

## Ovulation Test Operating Instructions

This product is composed of the glass fiber strips of monoclonal antibody against luteinizing hormone (LH), anti-mouse IgG solid cellulose nitrate membrane and the bonders of absorptive colloidal gold - monoclonal antibody against LH. It adopts the principles of double antibody sandwich method and immunochromatography to test the LH in the urine.

**Intended Use :** used for the prediction of ovulation

**Model:** Cassette

**User:** for lay person

**Kit list:** each pouch contains one test cassette and one desiccant

Each box contains 5 pouch, 5 urine cup, 5 urine dropper, 5 disposable glove and one operating instruction

### Specimen Collection:

The sample must be collected once each day in one of the urine cups in the kit. Use a new cup each day. For best results, try to collect urine at about the same time each day when conducting the tests. The liquid intake should be reduced for two hours before collecting the urine. The urine can be stored at room temperature for up to 8 hours or in the refrigerator for up to 24 hours. Do not freeze. If sample was refrigerated, it must be equilibrated to room temperature before testing.

### Determine the Beginning Time of Test:

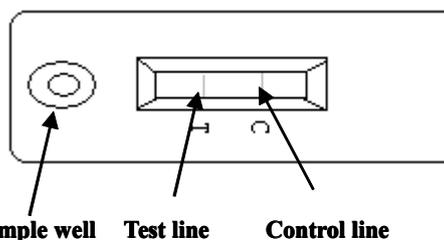
The bearing-aged women should first make sure of menstrual cycle before the test, that is to take the first day of last menstrual cycle as the beginning of a period. Since the days of menstrual cycle of each female are different, one can consult the listed time in Periodical Testing Form, and takes it as the first day of test. One should choose a period for the test, compare the results of the test after continuous testing for 5 days or the maximum of LH appears, and find out LH surge level . To forecast the ovulation period. If the menstrual cycle is less than 21 days or more than 38 days, one should take tests according to the enjoin of doctor.

Menstrual Cycle	Beginning Time of Testing
21-22 days	The 6 <sup>th</sup> day
23-24 days	The 7 <sup>th</sup> day
25 days	The 8 <sup>th</sup> day
26 days	The 9 <sup>th</sup> day
27 days	The 10 <sup>th</sup> day
28 days	The 11 <sup>th</sup> day
29 days	The 12 <sup>th</sup> day
30 days	The 13 <sup>th</sup> day
31 days	The 14 <sup>th</sup> day
32 days	The 15 <sup>th</sup> day
33 days	The 16 <sup>th</sup> day
34 days	The 17 <sup>th</sup> day
35 days	The 18 <sup>th</sup> day
36 days	The 19 <sup>th</sup> day
37 days	The 20 <sup>th</sup> day
38 days	The 21 <sup>st</sup> day

### Test Procedure:

**Before the use please prepare a timer.**

- 1、 The Ovulation test is formulated for use with fresh urine specimens. Wear glove and use urine cup to collect urine
- 2、 Remove the test cassette from its foil pouch.
- 3、 Draw urine sample into dropper, and dispense it into the sample well on the cassette (2~3 drops, approximately 100uL). Be careful not to overfill the absorbent pad.
- 4、 Read results within 10 minutes.
- 5、 Discard the test device after single use in the dustbin.

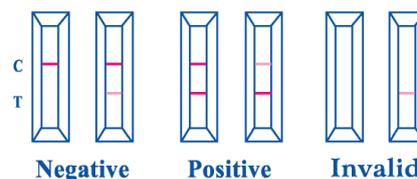


## Interpretation of results

**Negative:** One pink/purple band forms in the control region; no band is found in the test region, or the color of the test band is less intense than that of the control/reference band. The result indicates basal LH level of the tested specimen.

**Positive:** Two pink/purple bands form, and the color of the test band is equal to or more intense than that of the control/reference band. This result indicates an LH surge level of the tested specimen.

**Invalid:** If there is no pink/purple band in the control region, the test result is invalid. Retest the sample using a new device. If the problem persists, contact your local distributor.



## Warnings & Precautions

### For in vitro diagnostic use only

1. When using this product, you should not take the hCG or the LH medicine which may influence the test result; moreover, in pregnancy, menopause or use of prophylactic drugs during the test, the result will not be normal.
2. As with all diagnostic tests, a definitive diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and lab findings have been evaluated.
3. Read directions for use carefully before performing this test. Pay attention to the position of the C and T line.
4. Do not use beyond the labeled expiration date.
5. Do not reuse the test devices. Discard it in the dustbin after single use.
6. Do not use if the pouch is damaged or opened.
7. Do not touch the membrane located within the windows.
8. Once open the pouch, the test device should be used immediately. Prolonged exposure to ambient humidity will cause product deterioration.
9. Treat urine samples and used devices as if they are potentially infectious. Avoid contact with skin.
10. Examine if the urine dropper and urine cup exist before usage.



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Rev-01: 20080508