Hormone

AFIAS LH

INTENDED USE

AFIAS LH is a fluorescence immunoassay (FIA) for the quantitative determination of LH (Luteinizing hormone) in human whole blood/serum/plasma. It is useful as an aid in management and monitoring of determination of evaluating fertility issues, function of reproductive organs (ovaries or testicles), or detection of the ovulation.

For *in vitro* diagnostic use only.

INTRODUCTION

Luteinizing hormone (LH) is produced in both men and women from the anterior pituitary gland in response to gonadotrophin releasing hormone (GnRH), which is released by the hypothalamus. LH, also called interstitial cell-stimulating hormone (ICSH) in men, is a glycoprotein with a molecular weight of approximately 30,000 Da. In women, LH helps regulate the menstrual cycle and egg production (ovulation). The level of LH in a woman's body varies with the phase of the menstrual cycle. It increases rapidly just before ovulation occurs, about midway through the cycle (day 14 of a 28-day cycle). This is called an LH surge together during the monthly menstrual cycle. In men, LH stimulates the production of testosterone, which plays a role in sperm production.

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 a test strip.

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

COMPONENTS

AFIAS LH consists of 'cartridges.'

- Each sealed aluminum pouch contains two cartridges.
- Each cartridge packaged in an aluminum pouch has three components including a cartridge part, detector part and diluent part.
- The cartridge part contains the membrane called a test strip which has anti-LH at the test line, and rabbit IgG at the control line.
- The detector part has a granule containing anti-LH-fluorescence conjugate, anti-rabbit IgG-fluorescence conjugate and sodium azide as a preservative in potassium phosphate buffer.
- The diluent part contains tween 20 and sodium azide as a preservative in CAPSO buffer.

WARNINGS AND PRECAUTIONS

- For *in vitro* diagnostic use only.
- Follow the instructions and procedures described in this 'Instructions for use'.
- Use only fresh samples and avoid direct sunlight.
- Lot numbers of all the test components (cartridge and an 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. A cartridge should be used for testing one sample only.
- The cartridge should remain sealed in its original pouch until just before use. Do not use cartridge, if the 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. Sample with severe hemolysis and/or hyperlipidemia must not be used.
- If the components and/or sample are stored in refrigerator, then allow cartridge and sample to be at room temperature for approximately 30 minutes before use.
- The instrument for AFIAS tests may generate slight vibration during use.
- Used cartridges and pipette tips should be handled carefully and discarded by an appropriate method in accordance with relevant local regulations.
- The cartridge contains sodium azide (NaN_3), and it may cause certain health issues like convulsions, low blood pressure, low heart rate, loss of consciousness, lung injury and respiratory failure. Avoid contact with skin, eyes, and clothing. In case of contact, rinse immediately with running water.
- **AFIAS LH** will provide accurate and reliable results subject to the below conditions.
  - **AFIAS LH** should be used only in conjunction with the instrument for AFIAS tests.
  - Have to use recommended anticoagulant.

Recommended anticoagulant
K_2EDTA, K_3EDTA, Sodium heparin

LIMITATIONS 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 antigens to the antibodies which is the 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 antigens with time and/or temperature may also cause false negative result as it makes antigens 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 in conjunction with clinical symptoms and other relevant test results.

STORAGE AND STABILITY

Storage condition			
Component	Storage Temperature	Shelf life	Note
Cartridge	2 - 30°C	20 months	Unopened
		1 month	Resealed

- Return an unused cartridge to the spare cartridge zipper bag containing the desiccant pack. Reseal along entire edge of zip-seal.

MATERIALS SUPPLIED

REF SMFP-6

Components of **AFIAS LH**

- Cartridge box:
  - Cartridge 24
  - Pipette tip (zipper bag) 24
  - Spare cartridge zipper bag 1
  - ID chip 1
  - Instructions for use 1

MATERIALS REQUIRED BUT SUPPLIED ON DEMAND

Following items can be purchased separately with **AFIAS LH.** Please contact our sales division for more information.

