Infection

AFIAS Anti-HCV

INTENDED USE

AFIAS Anti-HCV is a fluorescence Immunoassay (FIA) for the qualitative determination of Anti-HCV in human whole blood/serum/plasma. It is useful as an aid to diagnosis of Hepatitis C virus infection.

For *in vitro* diagnostic use only.

INTRODUCTION

Hepatitis C virus (HCV) infection is a worldwide public health problem with a global prevalence of 2-3 %. It is believed that about 170 million people are currently infected (about 3 % of the world's population), and a further 3-4 million are infected each year. HCV is a frequent cause of chronic liver diseases such as hepatitis. HCV is the main reason for liver transplantation in the developed world and, it is primarily transmitted via blood.[1)2)] After 1-3 weeks of acute HCV infection, HCV RNA becomes detectable in blood and rapidly increases. Most infection is asymptomatic (70-80 %) but symptoms including flu-like symptoms, fatigue, vomiting, nausea, right upper quadrant pain, muscle pain, or pruritus may develop within 2-12 weeks. About 50-80 % of HCV infected patients progress to chronic infection. Once it becomes chronic hepatitis, it can cause persistent liver injury without spontaneous recovery leading to cirrhosis and HCC. Most (60-80 %) patients with chronic hepatitis show no symptoms, but some can experience abdominal discomfort, fatigue, nausea, muscle pain, arthritis, or weight loss. Serologic assays testing are needed to confirm HCV infection. Physical examination, treatment and history taking should be done to understand the routes of transmission and block further reinfection. Detection of anti-HCV in serum or plasma is used for screening of a high risk group and for diagnosis of acute or chronic hepatitis C.[3)]

PRINCIPLE

The test uses a sandwich immunodetection method; the detector antibody in buffer bind to antigens in the sample, forming antigen-antibody complexes, and migrates onto nitrocellulose matrix to be captured by the other immobilized-antibodies on the 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 the instrument for AFIAS test to display the 'Positive' / 'Negative' / 'Indeterminate' in the sample.

COMPONENTS

AFIAS Anti-HCV consists of 'cartridge' and 'pipette tips'.

- Each sealed aluminum pouch contains two cartridges.
- Each cartridge packaged in an aluminum pouch has two components including a detector part and cartridge part.
- Cartridge part contains the membrane called a test strip which has recombinant HCV antigen at test line, respectively, while Chicken IgY at the control line.
- Detector part contains recombinant HCV antigen fluorescence conjugate, anti-chicken IgY 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.
- 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 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 aluminum pouch until just before use. Do not use the 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.
- Allow cartridge, detection buffer 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 disposed by an appropriate method in accordance with relevant local regulations.
- It is possible to use frozen samples. Please refer to "SAMPLE COLLECTION AND PROCESSING".
- 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 Anti-HCV** will provide accurate and reliable results subject to the below conditions.
  - **AFIAS Anti-HCV** should be used only in conjunction with the instrument for AFIAS test.
  - Have to use recommended anticoagulant sample.

Recommended anticoagulant
EDTA, K_2EDTA, K_3EDTA, Sodium-heparin, Lithium-heparin, Sodium citrate

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

Components	Storage condition: Storage Temperature	Shelf life	Note
Cartridge	2-8℃	20 months	Unopened
		1 month	Resealed

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

MATERIALS SUPPLIED

REF SMFP-17

Components of **AFIAS Anti-HCV**

- Cartridge Box Contains
  - Cartridge 24
  - Pipette tip (zipper bag) 24
  - Spare cartridge zipper bag 1
  - ID chip 1
  - Instruction for Use 1

MATERIALS REQUIRED BUT SUPPLIED ON DEMAND

Following items can be purchased separately from **AFIAS Anti-HCV**.

Please contact our sales division for more information.

- **AFIAS-1** REF FPRR019
- **AFIAS-6** REF FPRR020
- **Boditech Anti-HCV Control** REF CFPO-143

SAMPLE COLLECTION AND PROCESSING

The sample type for **AFIAS Anti-HCV** 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.
- Samples may be stored for up to a week at 2-8 °C prior to being tested. If testing will be delayed more than a week, serum or plasma sample should be frozen at -20 °C.
- Serum or plasma sample stored frozen at -20 °C for 2 months showed no performance difference.
- 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.

TEST SETUP

- Check the components of the **AFIAS Anti-HCV** as described below. : Cartridges, Pipette tips, ID chip, Spare cartridge zipper bag 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 test.
- Empty the tip box.
- Insert the ID chip into the "ID chip port".
- Please refer to the instrument for AFIAS test 'Operation Manual' for complete information and operating instructions.

