

Diagnostic Kit for Luteinizing Hormone (LH)

A test for detection of luteinizing hormone (LH) in human whole blood/serum/plasma with the use of Immunofluorescence Analyzer.

English

► For *in-vitro* diagnostic use

PACKING SPECIFICATION

25 Tests/ Kit (07LH5025)

INTENDED USE

The LH Test Cassette (Whole Blood/Serum/Plasma) is intended for *in-vitro* quantitative determination of luteinizing hormone (LH) in human whole blood/serum/plasma as an aid in the detection of ovulation. The test is intended for healthcare professionals use.

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 1 mIU/mL.

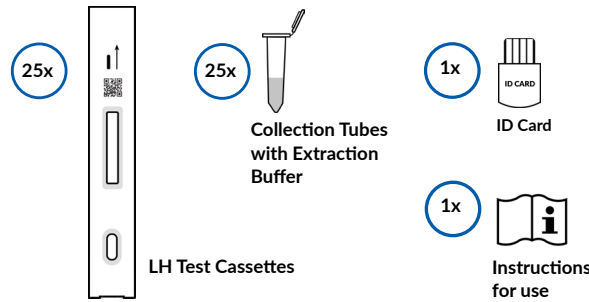
PRINCIPLE

The LH Test Cassette (Whole Blood/Serum/Plasma) is based on Fluorescence Immunoassay for the detection of LH in human whole blood/serum/plasma to evaluate the onset of menopause in women. The specimen moves through the strip from specimen 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 specimen 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 specimen can be calculated by standard curve to show LH concentration in specimen.

REAGENTS

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

MATERIALS PROVIDED



MATERIALS REQUIRED BUT NOT PROVIDED

- Immunofluorescence Analyzer MPQuanti® (07IMA001)
- Pipette
- Centrifuge
- Timer

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.
5. 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.
6. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
7. Do not interchange or mix reagents from different lots.
8. Humidity and temperature can adversely affect results.
9. Used testing materials should be discarded in accordance with local regulations.
10. Read the entire procedure carefully prior to any testing.
11. The LH Test Cassette should only be used with the Analyzer by approved medical professionals.

STORAGE AND STABILITY

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.

SAMPLE COLLECTION AND PREPARATION

Preparation

1. Before performing the test, please make sure that all components are brought to room temperature (15 - 30 °C). 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.

Specimen 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.

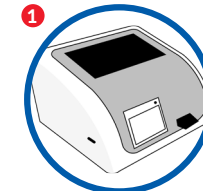
Specimen Dilution

1. The specimen (75 µL of serum/plasma/whole blood) can be added directly with the micro pipette into the buffer.
2. Close the tube and shake the specimen by hand for approximately 10 seconds so specimen and dilution buffer mix well.
3. Let the diluted specimen homogenize for approximately 1 minute.
4. It is best to place the diluted specimen on an ice pack and leave the specimen at room temperature for no more than 8 hours.

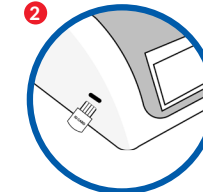
TEST PROCEDURE

Refer to Immunofluorescence Analyzer User Manual for the complete instructions for use of the Test. The test should be in room temperature.

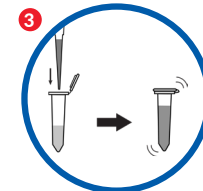
Allow the test cassette, specimen and buffer to reach room temperature (15 - 30 °C) prior to testing.



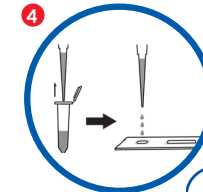
Turn on the Analyzer power. Then according to the requirement, select "Standard Test" or "Quick Test" mode.



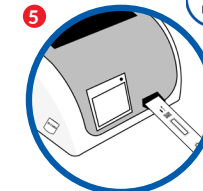
Take out the ID Card and insert it into the Analyzer ID Card Slot.



Transfer 75 µL of whole blood/serum/plasma into the buffer tube by pipette; mix the specimen and the buffer well.



Add diluted specimen with a Pipette: Transfer 75 µL of diluted specimen into the specimen well of the test cassette. Start the timer at the same time..



There are two test modes for Immunofluorescence Analyzer, Standard Test mode and Quick Test mode. Please refer to the user manual of Immunofluorescence Analyzer for details

"Quick Test" mode: After 15 minutes of adding specimen, 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 TEST RESULTS

Results read by Immunofluorescence Analyzer.

The result of tests for LH is calculated by Immunofluorescence Analyzer and display the result on the screen. For additional information, please refer to the user manual of Immunofluorescence Analyzer.

Linearity range of LH Test is 1-300 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 specimen is tested. This control indicates that the test cassette was inserted and read properly by Immunofluorescence Analyzer An invalid result from the internal control causes an “N/A” message on Immunofluorescence 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 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.

EXPECTED VALUES

Gender	Period	Reference range(mIU/mL)
Male	/	1.7 - 8.6
Female	Follicular period	2.4 - 12.6
	Ovulation	14.0 - 95.6
	Luteal period	1.0 - 11.4
	Menopause	7.7 - 58.5

Note: The establishment of the reference interval for this test cassette is only for specimens from local populations. It is recommended that each laboratory establish an actual reference interval based on the population, age, gender, diet, etc. in each region.

PERFORMANCE CHARACTERISTICS

1. Accuracy

The test deviation ≤ ±15%.

2. Sensitivity

The LH Test Cassette (Whole Blood/Serum/Plasma) can detect levels of LH as low as 1 mIU/mL in whole blood/serum/plasma.

3. Detection range

1 - 300 mIU/mL

4. Linearity range

1 - 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 (1,000 mIU/mL), TSH (1,000 µIU/mL), and hCG (100 mIU/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.


SYMBOLS




Consult Instructions For Use




Catalogue Number




For *In-vitro* Diagnostic use




Authorized Representative




Store at 4 °C ~ 30 °C




Do Not Reuse




Keep away from Sunlight




Do Not Use if Package is Damaged




Lot Number




European Conformity




Manufacturer




Date of Manufacture




Expiration Date






Tests per Kit



Unique Device Identifier



MP Biomedicals Germany GmbH
Thueringer Str. 15
37269 Eschwege
Germany

Customer Service:
 +49 (0) 5651 – 921-186
 +49 (0) 5651 – 921-181
 diagnostics@mpbio.com

Rev: 07LH5025-014-03-42-EN
Effective date: 22.03.2024