ENO Hepatitis C Virus (HCV) Antibody Rapid Test Kit

PRODUCT NAME

ENO Hepatitis C Virus (HCV) Antibody Rapid Test Kit

PACKAGE SPECIFICATION

40 tests/kit

INTENDED USE

ENO Hepatitis C Virus (HCV) Antibody Rapid Test Kit is a rapid chromatographic immunoassay for the qualitative detection of antibody to Hepatitis C Virus in serum, plasma and whole blood samples to aid in the diagnosis of HCV infection.

SUMMARY AND PRINCIPLES OF THE PROCEDURE

ENO Hepatitis C Virus (HCV) Antibody Rapid Test Kit is a qualitative, membrane based immunoassay for the detection of antibody to HCV in serum, plasma and whole blood samples. The membrane is coated with recombinant HCV antigen on the test line region of the device. During testing, the specimen reacts with recombinant HCV antigen coated particles. The mixture migrates upward on the membrane chromatographically by capillary action to react with recombinant HCV antigen on the membrane and generate a colored line. Presence of this colored line indicates a positive result, while its absence indicates 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.

MATERIALS PROVIDED

Each kit contains:

1. Test Devices: 40 pieces test devices individually pouched.
2. Wash Buffer Solution: 2.0 ml in dropper bottle.
3. Package insert: 1 piece attached.

MATERIALS REQUIRED BUT NOT PROVIDED

- □ Timer or stopwatch.
- □ Specimen collection containers
- □ Disposable gloves and/or protective clothing
- □ Centrifuge(for plasma only)
- □ Micropipette
- □ Lancets(for fingertip whole blood only)

WARNINGS

1. Read the package insert completely before using the product. The instructions must be followed carefully as not doing so may result in inaccurate results.
2. The kitis for diagnostic use only.
3. Perform test at room temperature.

PRECAUTIONS

1. The kit rapid test is for professional use only.
2. The package insert instructions must be followed to ensure optimum test performance.
3. The kit is intended for *in vitro* diagnostic use.
4. As with all screening assays, any results should be considered presumptive until confirmatory assays have been performed according to local practice or WHO guidelines.

Safety Precautions

1. Standard precautions for handling infectious agents should be observed when using this kit.
2. Wear protective clothing such as lab coat, safety glasses and disposable gloves when handling specimens and assay reagents.
3. Wash hands thoroughly after use.
4. In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

Bio safety Precautions

Appropriate bio safety practices should be used when handling specimens and reagents. These precautions include, but are not limited to the following:

1. Do not smoke,eat,drink,apply cosmetics or handle contact lenses in areas in which specimens are handled.
2. Dispose of all specimens, used devices and tubes as though they are capable of transmitting infection. The preferred methods of disposal are by autoclave at 121°C for a minimum of 60 minutes or by incineration. Disposable materials may be incinerated. Liquid waste may be mixed with appropriate chemical disinfectants. A solution of 10% bleach is recommended. Allow 60 minutes for effective decontamination. NOTE: Do not autoclave solutions containing bleach.
3. When disposing of extraction Solution, avoid contact with acid to prevent liberation of a toxic gas.
4. All spills should be wiped thoroughly using a suitable disinfectant such as a sodium hypochlorite solution.
5. Use a separate dropper and device for each specimen tested.

Handling Precautions

1. Do not use if the kit box safety seal is absent, damaged or broken.
2. Do not use any device if the pouches have been perforated.
3. Each device is for single use only.
4. Do not mix wash buffer solution/test devices from different kit lots.
5. Do not use the kit past the expiration date (this date is printed on the kit box).
6. Adequate lighting is required to read the test results.
7. The result should be read immediately after the end of the 10 minutes incubation time following the addition of specimen and wash buffer solution. Do not read results beyond 15 minutes.

STORAGE INSTRUCTIONS

1. The kit should be stored between 2-30°C and the shelf life is 24 months.
2. The Kit components are stable until the expiration date printed on the outer label, when stored as directed. The kit expiry date is determined by whichever of the components has the shortest expiry date. The kit expiry date is not impacted once the wash buffer solution has been opened. Do not use kit components beyond overall kit expiry date.
3. If stored refrigerated, ensure that the pouched device is brought to room temperature before opening.
4. Do not freeze the kit.

