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Hormone

# AFIAS Cortisol

## INTENDED USE

**AFIAS Cortisol** is a fluorescence immunoassay (FIA) for the quantitative determination of Cortisol in human whole blood/serum/plasma. It is useful as an aid in management and monitoring of concentration of cortisol.

For *in vitro* diagnostic use only.

## INTRODUCTION

Cortisol is a potent hormone known as a glucocorticoid that affects the metabolism of carbohydrates, proteins, and fats, but especially glucose. Cortisol test is performed on patients who may have malfunctioning adrenal glands. Cortisol level normally rises and falls during the day. It peaks its highest level between 6 and 8 AM and gradually falls, reaching its lowest point around midnight. When cortisol level is measured, blood specimen is usually collected at 8 AM and again at 4 PM. It should be noted that normal values may be adjusted in individuals who have worked during the night and slept during the day for long periods of time.

## PRINCIPLE

The test uses a competitive immunodetection method.

Cortisol in the sample binds to the fluorescence-labeled detector antibodies in buffer, forming the complexes as a sample mixture. They will migrate onto nitrocellulose matrix, which will interfere with the binding of the free fluorescence-labeled detector antibodies to the immobilized-cortisol on the test strip.

More cortisol in the sample will result in less free detection antibodies to accumulate, which lead to less fluorescence signal by the free fluorescence-labeled detector antibodies. The signal is processed by the instrument for AFIAS tests to show cortisol concentration in the sample.

## COMPONENTS

**AFIAS Cortisol** 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 a diluent part.
- The cartridge part contains the membrane called a test strip, which has BSA-human cortisol at the test line, and streptavidin at the control line.
- The detector part has a granule containing anti human cortisol-fluorescence conjugate, biotin-BSA-fluorescence conjugate, bovine serum albumin (BSA) as a stabilizer and sodium azide as a preservative.
- The diluent part contains bovine serum albumin(BSA) as a stabilizer and sodium azide as a preservative in phosphate buffered saline (PBS).

## WARNINGS AND PRECAUTIONS

- For *in vitro* diagnostic use only.
- Follow 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 ID chip) must match each other.
- Do not interchange 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 a 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. Sample with severe hemolysis and/or hyperlipidemia must not be used.
- If test components and/or sample are stored in refrigerator, then allow cartridge and the 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 they may cause certain health issues like convulsions, low blood pressure and 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
- No Biotin interference was observed in **AFIAS Cortisol** when biotin concentration in the sample was below 750 ng/mL. If a patient has been taking biotin at dosage of more than 0.03 mg a day, it is recommended to test again 24 hours after discontinuation of biotin intake.
- **AFIAS Cortisol** will provide accurate and reliable results subject to the below conditions.
  - **AFIAS Cortisol** should be used only in conjunction with the instrument for AFIAS tests.
  - Have to use recommended anticoagulant

| Recommended anticoagulant |
|---|
| $K_2$ EDTA, $K_3$ EDTA, Lithium 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 antigen 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 antigen with time and/or temperature may also cause false negative result as it makes the 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 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 | Unopend |
| | | 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-22

Components of **AFIAS Cortisol**

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

## MATERIALS REQUIRED BUT SUPPLIED ON DEMAND

Following items can be purchased separately from **AFIAS Cortisol.**

Please contact our sales division for more information.

- **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 Cortisol Control** REF CFPO-236
- **Boditech Cortisol Calibrator** REF CFPO-262

## SAMPLE COLLECTION AND PROCESSING

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

- It is recommended to test the sample within 24 hours after collection.
- The sample (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 Cortisol** as described below. : Cartridges, pipette tips, 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 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 100 µL of the 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 10 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 10 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 100 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 10 minutes.

