BIO TECHNOLOGY boditech

Hormone

ichroma™ FSH

INTENDED USE

ichroma™ FSH is a fluorescence Immunoassay (FIA) for the quantitative determination of follicle stimulating hormone(FSH) in human serum/ plasma. It is useful as an aid in management and monitoring of concentration of FSH.

For *in vitro* diagnostic use only.

INTRODUCTION

Follicle-stimulating hormone (FSH) is synthesized and secreted by gonadotrophs of the anterior pituitary gland. The alpha subunits of LH, FSH, TSH, and hCG are identical, and contain 92 amino acids. FSH has a beta subunit of 118 amino acids (FSHB), which confers its specific biologic action and is responsible for interaction with the FSH-receptor. FSH regulates the development, growth, pubertal maturation, and reproductive processes of the body. FSH and Luteinizing hormone (LH) act synergistically in reproduction.

The most common reason for high serum FSH concentration is in a female who is undergoing or has recently undergone menopause. High levels of Follicle-Stimulating Hormone indicate that the normal restricting feedback from the gonad is absent, leading to an unrestricted pituitary FSH production. If high FSH levels occur during the reproductive years, it is abnormal. Conditions with high FSH levels include: Premature menopause also known as Premature Ovarian Failure, Poor ovarian reserve also known as Premature Ovarian Aging, Gonadal digenesis, Turner syndrome, Castration, Swyer syndrome, Certain forms of Congenital adrenal hyperplasia (CAH), Testicular failure.

Most of these conditions are associated with subfertility and/or infertility. Therefore high FSH levels are an indication of subfertility and/or infertility.

PRINCIPLE

The test uses a sandwich immunodetection method; the detector antibodies in buffer bind to antigens in the sample, forming antigen-antibody complexes, and migrate onto nitrocellulose matrix to be captured by the other immobilized-antibodies on test strip.

More antigens in the sample will form more antigen-antibody complexes which lead to stronger fluorescence signal by detector antibodies, which is processed by instrument for ichroma™ tests to show FSH concentration in the sample.

COMPONENTS

ichroma™ FSH consists of 'cartridges', 'detection buffer tubes', 'ID chip' and 'instruction for use'.

- The cartridge contains the membrane called a test strip which has anti human FSH at the test line, and chicken IgY at the control line. All cartridges are individually sealed in an aluminum foil pouch containing a desiccant in a box.
- The detection buffer containing anti human FSH-fluorescence conjugate, anti chicken IgY-fluorescence conjugate, bovine serum albumin (BSA) as a stabilizer and sodium azide as a preservative in phosphate buffered saline.
- The detection buffer is pre-dispensed in a tube. All detection buffer tubes are packaged in a Box and further packed in a Styrofoam box with ice-pack for the shipment.

WARNINGS AND PRECAUTIONS

- For in vitro diagnostic use only.
- Follow the instructions and procedures described in this 'Instruction for use'.
- Use only fresh samples and avoid direct sunlight.
- Lot numbers of all the test components (cartridge, detection buffer and ID chip) must match each other.
- Do not interchange the test components between different lots or use the test components after the expiration date, either of which might yield incorrect test result(s).
- Do not reuse cartridges or detection buffer tubes. A cartridge should be used for testing one sample only. A detection buffer tube should be used for processing of one sample only.
- The cartridge should remain sealed in its original pouch until just before use. Do not use cartridge, if pouch is damaged or has already been opened.
- Frozen sample should be thawed only once. For shipping, samples must be packed in accordance with local regulations.
- Allow cartridge, detection buffer and sample to be at room temperature for approximately 30 minutes before use.
- The instrument for ichroma™ tests may generate slight vibration during use.
- Used cartridges, detection buffer tubes and pipette tips should be handled carefully and discarded by an appropriate method in accordance with relevant local regulations.
- An exposure to larger quantities of sodium azide may cause certain health issues like convulsions, low blood pressure and heart rate, loss of consciousness, lung injury and respiratory failure.
- ichroma™ FSH will provide accurate and reliable results subject to the below conditions.
  - **ichroma™ FSH** should be used only in conjunction with instrument for ichroma™ tests.
  - Have to use recommended anticoagulant sample

Recommended anticoagulant
K_2 EDTA, K_3 EDTA, sodium heparin

STORAGE AND STABILITY

Storage condition		
Component	Storage Temperature	Shelf life
Cartridge	4 - 30 °C	20 months
Detection buffer tube	2 - 8 °C	20 months

- After the cartridge pouch is opened, the test should be performed immediately.

