Diagnostic Kit for Follicle-stimulating Hormone (Fluorescence Immunochromatographic Assay) Instructions for Use

INTENDED USE

This kit is intended for in vitro quantitative detection on the content of follicle-stimulating hormone (FSH) in the human serum/plasma/whole blood/fresh finger terminal blood samples and is intended for assisting in judging the occurrence of female climacteric period. This kit only provides the test result of follicle-stimulating hormone (FSH), and the obtained result shall be analyzed in combination with other clinical information. This kit is for healthcare professionals.

SUMMARY

Follicle-stimulating hormone is a glycoprotein hormone secreted by the anterior pituitary gland that can enter the blood through the blood circulation. In males, its function is to promote the maturation of the testicular seminiferous tubules and sperm production; in females, FSH function is to promote follicle development and maturation, and cooperate with luteinizing hormone (LH) to promote the mature follicles to secrete estrogen and ovulation and participate in the formation of normal menstruation. FSH maintains a continuous and stable basal level of about 5~20mIU/mL in normal human body. In females, FSH undergoes cyclic changes during the menstrual cycle, which reaches a maximum of about 15~35mIU/mL in the middle of menstruation (before ovulation) and decreases to basal levels after ovulation. Female menopause generally occurs between the ages of 49 and 54 years and lasts an average of 4-5 years. During this period, due to ovarian atrophy, follicular atresia and degeneration, estrogen secretion is significantly reduced stimulating the pituitary gland to secrete many gonadotropins. Especially the level of FSH will be significantly increased, generally 40~200mIU/mL, and maintain this level for a long time, so the significantly and continuously increase of FSH level can assist in judging the occurrence of female menopause. Detection of follicle-stimulating hormone concentration has important clinical significance in the diagnosis of amenorrhea, primary hypogonadism, secondary hypogonadism, precocious puberty, ovarian syndrome, orgasm syndrome and pituitary adenoma.

PRINCIPLE OF DETECTION

This kit uses the double-antibody sandwich reaction principle with high specificity and fluorescence immunochromatography to quantitatively detect the follicle-stimulating hormone (FSH) in the human serum/plasma/ whole blood/fresh finger terminal blood samples. The strip contains anti-FSH antibody pre-immobilized on the test area (T) of the membrane and goat anti-rabbit IgG antibody in the quality control area (C). The label pad contains pre-coated fluorescently labeled anti-FSH antibody and rabbit IgG antibody. When the sample is tested, the FSH antigen in the sample binds to the fluorescently labeled anti-FSH antibody to form an immune complex. Under the immunochromatographic effect, the complex and sample flow towards the absorbent paper inside the nitrocellulose membrane. The complex binds with the coated anti FSH antibody while it passes through test area (T), to form “anti FSH antibody-FSH antigen-fluorescence-labeled anti FSH antibody” complex and thus aggregate. When passing through the quality control area (C), the fluorescently labeled rabbit IgG antibody binds to the coated goat anti-rabbit IgG antibody to form a "goat anti-rabbit IgG antibody-

fluorescently labeled rabbit IgG antibody" complex and agglutinates. The FSH concentration in the sample is positively correlated with the fluorescence intensity, and the concentration of FSH in the sample can be detected by the fluorescence immune analyzer.

MAIN KIT COMPONENTS

Catalogue number	51310401	51310405	51310420	51310425
Specification / Components	1 Test/Kit	5 Tests/Kit	20 Tests/Kit	25 Tests/Kit
Test Device(s)	1	5	20	25
Sample Diluents	1	5	20	25
Instructions for Use	1	1	1	1

MAIN ACTIVE INGREDIENTS

1 Test line (T line): T line area of nitrocellulose membrane is coated with anti-FSH antibody.

2 Control line (C line): C line area of nitrocellulose membrane is coated with goat anti-rabbit IgG antibody.

3 Label pad: Fluorescently labeled anti-FSH antibody and rabbit IgG antibody are coated.

4 Main component of sample diluent is 20mM, pH7.4 PBS solution.

Warning： The diluent includes 0.1% Proclin300

H317: May cause an allergic skin reaction.

H412: Harmful to aquatic life with long lasting effects.