- **Instrument for AFIAS tests**
  - **AFIAS-1** REF FPRR019
  - **AFIAS-3** REF FPRR040
  - **AFIAS-6** REF FPRR020
  - **AFIAS-10** REF FPRR038
- **Boditech Hormone Control** REF CFPO-95
- **Boditech Hormone Calibrator** REF CFPO-107
- **Boditech LH Control** REF CFPO-234
- **Boditech LH Calibrator** REF CFPO-260

SAMPLE COLLECTION AND PROCESSING

The sample type for **AFIAS LH** is human whole blood/serum/plasma.

- It is recommended to test the sample within 24 hours after collection when collected sample is stored at room temperature.
- The samples (serum, plasma) should be separated from the clot by centrifugation within 3 hours after the collection of whole blood.
- The samples (whole blood, serum, plasma) may be stored for a week at 2 - 8°C prior to being tested. If testing will be delayed more than a week, samples should be frozen at -20°C.
- The samples (serum, plasma) stored frozen at -20°C for 3 months showed no performance difference.
- However, the whole blood sample should not be kept in a freezer in any case.
- As a repeated freeze-thaw cycle may affect the test result, do not refreeze previously frozen samples.

TEST SETUP

- Check the components of the **AFIAS LH** as described below. : Cartridges, pipette tips, an ID chip, a spare cartridge zipper bag and an instructions for use.
- If the sealed cartridge has 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 AFIAS tests.
- Empty the tip box.
- Insert the ID chip into the 'ID chip port'.

※ **Please refer to the instrument for AFIAS tests operation manual of instrument for complete information and operating instructions.**

TEST PROCEDURE

▶ **AFIAS-1, AFIAS-3, AFIAS-6**

General mode

1) Insert a cartridge into the cartridge holder.
2) Insert a tip into the tip hole of the cartridge.
3) Select the 'General mode' in the instrument for AFIAS tests.
4) Take 150 µL of sample (whole blood/serum/plasma/control) using a pipette and dispense it into the sample well of the cartridge.
5) Tap the 'Start' button on the screen.
6) The test result will be displayed on the screen after 12 minutes.

▶ **AFIAS-10**

Normal mode

1) Insert a cartridge into the cartridge holder.
2) Insert a tip into the tip hole of the cartridge.
3) Tap the 'Load' button of the bay that holds the cartridge with the tip to read the barcode of the cartridge and please confirm the item name written on the cartridge.
4) Insert the sample tube into the tube rack.
5) Insert the tube rack into the loading part of the sampling station.
6) Tap the 'Start' button on the screen.
7) The test result will be displayed on the screen after 12 minutes.

Emergency mode – General tip

1) The test procedure is same with the 'Normal mode 1) – 3)'.
2) Convert the 'Emergency mode' in AFIAS-10.
3) Select the tip type (general tip) on the screen.
4) Select the sample type (whole blood/serum/plasma) on the screen.
5) Take 150 µL of the sample using a pipette and dispense it into the sample well of the cartridge.
6) Tap the 'Start' button on the screen.
7) The test result will be displayed on the screen after 12 minutes.

INTERPRETATION OF TEST RESULT

- The instrument for AFIAS tests calculates the test result automatically and displays LH concentration of the test sample in terms of mIU/mL.
- Working range : 1 - 100 mIU/mL.
- Reference range

Type		mIU/mL
Males		1.24–8.62
Females	Follicular phase	2.12–10.89
	Mid-cycle	19.18–103.03
	Luteal phase	1.20–12.86
	Postmenopausal	10.87–58.64

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.
- 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 **AFIAS LH**. For more information regarding obtaining the control materials, contact Boditech Med Inc.'s Sales Division for assistance.
  (Please refer to the instructions for use of control material.)

PERFORMANCE CHARACTERISTICS

- **Analytical sensitivity**
  - Limit of Blank (LoB) 0.236 mIU/mL
  - Limit of Detection (LoD) 0.723 mIU/mL
  - Limit of Quantitation (LoQ) 1 mIU/mL

- **Analytical Specificity**
  - Cross-reactivity
    Biomolecules such as below the ones in the table were added to the test sample(s) at concentrations much higher than their normal physiological levels in the blood. **AFIAS LH** test results did not show any significant cross-reactivity with these biomolecules.

