

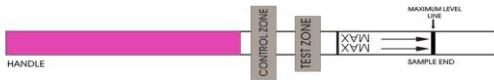
## One Step LH Test Strip Instruction Insert

Please read all the information in this Insert before performing the test.

One Step LH Test Strip is an in vitro diagnostic test device intended for the rapid determination of human Luteinizing Hormones (LH) in urine to predict when there is a LH surge, and in turn, when you are likely to ovulate. You can easily carry out yourself.

It is intended for self-testing use.

For in vitro diagnostic use only.



### HOW DOES IT WORK ?

The LH (Luteinizing Hormone) which is in the urine of normal women will increase dramatically in the middle of the menstrual cycle. The LH increase triggers ovulation which is when the egg is released periodically from Normal fertile women. WHO experts state that LH testing is a reliable way to detect ovulation. Ovulation will occur after 24-48 hours following a positive test.

The ovulation test contains antibodies which specifically react with LH. When the sample end of the test is dipped in the urine specimen, the urine specimen is applied to the strip and migrates along the strip. A colored line will appear at the Control Zone region if the test has been performed properly. The control line also works as a reference line for you to find the LH peak time when the test line is as dark or darker than the control line.

### CONTENT OF THE TEST KIT

1. One pouch containing a reaction strip.
2. Leaflet with instructions for use.

### WHAT ELSE DO YOU NEED ?

A clean, dry, plastic or glass container to collect the urine.  
Timer or clock.

### PRECAUTIONS

1. This kit is for external use only. Do not swallow.
2. Discard after first use. The test strip cannot be used more than once.
3. Do not use the test past the expiration date printed on the foil pouch.
4. Do not use the kit if the pouch is punctured or not well sealed.
5. Keep out of the reach of children.

### STORAGE AND STABILITY

1. Store at 39°F to 86°F (4°C to 30°C) in the sealed pouch up to the expiration date.
2. Keep away from direct sunlight, moisture and heat.
3. DO NOT FREEZE.
4. You should perform the test soon after opening the pouch. You should keep the test in a dry environment before use.

### WHEN TO COLLECT URINE FOR THE TEST ?

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 is shorter than 21 days or longer than 38 days, consult a physician.

If you do not know your cycle length, you may begin the test 11 days after your first period since the average cycle length is 28 days. Perform 1 test each day over a 5 days period, or until the LH surge has been detected.

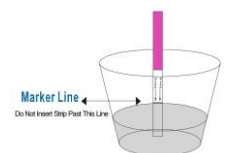
Cycle Length	Day of Cycle to Begin Testing	
	day	day
21	days	5
22	days	6
23	days	7
24	days	8
25	days	9
26	days	10
27	days	11
28	days	12
29	days	13
30	days	14
31	days	15
32	days	16
33	days	17
34	days	18
35	days	19
36	days	20
37	days	21
38	days	22
39	days	23
40	days	24

### HOW TO COLLECT URINE?

Urine specimens may be collected in any clean, dry, plastic or glass container.

### HOW TO DO THE TEST?

1. The test strip and urine have to be at room temperature 59-86°F (15-30°C) for testing.



2. Remove the test strip from the sealed pouch.
3. Immerse the strip into the urine with the arrow pointing towards the urine. Take the strip out after 5 seconds and lay the strip flat on a clean, dry, non-absorbent surface (such as the mouth of the urine container).  
**IMPORTANT:** Do not allow the urine level to exceed the MAX (marker line), otherwise the test will not perform correctly.

4. Read results in five minutes. **Do not read results after more than 5 minutes.**

## HOW TO READ THE RESULTS?

### Negative (No LH Surge) :

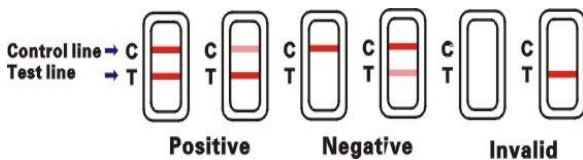
Only one color band appears on the control region, or the test band appears but is lighter than the control band. This means there is no LH surge.