P280: Wear protective gloves/protective clothing/face protection.

P333+P313: If skin irritation or a rash occurs: Get medical advice/attention.

P362+P364: Take off contaminated clothing and wash it before reuse.

STORAGE CONDITION

1. The kit should be stored at 2℃~30℃. The shell life of the kit is 24 months.
2. Do not use the kit after the expiration date

APPLICABLE INSTRUMENT

The product can only be used with portable immune analyzer WIZ-A101 from WIZ BIOTECH.

SAMPLE COLLECTION AND STORAGE

1. This kit is indicated for testing of venous whole blood, serum, plasma, and fresh finger terminal blood. For whole blood and plasma samples, can use anticoagulant such as EDTA-K2, heparin, and sodium citrate.
2. Any sample taken from human may be infectious and shall be disposed using standard bio-safety procedures.
3. To avoid interference with the test result, do not use hyperlipidemic, hemolytic or turbid sample.
4. Whole blood collection: According to standard blood sampling procedure, use blood collection tube containing suitable anticoagulant to collect whole blood sample by venous puncture. Whole blood shall be tested as soon as possible after collected. If test cannot be performed in time, the sample shall be stored at 2℃~8℃ for up to 2 days.
5. Serum/plasma collection: According to standard blood sampling procedure, use blood collection tube containing suitable anticoagulant to collect whole blood sample by venous puncture. Serum and plasma shall be separated

as soon as possible after blood sampling to avoid hemolysis. The separated serum and plasma shall be tested immediately. If test cannot be performed in time, the separated samples can be stored at 2℃~8℃ for 7 days. If frozen below -15℃, samples can be stores for 6 months.

6. Fresh terminal blood of fingertips should be used immediately after collection.

7. Avoid repeated freezing-thawing of sample. Turbid sample or sample with sediment shall be tested after centrifugation or filtered to clarity.

8. Before test, sample should be in room temperature and mixed thoroughly.

REAGENT PREPARATION

1. Use immediately after open the aluminum foil bag.

2. Before test, restore the reagent to room temperature.

TEST METHOD

Read the instruction for use and test operation manual completely before the test and restore the reagent to room temperature before the test. Do not perform the test without restoring the reagent to room temperature to avoid affecting the accuracy of the test results.

The following operation steps are all performed provided that WIZ-A101 portable immune analyzer has been ready for use. To select or change any setting of WIZ-A101 portable immune analyzer, please refer to user manual of WIZ-A101 portable immune analyzer.

WIZ-A101 portable immune analyzer has two test modes: I standard test mode; II quick test mode. It is required to select corresponding test mode before test, and then go into the next operation:

I Select standard test mode of WIZ-A101 portable immune analyzer

I-1: Use of portable immune analyzer

(1) Open the aluminum foil bag package of reagent, and take out the test device;

(2) Horizontally insert the test device into the slot of immune analyzer;

(3) On home page of operation interface of immune analyzer, click “Standard” to enter test interface;

(4) Click “QC Scan” to scan the QR code on inner side of the kit; input kit related parameters into instrument, and select sample type;

Note: Each batch number of the kit shall be scanned for once. If the batch number has been scanned, then skip this step;

(5) Check the consistency of “Product Name”, “Batch Number” and etc. on test interface with information on the kit label;

(6) After information consistency is confirmed, take out sample diluents, add 20μL of serum/plasma/whole blood/fresh finger terminal blood sample, and sufficiently mix;

(7) Add 80μL of above mixed solution into the sample hole of test device;

(8) After complete sample addition, click “Timing” and remaining test time will be automatically displayed on the interface.

(9) Immune analyzer will automatically complete test and analysis when test time is reached.

I-2: Result calculation and display

After the test by immune analyzer is completed, test result will be displayed on test interface or can be viewed through “History” on home page of operation interface.

II Select quick test mode of WIZ-A101 portable immune analyzer

II-1: Drip the sample into the test device

(1) Open the aluminum foil bag package, take out the test device, and horizontally place it on examination table;
(2) Take out sample diluents, add 20μL of serum/plasma/whole blood/fresh finger terminal blood sample and mix;
(3) Add 80μL of above mixed solution into the sample hole of test device;
(4) Start stopwatch and wait for 15 minutes.

