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

INTENDED USE

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

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 a woman's menstrual cycle. As soon as the last menstrual cycle ends, the process of maturation of an ovarian follicle and its oocyte begins. Corresponding with 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, and the mature ovum is released. This is called ovulation. Within 2 days of ovulation, LH activity returns to its baseline 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 DRG® Ovulation Rapid Test is a chromatographic immunoassay (CIA) for the rapid qualitative determination of LH in 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

The DRG® LH Rapid Test is a qualitative, two-site sandwich immunoassay for the determination of LH in human urine specimens. The test strip membrane is 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 is pre-dried on the test strip. The mixture then moves upward on the membrane chromatographically by 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 reagent 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 will always appear in the control region regardless the presence of LH.

STORAGE AND STABILITY

The DRG® LH Rapid Test can be store refrigerated or at room temperature (2-28ºC) in sealed pouch. Avoid freezing.

PRECAUTION

- Do not use this test after the expiration date printed on the pouch.
- Test device should remain sealed until ready for use.
- The reagents in this kit contain sodium azide which may react with lead or copper plumbing to form potentially explosive metal azide build up.
- Sample should be considered hazardous and handled appropriately.

SPECIMEN COLLECTION

Collect and store 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. Do not use the first urine you pass in the morning for this test.
3. If specimens cannot be tested after collection, they should be stored refrigerated at 2-8ºC.

ASSAY PROCEDURE

- Remove the test from protective pouch.
- Remove the cap and place the exposed absorbent wick directly into the urine stream for 10 seconds or until the absorbent wick is saturated with urine.
- Remove the test from the urine stream, re-cap and lay flat on a clean surface.
- Read the test result at 5 minutes.

Note: To avoid confusion, discard the test device after interpreting results.

INTERPRETATION OF RESULT

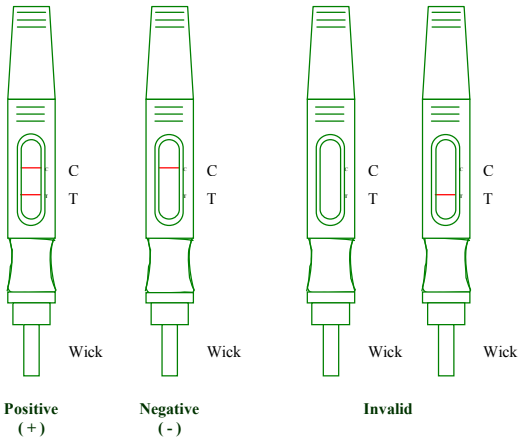
To determine you result, compare the intensity (i.e., the lightness or darkness of the color) of the test band to the color of the control band.

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.



LIMITATIONS

- The directions must be followed exactly to provide accurate results.

- 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.
- If a specimen is too diluted (i.e. low specific gravity), it may not contain representative levels of hLH. hLH concentrations of less than 35 mIU/ml will have negative test results.
- Women suffering from polycystic ovary syndrome may have an elevated LH concentration. This diagnosis should only 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 the DRG® LH Rapid Test has been set at 35 mIU/ml or higher of hLH (calibrated to WHO 2nd International Standard 80/552). The 40 mIU/ml positive control was designed as the cut-off for the test because hLH concentrations in this range are usually achieved at 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). Concentrations of 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 results.

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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