Document No. : INS-CR_F-EN (Rev. 06)
Revision date : December 16, 2016

Infection

AFIAS CRP

INTENDED USE

AFIAS CRP is a fluorescence Immunoassay (FIA) for the quantitative determination of C-Reactive Protein (CRP) in human whole blood/serum/ plasma. It is useful as an aid in management and monitoring of autoimmune diseases and infectious processes, such as rheumatoid arthritis.[1,2]

For *in vitro* diagnostic use only.

INTRODUCTION

The C-Reactive Protein (CRP) is synthesized by the liver in response to interleukin-6 and well known as one of the classical acute-phase reactants and as a marker of inflammation. CRP is the first acute-phase protein to be described and is an exquisitely sensitive systemic marker of inflammation and tissue damage. The acute-phase response comprises the nonspecific physiological and biochemical responses of endothermic animals to most forms of tissue damage, infection, inflammation, and malignant neoplasia. The serum CRP level may rise from a normal level of <5 mg/L to 500 mg/L during the body's general, non-specific response to infectious and other acute inflammatory events. For some time, the measurement of CRP concentration has been used as a clinical tool for monitoring autoimmune diseases and infectious processes, such as rheumatoid arthritis.[1,2]

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 CRP concentration in sample.

COMPONENTS

AFIAS CRP consists of 'Cartridge', 'Pipette tip', 'ID chip', 'Instruction for use' and 'C-tip (On demand)'.

- 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 CRP at the test line, while rabbit IgG at the control line.
- Detector part contains anti human CRP-fluorescence conjugate, anti rabbit IgG-fluorescence conjugate, bovine serum albumin (BSA) as a stabilizer and sodium azide in phosphate buffered saline (PBS) as a preservative.
- C-tip (Capillary tip) is a useful tool for point of care testing which requires a small volume of capillary blood from fingertip, heel site (in infants) or ear-lobe.

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 CRP** 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, C-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 CRP** will provide accurate and reliable results subject to the following conditions.
  - Use **AFIAS CRP** should be used only in conjunction with the instrument for AFIAS tests.
  - Any anticoagulants other than **EDTA, heparin, sodium citrate** should be avoided.
- **C-tip should be used when the following conditions are met.**
  - C-tip provided with the kit is recommended to obtain correct test result.
  - Capillary blood should be immediately tested after collection.
  - Do not leave C-tip after collection of blood, test immediately.
  - Do not perform a test with C-tip on General Mode. It might cause an erroneous result.
  - Excess capillary blood around the C-tip should be wiped off.
  - In order to avoid cross-contamination, please do not re-use C-tip for multiple samples.
  - AFIAS cartridge should be inserted and positioned in the cartridge holder prior to the blood sample collection.

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.

MATERIALS SUPPLIED

REF SMFP-2

Components of **AFIAS CRP**

- Cartridge Box Contains
  - Cartridge 24
  - Pipette tip (Zipper bag) 24
  - ID Chip 1
  - Instruction For Use 1

MATERIALS REQUIRED BUT SUPPLIED ON DEMAND

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

- **AFIAS-1** REF FPRR019
- **AFIAS-6** REF FPRR020
- **Boditech CRP Control** REF CFPO-100
- **Boditech CRP Calibrator** REF CFPO-112
- **C-tip (10 µL)** REF CFPO-91

SAMPLE COLLECTION AND PROCESSING

The sample type for **AFIAS CRP** 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 thawed one time and only for test, because repeated freezing and thawing can result in the changed test values.
- Collection of capillary blood sample using C-tip
  (1) Clean the area with a pre-injection swab.
  (2) Pierce with a sterile lancet.
  (3) Wipe away first drop of blood.
  (4) Gently massage the surrounding area towards a C-tip for a second drop.
  (5) Hold a C-tip horizontally and touch the tip of C-tip to the blood drop.
  (6) Capillary action will automatically draw the blood sample to C-tip and stop
  (7) Wipe off any excess blood around the tip.
  (8) Double-check if capillary blood is fully filled in the C-tip and AFIAS reader is ready for a test on the 'C-tip mode'.

