Hipro Hipro Biotechnology Co.,Ltd

EN
ENGLISH

LH

Luteinizing Hormone Test Kit
(Fluorescence Immunoassay Method)
Instructions for Use

Version:A/1

REF HP-Palm-LH-25

Manufacturer

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Product Name

General Name：Luteinizing Hormone Test Kit
(Fluorescence Immunoassay Method)

Package Specification

25 Tests/Kit.

Intended Use

The Hipro Luteinizing Hormone(LH) Test Kit is an vitro diagnostic test for the quantitative measurement of Luteinizing Hormone(LH) in human serum, plasma or whole blood.

Luteinizing hormone (LH) is secreted by basophilic granulocytes of the pituitary gland. In women LH and FSH works together to maintain the menstrual cycle of the ovaries, leading to ovulation and luteum formation. The production of LH is controlled by hypothalamic gonadotropin-releasing hormone, and is also regulated by positive and negative feedback from the ovary. The combined detection of LH and FSH can distinguish primary (ovarian) or secondary (pituitary) amenorrhea in women. Used in males to identify primary or secondary testicular hypofunction; It can also identify true or false precocious puberty in prepubertal children. This test result is expressed in milliinternational units per milliliter (mIU/mL).

Test Principle

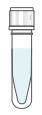
This test kits based on the double antibody sandwich method to determine the concentration of LH in human serum, plasma or whole blood.

The LH antigen in the sample binds to the mouse anti-human LH antibody labeled with fluorescent microspheres on the binding pad to form an immune complex. Immune complex under the capillary action to move forward along the cellulose nitrate membrane, by testing area on nitrocellulose membrane (T) in advance of package is another resistance strain rat LH antibody capture, extra marks antibodies are in quality control area (C) be wrapped up on the NC membrane sheep polyclonal antibody against rat IgG capture. After the reaction is complete, the fluorescence intensity on the T and C lines is detected by the immunofluorescence quantitative analyzer, and the LH concentration in the sample is calculated.

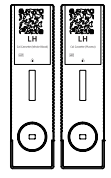
Material Provided

Component	25Kits
Sample Diluent	25
Calibration Cassette	2
Test Cassette	25
Instructions for Use	1
Disposable tube with 100μL	25

Sample Diluent

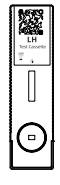


Calibration Cassette



QR code is with built-in parameter for each assay.

Test Cassette



Disposable tube with 100μL

Volume 100μL

Material Needed but Not Provided

1. Timing device.

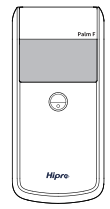
Storage&Validity

Store test kit at: 2°C-30°C until the expiration date indicated on the label.

Avoid exposure to direct sunlight. The test kit is stable for 18months when unopened.

Perform the test within 1 hour when opened.

Applicable Instrument



Palm F Fluorescence Immunoassay Analyzer

Specimen type

1. The specimen type of LH test kit is human serum, plasma or whole blood.
2. Plasma/whole blood recommended use EDTA.
3. After sample collection, please test as soon as possible.
4. Fresh collected specimen should be measured within 2 hours otherwise should be stored at 2°C~8°C up to 24 hours .

Storage

1. For long-term storage the whole blood should centrifuged into plasma and serum/plasma stored at -20 °C up to 3 months.
2. Avoid repeated freezing and thawing.
3. Avoid hemolysate.

Required volume

100μL is required for serum,plasma or whole blood, used for dilution.

100μL is required of diluted sample for each determination.

This volume does not include the dead volume(unusable volume inthe sample container) or the additional volume required to make replicate test or other tests to be performed on the same sample.

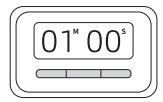
LH Test Kit Instructions Guide

Before You Begin

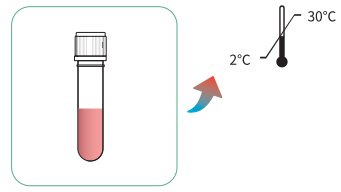
1a Please read the LH IFU and applicable instrument User Manual carefully before operation. Please follow the instructions strictly.

Before You Begin

1b A timing device (phone, clock or timer) is required but not provided.

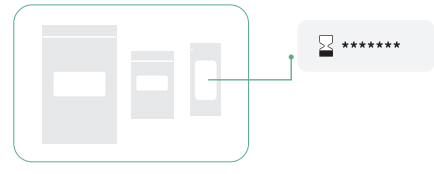


1c Allow the sample back to room temperature.



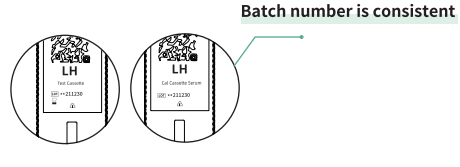
1d Ensure the test kit is at room temperature for at least 30 minutes prior to use.

1e Check on the expiration date on labels of different component.



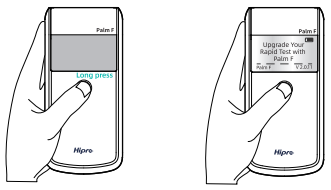
1f Make sure the lot number on calibration cassette and test cassette are same.

Do not misuse the cassettes with different lot.

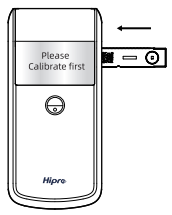


Test Procedures

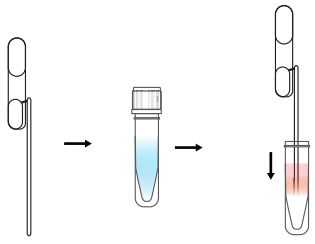
2a Turn on the applicable instrument according to the User Manual.



