SCREEN

SCREEN IFA TEST LH
(Whole Blood/Serum/Plasma)
Package Insert

REF: SC-1460	English

A test for the diagnosis of luteinizing hormone (LH) to detect luteinizing hormone (LH) in Whole Blood/Serum/Plasma with the use of SCREEN® fluorescence Immunoassay Analyzer. For professional in vitro diagnostic use only.

INTENDED USE

The LH Test Cassette (Whole Blood/Serum/Plasma) is intended for in vitro quantitative determination luteinizing hormone (LH) in Whole Blood/Serum/Plasma as an aid in the detection of ovulation.

SUMMARY

Ovulation is the release of an egg from the ovary. The egg then passes into the fallopian tube where it is ready to be fertilized. In order for pregnancy to occur, the egg must be fertilized by sperm within 24 hours after its release. Immediately prior to ovulation, the body produces a large amount of luteinizing hormone (LH) which triggers the release of a ripened egg from the ovary. This "LH surge" usually takes place in the middle of the menstrual cycle.[1]
The LH Test Cassette (Whole Blood/Serum/Plasma) is a complete system to help predict the time of ovulation, and peak fertility. It is during this fertile time that pregnancy is most likely to occur.
The LH Test Cassette (Whole Blood/Serum/Plasma) detects the LH surge in Whole Blood /Serum/Plasma, signaling that ovulation is likely to occur in the next 24-36 hours. The test utilizes a combination of antibodies including a monoclonal LH antibody to selectively detect elevated levels of LH.
Important: The LH surge and ovulation may not occur in all menstrual cycles.
The LH Test cassette is a test that quantitatively detects the LH level in Whole Blood/Serum/Plasma specimen. The test utilizes a combination of antibodies including a monoclonal anti-LH antibody to selectively detect elevated levels of LH. The minimum detection level is 20mIU/mL.

PRINCIPLE

The LH Test Cassette (Whole Blood/Serum/Plasma) is based on Fluorescence Immunoassay for the detection of LH human Follicle Stimulating Hormone in Whole Blood/Serum/Plasma to evaluate the onset of menopause in women. The sample moves through the strip from sample pad to absorbent pad. If the specimen contains LH, it attaches to the fluorescent microspheres-conjugated anti- LH antibodies. Then the complex will be captured by the capture antibodies coated on the nitrocellulose membrane (Test line). The concentration of LH in the sample correlates linearly with the fluorescence signal intensity captured on the T line. According to the fluorescence intensity of the test and standard curve, the concentration of LH in the sample can be calculated by SCREEN® Analyzer to show LH concentration in specimen.

REAGENTS

The test contains anti-LH antibody conjugated fluorophores and capture reagents coated on the membrane.

PRECAUTIONS

1. For professional *in vitro* diagnostic use only.
2. Do not use after the expiration date indicated on the package. Do not use the test if the foil pouch is damaged. Do not reuse.
3. Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
4. Do not eat, drink or smoke in the area where the specimens and tests are handled. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
5. Do not interchange or mix reagents from different lots.
6. Humidity and temperature can adversely affect results.
7. Used testing materials should be discarded in accordance with local regulations.
8. Read the entire procedure carefully prior to any testing.
The LH Test Cassette should only be used with the SCREEN® Analyzer by approved medical professionals.

STORAGE AND STABILITY

1. 1. The kit should be stored at 4-30 °C until the expiry date printed on the sealed pouch.
2. The test must remain in the sealed pouch until use.
3. Do not freeze.
4. Care should be taken to protect the components of the kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipment, containers or reagents can lead to false results.

SPECIMEN COLLECTION AND PREPARATION

Preparation
1. Before performing the test, please make sure that all components are brought to room temperature (15-30℃). Cold buffer solution or moisture condensation on the membrane can lead to invalid test results.
2. Take a tube with buffer solution out of the kit. Document patients name or ID on it.
Sample Handling
1. Collect the specimen according to standard procedures.
2. Do not leave specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 1 day, for long term storage, specimens should be kept below -20°C. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be used within 1 day of collection. Do not freeze whole blood specimens. Whole blood collected by finger stick should be tested immediately.
3. Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Avoid repeated freezing and thawing of specimens.
4. EDTA K2, Heparin sodium, Citrate sodium and Oxalate potassium can be used as the coagulant tube for collecting the blood specimen.
Sample Dilution
1. The specimen **(75ul of serum/plasma/whole blood)** can be added directly with the micro pipette into the buffer.
2. Close the tube and shake the sample by hand for approximately **10 seconds** so sample and dilution buffer mix well.
3. Let the diluted sample homogenize for approximately **1 minute.**
It is best to place the diluted sample on an ice pack and leave the sample at room temperature for no more than 8 hours.

