



# FSH

## Fast Test Kit

### (Immunofluorescence Assay)

IF1056 for Getein 1100  
 IF5056 for Getein 1160  
 IF3056 for Getein 1180  
 IF2056 for Getein 1600  
 IF4056 for Getein 1200

#### Instructions for Use



#### INTENDED USE

FSH Fast Test Kit (Immunofluorescence Assay) is intended for *in vitro* quantitative determination of FSH in human serum and plasma. The test is used as an auxiliary diagnosis for evaluating pituitary endocrine function and ovarian diseases. For professional and laboratory use only.

#### 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 structural-ly, 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 Klinefelter syndrome. Elevated concentrations are also present in cases of starvation, renal failure, hyperthyroidism and cirrhosis.

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

#### PRINCIPLE

FSH Fast Test Kit (Immunofluorescence Assay) is a lateral flow immunoassay designed in a sandwich format. After the sample is applied to the test strip, the fluorescence-labelled FSH monoclonal antibody binds with the FSH in the sample to form a marked antigen-antibody complex. This complex moves to the detection zone on the test card by capillary action and is captured by another FSH monoclonal antibody. The fluorescence intensity of the test line increases in proportion to the amount of FSH in the sample. The fluorescent signal intensity can then be analyzed by an appropriate device to quantitatively detect the FSH in the sample.

#### APPLICABLE DEVICE

Getein 1100 Immunofluorescence Quantitative Analyzer  
 Getein 1160 Immunofluorescence Quantitative Analyzer  
 Getein 1180 Immunofluorescence Quantitative Analyzer  
 Getein 1200 Immunofluorescence Quantitative Analyzer  
 Getein 1600 Immunofluorescence Quantitative Analyzer

#### CONTENTS

Materials provided	Getein 1100/Getein 1160/ Getein 1180		Getein 1200/ Getein 1600	
	10 T/kit	25 T/kit	2*24 T/kit	2*48 T/kit
FSH test card*	10 pcs	25 pcs	24 test cards in 1 cartridge, and 2 cartridges in 1 box	48 test cards in 1 cartridge, and 2 cartridges in 1 box
Disposable pipet	10 pcs	25 pcs	/	/
Instructions for use	1 pc	1 pc	1 pc	1 pc
SD card	1 pc	1 pc	1 pc in each cartridge	1 pc in each cartridge

\* FSH test card  
A test card mainly consists of: Fluorescence-labelled FSH monoclonal antibody, FSH monoclonal antibody, Consumables for Getein 1200/ Getein 1600 - Box with pipette tips (96 tips/box) - Mixing plate (1 piece/box)

#### Note:

- The standard curve data can be written to RFID card in the kit. According to the function of RFID card, we define it as "Standard Curve Data Card", short for "SD Card".
- Do not mix or interchange different batches of kits.

#### STORAGE AND STABILITY

**Realtie stability:**  
 Store the kit at 4~30°C with a valid period of 24 months. The test kits are stable until the expiry date printed on the labels.

#### In-use stability:

-For the test card of Getein 1100/Getein 1160/Getein 1180: Use the test card within 1 hour once the foil pouch is opened.  
 -For test card of Getein 1200/Getein 1600: If the cartridge is opened, it could be stable within 24 hours once exposure to air. The valid period after opening is 7 days, it is recommended to put the cartridge back to the foil bag and reseal along the entire edge of zip-seal if not used up.

#### PRECAUTIONS

- For *in vitro* diagnostic use only.
- Do not use the kit beyond the expiration date.
- Do not use the test card if the foil pouch or the cartridge is damaged.
- Do not open pouches or the cartridge until ready to perform the test.
- Do not reuse the test card or pipet.
- Handle all specimens as potentially infectious. Proper handling and disposal methods should be followed in accordance with local regulations.
- Carefully read and follow instructions for use to ensure proper test performance.

#### SPECIMEN COLLECTION AND PREPARATION

- 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.
- The test should be performed within 4 hours after blood collection.
- If testing is delayed, serum and plasma samples may be stored up to 7 days at 2~8°C or stored at -20°C for 3 months before testing.
- Refrigerated or frozen sample should reach room temperature and be homogeneous before testing. Avoid multiple freeze thaw cycles.
- Do not use heat-inactivated samples or hemolysis samples.
- Sample volume (**Getein 1100/Getein 1160/Getein 1180**): 100 µL.

