## INTENDED USE

This LH Rapid Test is intened for detecting the presence of LH in urine specimens in a qualitative format sensitive to 35 mIU/ml. This test is for in vitro screenning use in obtaining a visual qualitative result for LH in urine to predict the time of ovulation.

**For the rapid detection of human luteinizing hormone (hLH) in urine specimens**

**For *in vitro* diagnostic use only**

## INTRODUCTION

Luteinizing hormone (LH) is one of the steroid hormones known to play an essential role for the regulation of ovulation and ovarian functions during the women's menstrual cycle. As soon as the last menstrual cycle ends, the process of maturation of an ovarian follicle and its oocyte begins. Corresponding to the development of the follicle, the blood level of the LH in the woman's body begins to rise and will peak around mid-cycle. Approximately 12-24 hours after the LH peak, the wall of the enlarged follicle ruptures, called ovulation, and the mature ovum is released. Within 2 days after ovulation, LH activity returns to its base line level. Unless a pregnancy occurs, this cycle of activity is repeated during the next menstrual cycle. Since LH is filtrated into the urine, it is an excellent marker to analyze the time point of ovulation.

The one-step LH Ovulation Test is a chromatographic immunoassay (CIA) for the rapid qualitative determination of LH in the urine. The immunological specificity of the test kit virtually eliminates cross reactivity and interference to structurally related glycoprotein hormones such as hFSH, hCG and hTSH.

## PRINCIPLE

This LH Rapid Test is a qualitative, two site sandwich immunoassay for the determination of human luteinizing hormone in urine specimens. The membrane was precoated with LH specific antibodies on the test region. During the test, the specimen is allowed to react with the LH monoclonal antibody-colloid gold conjugate which was pre-dried on the test strip. The mixture then moves upward on the membrane chromatographically by the capillary action. For a positive specimen, the conjugate binds to the LH forming an antibody-antigen complex. This complex binds to the LH antibody as a capture regents on the test region and produces a colored band when LH concentration is equal to or greater than 35 mIU/ml. Absence of this colored band in the test region suggests a negative result. To serve as a procedural control, a colored band at control region will always appeared regardless the presence of LH.

## STORAGE AND STABILITY

This LH Rapid Test can be store refrigerated or at room temperature (2-28°C) in sealed pouch. **Avoid freezing.**

## PRECAUTION

1. For in vitro diagnostic use.
2. Do not use after expiration date.
3. Test device should remain sealed until ready for use.
4. The reagents in this kit contain sodium azide which may react with lead or copper plumbing to form potentially explosive metal azide build up. Specimens should be considered hazardous and handled appropriately.

## SPECIMEN COLLECTION

*NOTE: Collect and storage specimens following standard clinical procedures.*

1. The urine specimen must be collected in a clean dry container either plastic or glass, without preservative. No centrifugation or filtration of urine is required.
2. The test can be performed at anytime during the day, however, for best results, the urine sample for the test should be collected at about the same time each day. Testing for the LH peak should begin on the 10th day after the beginning of a woman's current menstrual cycle. Testing should continue every day until the LH peak is detected.
3. If specimens cannot be tested after collection, they should be stored refrigerated at 2-8℃. If samples are refrigerated, they must be equilibrated to room temperature before testing

## ASSAY PROCEDURE

***For Card Test:***

1. Remove the device from pouch and label the device with specimen identification.
2. Add 3 drops (150 µl) of urine or serum to the sample well (S).
3. Observe the result within 5 minutes, no longer than 10 minutes.

## INTERPRETATION OF RESULT

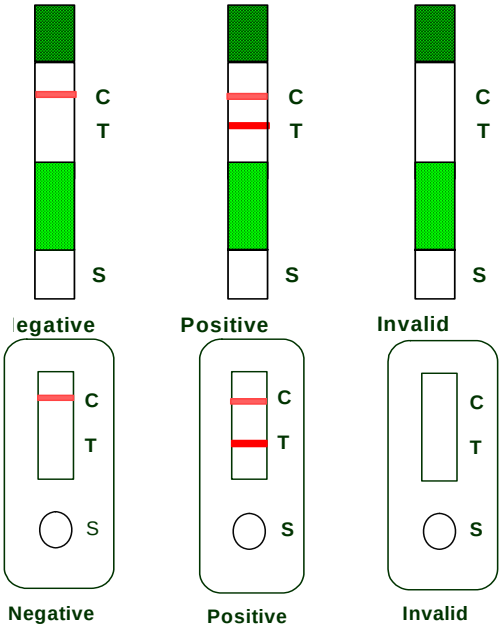
To determine you result, compare the intensity (i.e., the lightness or darkness of the color) of the test band to the color of the control band.