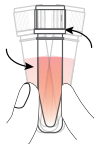
2b Insert the calibration cassette into the analyzer as the direction shows, to let the built-in parameter be read.



3a Use the disposable tube to collect and add 100μL specimen (serum/plasma/whole blood) into the sample diluent.

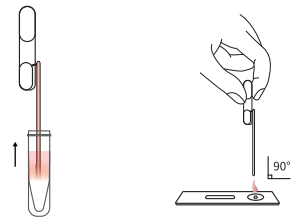


3b Mix the sample with diluent for 30 seconds.



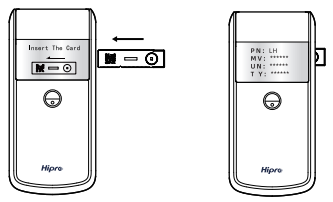
Test Procedures

3c Use a 100μL disposable tube to collect and add the mixed liquid onto the sample well of test cassette.



3d Wait for 15 minutes .

3e Insert the test cassette into the analyzer and the analyzer will display the results automatically.



! Avoid bubbles when collecting samples.

Reference Value

Blood samples were collected seperately from 153 healthy men, 153 postmenopausal women, 153 women in follicular phase, 153 women in ovulatory phase and 153 women in luteal phase and the results(95%) meet the linearity range:

Male: 1.92-8.32mIU/mL

Female: Follicular phase:3.03-12.95mIU/mL

Ovulatory period: 14.71-94.32mIU/mL

Luteal phase: 1.63-10.99mIU/mL

Menopause: 9.53-54.29mIU/mL

Recommended that each laboratory establish its own reference range.

Interpretation

1.For diagnostic purposes, the results obtained from this assay 1.should always be used in combination with the clinical examination, patient medical history, and other findings.

2. Dilution of superlinear range samples is not recommended.
3. If the test results are different from clinical symptoms, retesting is recommended.

Precautions and limitations

1.The Hipro Luteinizing Hormone(LH) test kit is an vitro diagnostic test for the quantitative measurement of Luteinizing Hormone in human serum, plasma or whole blood.

2.For terminal purposes, the results obtained from this assay should always be used in combination with the clinical examination, patient medical history, and other findings

3.Testing the same sample with test kits from different manufacturers may result in different test results due to methodological or antibody specificity reasons, so results from testing with different test kits should not be directly compared with each other to avoid incorrect medical interpretation.

4. Some drugs such as ethinylestradiol (100ng/mL) and progesterone (20ng/mL) may be cross-reactive.

5. When the LH concentration⩽500mIU/mL there will not be Hook effect.

Performance Characteristics

1. **Appearance**

   The inside package should be sealed tightly and no air leakage; the information on label is complete and clear. The surface of the test cassette should be smooth.

2. **Strip width**

   The width of strip should be ⩾2.5mm.

3. **Liquid flow speed**

   The speed should be ⩾10mm/min.

4. **Linearity**

   Within range 1mIU/mL-100mIU/mL, the correlation coefficient (r) should be ⩾0.990.

5. **Within-lot precision**

   The coefficient of variation (CV) should be ⩽15%.

6. **Between-lot precision**

   The relative deviation should be ⩽15%.

7. **Accuracy**

   The relative deviation should be⩽15%.

8. **Limit of blank(LoB)**

   The LoB should be ⩽0.8mIU/mL.

9. **Specificity**

   The FSH test result of 200IU/L should be ⩽ 0.8mIU/mL.

   The TSH test result of 200mIU/L should be ⩽ 0.8mIU/mL.

   The HCG test result of 1000IU/L should be ⩽ 0.8mIU/mL.

Precautions

1.For in vitro diagnostic us, do not reuse, do not use expired product.

2.All samples should be considered potentially infectious and suitable protective measures should be taken. Laboratory gloves should be worn while handling patient' sample,disposal of waste, storage, mixing and testing. Disposal of all wast material should be in accordance with local guidelines.

3.Do not use damaged test kits, or expired test cassette.

4.Make sure the lot number on ID card and test cassette are same. Do not misuse the reagents with different lot.

5.The desiccant inside the package not to be used for other purposes.

6.The test cassette and the components are only match with the suitable fluorescence immunoassay analyzer.

7.Avoid electromagnetic or vibration environment for analyzer; The vibration of the instrument is normal when it working.

8.Do not insert the polluted cassette into analyzer. Please dispose the used test cassette properly.

9.Any questions or suggestions about the test kits, please contact the manufacturer.

Symbols used on labels

Symbol	Usage
	Use-By date
LOT	Batch code
	Manufacturer
	Keep Away from Sunlight
2°C 30°C	Temperature Limit
IVD	In Vitro Diagnostic Medical device
EC REP	Authorized Representative in the European Community
CE	CE Mark
	Consult Instructions for use
	Do not freeze
Σ	Contains sufficient for <n> tests
	Biological risks
	Do not use if package is damaged
	Date of manufacture
	Do Not Reuse

Reference

1. Liwnicz BH, Liwnicz RG. The hypothalamopituitary system. In: Kaplan LA, Pesce AJ, editors. Clinical chemistry: theory, analysis, and correlation, 2nd ed St Louis: CV Mosby, 1989. p. 613-9.

2. Scott MG, Ladenson JH, Green ED, et al. Hormonal evaluation of female infertility and reproductive disorders. Clin Chem1989:35:620-29.

3. Butt WR, Blunt SM. The role of the Laboratory in the investigation of infertility. Ann Clin Biochem 1988: 25: 601-9.

Approval Date &Revision Date

Approval Date: Jul 10, 2023

Revision Date: Dec 22, 2023

CE IVD

工艺：70g双胶纸，双面印刷，横向4折页，竖向对折　展开尺寸：32*25cm，第一页的左上角项目名称为封面