Accu-Screen HCV Rapid Test Device (Serum/Plasma/Whole blood) Package Insert

A rapid test for qualitative detection of Hepatitis C Virus antibodies in Human Serum, Plasma or Whole Blood.
For professional in vitro diagnostic use only.

INTENDED USE

The HCV Rapid Test Device (Serum/Plasma/Whole blood) is a rapid chromatographic immunoassay for the qualitative detection of antibodies to Hepatitis C Virus (HCV) in Whole Blood/Serum/Plasma to aid in the diagnosis of Hepatitis C Virus infection

SUMMARY

Hepatitis C virus (HCV) now is recognized as a major agent of chronic hepatitis,transfusion acquired non-A,non-B hepatitis and liver disease throughout the world.HCV is an enveloped positive-sense,single-stranded RNA virus.Clinical diagnostic issues related to HCV is the detection of HCV antibodies in human serum,plasma or whole blood by immunoassay.We have constructed HCV genes for the expression of recombinant antigens in bacterium systems such as E.coli and focused on structural and non-structural regions of HCV-encoded polyprotein, which are definitely immunogenic.The major immunoreactive antigens of these proteins have been reported as core,NS3,NS4 and NS5 regions of HCV genome,which are known to be highly immunodominant regions. For diagnosis of HCV infection,these recombinant proteins were used as capture materials of a immunochromatographic (rapid) test.Compared to the first generation HCV test using single recombinant antigens, multiple antigens using recombinant proteins have been added in new serologic tests to avoid nonspecific cross-activity and to increase the sensitivity of the HCV antibody test.

PRINCIPLE

The HCV Rapid Test Device (Serum/Plasma/Whole blood) is a qualitative membrane strip based immunoassay for the detection of HCV antibodies in Whole Blood/Serum/Plasma.In this test procedure,recombinant HCV antigen is immobilized in the test line region of the device. After a Whole Blood/Serum/Plasma specimen is placed in the specimen well,it reacts with HCV antigen coated particles that have been applied to the specimen pad.This mixture migrates chromatographically along the length of the test strip and interacts with the immobilized HCV antigen. If the specimen contains HCV antibodies, a colored line will appear in the test line region indicating a positive result. If the specimen does not contain HCV antibodies,a colored line will not appear in this region indicating a negative result. To serve as a procedural control, a colored line will always appear at the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

REAGENTS

The test device contains recombinant HCV antigen conjugated colloid gold and HCV antigen coated the membrane.

PRECAUTIONS

- For professional in vitro diagnostic use only. Do not use after expiration date.
- The test must remain in the sealed pouch until use.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Do not use test if pouch is damaged.
- Handle all specimens as if they contain infectious agents.Observe established precautions against microbiological hazards throughout the testing and follow standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats,disposable gloves and eye protection when specimens are being tested.
- Standard personal hygiene measures should be taken in the case of ingestion or direct eye contact with the buffer.
- The used test should be discarded according to local regulations.
- Humidity and temperature can adversely affect results.

STORAGE AND STABILITY

Store as packaged in the sealed pouch either at room temperature or refrigerated (2-30°C). The test is stable through the expiration date printed on the sealed pouch.The test must remain in the sealed pouch until use.**DO NOT FREEZE.**Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

- The HCV Rapid Test Device (Serum/Plasma/Whole blood) 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 Fingerstick Whole Blood specimen to the test by using **a capillary tube**:
    - Touch the end of the capillary tube to the blood until filled to approximately 75µl. Avoid air bubbles.
    - Place the bulb onto the top end of the capillary tube,then squeeze the bulb to dispense the whole blood to the specimen area of the test Device.
  - Add the Fingerstick Whole Blood specimen to the test by using **hanging drops:**
    Position the patient's finger so that the drop of blood is just above the specimen area of the test Device.
    - Allow 3 hanging drops of fingerstick whole blood to fall into the center of the specimen area on the test Device,or move the patient's finger so that the hanging drop touches the center of the specimen area. Avoid touching the finger directly to the specimen area.
- 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 the specimens have been collected.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 1 day 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 local regulations covering the transportation of etiologic agents.

MATERIALS

Materials provided

- Test Device
- Buffer
- Droppers
- Package insert

Materials required but not provided

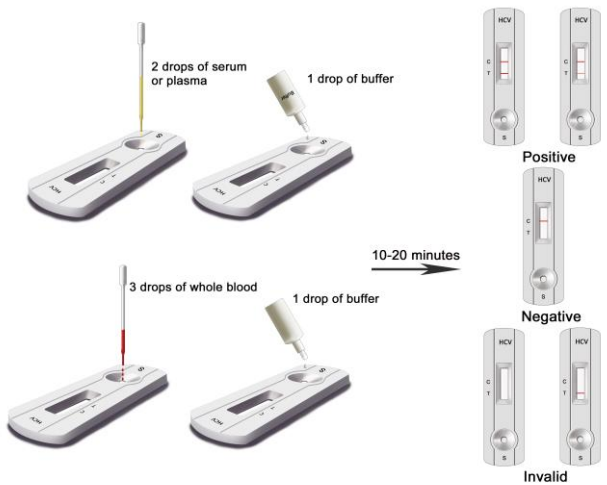
- Specimen collection containers
- Timer
- Heparinized capillary tubes and dispensing bulb
- Centrifuge(For plasma only)
- Lancets(For fingerstick whole blood)

DIRECTIONS FOR USE

Allow the test, specimen, buffer and/or controls to reach room temperature (15-30°C) prior to testing.