TEST SETUP

- Check the components of the **AFIAS CRP** 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

▶ General Method (with pipette tip)

1) Select "General Mode" in the instrument for AFIAS tests.
2) Take 100 µL of sample with a pipette and dispense it into the sample well on the cartridge.
3) Insert the cartridge into the cartridge holder.
4) Insert a tip into the tip hole of the cartridge.
5) Tap the 'START' icon on the screen.
6) The test result will be displayed on the screen after 3 minutes.

▶ C-tip Method

1) Select "C-tip Mode" in the instrument for AFIAS tests.
2) Insert the cartridge into the cartridge holder.
3) Take 10 µL of whole blood with a C-tip (Please refer to the sample collection.)
4) Insert the whole blood-filled C-tip into the tip hole of the cartridge.
5) Tap the 'START' icon on the screen.
6) The test result will be displayed on the screen after 3 minutes.

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

INTERPRETATION OF TEST RESULT

- The instrument for AFIAS tests calculate the test result automatically and displays CRP concentration of the test sample in terms of mg/L.
- The cut-off (reference value): 10 mg/L
- The working range of the **AFIAS CRP** is 0.5-200 mg/L.

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 CRP**. 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)	0.087 mg/L
Limit of Detection (LoD)	0.138 mg/L
Limit of Quantification (LoQ)	0.5 mg/L

- **Analytical Specificity**
  - **Cross-reactivity**

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

Cross-reactivity material	Standard material conc. (mg/L)		
	10	40	100
	Recovery (%)		
Troponin I (50 µg/mL)	101.70	100.33	97.60
D-Dimer (10 µg/mL)	99.20	97.43	99.26
CK-MB (500 ng/mL)	100.20	99.20	98.92
LDL (1,000 ng/mL)	99.70	100.33	98.68
RF (400 IU/L)	98.8	100.68	100.37

- **Interference**

There was no significant interference from these materials with the **AFIAS CRP** test measurement.

Interference material	Standard material conc. (mg/L)		
	10	40	100
	Recovery (%)		
Bilirubin (20 mg/dL)	101.20	101.48	97.14
BSA (20 mg/dL)	99.70	97.10	100.01
Triglyceride (20 mg/dL)	101.20	100.80	98.73
Hemoglobin (2 g/dL)	102.70	99.80	100.19
Atropine (20 mg/dL)	99.10	101.35	101.39
Glucose (20 mg/dL)	98.80	101.30	98.53

- **Precision**

[Between lot]
One person tested three different lots of **AFIAS CRP**, ten times at each concentration of the control standard.
[Between person]
Three different persons tested three different lots of **AFIAS CRP**; three times at each concentration of the control standard.

CRP Con. (mg/L)	Between lot		Between person	
	Avg.	CV (%)	Avg.	CV (%)
1	1.01	5.4	0.98	5.9
10	10.02	6.0	9.85	6.7
100	99.54	5.1	101.39	5.9

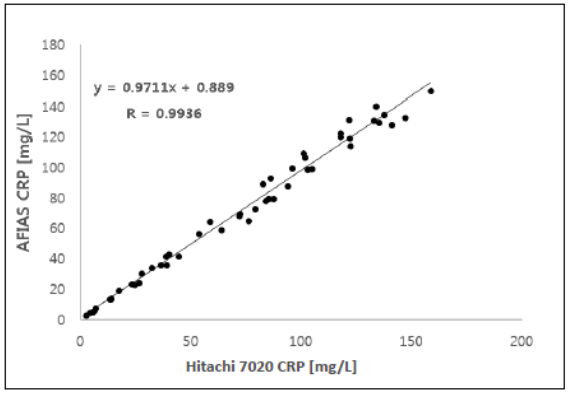
- **Accuracy**

The accuracy was confirmed by 3 different lots testing 10 time each different concentrations.

CRP Con.(mg/L)	Lot 1	Lot 2	Lot 3	AVG	Recovery (%)
1	1.01	1.00	1.01	1.01	101
10	10.21	9.93	9.93	10.01	100
100	102.74	96.35	99.52	99.53	100

- **Comparability**

CRP concentration of 50 clinical samples were independently with **AFIAS CRP** and Hitachi 7020 (HITACHI Ltd. Japan) 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=0.9711X +0.889 and R = 0.9936 respectively.



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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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