drugs containing hCG or LH can affect the test results, and clomid can cause false positives if you begin testing too early in your cycles.

***Q: Why is first morning urine not a good sample?***

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

***Q: Can test results be interpreted after five 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 within minutes after the end of the testing period, which would not be an accurate reading. Therefore, do not read the result after 10 minutes and discard the test strip after reading the test.

***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 day the test is performed. Do not compare bands from different devices.

***Q: A pink 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 its chemical makeup, as will the humidity of the air in testing chamber (room). Such variations in physical conditions can cause the vertical streaking and/or the pink-rose background colour but will not affect the test results. As long as the control band appears within five minutes, the test is working properly.

***Q: How long should I continue to perform the test?***

A: Unless otherwise specified by a doctor, stop testing once the LH surge is detected. Five to ten days of testing may be needed to detect the LH surge, though additional testing may be required.

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

A: If you are still uncertain when the test kit is positive, try this exercise. 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 past. This will help you see the maximum darkness of your test line. Knowing that the ovulation signal (LH surge) only lasts 48-60 hours, your test line will eventually start to fade away if you continue testing after ovulation. Seeing this line fade will help you know the peak darkness of your test line and give you more confidence in pinpointing your most fertile time.

***Q: I have received a positive 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 physician should be consulted if pregnancy is not achieved after 3-4 months.

4˚C 30˚C IVD

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

EC REP Shanghai International Holding Corp. GmbH (Europe)
Eiffestrasse 80, D-20537 Hamburg, Germany



**INDEX OF SYMBOLS:** See overleaf.

INSTRUCTIONS FOR USE

# EasyCheck® Pregnancy Test

**Over 99% Accurate***
Sensitivity of 25mIU/mL

CE 0197

## hCG Pregnancy Rapid Test Midstream

## INTENDED USE

The EasyCheck Midstream Pregnancy Test is a rapid one step assay designed for qualitative detection of human chorionic gonadotropin (HCG) in urine for early detection of pregnancy.

For self-testing and in vitro diagnostic use only

## PRINCIPLE

Because the amount of a hormone called human chorionic gonadotropin (HCG) in your body increases rapidly during the first two weeks of pregnancy, the test midstream will detect the presence of this hormone in your urine as early as the first day of a missed period. The test midstream can accurately detect pregnancy when the level of HCG is between 25mIU/ml to 500,000mIU/ml.

The test reagent is exposed to urine, allowing urine to migrate through the absorbent test midstream. The labelled antibody-dye conjugate binds to the HCG in the specimen forming an antibody-antigen complex. This complex binds to the anti-HCG antibody in the test region (T) and produces a red line when HCG concentration is equal to or greater than 25mIU/ml. In the absence of HCG, there is no line in the test region (T). The reaction mixture continues flowing through the absorbent device past the test region (T) and control region (C). Unbound conjugate binds to the reagents in the control region (C), producing a red line, demonstrating that the test midstream is functioning.

## WARNINGS AND PRECAUTIONS ⚠

- For in vitro diagnostic use only.
- Please read all the information in this leaflet before performing the test.
- Do not use the kit beyond the labelled expiry date.
- Do not open the sealed foil pouch until you are ready to start the test.
- Do not touch the membrane located within the Result Window.
- This test provides a presumptive diagnosis for pregnancy. If you receive positive or dubious results, we suggest that you go to the hospital for further diagnosis with other clinical methods, such as a quantitative assay for detection of HCG is recommended. You should not take any decision of medical relevance without first consulting your medical practitioner.
- Do not reuse the test midstream. Discard it in the dustbin after single use.
- All urine specimens and used midstream should be considered potentially infectious and avoided contact with skin.

## COMPOSITION

The test midstream consists of colloidal gold-monoclonal antibody against HCG coated on polyester membrane, and monoclonal antibody against HCG and goat-anti-mouse IgG coated on nitrocellulose membrane.

Each pouch contains one test midstream and one desiccant. Each box contains one pouch and one instruction for use.

## STORAGE AND STABILITY

- 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 labeling.

- Once open the pouch, the test midstream should be used within one hour. Prolonged exposure to hot and humid environment will cause product deterioration.

## ADDITIONAL EQUIPMENT REQUIRED

- Timer

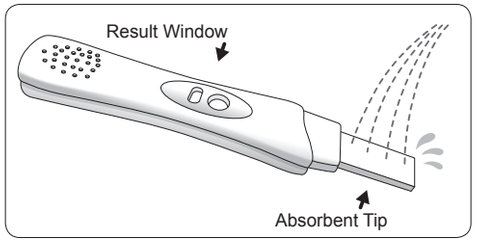
## SPECIMEN

First morning urine usually contains the highest concentration of HCG and is therefore the best specimen when performing the urine test. However, urine collected at any time of day may be used.