**Positive:** The test band is approximately the same color or darker than the control band. This provides a good indication that the LH surge is occurring.

**Negative:** The test band is lighter than the control band or can not be seen. This means the LH level of the sample is at, or is near to, its basal (normal) level and that the LH surge has not yet begun.

**Invalid:** Lack of bands (no bands), the test result is invalid and should be ignored. Lack of bands indicates either that the test procedures were not followed correctly. Carefully review the procedures and retest using a fresh (unused) test device.

***Note: Do not interpret results after 10 minutes.***




**PROCEDURAL NOTE**

If the flow of the specimen is not observed through the test area, this is due to an insufficient amount of specimen dispensed into the sample well or pad. The test performer should re-read the instructions thoroughly prior to performing the test again.

**EXPECTED VALUE**

LH is normally detectable at low levels in urine or serum of healthy men or premenopausal women not during the LH surge. Prior to the tests the following charts should be consulted.

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|---|---|
| **Baseline level of premenopausal women:** | **5-20 mIU/ml** |
| **Surge level of premenopausal women:** | **40-200 mIU/ml** |
| **Postmenopausal women:** | **10-200 mIU/ml** |
| **Men:** | **2-15 mIU/ml** |

**QUALITY CONTRIL**

The procedural control is included in the test. A colored band appearing on the control region indicates proper performance and reactive reagents.

Good laboratory practices include the use of control to ensure proper test performance. LH negative and positive controls (calibrated to WHO 2nd IS 80/552) are available commercially. Each laboratory should establish their own criteria for interpretation of results as baseline LH levels and patterns of LH secretion can vary among individuals. When the baseline is in doubt, a urine sample collected 7 days after the beginning of

the menstrual cycle can be used as the negative reference. If a sample produced more intense test band than the day 7 urine sample, a LH surge is indicated.

## LIMITATIONS

1. The directions must be followed exactly to provide accurate results.
2. Women who are pregnant, menopausal or who have recently received an hCG injection should not use this test. Their urine will not provide accurate results.
3. If a specimen is too diluted (i.e. low specific gravity), it may not contain representative levels of hLH. If hLH concentrations less than 35 mIU/ml will be detected as negative.
4. Women suffering from polycystic ovary syndrome may have elevated LH concentration. These diagnosis should be considered if appropriate to the clinical evidnece. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

## PERFORMANCE AND CHARACTERISTICS

***Sensitivity:***
The analytical sensitivity of this LH Rapid Test has been set at 35 mIU/ml or higher of hLH (calibrated to WHO 2nd International Standard 80/552). The 50 mIU/ml positive control was designed as the cutoff for the test because hLH concentrations in this ranges are usually achieved the surge level (40-200 mIU/ml) of premenopausal women.

***Specificity:***
The specificity was determined from cross reaction studies with known amounts of Chorionic Gonadotropin Hormone (hCG), Follicle Stimulating Hormone (hFSH), and Thyroid Stimulating Hormone (hTSH). 200 mIu/ml hCG, 200mIU/ml hFSH and 200 mIU/ml hTSH all gave negative results.

***Interference Testing:***
The following substances at certain concentrations do not interfere with the LH rapid test in the assay:

| | |
|---|---|
| **Acetaminophen** | **20 mg/dl** |
| **Acetysalicylic Acid** | **20 mg/dl** |
| **Ascorbic Acid** | **20 mg/dl** |
| **Atropine** | **20 mg/dl** |
| **Caffeine** | **20 mg/dl** |
| **Gentesic Acid** | **20 mg/dl** |
| **Glucose** | **2.0 mg/dl** |
| **Hemoglobin** | **1.0 mg/dl** |

## REFERENCES

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