MATERIALS

Materials Provided
• Test Cassettes • Specimen Collection Tubes with Extraction Buffer • *ID Card*
• *Package Insert*
Materials Required But Not Provided
• Timer. • Centrifuge
• SCREEN® Fluorescence Immunoassay Analyzer • Pipette

DIRECTIONS FOR USE

Refer to SCREEN® Fluorescence Immunoassay Analyzer Operation Manual for the complete instructions on use of the Test. The test should be conducted in room temperature.
Allow the test, specimen, buffer and/or controls to reach room temperature (15-30°C) prior to testing.
2. Turn on the Analyzer power. Then according to the need, select "Standard Test" or "Quick Test" mode.
3. Take out the ID card and insert it into the Analyzer ID Card Slot.
4. Squeeze **75μl Whole Blood /Serum/Plasma** into the buffer tube by pipette; mix the specimen and the buffer well.
5. **Add diluted specimen with a Pipette:** Pipette **75μl diluted specimen** into the sample well of the test cassette. Start the timer at the same time.
6. There are two test modes for SCREEN® Fluorescence Immunoassay Analyzer, Standard Test mode and Quick Test mode. Please refer to the user manual of SCREEN® Fluorescence Immunoassay Analyzer for details.
"Quick Test" mode: After **15 minutes** of adding sample, Insert the test cassette into the Analyzer, click "**QUICK TEST**", fill the test information and click "**NEW TEST**" immediately. The Analyzer will automatically give the test result after a few seconds.
"Standard Test" mode: Insert the test cassette into the Analyzer immediately after adding specimen, click "**STANDARD TEST**", fill the test information and click **"NEW TEST"** at the same time, The Analyzer will automatically countdown **15 minutes**. After the countdown, the Analyzer will give the result at once

INTERPRETATION OF RESULTS

Results read by SCREEN® Fluorescence Immunoassay Analyzer.
The result of tests for LH is calculated by SCREEN® Fluorescence Immunoassay Analyzer and display the result on the screen. For additional information, please refer to the user manual of SCREEN® Fluorescence Immunoassay Analyzer.
Linearity range of LH Test is 20-300 mIU/mL.

QUALITY CONTROL

Each LH Test Cassette contains internal control that satisfies routine quality control requirements. This internal control is performed each time a patient sample is tested. This control indicates that the test cassette was inserted and read properly by SCREEN® Fluorescence Immunoassay Analyzer. An invalid result from the internal control causes an error message on SCREEN® Fluorescence Immunoassay Analyzer indicating that the test should be repeated. An invalid result from the internal control causes an "N/A" message on SCREEN® Fluorescence Immunoassay Analyzer. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

LIMITATIONS

1.The LH Test Cassette (Whole Blood/Serum/Plasma) is for professional in vitro diagnostic use, and should only be used for the quantitative detection of LH. The test works only when the test procedures are precisely followed.
2.The LH Test Cassette (Whole Blood/Serum/Plasma) will only indicate the presence of LH in the specimen and the test may not be used as a form of birth control.
3.Like with all diagnostic tests, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.
4. The test results should not be affected by pain relievers, antibiotics and other common drugs. Medication containing hCG or LH may affect the test and should not be taken while using the LH Test Cassette (Whole Blood/Serum/Plasma). In addition, the test will not work properly for subjects who are pregnant, in menopause, or taking birth control pills.
5.The results of LH Tests are based on measuring the levels of LH in a specimen. It should not be used as the sole criterion for treatment decisions. If the result is positive, other clinical findings and alternative test methods are recommended to reach proper medical treatments.
6.Keep out of the reach of children.

EXPECTED VALUES

> 40 mIU/mL	Ovulation is likely to occur in the next 24-36 hours.
< 40 mIU/mL	This indicates that no LH surge has been detected. ovulation is unlikely to occur in the next 24-36 hours.

PERFORMANCE CHARACTERISTICS

1. Accuracy
The test deviation is ≤±15%.
2. Sensitivity
The LH Test Cassette (Whole Blood/Serum/Plasma) can detect levels of LH as low as 20 mIU/mL in Whole Blood/Serum/Plasma.
3. Detection range
20~300 mIU/mL
4. Linearity range
20~300 mIU/mL, R≥0.990
5. Cross-reactivity
The LH Test Cassette (Whole Blood/Serum/Plasma) has been tested with commonly known drugs and hormones including FSH (1,000mIU/ml), TSH (1,000μIU/ml), and hCG (100mIU/ml). At the levels tested, none of these substances interfered with the expected test results

BIBLIOGRAPHY

1. Elkind-Hirsch, K; Goldzieher, JW; Gibbons, WE and Besch, PK. Obstetrics and Gynecology, 67(3): 450-453,1986.

INDEX OF SYMBOL

Index of Symbols

	Consult Instructions for Use		Tests per kit		Authorized Representative
	For in vitro diagnostic use only		Use by		Do not reuse
	Store between 4-30°C		Lot Number		Catalog #
	Do not use if package is damaged		Manufacturer		

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