Portable Medical Diagnostic Test Kits Fast Detection Hepatitis C HCV Rapid Test Kit

Our Product Introduction

Basic Information

- Place of Origin: China
- Brand Name: DVOT
- Certification: CE/BfArM/ PEI
- Model Number: HCV
- Minimum Order Quantity: 1250Test
- Price: 0.17~0.18USD per Test
- Packaging Details: Each boxes 25tests
- Delivery Time: 5-8 Working days
- Payment Terms: T/T, Western Union
- Supply Ability: 1000000pcs

Product Specification

- Product Name: HCV Rapid Test
- Formats: Cassette
- Reaction Time: 10-15 Minutes
- Shelf Life: 24 Months At Room Temperature 4- 30 Degrees
- Others: The Kits Can Be Made According To The Customers' Artwork Or Design
- Time Of Use: Disposable
- Highlight: **Portable Medical Diagnostic Test Kits**, **Medical Diagnostic Test Kits Fast Detection**, **HCV Hepatitis C Rapid Test Kit**

Convenient To Use, Efficient And Fast Detection Of Hepatitis C Virus

The HCV Rapid Test Device (Whole Blood /Serum/Plasma) is a rapid visual immunoassay for the qualitative presumptive detection of antibodies to HCV in human whole blood, serum or plasma specimens. This kit is intended to be used as an aid in the diagnosis of HCV infection.

Detection Principle

The HCV Rapid Test Device (Whole Blood /Serum/Plasma) has been designed to detect antibodies to HCV through visual interpretation of color development in the internal strip. The membrane was immobilized with protein A on the test region. During the test, the specimen is allowed to react with colored recombinant HCV antigens colloidal gold conjugates, which were precoated on the sample pad of the test. The mixture then moves on the membrane by a capillary action, and interacts with reagents on the membrane. If there were enough HCV antibodies in specimens, a colored band will from at the test region of the membrane. Presence of this colored band indicates a positive result, while its absence indicates a negative result. Appearance of a colored band at the control region serves as a procedural control. This indicates that proper volume of specimen has been added and membrane wicking has occurred.

SPECIMEN COLLECTION AND STORAGE

The HCV Rapid Test device (Whole Blood/Serum/ Plasma) can be performed using whole blood (from venipuncture or fingerstick), serum, or plasma.
To collect Fingerstick Whole Blood specimens:

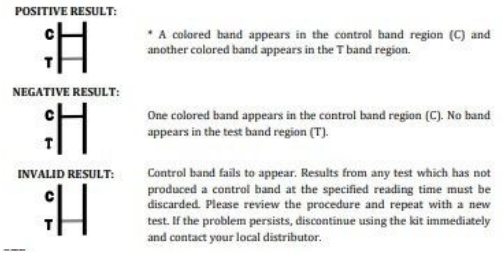
Wash the patient's hand with soap and warm water or clean with an alcohol swab. Allow to dry.
Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.
Puncture the skin with a sterile lancet. Wipe away the first sign of blood.
Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site.

Add the Fingersitck Whole Blood specimen to the test device by using a capillary tube:
Touch the end of the capillary tube to the blood until filled to approximately 50 µl. Avoid air bubbles.
Place the bulb onto the top end of the capillary tube, then squeeze the bulb to dispense the whole blood onto the specimen well (S) of the test device.
Add the Fingersitck Whole Blood specimen to the test device by using hanging drop:
Position the patient's finger so that the drop of blood is just above the specimen well (S) of the test device.
Allow 2 hanging drops of fingerstick whole blood to fall onto the specimen well (S) of the test device, or move the patient's finger so that the hanging drop touches the specimen well (S). Avoid touching the finger directly to the specimen well (S).
Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens.
Testing should be performed immediately after specimen collection. Do not leave the specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2- 8°C for up to 3 days. For long term storage, specimens should be kept below -20°C. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 2 days of collection. Do not freeze whole blood specimens. Whole blood collected by fingerstick should be tested immediately. Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
If specimens are to be shipped, they should be packed in compliance with federal regulations covering the transportation of etiologic agents.

PROCEDURE

Bring tests, specimens, buffer and/or controls to room temperature (15-30°C) before use.
1. Remove the test from its sealed pouch, and place it on a clean, level surface. Label the device with patient or control identification. To obtain a best result, the assay should be performed within one hour.
2. For S**erum or Plasma specimen**: Hold the dropper vertically and transfer 2 drops of serum or plasma (approximately 50 µl) and 1 drop buffer to the specimen well (S) of the test device, and start the timer.
For **Venipuncture Whole Blood** specimen: Hold the dropper vertically and transfer 2 drops of venipuncture whole blood (approximately 50 µl) to the specimen well (S) of the test device, then add 2 drops of buffer and start the timer.
For **Fingerstick Whole Blood** specimen:
To use a capillary tube: Fill the capillary tube and transfer approximately 50 µl of fingerstick whole blood specimen to the specimen well (S) of the test device, then add 2 drops of buffer and start the timer.
To use hanging drop: Allow 2 hanging drop of fingerstick whole blood specimen (approximately 50 µl) to fall into the center of the specimen well (S) on the test device, then add 2 drops of buffer and start the timer.
3. Wait for the red line(s) to appear. The result should be read at 10 minutes. Do not interpret the result after 20 minutes.

INTERPRETATION OF RESULTS



NOTE:

The intensity of the color in test region (T) may vary depending on the concentration of aimed substances present in the specimen. Therefore, any shade of color in the test region should be considered positive. Besides, the substances level can not be determined by this qualitative test.

Insufficient specimen volume, incorrect operation procedure, or performing expired tests are the most likely reasons for control band failure

LIMITATIONS OF THE TEST

Internal procedural controls are included in the test. A colored band appearing in the control region (C) is considered an internal positive procedural control. It confirms sufficient specimen volume and correct procedural technique.

External controls are not supplied with this kit. It is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

Preservation and stability of products

The kit should be stored at 2-30°C until the expiry date printed on the sealed pouch.

The test must remain in the sealed pouch until use.

Do not freeze.

Cares should be taken to protect components in this kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipments, containers or reagents can lead to false results.

KIT COMPONENTS

Disposable pipettes For adding specimens use.
Buffer Phosphate buffered saline and preservative
Package insert For operation instruction
Individually packed test devices Each device contains a strip with colored conjugates and reactive reagents pre-spreaded at the corresponding regions.

MATERIALS REQUIRED BUT NOT PROVIDED

Specimen collection container For specimens collection use.
Lancets For fingerstick whole blood only
Disposable heparinized capillary tubes and dispensing bulb For fingerstick whole blood only
Timer For timing use.
Centrifuge For preparation of clear specimens

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