

FSH

Follicle-stimulating Hormone (FIA)

REF: IN027704



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Intended use

The infinosiTM FSH is a fluorescence immunoassay (FIA) for the in vitro quantitative determination of follicle-stimulating hormone (FSH) in Human serum or plasma. For professional use only.

Summary

References¹⁻⁵

FSH (follicle stimulating hormone), together with LH (luteinizing hormone), belongs to the gonadotropin family. FSH and LH regulate and stimulate the growth and function of the gonads (ovaries and testes) synergistically. Like LH, TSH and hCG, FSH is a glycoprotein consisting of two subunits (α - and β -chains). Its molecular weight is approx. 32000 daltons. In women, the gonadotropins act within the hypothalamus-pituitary-ovary regulating circuit to control the menstrual cycle. FSH and LH are released in pulses from the gonadotropic cells of the anterior pituitary. The levels of the circulating hormones are controlled by steroid hormones via negative feedback to the hypothalamus. In the ovaries FSH, together with LH, stimulates the growth and maturation of the follicle and hence also the biosynthesis of estrogens in the follicles. The FSH level shows a peak at mid-cycle, although this is less marked than with LH. Due to changes in ovarian function and reduced estrogen secretion, high FSH concentrations occur during menopause. In men, FSH serves to induce spermatogonium development. Determination of the FSH concentration is used in the elucidation of dysfunctions within the hypothalamus-pituitary-gonads system. The determination of FSH in conjunction with LH is utilized for the following indications: congenital diseases with chromosome aberrations, polycystic ovaries (PCO), amenorrhea (causes), and menopausal syndrome. Depressed gonadotropin levels in men occur in azoospermia.

Test principle

Sandwich principle. Total duration of assay: **15 minutes**

Sample is added to the sample well of the test, then the fluorescence-labeled detector anti-FSH antibody binds to FSH antigen in blood specimen. As the sample mixture migrates on the nitrocellulose matrix of test strip by capillary action, the complexes of detector antibody and LH are captured to anti-FSH antibody that has been immobilized on test strip.

The more FSH antigen is in blood specimen, the more complexes are accumulated on test strip. Signal intensity of fluorescence of detector antibody reflects amount of FSH captured and the instrument for infinosiTM tests shows FSH concentrations in blood specimen.

Reagents

Materials provided

- **Test Cartridge**, 25 pcs, individually packaged
- **ID Chip or QR code of Calibration Curve**, 1 pcs
- **Sample Buffer**, 25 tubes
- **IFU**, 1 copy

Materials required (but not provided)

- infinosiTM FIA analyzer
- FSH control (DiaSino control is recommended)
- Transfer pipette set (100 μ L size)
- Centrifuge (for plasma and serum only)
- Timer

Precautions and warnings

- For in vitro diagnostic use only.
- Carefully follow the instructions and procedures described in this instructions before testing.
- The test cartridge should remain in its original sealed pouch until ready to use. Do not use it if the pouch is damaged or the seal is broken.
- Do not use reagents beyond the labeled expiry date.
- Do not mix or use components from kits with different Lots.
- Don't use Test Cartridge if its Lot does not match with ID Chip that is inserted onto the instrument.
- The infinosiTM FSH should be used only in conjunction with the instrument for infinosiTM tests.
- The tests should be applied by professionally trained staff working in certified laboratories at some remove from the patient and clinic at which the sample is taken by qualified medical personnel.
- infinosiTM FSH assay is single use only. Do not reuse it.

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- The Test Cartridge and instrument for infinosiTM tests should be used away from vibration and magnetic field. During normal usage, the Test Cartridge may generate slight vibration, which should be regarded as normal.
- Use separate clean pipette tips and buffer tubes for different specimens. The pipette tips and detector buffer tubes should be used for one specimen only.
- Do not smoke, eat, or drink in areas in which specimens or kit reagents are handled.
- Blood specimens, used test cartridges, pipette tips and sample buffer tubes are potentially infectious. Proper laboratory safety techniques, handling and disposal methods should be followed in accordance with standard procedures and relevant regulations observed by microbiological hazard materials.
- The results should be interpreted by the physician along with clinical findings and other laboratory test results.

Incident report

Any suspected serious incidents related to this assay shall be immediately reported to DiaSino, DiaSino's Authorized Representative in the EU, and the national competent authorities of the Member States where the users and/or patients are located.

Storage and stability

- Store the test kit at 2-30°C, the stability is up to the expiration date printed on package.
- Test cartridge and sample buffer should be used within 1 hour after opening the pack.

Specimen collection and preparation

- The test can be performed with either serum or plasma.
- Collect serum samples in accordance with correct medical practices.
- Using standard phlebotomy procedure, collect a venipuncture whole blood specimen using a blood collection tube. If collecting plasma use a blood collection tube containing suitable anticoagulant (EDTA recommended).
- Separate the serum/plasma from blood as soon as possible to avoid hemolysis.
- Test should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Specimens may be stored at 2-8°C for up to 3 days. For long-term storage, specimens should be kept below -20°C.