#### TEST PROCEDURE

- User must carefully read and operate in strict accordance with the instructions for use before testing, otherwise reliable results cannot be guaranteed.
- Test kit and sample should be brought to room temperature before testing.

#### For Getein 1100:

- Confirm SD card lot No. in accordance with test kit lot No.. Perform "SD card" calibration when necessary.
- Select the corresponding "Sample" on the analyzer according to the sample type (see the user manual of analyzer for details).
- Remove the test card from the sealed pouch before use and put the test card on a clean table, horizontally placed.
- Use disposable pipet or pipette to drop 100 µL of sample into the sample well on the test card.
- Reaction time: **15 minutes**. Insert the test card into Getein 1100 and click on "Start" icon after reaction time is elapsed. The result will be shown on the screen and printed automatically.

#### For Getein 1160/Getein 1180:

- Confirm SD card lot No. in accordance with test kit lot No.. Perform "SD card" calibration when necessary.
- Select the corresponding "Sample" on the analyzer according to the sample type (see the instructions of analyzer for details).
- Remove the test card from the sealed pouch immediately before use and put the test card on a clean table, horizontally placed.
- Use disposable pipet or pipette to drop 100 µL of sample into the sample well on the test card.
- Insert the test card into Getein 1160/Getein 1180 **immediately** after sample loading. The analyzer will count down the reaction time (15 minutes) and automatically test the card after reaction time is elapsed. The result will be shown on the screen and displayed automatically.

#### For Getein 1200/Getein 1600:

- Each cartridge for Getein 1200/Getein 1600 contains a specific RFID card which can calibrate automatically.
- Put the consumables at the correct position in Getein 1200/Getein 1600.
- Place samples in the designed area of the sample holder, insert the holder, set parameters (more operational details refer to the user manual of analyzer) and run the instrument. Getein 1200/Getein 1600 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 Getein 1100/Getein 1160/Getein 1180.
3. Make sure the insertion of test card and the sample are correct and complete.

#### TEST RESULTS

Getein 1100/Getein 1160/Getein 1180/Getein 1200/Getein 1600 can scan the test card automatically and display the result on the screen. For additional information, please refer to the user manual of Getein 1100/Getein 1160/Getein 1180/Getein 1200/Getein 1600.

#### 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. Some substances in blood as listed below may interfere with the test and cause erroneous results. The maximum allowance concentration of each is as follows:

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

#### EXPECTED VALUE

The expected normal value for FSH was determined by testing blood 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 determine the applicability of the reference ranges through experimentation and establish their own laboratory-specific reference ranges if necessary.

#### PERFORMANCE CHARACTERISTICS

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

#### REFERENCES

1. Aurore C, Kalyane BN, Justine B, et al. Abnormally Elevated Follicle-Stimulating Hormone(FSH) Level in an Infertile Woman. Case Reports in Endocrinology, 2019, 2019.
2. Passing H, Bablok W, et al. A General regression procedure for method transformation [J]. J Clin Chem Clin Biochem, 1988, 26: 783-790.
3. Souvik SS, Amandeep V, Subeer M. Regulation of Hippo pathway components by FSH in testis [J]. Reproductive Biology, 2019.
4. Mia VG, Julia R, et al. Persistent organic pollutants as predictors of increased FSH: LH ratio in naturally cycling, reproductive age women [J]. Environmental Research 2018,164.
5. Piketty V, Kara E et al. Follicle-stimulating hormone (FSH) activates extracellular signal-regulated kinase phosphorylation independently of beta-arrestin- and dynamin-mediated FSH receptor internalization [J]. Reproductive Biology and Endocrinology 2006, 4(1).

#### 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 15223-1:2021.

Key to symbols used			
	Manufacturer		Use-by date
	Do not re-use		Date of manufacture
	Consult instructions for use or consult electronic instructions for use		Batch code
	Temperature limit		In vitro diagnostic medical device
	Contains sufficient for <n> tests		Authorized representative in the European Community/ European Union
	CE mark		Do not use if package is damaged and consult instructions for use
	Catalogue number		Caution

Thank you for using FSH Fast Test Kit (Immunofluorescence Assay). Please read the instructions for use carefully before operating to ensure proper use. Please report any product problems or adverse events to the below manufacture or authorized representative in the European Community in time.

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