CE IVD

LH

Fast Test Kit

(Immunofluorescence Assay)

User Manual

REF IF1055 for Getein1100
IF2055 for Getein1600

INTENDED USE

LH Fast Test Kit (Immunofluorescence Assay) is intended for in vitro quantitative determination of LH in human serum and plasma. This test is used to determine menopause, pinpoint ovulation and monitor endocrine therapy.

SUMMARY

Luteinizing hormone (LH) is produced in both men and women from the anterior pituitary gland in response to luteinizing hormone-releasing hormone (LH-RH or Gn-RH), which is released by the hypothalamus.
LH is a glycoprotein hormone having two subunits. The alpha subunit is similar to FSH, HCG and TSH. The beta subunit is different from those of the other glycoprotein hormones and confers its biochemical specificity.
In males, LH is also called interstitial cell-stimulating hormone (ICSH). In both males and females, LH secretion is regulated by a balance of positive and negative feedback mechanisms involving the hypothalamic-pituitary axis, the reproductive organs and the pituitary and sex steroid hormones. LH and the other pituitary gonadotropin, FSH, play a critical role in maintaining the normal function of the male and female reproductive sys-tems.
Patients suffering from hypoginadism show increased concen-tration of serum LH. A decrease in steriod hormone production in females is a result of immature ovaries, primary ovarian failure, polycystic ovary disease or menopause. In these cases, LH secretion is not regulated. A similar loss of regulatory hormones occurs in males when the testes develop abnormal-ly or anorchia exists. Increased concentrations of LH may be found in primary testicular failure, Klinefelter syndrome, renal failure, cirrhosis, hyperthyrodism and severe starvation.
LH is a useful marker in determining the homeostasis fertility regulation via the hypothalamic-pituitary-gonadal axis.

PRINCIPLE

The test uses an anti-human LH monoclonal antibody Ⅰ conjugated with fluorescence latex coated on the fluorescent pad and another anti-human LH monoclonal antibody Ⅱ coated on the test line. After the sample has been applied to the test strip, the fluorescence latex-labelled anti-human LH antibody Ⅰ binds with the LH 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 LH antibody Ⅱ. The fluorescence intensity of test line increases in proportion to the amount of LH in sample.
Then insert test card into Getein1100 Immunofluorescence Quantitative Analyzer/Automatically inserted by Getein1600 Immunofluorescence Quantitative Analyzer (hereafter referred to as Getein1100 and Getein1600), the concentration of LH in sample will be measured and displayed on the screen. The value will be stored in Getein1100/Getein1600and 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 LH 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 LH 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 fluores-cence latex-labelled anti-human LH monoclonal antibody Ⅰ), nitrocellulose membrane (test line is coated with another LH 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 st-ored 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 identi -fication.
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 LH 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 LH was determined by testing samples from apparently healthy individuals.

Reference range of LH:

Group	No.		Reference Range (mIU/mL)
Male	221		1.21-8.69
Female	Mid-follicle	210	2.03-11.21
	Mid-cycle peak	188	19.41-103.58
	Mid-luteal phase	211	1.28-12.82
	Postmenopausal	195	11.01-58.99

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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5. 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.
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DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on LH 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
	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 LH Fast Test Kit (Immunofluorescence Assay).

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

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Getein Biotech, Inc.
Add: No.9 Bofu Road, Luhe District, Nanjing, 211505, China
Tel: +86-25-68568508
Fax: +86-25-68568500
E-mail: tech@getein.com.cn overseas@getein.com.cn
Website: www.bio-gp.com.cn

EC REP Lotus NL B.V.
Address: Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.
Tel: +31645171879(English)
+31626669008(Dutch)
E-mail: peter@lotusnl.com