Quality control

- Quality control tests are a part of the good testing practice to confirm the expected results and validity of the assay and should be performed at regular intervals.
- The control tests should be performed immediately after opening a new test lot to ensure the test performance is not altered.
- Quality control tests should also be performed whenever there is any question concerning the validity of the test results.
- Control materials are provided on demand with infinosiTM tests. For more information regarding obtaining the control materials, contact [DiaSino Laboratories Co., Ltd](#) for assistance.

Test setup

- Ensure that the lot number of the cartridge matches that of the sample buffer, and the ID Chip.
- If the sealed cartridge and sample buffer have been stored in refrigerator, place them at room temperature (18-25 °C) at least 30 minutes before measurement.
- Turn on the instrument for infinosiTM tests.
Refer to the 'instrument for infinosiTM tests Operation Manual' for the complete information and operating instructions.

Test procedure

1. Insert ID Chip into the instrument for infinosiTM tests or Scan the QR code to read the calibration curve.
2. Using a pipette to transfer **50 μ L** of sample (Human plasma/serum) to the **sample buffer tube** provided in the kit.
3. Close the lid of the sample mixing tube and mix the sample thoroughly for **5-10 seconds** by tapping or inverting the tube.
4. Pipette out **100 μ L** of **sample mixture** and load it onto the sample well on the cartridge.
5. Leave the sample-loaded cartridge at room temperature for **15 minutes**.
6. Insert the sample-loaded cartridge into the cartridge holder of instrument for infinosiTM tests.
Ensure proper orientation of the cartridge before pushing it all the way inside the cartridge holder.

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- Press **"Test"** button on the instrument for infinosiTM tests.
- Instrument for infinosiTM tests will start scanning the sample-loaded cartridge immediately.
- Read the test result on the display screen of the instrument for infinosiTM tests.
- Print out the testing results when press **"Print"** button on the instrument for infinosiTM tests.

Limitations - interference

- The assay is unaffected by icterus (bilirubin < 1094 µmol/L or < 64 mg/dL), hemolysis (Hb < 0.621 mmol/L or < 1.0 g/dL), lipemia (Intralipid < 1900 mg/dL) and biotin (< 246 nmol/L or < 60 ng/mL).
- Criterion: Recovery within ± 10 % of initial value.
- Samples should not be taken from patients receiving therapy with high biotin doses (i.e. > 5 mg/day) until at least 8 hours
- following the last biotin administration.
- No interference was observed from rheumatoid factors up to a concentration of 2250 IU/mL.
- In rare cases, interference due to extremely high titers of antibodies to analyte-specific antibodies, streptavidin or ruthenium can occur. These effects are minimized by suitable test design.
- For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.

Measuring range

1.0-150 mIU/mL (defined by the lower detection limit and the maximum of the master curve). Values below the lower detection limit are reported as < 1.0 mIU/mL. Values above the measuring range are reported as > 150 mIU/mL.

Lower detection limit

1.0 mIU/mL

The detection limit represents the lowest analyte level that can be distinguished from zero. It is calculated as the value lying two standard deviations above that of the lowest standard (master calibrator, standard 1 + 2 SD, repeatability study, n = 20).

Expected values

Men: 1.1-14.4 mIU/mL

Women:

- Follicular phase: 3.2-12.7 mIU/mL
- Ovulation phase: 4.5-22.8 mIU/mL
- Luteal phase: 1.2-8.9 mIU/mL
- Postmenopause: 22-146 mIU/mL

LH/FSH quotient: Quotients have been calculated from the results obtained with the infinosiTM LH assay and the infinosiTM FSH assay in the samples of healthy women of child-bearing age. The following medians have been calculated:

Follicular phase: 0.89 (n=331)
Luteal phase: 1.15 (n=306)

Each laboratory should investigate the transferability of the expected values to its own patient population and if necessary determine its own reference ranges.

Specific performance data

Representative performance data are given below. Results obtained in individual laboratories may differ.

Precision

Intra-assay

Determined by using 10 tests in the same batch to test with FSH control, CV ≤ 15%

Inter-assay

Determined by using 3 tests in 3 random and continuous batches to test with FSH control, CV ≤ 20%

Method comparison

A comparison of the infinosiTM FSH assay (y) with the Roche Elecsys FSH (x) using clinical samples gave the following correlations:

Number of samples measured: 138

Linear regression

y = 0.9874x + 0.083

r = 0.9855

Analytical specificity

For the monoclonal antibodies used, the following cross-reactivities were found: LH 0.045%, hGH and hCG no cross-reactivity.

Functional sensitivity

1.08 mIU/mL

The functional sensitivity is the lowest analyte concentration that can be reproducibly measured with an intermediate precision CV of ≤ 20 %

Hook effect

There is no high-dose hook effect at FSH concentrations up to 2000 mIU/mL.

References

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- Schmidt-Mathiesen H. Gynäkologie und Geburtshilfe. Schattauer Verlag 1992.
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Symbols

 In vitro diagnostic medical device	 Temperature limit	 Consult instructions for use	 Catalog number
 Batch code	 Date of manufacture	 Use-by date	 Contains sufficient for <n> tests
 Manufacturer	 Do not re-use	 Do not use if package is damaged and consult instructions for use	 European Conformity
 Authorized representative in the European Community			

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