GP

IVD

Anti-HBs

Fast Test Kit

(Immunofluorescence Assay)

IF1063 for Getein 1100
IF3063 for Getein 1180
IF2063 for Getein 1600
REF IF5063 for Getein 1160
IF4063 for Getein 1200

Instructions for Use

INTENDED USE

Anti-HBs Fast Test Kit (Immunofluorescence Assay) is intended for in vitro quantitative determination of hepatitis B surface antibody (Anti-HBs) in human serum, plasma and whole blood samples. The test can aid to monitor the recovery of patients with hepatitis B virus (HBV) and evaluate the efficacy of hepatitis B vaccine.

SUMMARY

Anti-HBs is a protective antibody produced by the human immune system after being stimulated by hepatitis B virus surface antigen (HBsAg). It can neutralize the infection of HBV and protect the human body from another attack. The appearance of Anti-HBs and the disappearance of HBsAg indicate that hepatitis B is cured. Therefore, the concentration of Anti-HBs in blood can be used to monitor the recovery of HBV patients. In addition, a large number of studies show that hepatitis B vaccine stimulates the immune system to produce Anti-HBs, which can effectively prevent infection of HBV. Therefore, the monitor of Anti-HBs can also be used to evaluate the efficacy of hepatitis B vaccine.

PRINCIPLE

The test kit adopts a double-antigen sandwich method to quantitatively detect the concentration of Anti-HBs in human serum, plasma and whole blood samples. After the sample has been applied to the test card, the fluorescence latex-labelled HBsAg antigen I binds with Anti-HBs in sample and forms a marked antigen-antibody complex. The complex moves to the detection area by capillary action, then it is captured by HBsAg antigen II coated on the detection area of nitrocellulose membrane, forming a double-antigen complex. Fluorescent signals intensity can be analyzed by applicable device thus the Anti-HBs in sample be detected quantitatively.

CONTENTS

Materials provided	Getein 1100/ Getein 1160/ Getein 1180		Getein 1200/ Getein 1600	
	10 T/kit	25 T/kit	2*24 T/kit	2*48 T/kit
Anti-HBs test card*	10 pcs	25 pcs	24 test cards in 1 cartridge, and 2 cartridges in 1 box	48 test cards in 1 cartridge, and 2 cartridges in 1 box
Disposable pipet	10 pcs	25 pcs	/	/
Sample diluent**	10*0.1 mL/tube	25*0.1 mL/tube	1 box	1 box
Instructions for use	1 pc	1 pc	1 pc	1 pc
SD card	1 pc	1 pc	1 pc in each cartridge	1 pc in each cartridge

* Anti-HBs test card

A test card main consists of: Fluorescence latex-labelled HBsAg antigen, HBsAg antigen and polyclonal IgG antibody.

** Sample diluent

(1)Sample diluent for Getein 1100/ Getein 1160/ Getein 1180 is 0.1 mL contained in each tube consists of:

-Sample diluent main contains phosphate buffer (20 mmol/L), NaN3 (＜0.1%).

(2)Sample diluent for Getein 1200/ Getein 1600 is an independent packing box consists of:

-Sample diluent main contains phosphate buffer (20 mmol/L), NaN3 (＜0.1%) (25 mL/bottle for Getein 1200, 40 mL/bottle for Getein 1600),

-Box with pipette tips (96 tips/box),

-Mixing plate (1 piece/box).

Note:

1. The standard curve data can be written to RFID card in the kit. According to the function of RFID card, we define it as "Standard Curve Data Card", short for "SD Card".
2. Do not mix or interchange different batches of kits.

APPLICABLE DEVICE

Getein1100 Immunofluorescence Quantitative Analyzer
Getein1160 Immunofluorescence Quantitative Analyzer
Getein1180 Immunofluorescence Quantitative Analyzer
Getein1200 Immunofluorescence Quantitative Analyzer
Getein1600 Immunofluorescence Quantitative Analyzer

STORAGE AND STABILITY

Store the test kit at 4~30°C with a valid period of 24 months.

Use the test card for Getein1100/Getein1160/Getein1180 within 1 hour once the foil pouch is opened.

For test card of Getein1200/Getein1600: If the cartridge is opened, it could be stable within 24 hours once exposure to air. Please put the cartridge back to the foil pouch and reseal along the entire edge of zip-seal. The remaining test cards should be used up within 7 days.

PRECAUTIONS

1. For *in vitro* diagnostic use only.
2. For professional use only.
3. Do not use the kit beyond the expiration date.
4. Do not use the test card if the foil pouch or the cartridge is damaged.
5. Do not open pouches or the cartridge until ready to perform the test.
6. Do not reuse the test card.
7. Do not reuse the pipet.
8. Handle all specimens as potentially infectious. Proper handling and disposal methods should be followed in accordance with local regulations.
9. Carefully read and follow instructions for use to ensure proper test performance.

SPECIMEN COLLECTION AND PREPARATION

1. Serum, plasma or whole blood samples can be used for the test. Other body fluids and samples may not give accurate results. Samples should be free of hemolysis.
2. Venous blood should be collected under aseptic conditions; serum or plasma is preferred for testing.
3. Heparin, sodium citrate or EDTA can be used as the anticoagulant for plasma and whole blood samples.
4. The test should be performed at room temperature within 4 hours after sample collection.
5. If testing is delayed, serum and plasma samples may be stored up to 5 days at 2~8°C and 6 months at -20°C before testing. Whole blood samples should not be frozen and can be stored at 2~8°C for 3 days. Do not heat inactivated samples or use hemolyzed blood samples.
6. Refrigerated or frozen sample should be reached to room temperature before testing. Frozen samples must be completely thawed, rewarmed and evenly mixed. Avoid multiple freeze-thaw cycles.
7. Sample volume ***(for Getein1100/Getein1160/Getein1180): 100 μL***

TEST PROCEDURE

1. Collect specimens according to instructions for use.
2. Test card, sample and reagent should reach to room temperature before test.