SAMPLE COLLECTION AND PREPARATION

1. Applicable samples：Whole Blood/Serum/Plasma.
2. Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear nonhemolysis specimens.
3. Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods.
4. Serum and plasma specimens may be stored at 2~8 ℃ for up to 7 days, for long term storage, serum/plasma specimens should be kept below -20℃. Whole blood collected by venipuncture should be stored at 2~8℃ if the test is to be run within 2 days of collection.
5. Do not freeze whole blood specimens.
6. Whole blood collected by finger stick should be tested immediately.
7. 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.

8. If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiological agents.

9. EDTA K2,Heparin sodium,Citrate sodium and Potassium Oxalate can be used as the anticoagulant for collecting the specimen.

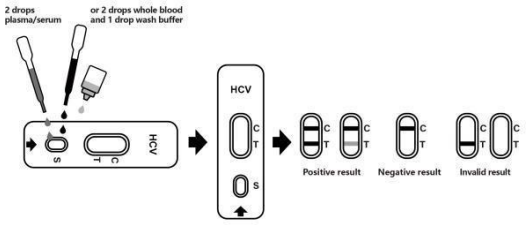
QUALITY CONTROL

An internal procedural control is included in the test. a colored line appearing in the control line region (C) is an internal valid procedural control, it confirming adequate membrane wicking. 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.

TEST PROCEDURE

Allow the test device, specimen, extraction solution to equilibrate to room temperature (15-30°C) prior to testing.

1. Remove the test cassette from the sealed pouch and use it within one hour. Place the test cassette on a clean and level surface.
2. For Serum or Plasma Specimens
   Hold the dropper vertically, draw the specimen and transfer the specimen to the sample well of the test cassette (two drops/approximately 50ul), Avoid trapping air bubbles in the sample well and start the timer.
   For Whole Blood Specimens
   To use a dropper: Hold the dropper vertically, draw the specimen and transfer the specimen to the sample well of the test cassette (two drops/approximately 50ul), then add one drop of buffer(approximately 30ul)to the sample well and start the timer. Avoid trapping air bubbles in the sample well.
3. Wait for the colored line(s)to appear. The test result should be read at 10 minutes. Do not interpret the result after 15 minutes.



INTERPRETATION OF RESULTS

Negative result: if there is only a quality control line C, the detection line is colorless, indicating that HCV antibody has not been detected and the result is negative.

Positive result: if both the quality control line C and the detection line appear, HCV antibody has been detected and the result is positive.

Invalid result: if the quality control line C is not observed, it will be invalid regardless of whether there is detection line (as shown in the figure below), and the test shall be conducted again.

LIMITATIONS

1. This reagent is only used for in vitro diagnosis.
2. This reagent is only used to detect human serum, plasma and whole blood samples. The results of other specimens may be wrong.
3. This reagent is only used for qualitative detection and cannot indicate the level of HCV in the specimen.
4. This reagent is only a clinical auxiliary diagnostic tool. If the result is positive, it is recommended to use other methods for further examination in time and the doctor's diagnosis shall prevail.

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity

The serum and plasma samples of patients with or without symptoms were detected with The kit and ELISA were used as reference. If the specimen is positive by Elisa, it is regarded as positive; if it is negative by Elisa, it is regarded as negative. The results indicated that The kit(Whole Blood/ Serum/ Plasma)has a high sensitivity and specificity as summarized below：

HCV clinical study		ELISA		
Hepatitis C Virus Rapid Test Kit	Results	Positive	Negative	Total Results
	Positive	120	1	121
	Negative	4	731	735
Total Results		124	732	856

Accuracy Results:

Clinical sensitivity:=99.17%

Clinical specificity=99.50%

Accuracy:=99.42%

Interference Substances

The following potential interfering substances have been tested using The kitand no interference was observed：

Substance	Tested Concentration
Bilirubin	20mg/dL
Creatinine	442mmol/L
Glucose	55mmol/L
Albumin	60g/L
Salicylic acid	4.34mmol/L
Heparin	3000U/L
EDTA	3.48 μ mol/L
Human IgG	1000mg/dL
Sodium citrate	3.8%

Cross Reaction

Cross-reactivity of The kit was evaluated using serum samples containing antibodies to other pathogens., which has no effect on the negative and positive test results, and there is no cross-reaction.

Specimen	HCV Reactivity
Dengue Positive Serum	Negative
HAV Positive Serum	Negative
HBsAg Positive Serum	Negative
HIV Positive serum	Negative
Syphilis Positive Serum	Negative
ANA Positive Serum	Negative
RF positive Serum (≤2,500 IU/ml)	Negative

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