II-2: Use of portable immune analyzer

(1) After post-sample-addition reaction for 15 minutes, horizontally insert the test device into the slot of immune analyzer;
(2) On home page of operation interface of immune analyzer, click “Quick Test” to enter test interface;
(3) Click “QC Scan” to scan the QR code on inner side of the kit; input kit related parameters into instrument, and select sample type;
Note: Each batch number of the kit shall be scanned for once. If the batch number has been scanned, then skip this step.
(4) Check the consistency of “Product Name”, “Batch Number” and etc. on test interface with information on the kit label;
(5) After information consistency is confirmed, click “Test”. The immune analyzer will automatically complete test and analysis.

II-3: Result calculation and display

After the test by immune analyzer is completed, results will be displayed on test interface or can be viewed through “History” on home page of operation interface.

INTERPRETATION OF THE RESULT

Gender		Range (mIU/mL)
Male		1.25-13.50
Female	Follicular phase	2.45-15.55
	Ovulatory phase	5.35-24.80
	Luteal phase	1.65-10.25
	Menopause	24.60-135.75

1. For the reference intervals established based on the above data of test kit, it is recommended that each laboratory establish the reference intervals based on the clinical significance of the population in its region.
2. If the FSH measured concentration of sample is higher than the reference value range, the physiological change or stress response and other states shall be excluded. Tangible abnormal should be diagnosed in combination with clinical symptoms.
3. Test result of this method is only applicable to evaluation using the reference value established in this method and cannot be directly compared with result of other method.
4. Other factors that may cause wrong test result include technical reason, operation error and other sample factors.
*Invalid result: If the assay result is invalid, the WIZ-A101 portable immunoassay analyzer will display an "invalid" result. The test personnel should read the kit instructions and portable immunoassay analyzer instructions carefully and repeat the test. If the "invalid" result is persists, please contact Xiamen Wiz Biotech Co., Ltd.

PRECAUTIONS

1. This kit can only be used for in vitro diagnosis.

2. This kit is for healthcare professionals only.
3. Before test, restore reagent and sample to room temperature.
4. This kit is disposable.
5. Do not use expired reagent.
6. Sample collection and storage must be performed in strict accordance with this instruction.
7. The reagent should be stored in strict accordance with the conditions specified in this instruction for use. Do not store the reagent under freezing condition.
8. Do not open the aluminum foil bags before test and protect the products from moisture; do not use if the aluminum foil bags are damaged or if the test reagents are wet.
9. For all components of the kit, it is recommended not to mix or interchange different batches.
10. Excessive or insufficient sample may lead to deviation of result.
11. Do not confuse sample hole with result observation window. Adding sample to result observation window will make test result invalid.
12. Test method should strictly follow the instruction for use.
13. For specific explanation of test result, analysis shall be performed in combination with clinical information.
14. The used reagent and sample shall be properly disposed as medical waste with risk of biological infection and handled safely.
15. Desiccant in aluminum foil bag is inedible.
16. Sample diluent is only used for test. Do not drink it. Wrong use may lead to biological hazard.
17. During test, test procedure, precautions and result explanation of the reagent must be followed to avoid wrong result.

PRODUCT PERFORMANCE INDEX

Evaluation performed using internal enterprise reference, that all performance indexes of this kit conform to standard. Specific performance indexes are as below:
1. Reportable range of the reagent (kit): Range of 1~2000mIU/mL;
2. Linearity range: Linearity of the reagent (kit) is within 1mIU/mL~200mIU/mL, The correlation coefficient (r) of linearity should be≥0.9900;
3. Accuracy: The relative deviation is within ± 15%;
4. Limit of detection: ≤0.5mIU/mL;
5. Repeatability: CV≤15%;
6. HOOK effect: When FSH concentration is ≤3000mIU/mL, there is no HOOK effect.
7. Specificity: LH and TSH are detected under the following concentration conditions and no cross phenomenon occurs.