For Getein 1100:

1. Confirm SD card lot No. in accordance with test kit lot No. Perform “SD card” calibration when necessary.
2. Remove the test card from the sealed pouch immediately before use. Put the test card on a clean table, horizontally placed.
3. Using sample transfer pipette, deliver ***100 μL*** (reach the black scale line of the pipette) of sample into one tube of sample diluent and blow 3-5 times repeatedly. Then drop ***100 μL*** (reach the black scale line of the pipette) of sample mixture into sample well on the test card.
4. ***Reaction time: 15 minutes***. Insert the test card into Getein1100 and click on “Start” icon (for Android Getein1100) after reaction time is elapsed. The result will be shown on the screen and printed automatically.

For Getein 1160/Getein 1180:

1. Confirm SD card lot No. in accordance with test kit lot No. Perform “SD card” calibration when necessary.
2. Enter testing interface of Getein1160/Getein1180.
3. Remove the test card from the sealed pouch immediately before use. Put the test card on a clean table, horizontally placed.
4. Using sample transfer pipette, deliver ***100 μL*** (reach the black scale line of the pipette) of sample into one tube of sample diluent and blow 3-5 times repeatedly. Then drop ***100 μL*** (reach the black scale line of the pipette) of sample mixture into sample well on the test card.

4. Insert the test card into Getein1160/Getein1180 immediately after sample loading. The analyzer will count down the reaction time (15 minutes) and automatically test the card after reaction time is elapsed. The result will be shown on the screen and printed automatically.

For Getein1200/Getein1600:

1. Each cartridge for Getein1200/Getein1600 contains a specific RFID card which can calibrate automatically.
2. Put the sample diluent at the correct position in Getein1200/Getein1600.
3. Place samples in the designed area of the sample holder, insert the holder and select the right test item, Getein1200/Getein1600 will do the testing and print the result automatically.

Notes:

1. It is required to perform “SD card” calibration when using a new batch of kits.
2. It is suggested to calibrate once for one batch of kits for Getein1100/ Getein1160/Getein1180.
3. Make sure the test card and he sample insertion are correct and complete.

TEST RESULTS

Getein1100/Getein1160/Getein1180/Getein1200/Getein1600 can scan the test card automatically and display the result on the screen. For additional information, please refer to the instructions for use of Getein1100/Getein1160/Getein1180/Getein1200/Getein1600.

Others: Measuring range of the Anti-HBs test kit is 10.00 ~ 1000.00 mIU/mL. Dilute the sample which concentration is higher than the upper limit (1000.00 mIU/mL) with sample diluent, and the dilution ration should be less than 10 times.

EXPECTED VALUE

The expected normal value is determined by testing samples from 614 apparently healthy individuals. The upper 99th percentile value is 10.00 mIU/mL.

Due to different methodologies or antibody specificity, there may be deviations in the test results of different manufacturers' reagents, so they should not be directly compared with each other to avoid false medical interpretations.

PERFORMANCE CHARACTERISTICS

1. Measuring Range	10.00-1000.00 mIU/mL
2. Limit of Detection	≤10.00 mIU/mL
3. Within-Run Precision	≤10%
4. Between-Run Precision	≤15%

LIMITATIONS

1. Triglyceride and bilirubin in the sample may interfere with the test results, and the maximum allowable concentrations are 18 g/L and 0.1 g/L respectively.
2. The test results of this kit are for clinical reference only, and should not be used as the sole criteria for clinical diagnosis. It is recommended to conduct a comprehensive analysis on the condition in combination with symptoms/signs, history and other laboratory tests.

REFERENCES

1. Jilg W, Schmidt M, Deinhardt F. Immune Response to Hepatitis B Revaccination. J Med Virol 1988, 24: 377-84.
2. Yuan R, Tang DP, Chai YQ, et al. Ultrasensitive potentiometric immunosensor based on SA and OCA techniques for immobilization of HBsAb with colloidal Au and polyvinyl butyral as matrixes. Langmuir 2004, 20(17): 7240-7245
3. Ostrow, DH, Edwards. B, Kimes, D, et. al. Quantitation of hepatitis B surface antibodies by an automated microparticle enzyme immunoassay. J. Virol. Methods. 1991, 32:265-276
4. Colson P, Borentain P, Motte A, et al. Clinical and virological significance of the co-existence of HBsAg and anti-HBs antibodies in hepatitis B chronic carriers. Virology 2007, 367(1): 30-40

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on the test kit are the most common ones appearing on medical devices and their packaging. They are explained in more details in the European Standard EN ISO 15223-1:2021.

Key to symbols used			
	Manufacturer		Use-by date
	Do not re-use		Date of manufacture
	Consult *instructions for use* or consult electronic *instructions for use*	LOT	Batch code
	Temperature limit	IVD	*In vitro* diagnostic medical device
	Contains sufficient for <n> tests		Do not use if package is damaged and consult *instructions for use*
REF	Catalogue number		

Thank you for purchasing Anti-HBs Fast Test Kit (Immunofluorescence Assay).

Please read this instructions for use carefully before operating to ensure proper use.

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