HCV Rapid Test（Fluorescence Immunoassay）

IVD

INTENDED USE

The HCV Rapid Test is an in vitro immunoassay for the detection of antibodies to hepatitis c virus (HCV) in human serum or plasma on Biotime FIA Analyzer by fluorescent immunoassay. The test is used as an aid detection of Hepatitis C Virus infection.
-Fluorescent immunoassay
-Hepatitis C Virus infection
For in vitro diagnostic use only. For professional use only.

INTRODUCTION

Hepatitis C virus (HCV) is a blood borne virus. 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 primarily transmitted via blood, about 50-80% of HCV infected patients progress to chronic infection. The presence of anti-HCV indicates that an individual may have been infected with HCV, may harbor infectious HCV, and/or may be capable of transmitting HCV infection. Although the majority of infected individuals may be asymptomatic, HCV infection may develop into chronic hepatitis, cirrhosis, and/or increased risk of hepatocellular carcinoma. 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.

PRINCIPLE

This reagent is based on fluorescent lateral flow immunoassay competition method.
HCV antibodies in specimen reacted with detector recombinant HCV antigen labeled with fluorescent microsphere (contain Europium) on the fiberglass, forming antigen-antibody complexes. The complex migrates across the membrane and captured by the other immobilized-recombinant HCV antigen on test strip, and gives fluorescent signal upon stimulation. Thus the fluorescent signals are positively correlated with the concentrations of HCV antibodies. The fluorescent signal will be recorded and calculated according to the calibration curve (provided with the reagents) to represent concentration of HCV antibodies in specimen.

PRECAUTIONS

1. This reagent is used for in vitro diagnosis only, please do not use expired products.
2. All blood samples (including the remaining samples after testing), used reagents and waste should be treated as infectious materials.
3. The reagent is for one-time use. Once the pouch is opened, it should be used within 30 minutes to avoid failure caused by the moisture absorption.
4. While using the test cartridge and instruments, vibration and electromagnetic environment should be avoided.
5. Lot number of buffers and test cartridges must be matched.
6. Do not insert the cartridges that are contaminated with blood or other liquids on the surface. It may cause damages to the instrument.

MATERIAL

Material Provided
The following components are included in the HCV Rapid Test.
Specification and Component
1. For type A reagent

Packing specification				
Catalog No.	Test cartridge	Detection buffer	SD card	Instructions for Use
BT21102	25 tests/kit	25 tubes/kit	1 piece/kit	1 copy/kit

2. For type B reagent

Packing specification				
Catalog No.	Test cartridge	Detection buffer	SD card	Instructions for Use
BT0207901	25 tests/kit	1 panel/25 tests	1 piece/kit	1 copy/kit

3. Main components of the test kits

Main components	Function
HCV fusion antigen 1 labeled with fluorescent microspheres	Applied to the conjugate pad
DNP-BSA labeled with fluorescent microspheres	Applied to the conjugate pad
rabbit anti-DNP antibody	Applied to the nitrocellulose membrane in the control area
HCV fusion antigen 2	Applied to the nitrocellulose membrane in the test area
Other supported test devices	/

Material Required But Not Provided
1. Biotime FIA Analyzer

Applied information	Biotime FIA Analyzer	Applicable model
For type A reagent	Semi-automatic	BIOT-YG-I, FLI-100, FLI-600, FLI-1200
For type B reagent	Automatic	FLI-4000

2. Transfer Pipette Set (5~50μL and 10~100μL size)
3. Specimen collection containers
4. Timer

STORAGE AND STABILITY

1. Store the detection buffer at 2-30℃, and the shelf life is 24 months.
2. Store the test cartridge at 2-30℃, the shelf life is 24 months.
3. For Type A reagent: Test cartridge should be used within 30 min after opening the pouch. For Type B reagent: After opening the packaging bag, place the reagent kit in the instrument and expose it to the air for a cumulative duration of no more than 24 hours. For unused test cards, it is recommended to use the original self sealing packaging bag for sealed storage and use within 7 days.Detection buffer should be used immediately once opening the tube.

SPECIMEN COLLECTION AND PREPARATION

1. The test can be performed with plasma and serum sample using EDTA, immune tube or pro-coagulant tube.
2. The collecting of the sample: The venipuncture for human serum or plasma blood collection method referring to the National Clinical Laboratory Procedures, if the sample can’t be detected timely, it can be stored in refrigerator at 2-8℃ for 6 days，or at -20℃ for 6 months.
3. Separate the plasma or serum from blood as soon as possible to avoid hemolysis.