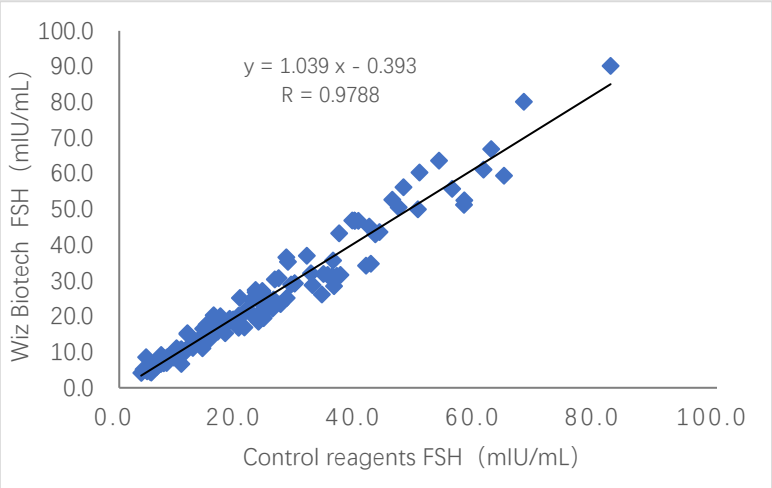
Material	Concentration	Material	Concentration
LH	200 mIU/mL	TSH	200μIU/mL

8. Interfering substance: Following substances are tested at the given concentration with no interference.

Interfering substance	Concentration	Interfering substance	Concentration
Bilirubin	2 mg/mL	Hemoglobin	10.0 mg/mL
Triglyceride	40.0 mg/mL	Rheumatoid factor	1500.0 IU/mL

9. Clinical performance
Clinical evaluation performance of the product is assessed through collecting 150 clinical samples. The results are compared by using the corresponding kit of marketed chemiluminescence method as the reference reagent. Their

comparability is studied by linear regression. The correlation coefficients of the two tests are Y=1.039X-0.393 and R=0.9788, respectively.



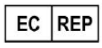
LIMITATION

1. This reagent is only used for testing human whole blood, serum, plasma, and fresh finger terminal blood.
2. Do not agitate the sample. Insert a pipette just below the surface of the sample to collect the specimen.
3. Test shall be carried out at normal room temperature (18℃~25℃).
4. Linearity range of this kit is 1mIU/mL~200mIU/mL. To measure accurate concentration of high-concentration sample that exceeds measurement linearity range of the kit, measurement and calculation should be performed after dilution to within the linearity range of the kit. Under the conditions of normal saline or sample diluents, the maximum dilution multiple of this kit is 10 times and the reportable range is 1~2000mIU/mL
5. Due to low concentration of the analyte, this method cannot detect analyte, this will lead to result deviation.
6. Since some non-specific reactions or other cross reactions cannot be fully studied, false positive results may occur in this test.
7. This test has a low probability of false positive results. Therefore, all positive results must be verified by other method.
8. If the obtained result is questionable, immediately re-test or use other method to test the sample.
9. Test result of this reagent can only be used as an auxiliary means for doctor or other diagnosis. Test result should be combined with other clinical and laboratory data. If test result is not consistent with clinical evaluation, further examination will be required.

LITERATURE REFERENCES

[1] Sowers MR, Zheng H, McConnell D, Nan B, Harlow S, Randolph JF Jr. Follicle stimulating hormone and its rate of change in defining menopause transition stages. J Clin Endocrinol Metab. 2008;93(10):3958-3964.
[2] Randolph JF Jr, Zheng H, Sowers MR, etc. Change in follicle-stimulating hormone and estradiol across the menopausal transition: effect of age at the final menstrual period. J Clin Endocrinol Metab. 2011;96(3):746-754.
[3] Recchia K, Jorge AS, Pessôa LVF, et al. Actions and Roles of FSH in Germinative Cells. Int J Mol Sci. 2021;22(18):10110. Published 2021 Sep 18.

SYMBOLS

Symbol	interpretation	Symbol	interpretation	Symbol	interpretation
	Consult instructions for use		Tests per kit		Manufacturer
	In Vitro Diagnostic Medical Device		Use-by date		Do not re-use
	Store at 2℃～30℃		Catalogue number		Batch code
	Authorized Representative in the European Community		Caution		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