LIMITATION OF THE TEST SYSTEM

- The test may yield false positive result(s) due to the cross-reactions and/or non-specific adhesion of certain sample components to the capture/detector antibodies.
- The test may yield false negative result(s) due to the non-responsiveness of the antigen to the antibodies which is most common if the epitope is masked by some unknown components, so therefore not being able to be detected or captured by the antibodies. The instability or degradation of the antigen with time and/or temperature may also cause the false negative result as it makes antigen unrecognizable by the antibodies.
- Other factors may interfere with the test and cause erroneous results, such as technical/procedural errors, degradation of the test components/reagents or presence of interfering substances in the test samples.
- Any clinical diagnosis based on the test result must be supported by a comprehensive judgment of the concerned physician including clinical symptoms and other relevant test results.

MATERIALS SUPPLIED

REF CFPC-35

Components of **ichroma™ FSH**

- Cartridge Box:
  - Cartridge 25
  - ID Chip 1
  - Instruction for Use 1
- Box containing Detection Buffer Tubes
  - Detection Buffer tube 25

MATERIALS REQUIRED BUT SUPPLIED ON DEMAND

Following items can be purchased separately from **ichroma™ FSH**.

Please contact our sales division for more information.

- Instrument for ichroma™ tests
  - **ichroma™ Reader** **REF** FR203
  - **ichroma™ II** **REF** FPRR021
- **Printer** **REF** FPRR007
- **Boditech Hormone Control** **REF** CFPO-95

SAMPLE COLLECTION AND PROCESSING

The sample type for **ichroma™ FSH** is human serum/plasma.

- It is recommended to test the sample within 24 hours after collection.
- The serum or plasma should be separated from the clot by centrifugation within 3 hours after the collection of whole blood. If longer storage is required, e.g. if the test could not be performed within 24 hours, serum or plasma should be immediately frozen below -20 °C. The freezing storage of sample up to 3 months does not affect the quality of results.
- Once the sample was frozen, it should be used one time only for test, because repeated freezing and thawing can result in the change of test values.

TEST SETUP

- Check the contents of ichroma™ FSH: Sealed Cartridges, Detection Buffer Tubes, ID chip and Instruction for use.
- Ensure that the lot number of the cartridge matches that of the detection buffer tube as well as an ID Chip.
- If the sealed cartridge and the detection buffer have been stored in a refrigerator, place them on a clean and flat surface at room temperature for at least 30 minutes before testing.
- Turn on the instrument for ichroma™ tests. (Please refer to the 'Instrument for ichroma™ tests Operation Manual' for complete information and operating instructions.)

TEST PROCEDURE

< Multi mode >

1) Transfer sample 150 µL (Human serum/plasma/control) using a pipette to a detector tube.
2) Close the lid of the detector tube and mix the sample thoroughly by shaking it about 10 times. (The sample mixture must be used immediately within 3 minutes)
3) Pipette out 75 µL of a sample mixture and load it into the sample well on the cartridge.
4) Leave the sample-loaded cartridge at room temperature for 15 minutes before inserting the cartridge into the holder.
   ⚠ *Scan the sample-loaded cartridge immediately when the incubation time is over. If not, it will cause inaccurate test result.*
5) To scan the sample-loaded cartridge, insert it into the cartridge holder of the instrument for ichroma™ tests. Ensure proper orientation of the cartridge before pushing it all the way inside the cartridge holder. An arrow is marked on the cartridge especially for this purpose.
6) Press the 'Select' or Tap the 'START' button on the Instrument for ichroma™ tests to start the scanning process.
7) Instrument for ichroma™ tests will start scanning the sample-loaded cartridge immediately.
8) Read the test result on the display screen of the Instrument for ichroma™ tests.