1. Bring the pouch to room temperature before opening it.Remove the test Device from the sealed pouch and use it as soon as possible.
2. Place the Device on a clean and level surface.
- For **Serum or Plasma specimen:**
  Hold the dropper vertically and transfer 2 drops of serum or plasma (approximately 50µl) to the specimen area,then add 1 drop of buffer (approximately 40µl),and start the timer.See illustration below.
- For **Venipuncture Whole Blood specimen:**
  Hold the dropper vertically and transfer 3 drops of whole blood (approximately 75µl) to the specimen area,then add 1 drop of buffer (approximately 40µl),and start the timer.See illustration below.
- For **Fingerstick Whole Blood specimen:**
  - To use a capillary tube:Fill the capillary tube and transfer approximately 75µl of fingerstick whole blood specimen to the specimen area of test Device,then add 1 drop of buffer (approximately 40µl) and start the timer. See illustration below.
  - To use hanging drops:Allow 3 hanging drops of fingerstick whole blood specimen(approximately 75µl) to fall into the specimen area of test Device,then add 1 drop of buffer (approximately 40µl) and start the timer.

3. Wait for the colored line(s) to appear.**Read results at 10 minutes.**Do not interpret the result after 20 minutes.



INTERPRETATION OF RESULTS

(Please refer to the illustration above)

POSITIVE:*Two distinct colored lines appear. One line should be in the control line region (C) and another line should be in the test line region (T).
***NOTE:**The intensity of color in the test line region (T) will vary depending on the concentration of HCV antibody present in the specimen.Therefore,any shade in the test region indicates positive result.
NEGATIVE: One colored line appears in the control line region (C). No apparent colored line appears in the test line region (T).
INVALID: No line appears in the control line region (C). If this occurs,read the directions again and repeat the test with a new test.If the result is still invalid,stop using the test kit immediately and contact your local distributor.

QUALITY CONTROL

A procedural control is included in the test. A colored line appearing in the control line region (C) is considered an internal procedural control.
Control standards are not supplied with this kit; however 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.

LIMITATIONS

1. The HCV Rapid Test Device (Serum/Plasma/Whole blood) is for in vitro diagnostic use only. The test should be used for the detection of Hepatitis C virus in Serum/Plasma/whole blood specimens only.Neither the quantitative value nor the rate of increase in Hepatitis C virus can be determined by this qualitative test.
2. The HCV Rapid Test Device (Serum/Plasma/Whole blood) will only indicate the presence of Hepatitis C virus in the specimen and should not be used as the sole criteria for the diagnosis of Hepatitis C infection.
3. As with all diagnostic tests,all results must be interpreted together with other clinical information available to the physician.
4. If the test result is negative and clinical symptoms persist,additional testing using other clinical methods is recommended.A negative result does not at any time preclude the possibility of Hepatitis C infection.

EXPECTED VALUES

The HCV Rapid Test Device (Serum/Plasma/Whole blood)has been compared with another leading commercial rapid test.The correlation between these two systems is 99.7%.

PERFORMANCE CHARACTERISTICS

Sensitivity

The recombinant antigen used for the HCV Rapid Test Device (Serum/Plasma/Whole blood) is encoded by genes for both structural (nucleocapsid) and non-structural proteins. The HCV Rapid Test Device (Serum/Plasma/Whole blood) has passed a seroconversion panel and compared with a leading commercial HCV EIA test using clinical specimens.The results show that the relative sensitivity of the HCV Rapid Test Device(Serum/Plasma/Whole blood) is 99.9%,and the relative specificity is 99.7%.

Method		EIA		Total Results
HCV Rapid Test Device(Serum/ Plasma/Whole blood)	Results	Positive	Negative	
	Positive	163	1	164
	Negative	0	336	336
Total Results		163	337	500

Relative Sensitivity:＞99.9% (95%CI*: 98.2%~100% *Confidence Intervals
Relative Specificity: 99.7% (95%CI*: 98.4%~100%)
Relative Specificity: 99.7% (95%CI*: 98.4%~100%)
Overall Accuracy: 99.8% (95%CI*: 99.0%~100%).

Precision

Cross-reactivity

The HCV Rapid Test Device (Serum/Plasma/Whole blood) has been tested by HAMA, Rheumatoid factor (RF),HAV, Syphilis,HIV,H.Pylori, MONO,CMV,Rubella and TOXO positive specimens. The results showed no cross-reactivity.

Specificity

The HCV Rapid Test Device(Serum/Plasma/Whole blood) has been tested for possible interference from visibly hemolyzed and lipemic specimeRns. No interference was observed. In addition, no interference was observed in specimens containing up to 2,000mg/dl Hemoglobin, 1000 mg/dl Bilirubin, and 2000 maldl human serum Albumin.

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SYMBOLS

Symbol	Meaning	Symbol	Meaning
IVD	In vitro diagnostic medical device		Storage temperature limit

	Manufacturer		Batch code
	Date of Manufacture		Use by date
	Do not reuse		Consult instruction foe use

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