Hipro Hipro Biotechnology Co.,Ltd

EN
ENGLISH

FSH

Follicle Stimulating Hormone Test Kit
(Fluorescence Immunoassay Method)
Instructions for Use

Version:A/1

REF HP-Palm-FSH-25

Manufacturer

Shijiazhuang Hipro Biotechnology Co.,Ltd.
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Product Name

General Name：Follicle Stimulating Hormone Test Kit
(Fluorescence Immunoassay Method)

Package Specification

25 Tests/Kit.

Intended Use

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

Follicle stimulating hormone (FSH), also known as Follicle stimulating hormone, is a glycoprotein, which is synthesized and secreted by the pituitary gland.In women, the function of FSH is to promote the development and maturation of follicles, and cooperate with luteinizing hormone (LH) to promote the secretion of estrogen and ovulation of mature follicles, and participate in the formation of normal menstruationIts production is controlled by hypothalamic gonadotropin-releasing hormone (GNRH), with feedback regulation by ovarian estrogen (E2). Follicle-stimulating hormone is one of the contents of endocrine detection, which can promote the development and maturation of follicles and promote ovulation. Follicle-stimulating hormone detection has important clinical significance for the treatment of infertility. If the FSH level is increased, it indicates that the female ovarian function is very poor, and there may be disorders such as ovarian dysgenesis, primary amenorrhea, and pituitary precocious puberty. If the FSH level is lower than the normal value, you may have a disease such as polycystic ovarian syndrome.

Test Principle

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

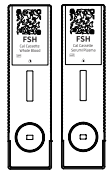
FSH antigen in the sample was combined with mouse anti-human FSH antibody labeled with fluorescent microspheres on the binding pad to form immune complexes. Under the capillary action, the complex moved forward along the nitrocellulose membrane and was captured by another strain of mouse anti-FSH antibody precoated on the nitrocellulose membrane detection region (T). The excess labeled antibody was captured by goat anti-mouse IgG polyclonal antibody coated on the NC membrane in the quality control region (C line). After the reaction was completed, the fluorescence intensity of T line and C line was detected by immunofluorescence quantitative analyzer, and the concentration of FSH in the sample was calculated.

Material Provided

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

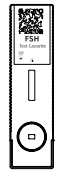
Sample Diluent

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

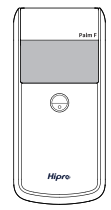
Storage&Validity

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 FSH test kit is human serum，plasma or whole blood.
2. EDTA, heparin, and sodium citrate anticoagulants are recommended for plasma/whole blood.
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 serum or plasma should stored at -20 °C up to 3 months.
2. Avoid repeated freezing and thawing.

Required volume

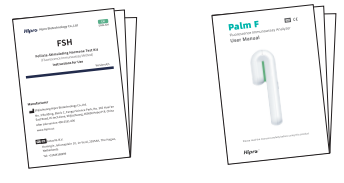
100μL is required for serum,plasma or whole boold used for dilution.100μL is required of diluted sample for each determination.

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

FSH Test Kit Instructions Guide

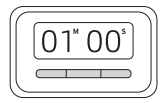
Before You Begin

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

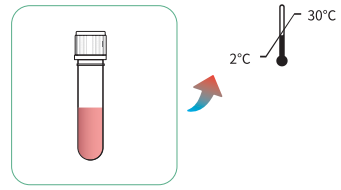


Before You Begin

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

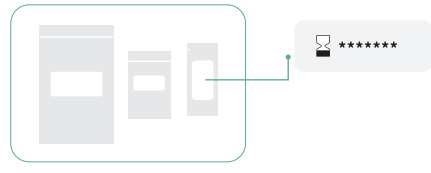


1c Allow the sample back to room temperature.



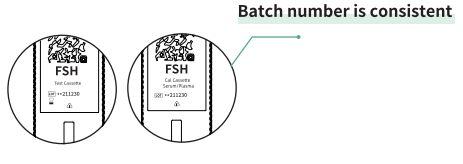
1d Ensure the test kit is at room temperature for at least 30 minutes prior to use.

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



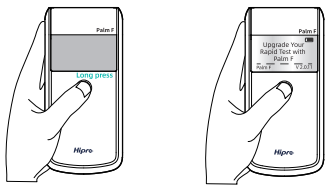
1f Make sure the lot number on calibration cassette and test cassette are same.

Do not misuse the cassettes with different lot.



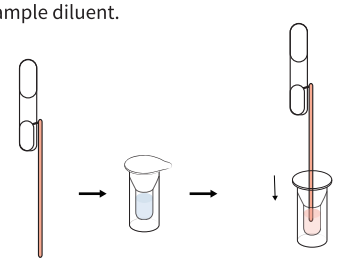
Test Procedures

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

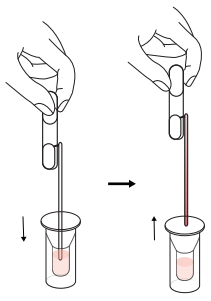


2b Insert the calibration cassette into the analyzer as the direction shows, to let the built-in parameter be read.

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



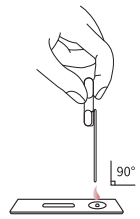
3b Repeated squeezing and absorbing to mix the samples.



Note:Do not make the liquid entering into the balloon interior during the squeezing and absorbing process.

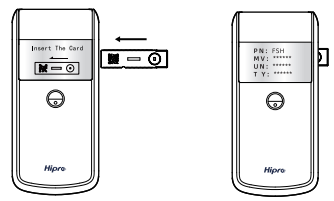
Test Procedures

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

The blood samples of a certain number of healthy men, postmenopausal women, and women during menstruation (follicular phase, mid-menstrual phase, and luteal phase) were tested (see the table below for the number of reference individual samples included), and the reference value range of this project was obtained based on the 95% confidence interval. The results are as follows:

Samples	n	mIU/mL
Male	150	0.97-12.22
Postmenopausal Women	150	26.85-134.24
Women During Menstruation		
Follicular Phase	150	3.08-8.10
Mid-menstrual cycle	150	2.66-16.82
Luteal Phase	150	1.47-5.61

Recommended that each laboratory establish its own reference range.

Precautions and limitations

1. The Hipro Follicle-Stimulating Hormone(FSH) test kit is an vitro diagnostic test for the quantitative measurement of Follicle-Stimulating 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. The structural analogue of follicle stimulating hormone prolactin >400ng/mL and human growth hormone>100ng/mL may cross-react.
5. When the FSH concentration⩽625mIU/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 0.5mIU/ml-200mIU/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 coefficient of variation (CV) should be ⩽15%.

7.Accuracy

The relative deviation should be ⩽15%

8.Limit of detection(LoD)

The LoD should be 0.3mIU/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
	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 evalua tion of female infertility and reproductive disorders. Clin Chem1989:35:620-29.

3. Butt WR, Blunt SM. The role of the Laboratory in the investiga tion 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