IVD

Anti-HCV

Fast Test Kit

(Immunofluorescence Assay)

User Manual

REF IF1057 for Getein1100
IF3057 for Getein1180
IF2057 for Getein1600

INTENDED USE

Anti-HCV Fast Test Kit (Immunofluorescence Assay) is intended for in vitro quantitative determination of hepatitis C virus (HCV) antibody in serum or plasma samples.This test can be used as an aid in the clinical diagnosis, prognosis and evaluation of hepatitis C.

SUMMARY

HCV is spherical, less than 80 nm in diameter (36 to 40 nm in hepatocytes, 36-62 nm in blood), is a single-stranded positive-strand RNA virus, and is surrounded by a lipid-containing capsule in the nucleocapsid. Hepatitis C is a viral hepatitis caused by HCV infection, which is mainly transmitted by blood transfusion, acupuncture and drug use. Hepatitis C is globally prevalent and can cause chronic inflammation, necrosis and fibrosis in the liver. Some patients can develop cirrhosis or even hepatocellular carcinoma. The mortality associated with HCV infection (hepatic failure and death from hepatocellular carcinoma) will continue to increase in the next 20 years, which is extremely harmful to patients' health and life.

HCV has high variability, and there is no effective hepatitis C vaccine available. Therefore, it is particularly important to prevent and control the infection and spread of hepatitis C. As an important hepatitis C marker, HCV antibody is one of the most important diagnostic methods for hepatitis C.

PRINCIPLE

This test uses an human HCV antigen I conjugated with fluorescence latex and another human HCV antigen II coated on the test line. After sample has been applied to the test strip, the fluorescence latex-labelled human HCV antigen I binds with the HCV antibodyin sample and forms marked antigen-antibody complex. The complex moves to the detection zone by capillary action. Then marked antigen-antibody complex is captured on the test line by the anti-human HCV antigen II. The fluorescence intensity of the test line increases in proportion to the amount of HCV antibody in the sample.

Then insert test card into Getein1100/Getein1180 Immunofluorescence Quantitative Analyzer/Automatically inserted by Getein1600 Immunofluorescence Quantitative Analyzer (hereafter referred to as Getein1100, Getein1180 and Getein1600), the concentration of HCV antibody in the sample will be measured and displayed on the screen. The value will be stored in Getein1100/Getein1180/Getein1600 and available for downloading. The result can be easily transmitted to the laboratory or hospital information system.

CONTENTS

1.A kit for Getein1100/Getein1180 contains:

Package specifications: 25 tests/box, 10 tests/box

1) Getein Anti-HCV test card in a sealed pouch with desiccant
2) Disposable pipet
3) Sample diluent
4) User manual: 1 piece/box
5) SD card: 1 piece/box

2. A kit for Getein1600 contains:

Package specifications: 2×24 tests/kit, 2×48 tests/kit

Sealed cartridge with 24/48 Getein Anti-HCV test cards

User manual: 1 piece/box Materials required for Getein1600:

1) Sample diluent: 1 bottle/box
2) Box with pipette tips: 96 tips/box
3) Mixing plate: 1 piece/box

3. Sample diluent composition:

Phosphate buffered saline, proteins, detergent, preservative, stabilizer.

4. A test card consists of:

A plastic shell and a reagent strip which is composed of a sample pad, nitrocellulose membrane (one end of the membrane is coated with fluorescence latex-labeled human HCV antigen I, the test line is coated with another human HCV antigen II, and the control line is coated with streptavidin), absorbent paper and liner.

Note: Do not mix or interchange different batches of kits.

APPLICABLE DEVICE

Getein1100 Immunofluorescence Quantitative Analyzer
Getein1180 Immunofluorescence Quantitative Analyzer
Getein1600 Immunofluorescence Quantitative Analyzer

STORAGE AND STABILITY

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

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

For test card of 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.

Store the sample diluent at 0~30°C with a valid period of 24 months.

PRECAUTIONS

1. For *in vitro* diagnostic use only.
2. Do not use the kit beyond the expiration date.
3. Do not use the test card if the foil pouch is damaged.
4. Do not open pouches until ready to perform the test.
5. Do not reuse the test card.
6. Do not reuse the pipet.
7. Handle all specimens as potentially infectious. Proper handling and disposal methods should follow by local regulations.
8. Carefully read and follow the user manual to ensure an appropriate test performance.