TEST PROCEDURE

1) Select 'General Mode' in the instrument for AFIAS test.
2) Take 100 µL of sample with a pipette and dispense it into the sample well in the cartridge.
3) Insert the cartridge into the cartridge holder.
4) Insert a tip in to the tip hole of the cartridge.
5) Input 'Patient ID' and select 'Sample type' into the instrument for AFIAS test.
6) Tap the 'START' icon on the screen.

7) Tap the 'Confirm start' icon on the screen after reconfirmation of 'Patient ID' and 'Sample type'
8) The test results will be displayed on the screen after 12 minutes.

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

INTERPRETATION OF TEST RESULT

- The result of a sample is given as 'Positive' or 'Negative' or 'Indeterminate'.
- And ancillary value is served in the form of a cut-off index (COI).

Cut-off index (COI) Value	Result	Note
≤ 0.90	Negative for Anti-HCV	No need additional test.
> 0.90, < 1.0	Indeterminate	Dilute the clinical sample with suitable diluent (2 times).
≥ 1.0	Positive for Anti-HCV	Need to confirmation test.

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 provided on demand with **AFIAS Anti-HCV**. 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**

- Cut-off

The **AFIAS Anti-HCV** test result indicates 'positive' or 'negative' of a sample defined by the algorithm of AFIAS reader based on COI (cut-off index)

Cut-off index (COI)	Result
COI ≥ 1.0	Positive
0.90< COI < 1.0	Indeterminate
COI ≤ 0.90	Negative

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

Cross-reactivity Materials	
#1	CMV
#2	EBV
#3	HAV
#4	Anti-HBV
#5	HBsAg
#6	HSV
#7	Rubella
#8	VZV
#9	Syphilis
#10	ANA
#11	Rheumatoid factor
#12	Samples of pregnant women

- Interference

Interference materials such as below the ones in the table were added to the test sample(s) the same as the below concentrations. AFIAS Anti-HCV test results did not show any significant interference with these materials.

Interference Materials	
#1	Heparin
#2	EDTA
#3	Sodium citrate
#4	Bilirubin
#5	Hemoglobin
#6	Triglycerides
#7	Cholesterol
#8	BSA

- **Precision**

- Between lots

One person tested three different lots of **AFIAS Anti-HCV**, ten times at each concentration of the control standard.

- Between person

Three different persons tested one lot of **AFIAS Anti-HCV**, five times at each concentration of the control standard.

- Between day

One person tested one lot of **AFIAS Anti-HCV** during three days**,** five times at each concentration of the control standard.

- Between site

One person tested **AFIAS Anti-HCV** at three different site, five times at each concentration of the control standard.

Cal.	Between LOTs		Between person	
	Positive /Sample no.	Positive	Positive /Sample no.	Positive
Negative	0/30	0 %	0/15	0 %
Mid	30/30	100 %	15/15	100 %
Low	30/30	100 %	15/15	100 %

Cal.	Between day		Between site	
	Positive /Sample no.	Positive	Positive /Sample no.	Positive
Negative	0/15	0 %	0/15	0 %
Mid	15/15	100 %	15/15	100 %
Low	15/15	100 %	15/15	100 %

- **Comparability**

HCV test results of 1500 clinical samples were qualitified independently with AFIAS Anti-HCV and Comparator A as per prescribed test procedures.

AFIAS Anti-HCV	Comparator A		
	Negative	Positive	Total
Negative	1090	5	1095 (73.0 %)
Positive	10	395	405 (27.0 %)
Total	1100 (73.3 %)	400 (26.7 %)	1500

- Percent Positive agreement (%) = 395/400 x 100 = 98.8 %
- Percent Negative agreement (%) = 1090/1100 x 100 = 99.1 %
- Overall Percent agreement (%) = (1090 + 395)/1500 x 100 = 99.0 %

REFERENCES

1. HCV infection: pathogenesis, clinical manifestations and therapy. Antonelli A *et al*., *Clin Exp Rheumatol*. 2008 Jan-Feb;26(1 Suppl 48):S39-47
2. Managing occupational risks for hepatitis C transmission in the health care setting. Henderson DK *et al.*, *Clin Microbiol*. Rev. 2003 Jul;16(3):546-68.
3. KASL clinical practice guidelines: management of hepatitis C. Korean Association for the Study of the Liver(KASL) *et al*., *Clin Mol Hepatol*. 2014; 20(2): 89-136.

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
IVD	In vitro diagnostic medical device
	Temperature limit
	Do not reuse

For technical assistance; please contact:
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