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Hormone

AFIAS Total βhCG

INTENDED USE

AFIAS Total βhCG is a fluorescence Immunoassay (FIA) for the quantitative determination of human chorionic gonadotrophin (Total βhCG) in human whole blood/serum/plasma. It is useful as an aid in management and monitoring of fertility.

For *in vitro* diagnostic use only.

INTRODUCTION

Human chorionic gonadotropin (hCG) is a glycoprotein hormone secreted by the developing placenta shortly after implantation. hCG can be detected in the urine and serum of pregnant women as early as 6 to 15 days after conception. The concentration of hCG increases to 50 mIU/mL one week post implantation and reaches to about 100 mIU/mL at the time of the first missed menstrual period and the peak at 100,000-200,000 mIU/mL at the first trimester.

PRINCIPLE

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

The more antigen in sample forms the more antigen-antibody complex and leads to stronger intensity of fluorescence signal on detector antibody, which is processed by the instrument for AFIAS tests to show total βhCG concentration in sample.

COMPONENTS

AFIAS Total βhCG consists of 'Cartridge', 'Pipette tip', 'ID chip' and 'Instruction for use'.

- Each cartridge packaged in an aluminum pouch has two components, a detector part and cartridge part.
- Cartridge part contains a test strip, the membrane which has anti human hCG at the test line, while streptavidin at the control line.
- Detector part contains anti human hCG-fluorescence conjugate, biotin-BSA-fluorescence conjugate, bovine serum albumin (BSA) as a stabilizer and sodium azide in phosphate buffered saline (PBS) as a preservative.

WARNINGS AND PRECAUTIONS

- For in vitro diagnostic use only.
- Carefully 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 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 misleading of test result(s).
- The cartridge should remain sealed in its aluminum pouch until use. Do not use the cartridge if that is damaged or already opened.
- For shipping, samples must be packed in accordance with the regulations. Sample with severe hemolytic and hyperlipidemia cannot be used and should be recollected.
- Just before use, allow the cartridge and sample to be at room temperature for approximately 30 minutes.
- **AFIAS Total βhCG** as well as the instrument for AFIAS tests should be used away from vibration and/or magnetic field. During normal usage, it can be noted that the instrument for AFIAS tests may produce minor vibration.
- Used pipette tips, and cartridges should be handled carefully and disposed 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.
- **AFIAS Total βhCG** will provide accurate and reliable results subject to the following conditions.
  - Use **AFIAS Total βhCG** should be used only in conjunction with the instrument for AFIAS tests.
  - Any anticoagulants other than **EDTA, heparin** should be avoided.

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. The non-responsiveness of the antigen to the antibodies is most common where the epitope is masked by some unknown components, so as not to be detected or captured by the antibodies. The instability or degradation of the antigen with time and/or temperature may cause the false negative 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.

STORAGE AND STABILITY

- The cartridge is stable for 20 months (while sealed in an aluminum pouch) if stored at 2-8 °C.
- Return an unused cartridge to the spare cartridge zipperbag containing the desiccant pack. Reseal along entire edge of zip-seal. May be stored for up to 1 month at 2-8 °C.

MATERIALS SUPPLIED

REF SMFP-3

Components of **AFIAS Total βhCG**

- Cartridge Box Contains

- Cartridge	24
- Pipette Tip (Zipper bag)	24
- ID Chip	1
- Instruction For Use	1
- Spare Cartridge zipperbag	1

MATERIALS REQUIRED BUT SUPPLIED ON DEMAND

Following items can be purchased separately from **AFIAS Total βhCG**.

Please contact our sales division for more information.

- **AFIAS-1** REF FPRR019
- **AFIAS-6** REF FPRR020
- **Boditech Hormone Control** REF CFPO-95
- **Boditech Hormone Calibrator** REF CFPO-107

SAMPLE COLLECTION AND PROCESSING

The sample type for **AFIAS Total βhCG** is human whole blood/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
- However, the whole blood sample should not be kept in a freezer in any case.
- 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 components of the **AFIAS Total βhCG** as described below. : Cartridge, pipette tip, ID chip and instruction for use
- Keep the sealed cartridge (if stored in refrigerator) at room temperature for at least 30 minutes just prior to the test. Place the cartridge on a clean, dust-free and flat surface.
- 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' for complete information and operating instructions.

TEST PROCEDURE

1) Take 100 µL of sample with a pipette and dispense it into the sample well on the cartridge.
2) Insert the cartridge into the cartridge holder
3) Insert a tip into the tip hole of the cartridge.
4) Tap the 'START' icon on the screen.
5) The test result will be displayed on the screen after 15 minutes.

※ Note: Refer to the instrument for AFIAS test Operation Manual to select a sample type.