TEST PROCEDURE

Please refer to the operation manual of Biotime FIA analyzers for details. The test should be operated at room temperature (~25℃).
For Type A reagent
Step 1: Preparation
Check the lot number and insert SD card into the equipment. Take out one tube of buffer from refrigerator and balance it to room temperature.
Step 2: Sampling
Take 40μL of serum with a transfer pipette and add it into the buffer tube.
Step 3: Mixing
Mix well the specimen with buffer by tapping or inverting the tube.
Step 4: Loading
Take 80μL of sample mixture and load it into the well of the test cartridge.
Note: Step 2 to step 4 should be completed within 1 minute to ensure the accuracy of the test results.
Step 5: Testing
Ensure that there are no air bubbles. Immediately insert the test cartridge into analyzer and incubate for 10 minutes.

For Type B reagent
Step 1: Preparation
Check the lot number. Tear the aluminum foil bag, take out the test cartridge and buffer, and put it into the analyzer card slot.
Step 2: Sampling
For Serum or plasma samples, after put the samples to be tested into the analyzer, the analyzer automatically absorbs 40μL samples.
Step 3: Mixing
The instrument automatically adds the sample into the sample buffer, and then fully mixed.
Step 4: Loading
The instrument automatically absorbs 80μL of the above mixed solution into the detection hole of the test cartridge, and moves it to the incubator;
Step 5: Testing
After sample mixture addition, the test cartridge reacts in the incubation tank for 10min, and the analyzer reads the result;
NOTE: Please refer to the operation manual of a specific model of the analyzer for details.

INTERPRETATION OF RESULTS

Negative：COI ＜1.0; Positive：COI ≥1.0

LIMITATIONS OF PROCEDURE

1. The test sample should be serum or plasma.
2. Human anti-mouse antibody (HAMA) may be present in patients who have received immunotherapy with a murine monoclonal antibody. This kit has been specially designed to minimize the effect of these antibodies on the test results. However, the test result must be carefully evaluated when patients are known to have these antibodies [4-5].
3. Other factors also can induce the false results, include the technology, operational error and other sample factors.

PERFORMANCE CHARACTERISTICS

Cut-off value
The detection of enterprise cut-off value positive reference and enterprise cut-off value negative reference, positive conformity rate and negative conformity rate should all be 100%.
LOD
HCV Rapid Test detection limit is 0.2COI.
HOOK
The Hook effect concentration for HCV Rapid Test detection is 18COI.
Clinical
The experiment of 600 cases showed that it had a high correlation with the marketed HCV electrochemiluminescence detection kit .
Positive coincidence rate: the positive coincidence rate of HCV was 100.0% .
Negative coincidence rate: the negative coincidence rate of HCV was99.3%.
The overall coincidence rate of HCV antibody detection was 99.7%.
Precision
Intra-Lot Precision:
a) The positive results are 100% while testing 10 replicates from same lot with positive control.
b) The negative results are 100% while testing 10 replicates from same lot with negative control.
Inter-Lot Precision:
a) The positive results are 100% while testing 10 replicates from 3 continuous lots with positive control.
b) The negative results are 100% while testing 10 replicates from 3 continuous lots with negative control.
Cross-reactivity
There was no false positive result from 121 samples containing

Clinical category		HCV Test results	
		Negative	Positive
CMV	10	10	0
EBV	10	10	0
HAV	10	10	0
HBsAg	10	10	0
HSV	10	10	0
HIV-1	10	10	0
Rubella	10	10	0
VZV	10	10	0
Syphilis	10	10	0
ANA	10	10	0
RF	10	10	0
Early stage of pregnancy	21	21	0
Middle stage of pregnancy	15	15	0
Total	156	156	0

Interference
There was no significant interference from these material with the HCV Rapid Test.

Materials	Concentration
EDTA	5 μM
Bilirubin	0.5 mM/L
Hemoglobin	2 g/L
Triglycerides	1.5 mg/mL
Cholesterol	20 mM
Albumin	60 mg/mL

SYMBOLS

Symbol	Description	Symbol	Description
REF	Catalogue number	IVD	In vitro diagnostic medical device
LOT	Batch code		Consult instructions for use
	Date of manufacture		Keep dry
	Use-by date		Keep away from sunlight
	Manufacturer		Caution
	Do not re-use	2℃ 30℃	Temperature limit is between at 2-30℃
	Do not use if package is damaged	Σ	Contains sufficient for <n> tests

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