## TEST PROCEDURE

Read the entire procedure carefully before performing any tests.

Allow test midstream and urine samples to equilibrate to room temperature (20-30 °C or 68-86 °F) prior to testing.




**1.** Remove the test midstream from the sealed pouch.

**2.** Remove the Cap and hold the midstream with the exposed Absorbent Tip pointing downward directly into your urine stream for at least 10 seconds until it is thoroughly wet.

**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.** After removing the midstream from your urine, immediately replace the Cap over the Absorbent Tip, lay the midstream on a flat surface with the Result Window facing, and then begin timing.

**4. Wait** for colored lines to appear. Interpret the test results at 3-5 minutes.

**NOTE:** Do not read results after 5 minutes.

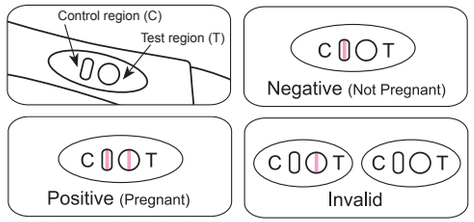
## INTERPRETATION OF RESULTS

**Positive: Two distinct red lines will appear**, one in the test region (T) and another in the control region (C). You can assume that you are pregnant.

**Negative: Only one red line appears** in the control region (C). No apparent line in the test region (T). You can assume that you are not pregnant.

**Invalid:** The result is invalid if no red line appears in the control region (C), even if a line appears in the test region (T). In any event, repeat the test. If the problem persists, discontinue using the lot immediately and contact your local distributor.

**NOTE:** Clear background in the Result Window can be seen as a basis for effective testing. If the test line is weak, it is recommended that the test be repeated with the first morning specimen obtained 48-72 hours later. **No matter how the test results, it is recommended to consult your physician**




NOTE: One line may be lighter than the other

## PERFORMANCE CHARACTERISTICS

**Sensitivity and Specificity**

The EasyCheck Midstream Pregnancy Test will detect HCG concentrations between 25mIU/ml to 500,000mIU/ml. The addition of Luteinizing Hormone (LH, 500mIU/ml), Follicle Stimulating Hormone (FSH, 1000mIU/ml) and Thyroid Stimulating Hormone (TSH, 1000μIU/ml) to negative specimens (0mIU/ml HCG) showed that these hormones do not impact the pregnancy test results.

**Cross-Reactivity**

The following potentially interfering substances were added to either hCG negative urine specimens or hCG positive urine specimens, none of the substances at the concentration tested interfered in the assay.

| | |
|---|---|
| Acetaminophen | 20mg/dl |
| Acetosalicylic Acid | 20mg/dl |
| Ascorbic Acid | 20mg/dl |
| Atropine | 20mg/dl |
| Caffeine | 20mg/dl |
| Gentisic Acid | 20mg/dl |
| Glucose | 2g/dl |
| Hemoglobin | 10mg/dl |
| Ampicillin | 20mg/dl |
| Tetracycline | 20mg/dl |
| Bilirubin | 2mg/dl |

## LIMITATIONS & POSSIBLE ERRORS

- False-negative readings can occur when testing is done too early. In order to get the most accurate results, it is a good idea to wait for about a week after your period is due before testing. This allows more HCG to build up in your urine, which will allow for a more accurate test.
- 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.
- Certain fertility medications which contain HCG (such as Pregnyl, Profasi, Novarel) 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.
- 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.
- 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 described above recently.

IVD

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

EC REP Shanghai International Holding Corp. GmbH (Europe)
Eiffestrasse 80, D-20537 Hamburg, Germany


Distributed by: Phoenix MedCare Ltd. AUCKLAND, New Zealand
Email: enquires@phoenixmedcare.co.nz www.phoenixmedcare.co.nz
NZ Freecall 0800 338 019 AU Freecall 1800 830 125

## INDEX OF SYMBOLS

| | | | |
|---|---|---|---|
| | Do not reuse | IVD | For in vitro diagnostic use only |
| | Stored between 4-30 °C | | Consult instruction for use |
| | Caution | LOT | Lot number |
| | Use by | | Contains sufficient for <n> tests |
| | Keep away from sunlight | | Keep dry |
| | Manufacturer | | Do not use if package is damaged |

EC REP Authorized Representative in the European Community