Cross-reactants	Concentration
FSH	1,500 mIU/mL
TSH	1,500 mIU/mL
hCG	200,000 mIU/mL
PRL	2,000 ng/mL
Progesterone	2,000 nmol/L

  - **Interference**
    Interferents listed in the following table were added to the test sample at the concentration mentioned below. **AFIAS LH** test results did not show any significant interference with these materials.

Interferents	Concentration
Ascorbic acid	350 µmol/L
Bilirubin	350 µmol/L
Albumin (Protein)	60 g/L
Glucose	120 mg/dL
Triglyceride mixture	500 mg/dL
Hemoglobin	2,000 µg/ml

- **Precision**
  - **Single-site study**
    Repeatability (within-run precision)
    Within-laboratory precision (Total precision)
    Lot to lot precision
    3 Lots of **AFIAS LH** were tested for 21 days. Each standard material was tested 2 times per day. For each test, each material was duplicated.
  - **Between person**
    Three different people tested three lots of **AFIAS LH**, ten times at each concentration of the standard material.
  - **Between site**
    One lot of **AFIAS LH** was tested at three different sites; ten times at each concentration of the standard material.
  - **Between reader**
    One lot of **AFIAS LH** was tested with three different instruments; five times at each concentration of the standard material.

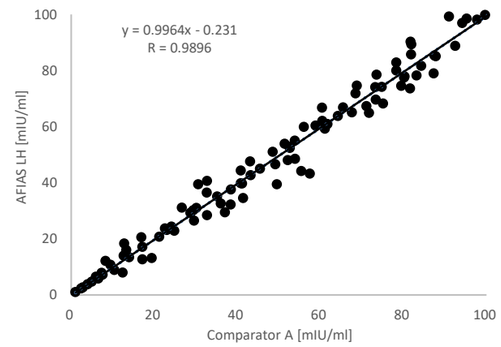
LH [mIU/mL]	Repeatability (within-run)		Total precision (within-laboratory precision)	
	AVG [mIU/mL]	CV (%)	AVG [mIU/mL]	CV (%)
5	5.09	5.4	5.00	6.0
10	10.08	6.0	9.97	5.6
50	50.38	5.2	50.09	5.3
LH [mIU/mL]	Lot to lot precision		Between-person	
	AVG [mIU/mL]	CV (%)	AVG [mIU/mL]	CV (%)
5	5.01	5.8	5.01	6.1
10	10.01	5.7	9.94	5.7
50	50.12	5.5	49.64	6.0

LH [mIU/mL]	Between-site		Between-reader	
	AVG [mIU/mL]	CV (%)	AVG [mIU/mL]	CV (%)
5	4.95	4.8	5.02	5.9
10	9.84	6.1	9.99	5.1
50	49.87	6.2	51.25	6.4

- **Accuracy**
  The accuracy was confirmed by testing with 3 different lots of **AFIAS LH.** The tests were repeated 10 times at each concentration of the control standard.

LH [mIU/mL]	Lot 1	Lot 2	Lot 3	AVG [mIU/mL]	Recovery (%)
1	1.0	1.0	1.0	1.01	101.0
2	2.03	1.97	1.94	1.98	99.0
3	3.04	2.97	3.01	3.01	100.3
4	3.96	3.98	3.97	3.97	99.3
5	4.95	4.99	5.12	5.02	100.4
10	10.23	9.92	10.11	10.09	100.9
30	29.68	30.80	28.93	29.80	99.3
50	50.19	49.35	50.66	50.07	100.1
100	102.26	99.93	100.10	100.76	100.8

- **Comparability**
  LH concentration of 100 clinical samples were quantified independently with **AFIAS LH (AFIAS-6)** and **Comparator A** as per prescribed test procedures. Test results were compared, and their comparability was investigated with linear regression and correlation coefficient (R). The regression equation and correlation coefficient are as follow.



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3. Kosasa T.S., "Measurement of Human Luteinizing Hormone." Journal of Reproductive Medicine, 26 (1981) pg. 203-6.
4. Danzer H., Braunstein G.D., et al., "Maternal Serum Human Chorionic Gonadotropic Concentrations and Fetal Sex Predictions." Fertility and sterility, 34 (1980) pg. 336-40.
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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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