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Infection

AFIAS Anti-HBs

INTENDED USE

AFIAS Anti-HBs is a fluorescence Immunoassay (FIA) for the qualitative determination of antibody to Hepatitis B surface antigen (anti-HBs) in human whole blood/serum/plasma. It is useful as an aid to diagnosis of susceptibility to HBV infection or following Hepatitis B virus vaccination.

For *in vitro* diagnostic use only.

INTRODUCTION

Viral hepatitis is a serious global health problem affecting over two billion people worldwide and approximately one million people die each year due to cirrhosis of the liver and hepatocellular carcinoma (HCC), which are commonly associated with chronic hepatitis. The majority of hepatitis viral infections are caused by three distinct virus types: Hepatitis A (HAV), Hepatitis B (HBV) and hepatitis C (HCV). [1, 2] The risk of developing chronic infection by HBV varies inversely with age and is highest for infants infected at birth compared to older children and adults. Up to 90% of infants infected with HBV will develop chronic infection leading to cirrhosis of the liver or HCC compared to 6-10% of adults who acquire HBV infection.[3] Determination of antibodies directed against HBV surface antigen (anti-HBs) is used to evaluate a person's immune status to HBV infection or to aid in the laboratory diagnosis of HBV infection when used in conjunction with other laboratory methods. The test is performed to assess the need for vaccination (if anti-HBs is absent or below levels considered protective), following completion of vaccination against HBV in high risk groups (healthcare workers, Chronic renal failure patients, HIV infected persons), or to monitor recovery from acute HBV infection. The presence of anti-HBs following acute infection generally indicates recovery and immunity from reinfection.

PRINCIPLE

The test uses a sandwich immunodetection method; the detector antibodies in buffer bind to antigens in the sample, forming antigen-antibody complexes, and migrates onto nitrocellulose matrix to be captured by the other immobilized-antigen 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-HBs consists of 'cartridges' and 'pipette tips'.

- Each sealed aluminum pouch contains two cartridges.
- Each cartridge packaged in an aluminum pouch has three components including a detector part, cartridge part and diluent part.
- Cartridge part contains the membrane called a test strip which has recombinant HBsAg at the test lines, while chicken IgY at the control line.
- Detector part contains dried detection buffer and granulated ball. It contains recombinant HBsAg 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.
- Diluent part contains 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 original pouch until just before use. Do not use the 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.
- Allow the cartridge and sample to be at room temperature for approximately 30 minutes before use.
- The instrument for AFIAS test 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.
- 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-HBs** will provide accurate and reliable results subject to the below conditions.
  - **AFIAS Anti-HBs** should be used only in conjunction with the instrument for AFIAS test.
  - Have to use recommended anticoagulant sample.

Recommended anticoagulant
Sodium EDTA, K_2 EDTA, 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(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 antigens. The instability or degradation of the antibody with time and/or temperature may also cause false negative result 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

Storage condition			
Components	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-16

Components of **AFIAS Anti-HBs**

- 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-HBs**.

Please contact our sales division for more information.

- **AFIAS-1** REF FPRR019
- **AFIAS-6** REF FPRR020
- **Boditech Anti-HBs Control** REF CFPO-144

SAMPLE COLLECTION AND PROCESSING

The sample type for **AFIAS Anti-HBs** 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-HBs** as described below. : Cartridge, pipette tip, ID chip, Spare cartridge zipper bag and instruction for use.
- If the sealed cartridge has been stored in a refrigerator, place them on a clean and flat surface at room temperature.
- 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 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 test calculates the test result automatically and displays “Positive”/ “Negative”/ ‘’Indeterminate’’.
- Ancillary value is served in form of ‘mIU/mL’.

Value (mIU/mL)	Result	Note
≤ 5	Negative for anti-HBs	No need to additional test
5 < Titer < 15	Indeterminate	Need to retest
≥ 15	Positive for anti-HBs	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-HBs**. 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) 2.29 mIU/mL
  - Limit of Detection (LoD) 3.71 mIU/mL
  - Cut-off 15 mIU/mL

- **Analytical specificity**
  - **Cross-reactivity**
    There was no cross-reactions with clinical category such as Cytomegalovirus (CMV), Epstein-Barr virus (EBV), Hepatitis A virus (HAV), Hepatitis C virus (HCV), Herpes simplex virus (HSV), Rubella virus, Varicella-zoster virus (VZV), *Treponema pallidum*, Anti Nuclear Antibody (ANA), Rheumatoid factor (RF), and Prenatal tests with the **AFIAS Anti-HBs** test measurement.
  - **Interference**
    Interference materials such as below the ones in the table were added to the test sample(s) the same as the brlow concentrations. AFIAS Anti-HBs test results did not show any significant interference with these molecules.

Materials	Concentration
Heparin	100,000 U/L
EDTA	4 μM
Sodium citrate	25 mg/ml
Hemoglobin	2 mg/mL
BSA	60 mg/mL
Bilirubin	400 μM
Triglycerides	1.5 mg/mL
Cholesterol	20 mM

- **Precision**
  - **Between Lot**
    One person tested three different lots of **AFIAS Anti-HBs**; ten times at each concentration of the control standard.
  - **Between persons**
    Three persons tested one lot of **AFIAS Anti-HBs**; five times at each concentration of the control standard.
  - **Between day**
    One person tested one lot of **AFIAS Anti-HBs** during three days; five times at each concentration of control standard.
  - **Between site**
    One person tested **AFIAS Anti-HBs** at three different site; five times at each concentration of the control standard.

Cal.	Between LOT		Between person	
	Positive /sample number	Positive	Positive /sample number	Positive
Negative	0/30	0 %	0/15	0 %
High	30/30	100 %	15/15	100 %
Mid	30/30	100 %	15/15	100 %
Low	30/30	100 %	15/15	100 %

Cal.	Between site		Between day	
	Positive	Positive /sample number	Positive	Positive /sample number
Negative	0/15	0 %	0/15	0 %
High	15/15	100 %	15/15	100 %
Mid	15/15	100 %	15/15	100 %
Low	15/15	100 %	15/15	100 %

- **Comparability**

		Reference Anti-HBs assay		
		Positive	Negative	Total
AFIAS Anti-HBs	Positive	200	0	200
	Negative	0	300	300
	Total	200	300	500

- Percent positive agreement: 100.0 %
- Percent Negative agreement: 100.0 %
- Overall percent agreement: 100.0 %

REFERENCES

1. The Global Burden of Liver Disease: The Major Impact of China. *Hepatology.* 2014, 60: 2099-2108.
2. Viral hepatitis in resource-limited countries and access to antiviral therapies: current and future challenges. *Future Virol*. 2013, 8: 371–380.
3. Mahoney FJ, et al. Update on diagnosis, management and prevention of hepatitis B virus infection, 1999 Clin Microbiol Rev, 12:351-366.

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

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