SPECIMEN COLLECTION AND PREPARATION

1. This test can be used for ***serum and plasma samples. Heparin, sodium citrate and EDTA*** can be used as the anticoagulant for plasma. Samples should be free of hemolysis.
2. The test should be performed within 4 hours after blood collection.
3. If testing will be delayed, serum and plasma samples may be stored up to 5 days at 2~8°C or stored at -20°C for 6 months before testing.
4. Refrigerated or frozen sample should be reached to room temperature and be homogeneous before testing. Avoid multiple freeze-thaw cycles.
5. Do not use heat-inactivated or hemolysis samples.
6. SAMPLE VOLUME(for Getein1100/Getein1180): ***100 µL***

TEST PROCEDURE

1. Collect specimens according to user manual.
2. Test card, sample and reagent should reach to room temperature before testing.

For Getein1100:

3. Confirm SD card lot No. in accordance with test kit lot No. Perform “SD card” calibration when necessary.
4. Remove the test card from the sealed pouch immediately

before use. Label the test card with patient or control identification.

5. Put the test card on a clean table, horizontally placed.
6. Using sample transfer pipette, deliver ***100 μL*** of sample into one tube of sample diluent and mix thoroughly. Then drop ***100 μL*** of sample mixture into sample port on the test card.
7. ***Reaction time: 15 minutes.*** Insert the test card into Getein 1100 and click on "Start" icon after reaction time is elapsed. The result will be shown on the screen and printed automatically.

For Getein1180:

8. Confirm SD card lot No. in accordance with test kit lot No. Perform "SD card" calibration when necessary.
9. Enter testing interface of Getein1180.
10. Remove the test card from the sealed pouch immediately before use. Label the test card with patient or control identification.
11. Put the test card on a clean table, horizontally placed.
12. Using sample transfer pipette, deliver ***100 μL*** of sample into one tube of sample diluent and mix thoroughly. Then drop ***100 μL*** of sample mixture into sample port on the test card.
13. ***Reaction time: 15minutes.*** Insert the test card into Getein 1180 immediately after sample loading. The analyzer will count down the reaction time and automatically test the card after reaction time is elapsed. The result will be shoe on the screen and printed automatically.

For Getein1600:

14. Each cartridge for Getein1600 contains a specific RFID card which can calibrate automatically.
15. Put the sample diluent at the correct position in Getein1600.
16. Place samples in the designed area of the sample holder, insert the holder and select the right test item, 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/Getein1180.
3. Make sure the test card and the sample insertion is correct and complete.

TEST RESULTS

1. Getein1100/Getein1180/Getein1600 can scan the test card automatically and display the result on the screen. For additional information, please refer to the user manual of Getein1100/ Getein1180/Getein1600.
2. Samples with concentration<1.00 S/CO are considered negative and no further testing is required.
3. Samples with concentration≥1.00 S/CO are considered positive. All positive samples that are initially tested should be retested twice. If both retests are negative, the sample must be considered Anti-HCV negative. If any of the retest values are positive, it is considered Anti-HCV positive.
4. Due to different methodologies or antibody specificity, there may be deviations between the test results of different manufacturers, so they can't be compared directly.

EXPECTED VALUE

The expected normal value for HCV antibody was determined by testing 400 HCV-positive and 400 HCV-negative serum samples.The reference range of Anti-HCV is <1.00 S/CO by statistical analysis.

It is recommended that each laboratory establish its own expected values for the population it serves.

PERFORMANCE CHARACTERISTICS

1. Measuring Range 1.00-20.00 S/CO
2. Lower Detection Limit ≤1.00 S/CO
3. Within-run Precision ≤10%
4. Between-run Precision ≤15%

LIMITATIONS

As with all diagnostic tests, a definitive clinical diagnosis should not be made based on the result of a single test. The test results should be interpreted considering all other test results and clinical information such as clinical signs and symptoms.

REFERENCES

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3. Ge DL, Fellay J, Thompson AJ, et al. Genetic variation in IL28B predicts hepatitis C treatment-induced viral clearance. Nature 2009, 461 (7262): 399-401
4. WakitaT, Pietschmann T, Kato T, et al. Production of infectious hepatitis C virus in tissue culture from a cloned viral genome. Nature Medicine 2005, 11 (7): 791-796
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DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on Anti-HCV Fast Test Kit (Immunofluorescence Assay) are the most common ones appearing on medical devices and their packaging. They are explained in more details in the European Standard EN ISO 15223-1:2016.

Key to symbols used			
	Manufacturer		Use-by date
	Do not re-use		Date of manufacture
	Consult 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
REF	Catalogue number		

Thank you for purchasing Anti-HCV Fast Test Kit (Immunofluorescence Assay). Please read this user manual carefully before operating to ensure proper use.

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