CE IVD

FSH

Fast Test Kit

(Immunofluorescence Assay)

User Manual

REF IF1056 for Getein1100
IF2056 for Getein1600

INTENDED USE

FSH Fast Test Kit (Immunofluorescence Assay) is intended for in vitro quantitative determination of FSH in human serum and plasma. FSH testing is used for women suspected of having polycystic ovary syndrome, and in individuals undergoing evaluation for infertility, also used for evaluation of individuals with suspected pituitary disorders or diseases of the ovaries.

SUMMARY

Follicle stimulating hormone (FSH) is one of the hormones essential to pubertal development and the function of women's ovaries and men's testes. Like other glycoproteins, such as LH, TSH and HCG, FSH consists of subunits designated as alpha and beta. Hormones of this type have alpha subunits that are very similarly structurally, therefore the biological and immunological properties of each are dependent on the unique beta subunit.

In women, this hormone stimulates the growth of ovarian follicles in the ovary before the release of an egg from one follicle at ovulation. FSH levels are elevated after menopause, castration and in premature ovarian failure. In men, FSH stimulates seminiferous tubule testicular growth, and is involved in the early stages of spermatogenesis. Oligospermic males usually have elevated FSH levels. High levels of FSH in men may be found in primary testicular failure and Kinefelter syndrome. Elevated concentrations are also present in cases of starvation, renal failure, hyperthyroidism and cirrhosis.

It is a useful marker in the study of pituitary disease, classification of pituitary tumors and in the differential diagnosis of primary and metastatic tumors of the pituitary.

PRINCIPLE

The test uses an anti-human FSH monoclonal antibody Ⅰ conjugated with fluorescence latex coated on the fluorescent pad and another anti-human FSH monoclonal antibody Ⅱ coated on the test line. After the sample has been applied to the test strip, the fluorescence latex-labelled anti-human FSH antibody Ⅰ binds with the FSH in sample and forms marked antigen-antibody complex. This complex moves to the test card detection zone by capillary action. Then marked antigen-antibody complex is captured on the test line by anti-human FSH antibody Ⅱ. The fluorescence intensity of test line increases in proportion to the amount of FSH in sample.

Then insert test card into Getein1100 Immunofluorescence Quantitative Analyzer/Automatically inserted by Getein1600 Immunofluorescence Quantitative Analyzer (hereafter referred to as Getein1100 and Getein 1600), the concentration of FSH in sample will be measured and displayed on the screen. The value will be stored in Getein1100/Getein1600 and available for downloading. The result can be easily transmitted to the laboratory or hospital information system.

CONTENTS

1. A kit for Getein1100 contains:
Package specifications: 25 tests/box, 10 tests/box
1) Getein FSH test card in a sealed pouch with desiccant
2) Disposable pipet
3) User manual: 1 piece/box
4) SD card: 1 piece/box

2. A kit for Getein1600 contains:
Package specifications: 2×24 tests/box, 2×48 tests/box
1) Sealed cartridge with 24/48 Getein FSH test cards
2) User manual: 1 piece/box

Materials required for Getein1600:
1) Box with pipette tips: 96 tips/box
2) Mixing plate: 1 piece/box

3. A test card consists of:
A plastic shell and a reagent strip which is composed of a sample pad (one end of the membrane is coated with fluorescence latex-labelled anti-human FSH monoclonal antibody Ⅰ), nitrocellulose membrane (test line is coated with another FSH monoclonal antibody Ⅱ and the control line C is coated with rabbit anti-mouse IgG antibody), absorbent paper and liner.

Note: Do not mix or interchange different batches of kits.

APPLICABLE DEVICE

Getein1100 Immunofluorescence Quantitative Analyzer
Getein1600 Immunofluorescence Quantitative Analyzer

STORAGE AND STABILITY

Store the test card at 4~30℃ with a valid period of 24 months. Use the test card for Getein1100 within 1 hour once the foil pouch is opened.

For test card of Getein1600: if the cartridge is opened, it could be stable within 24 hours once exposed to air. If the test cards can't be used up at a time, please put the cartridge back to the foil pouch and reseal along the entire edge of zip-seal. The remaining test cards should be used up within 7 days.

PRECAUTIONS

1. For *in vitro* diagnostic use only.
2. Do not use the kit beyond the expiration date.
3. Do not use the test card if the foil pouch is damaged.
4. Do not open pouches until ready to perform the test.
5. Do not reuse the test card.
6. Do not reuse the pipet.
7. Handle all specimens as potentially infectious. Proper handling and disposal methods should be followed in accordance with local regulations.
8. Carefully read and follow user manual to ensure proper test performance.