### Positive (LH Surge) :

If two color bands are visible, and the test band is equal to or darker than the control band, one will probably ovulate in the next 24-48 hours. If trying to get pregnant, the best time to have intercourse is after 24 but before 48 hours.

### Invalid:

No visible band at all, or there is a visible band only in the test region and not in the control region. Repeat with a new test kit.



## UNDERSTANDING TEST RESULTS

1. The test works only when the test procedures are precisely followed.
2. This test may not be used as a form of birth control.
3. Consult a doctor if irregular or unusually long cycles are experienced.

## QUESTIONS & ANSWERS

1. *My cycle length is outside of the range show in the table. How will I know when to start testing?* Simple start testing 17 days before you expect you expect your next period.

2. *I do not know my usual cycle length. How will I know when to start testing?* If you wish to star using the test before knowing your cycle length, we recommend you start testing on day 10.

3. *What time of day should I take the test?* You may test any time of day, but you should test at approximately the time each day. You should not have urinated for at least 4 hours before testing.

4. *There is much difference between the control lines of two tests. Is this a concern?* No. Variations in the color of the control band will not affect the test result. It is only effective to compare the color of the test band to that of the control band of the same device on the day the test is performed.

5. *Can test results be interpreted after more than five minutes?* No. Test results must be read at 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. It is always best to read the results at the 5 minute testing period and then discard the test to avoid confusion.

6. *How long should I continue to perform the test?* At least 5 days or until

the LH surge has been detected.

7. *Do alcohol or common medications affect the test?* No, but you should consult your physician if you are taking any medication.

8. *Once I see a positive result, when is the best time to have intercourse?* Ovulation is likely to occur within 24-48 hours. This is your most fertile time. Sexual intercourse is advised within this time frame.

9. *Will the amount of liquid I drink affect the result?* We suggest that you limit your fluid intake for about two hours before you collect your urine. Because heavy intake of fluids prior to testing will dilute the hormone in your urine.

## PERFORMANCE CHARACTERISTICS

### 1.Sensitivity:

One Step LH Test has a sensitivity of 25 mIU/ml.

### 2.Specificity

Cross reaction studies has been tested with known amounts of hormones. 200mIU/ml hFSH and 250uIU/ml hTSH were added to LH negative and positive specimens, no cross reaction were observed.

### 3.Interfering Substances:

The following potentially interfering substances were added to LH negative and positive specimens, no interferences were observed. Acetaminophen, aspirin, ascorbic acid, atropine, caffeine, glucose, hemoglobin, tetracycline, ampicillin , albumin, bilirubin.

### 4.Stability after first opening

The results of the package opened stability studies show that the products quality was stable and valid within 1.5 hours. Given variations in temperature and humidity that may occur , we suggest to use the test immediately after opening.

## MANUFACTURED BY

Co-Innovation Biotech Co. Ltd

No. 9 Baihe 3 Street, Economic And Technological Development East Zone, Guangzhou 510530, Guangdong P.R. CHINA

Tel:+86-20-82109823 Fax:+86-20-82109823

## INDEX OF SYMBOLS

	Consult instructions for use		Keep away from sunlight
	In vitro diagnostic medical device		Keep dry
	Store between 4 ~ 30 °C		Do not reuse

Co-Innovation Biotech Co. Ltd  
No. 9 Baihe 3 Street, Economic And Technological Development East Zone,  
**Manufacturer** Guangzhou 510530, Guangdong P.R. CHINA  
Tel:+86-20-82109823 Fax:+86-20-82109823

Shanghai International Holding Corp. GmbH  
(Europe)

Eiffestrasse 80, 20537 Hamburg, GERMANY  
TEL: +49-40-2513175

**0123** FAX: +49-40-255726

P/N: 181204 Rev. 12.2018