## INTERPRETATION OF TEST RESULT

- The instrument for AFIAS tests calculates the test result automatically and displays cortisol concentration of the test sample in terms of nmol/L.
- Reference range

| Time | Reference range [nmol/L] |
|---|---|
| Morning | 151.58 - 793.38 |
| Midnight | 80 - 473.22 |

- Working range : 80 - 800 nmol/L.
- 1 ng/mL = 2.76 nmol/L (SI unit)

## 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 Cortisol**. 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) 5.26 nmol/L
  - Limit of Detection (LoD) 6.712 nmol/L
  - Limit of Quantitation (LoQ) 80.0 nmol/L

- **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 Cortisol** test results did not show any significant cross-reactivity with these biomolecules.

| Cross reactivity materials | Concentration (nmol/L) |
|---|---|
| Cortisone | 1,000 |
| Corticosterone | 1,000 |
| Progesterone | 100 |
| Prednisone | 100 |
| Testosterone | 1,000 |
| Prednisolone | 100 |
| Deoxycortisol | 100 |
| DHEA | 1,000 |
| Dexamethasone | 2,000 |

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

| interference materials | Concentration |
|---|---|
| D-glucose | 55 mM |
| L-Ascorbic acid | 0.4 mM |
| Bilirubin [unconjugate] | 0.4 mM |
| Hemoglobin (human) | 2 g/L |
| Cholesterol | 13 mM |
| Triglyceride | 37 mg/mL |

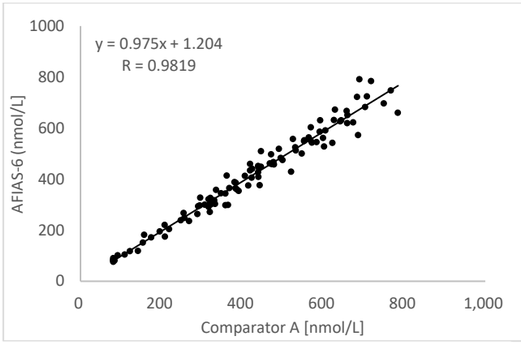
- **Precision**
  - Repeatability (with-run precision)
  - Total precision (within-laboratory precision)
  - Lot to lot precision
    3 Lots of **AFIAS Cortisol** were tested for 21 days. Each standard material was tested 2 times per day. For each test, each material was duplicated.
  - Between person
    Three different persons tested same lot of **AFIAS Cortisol**, ten times at each concentration of the control standard.
  - Between site
    Three different persons tested same lot of **AFIAS Cortisol** at three different sites, ten times at each concentration of the control standard.
  - Between reader
    Three different persons tested same lot of **AFIAS Cortisol** with three different readers, five times at each concentration of the control standard.

| Conc. | Repeatability | | Total precision | |
|---|---|---|---|---|
| [nmol/mL] | AVG | CV(%) | AVG | CV(%) |
| 80 | 80.59 | 5.8 | 80.46 | 5.7 |
| 270 | 270.49 | 5.6 | 268.31 | 5.7 |
| 560 | 648.58 | 5.3 | 652.39 | 5.5 |
| Conc. | Lot to lot precision | | Between person | |
| [nmol/mL] | AVG | CV(%) | AVG | CV(%) |
| 80 | 80.23 | 5.8 | 80 | 5.8 |
| 270 | 269.54 | 6.0 | 268.58 | 5.6 |
| 560 | 653.62 | 5.6 | 649.29 | 6.1 |
| Conc. | Between site | | Between reader | |
| [nmol/mL] | AVG | CV(%) | AVG | CV(%) |
| 80 | 80.28 | 6.1 | 77.16 | 6.8 |
| 270 | 270.53 | 5.7 | 272.72 | 5.7 |
| 560 | 644.98 | 5.7 | 652.82 | 6.4 |

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

| Expected value [nmol/mL] | Lot 1 | Lot 2 | Lot 3 | AVG | Recovery (%) |
|---|---|---|---|---|---|
| 80 | 79.83 | 82.34 | 80.45 | 80.87 | 101.1 |
| 220 | 215.09 | 218.84 | 215.67 | 216.53 | 98.4 |
| 360 | 341.63 | 357.94 | 345.47 | 348.34 | 96.8 |
| 500 | 474.29 | 494.20 | 502.75 | 490.41 | 98.1 |
| 640 | 621.05 | 610.50 | 620.29 | 617.28 | 96.5 |
| 800 | 792.46 | 782.61 | 790.94 | 788.67 | 98.6 |

- **Comparability**
  Cortisol concentrations of 100 clinical samples were quantified independently with **AFIAS Cortisol (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 follows.

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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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