SPECIMEN COLLECTION AND PREPARATION

1. This test can be used for ***serum and plasma samples. Heparin, EDTA and sodium citrate*** can be used as the anticoagulant for plasma. Samples should be free of hemolysis.
2. The test should be performed within 4 hours after blood collection.
3. If testing is delayed, serum and plasma samples may be stored up to 7 days at 2~8℃ or stored at -20℃ for 3 months before testing.
4. Refrigerated or frozen sample should reach room temperature and be homogeneous before testing. Avoid multiple freeze-thaw cycles.
5. Do not use heat-inactivated samples or hemolysis samples.
6. SAMPLE VOLUME ***: (for Getein1100):100 µl***.

TEST PROCEDURE

1. Collect specimens according to user manual.
2. Test card, sample and reagent should be brought to room temperature before testing.
   For Getein1100:
3. Confirm SD card lot No. in accordance with test kit lot No.. Perform "SD card" calibration when necessary.

4. Enter testing interface of Getein1100.
5. Remove the test card from the sealed pouch immediately before use. Label the test card with patient or control identification.
6. Put the test card on a clean table, horizontally placed.
7. Using sample transfer pipette, deliver ***100 µl*** of sample into the sample port on the test card.
8. ***Reaction time: 15 minutes.*** Insert the test card into Getein1100 and start test after reaction time is elapsed. The result will be shown on the screen and printed automatically.
   For Getein1600:
9. Each cartridge for Getein1600 contains a specific RFID card which can calibrate automatically.
10. Place the sample diluent at the correct position in Getein1600.
11. Place samples in the designed area of the sample holder, insert the holder and select the right test item, Getein1600 will do the testing and print the result automatically.

Notes:

1. It is required to perform "SD card" calibration when using a new batch of kits.
2. It is suggested to calibrate once for one batch of kits for Getein1100.
3. Make sure the test card and the sample insertion is correct and complete.

TEST RESULTS

Getein1100/Getein1600 can scan the test card automatically and display the result on the screen. For additional information, please refer to the user manual of Getein1100/Getein1600.

Others:

Measuring range of the FSH test kit is 0.20 mIU/mL~150.00 mIU/mL. Dilute the sample which concentration is higher than the upper limit with sample diluent, and the recommended dilution ratio is 2 times.

EXPECTED VALUE

The expected normal value for FSH was determined by testing samples from apparently healthy individuals.

Reference range of FSH:

Group	No.		Reference Range (mIU/mL)
Male	220		1.22-19.25
Female	Mid-follicle	217	3.82-8.74
	Mid-cycle peak	195	4.59-22.59
	Mid-luteal phase	202	1.76-5.14
	Postmenopausal	197	16.01-114.08

It is recommended that each laboratory establish its own expected values for the population it serves.

PERFORMANCE CHARACTERISTICS

Measuring Range	0.20~150.00 mIU/mL
Lower Detection Limit	≤0.20 mIU/mL
Within-Run Precision	≤10%
Between-Run Precision	≤15%

LIMITATIONS

1. As with all diagnostic tests, a definitive clinical diagnosis should not be made based on the result of a single test. The test results should be interpreted considering all other test results and clinical information such as clinical signs and symptoms.
2. Samples containing interferent may influence the results. The table below listed the maximum allowance of these potential interferent.

Interferent	Hemoglobin	Triglyceride	Bilirubin	Human serum albumin
Concentration (Max)	300 mg/dL	20.32 mmol/L	171.0 umol/L	3 g/dL

REFERENCES

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DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on FSH Fast Test Kit (Immunofluorescence Assay) are the most common ones appearing on medical devices and their packaging. They are explained in more details in the European Standard EN ISO 15223-1:2016/ISO 15223-1:2016.

Key to symbols used			
	Manufacturer		Use-by date
	Do not re-use		Date of manufacture
	Consult instructions for use	LOT	Batch code
	Temperature limit	IVD	*In vitro* diagnostic medical device
Σ	Contains sufficient for <n> tests	EC REP	Authorized representative in the European Community
CE	CE mark		Do not use if package is damaged
REF	Catalogue number		

Thank you for purchasing FSH Fast Test Kit (Immunofluorescence Assay).

Please read this user manual carefully before operating to ensure proper use.

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