< Single mode >

1) Transfer sample 150 µL (Human serum/plasma/control) using a pipette to a detector tube.
2) Close the lid of the detector tube and mix the sample thoroughly by shaking it about 10 times. (The sample mixture must be used immediately within 3 minutes)
3) Pipette out 75 µL of a sample mixture and load it into the sample well on the cartridge.
4) Insert the cartridge into the cartridge holder of the instrument for ichroma™ tests. Ensure proper orientation of the cartridge before pushing it all the way inside the cartridge holder. An arrow is marked on the cartridge especially for this purpose.
5) Press the 'Select' or Tap the 'START' button on the Instrument for ichroma™ tests to start the scanning process.
6) Cartridge goes inside the instrument for ichroma™ tests and will start scanning the sample-loaded cartridge after 15 minutes.
7) Read the test result on the display screen of the Instrument for ichroma™ tests.

INTERPRETATION OF TEST RESULT

- Instrument for ichroma™ tests calculates the test result automatically and displays FSH concentration of the test sample in terms of mIU/mL.
- The cut-off (reference range)

	Stage	Range (mIU/mL)
Females	Follicular Phase	3-11
	Mid-Cycle	6-21
	Luteal Phase	1-9
	Postmenopausal	22-153
	Males	1-11

- Working range: 1-100 mIU/mL

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 not provided with **ichroma™ FSH**. For more information regarding obtaining the control materials, contact Boditech Med Inc.'s Sales Division for assistance.
  (Please refer to the instruction for use of control material.)

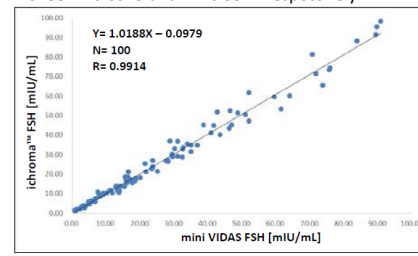
PERFORMANCE CHARACTERISTICS

- **Specificity**
  There, in test samples, are biomolecules such as D-glucose, bilirubin, hemoglobin, cholesterol, L-ascorbic acid, triglyceride mixture and disease related makers such as hCG, LH, TSH, PRL were added to the test sample(s) at concentrations much higher than their normal physiological levels in blood. **ichroma™ FSH** test results did not show any significant cross-reactivity with these biomolecules.

- **Precision**
  The intra-assay precision was calculated by one evaluator, who tested different concentration of control standard twenty times each with three different lots of **ichroma™ FSH.** The inter-assay precision was confirmed by 3 different evaluators with 3 different lots, testing five times each different concentrations.

FSH (mIU/mL)	Intra-assay		Inter-assay	
	Mean	CV (%)	Mean	CV (%)
5	5.05	3.61	5.05	3.45
25	25.75	3.73	25.77	4.02
50	52.32	2.99	52.45	3.16

- **Comparability**
  The FSH concentrations of 100 clinical samples were quantified independently with **ichroma™ FSH** and mini VIDAS (BioMerieux Inc. France) as per prescribed test procedures. Test results were compared and their comparability was investigated with linear regression and coefficient of correlation (R). Linear regression and coefficient of correlation between the two tests were Y= 1.0188X – 0.0979 and R = 0.9914 respectively.



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Note: Please refer to the table below to identify various symbols

	Sufficient for <n> tests
	Read instruction for use
	Use by Date
LOT	Batch code
REF	Catalog number
	Caution
	Manufacturer
EC REP	Authorized representative of the European Community
IVD	In vitro diagnostic medical device
	Temperature limit
	Do not reuse
CE	This product fulfills the requirements of the Directive 98/79/EC on in vitro diagnostic medical devices

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