INTERPRETATION OF TEST RESULT

- The instrument for AFIAS tests calculate the test result automatically and displays total βhCG concentration of the test sample in terms of mIU/mL.
- The cut-off (Reference value) : 20 mIU/mL
- Total βhCG level during pregnant stage

Pregnant women (week since LMP*)	Total βhCG level [mIU/mL] range
3	5–50
4	5-426
5	18-7,340
6	1,080-56,500
7 – 8	7,650-229,000
9 - 12	25,700-288,000
13 – 16	13,300-254,000
17 – 24	4,060-165,400
25 -40	3,640-177,000

* LMP is the last menstrual periods date from the first day of your last peraiod.

※ The hCG levels different for each person, so the result should be consulted by a doctor about the pregnancy cycle.

※ To confirm the exact pregnancy, retest 2-3 days after the first measurement.

- The working range of the **AFIAS Total βhCG** is 5-50,000 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 **AFIAS Total βhCG**. 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

- **Analytical Sensitivity**

Limit of Blank (LoB)	2.04 mIU/mL
Limit of Detection (LoD)	2.84 mIU/mL

- **Analytical Specificity**
  - Interference
    There was no significant interference from these materials with the **AFIAS Total βhCG** test measurement.

interference material	Concentration
L-Ascorbic Acid	170 µmol/L
Bilirubin (conjugated)	342 µmol/L
Cholesterol	13 mmol/L
Glucose	1,000 mg/dL
Hemoglobin	2 g/L
Triglycerides	37 mmol/L

  - Cross-reactivity
    There was no significant cross-reactivity from these materials with the **AFIAS Total βhCG** test measurement.

cross-reactivity material	Concentration
FSH	1,000 mIU/mL
PRL	100 ng/mL
hTSH	1,000 mIU/mL
LH	1,000 mIU/mL

- Anticoagulant
  There was no significant anticoagulant effect from these materials with the **AFIAS Total βhCG** test measurement

Anticoagulant	Concentration
EDTA	3.4 µmol/L
Heparin	3,000 U/L

■ **Precision**

- Between Lot
  One person tested three different lots of **AFIAS Total βhCG,** ten times at each concentration of the control standard.
- Between Person
  Three different persons tested three different lots of **AFIAS Total βhCG,** ten times at each concentration of the control standard.

Conc. [mIU/mL]	Between-lot		Between-person	
	AVG	CV (%)	AVG	CV (%)
19.6	19.42	7.0	19.80	7.3
5291	5332.17	5.0	5294.11	5.2
10647	10674.41	4.4	10770.58	5.3
45002	45322.66	5.1	45235.22	5.5

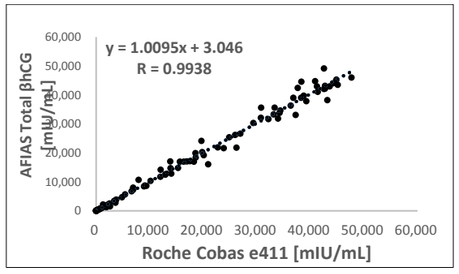
- Between Day
  One person tested **AFIAS Total βhCG** during five days, five times at each concentration of the control standard.
- Between Site
  Three different persons tested **AFIAS Total βhCG** at three different sites, five times at each concentration of the control standard.

Conc. [mIU/mL]	Between-day		Between-site	
	AVG	CV (%)	AVG	CV (%)
19.6	20.05	7.5	19.91	7.2
5291	5245.82	5.2	5301.86	6.6
10647	10736.44	5.4	10593.39	5.4
45002	45028.78	5.5	45108.43	4.9

■ **Accuracy**
The accuracy was confirmed by testing with 3 different lots of **AFIAS Total βhCG**. The tests are repeated 10 times in each different concentration.

conc. [mIU/mL]	Lot 1	Lot 2	Lot 3	Mean	CV (%)	Recovery (%)
19.6	20.21	18.20	18.49	18.97	9.1	96.8
5291.0	5337.7	5326.0	5402.5	5355.4	6.9	101.2
10647.0	10376.2	10986.3	9615.3	10326.0	9.0	97.0
45002.0	43865.7	44978.4	45703.8	44849.3	5.5	99.7

■ **Comparability**
Total βhCG concentration of 100 clinical samples were independently with **AFIAS Total βhCG** and Cobas e411 (Roche Diagnostics Inc. Switzerland) 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=1.0095X +3.046 and R = 0.9938.



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2. Steier JA, P Bergsjo, OL Myking “Human chorionic gonadotropin in maternal plasma after induced abortion, spontaneous abortion and removed ectopic pregnancy”, Obstet. Gynecol. 1984; 64(3): 391-394.
3. Lenton EA, LM Neal, R Sulaiman “Plasma concentration of human chorionic gonadotropin from the time of implantation until the second week of pregnancy”, Fertil. Steril. 1982; 37(6): 773-778.
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Note: Please refer to the table below to identify various symbols.

Σ	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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