AVECON™
Transforming Research into Innovations

One Step Rapid Test for HCV

MaxLINE HCV Rapid Test

Serum/Plasma Test Protocol

ORDERING INFORMATION

Ref. No.	Pack Size
AVHCV3SP-25	25 Tests
AVHCV3SP-30	30 Tests
AVHCV3SP-50	50 Tests

INTENDED USE :

MaxLINE HCV is a single test device used for the qualitative detection of HCV antibodies (IgM, IgG & IgA) in human Serum/Plasma samples by healthcare professionals.

PRODUCT FEATURES

1. Lateral flow immuno chromatography assay.
2. Uses HCV recombinant antigens from core, NS3, NS4 and NS5 regions.
3. Sensitivity : 100%.
4. Specificity : 99.8%.
5. Has been compared with a leading commercial HCV EIA and the accuracy between the systems is 99.8%.

INTRODUCTION

Hepatitis C virus (HCV) is now recognised as the primary cause of transfusion associated hepatitis. HCV is a single stranded positive-sense RNA virus and is globally present. In acute presentation of HCV infection patients may develop jaundice, others may go on to develop chronic hepatitis with life threatening conditions such as cirrhosis and hepatocellular carcinoma. Diagnosis of HCV is mainly done by either direct detection of viral RNA by PCR or by detection of anti-HCV antibodies. Recombinant DNA techniques have been used to develop structural and non-structural proteins derived from HCV RNA with utility for antibody screening. Anti-HCV assays have evolved as from first generation products, which used C-100-3 peptide. Second generation assay used recombinant viral proteins, Core, NS3 and NS4. Where as third generation anti HCV assay uses antigens from Core (structural), NS3 protease/helicase (non-structural), NS4 (non-structural) and NS5 replicase (non-structural) proteins, which provides greater sensitivity and specificity.

PRINCIPLE

The HCV One Step Test Device (Serum/Plasma) is a qualitative, membrane based immunoassay for the detection of antibody to HCV in Serum/Plasma. The membrane is coated with recombinant HCV antigens on the test line region of the device. During testing, the serum or plasma specimen reacts with the Protein A 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.

STORAGE AND STABILITY

Store as packaged in the sealed pouch either at room temperature or refrigerated (4-30°C). The test device is stable through the expiration date printed on the sealed pouch. The test device must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

KIT CONTAINS

Ref. No.	Pack Size	Test Device	Buffer Vial	Product Insert
AVHCV3SP-25	25 Tests	25 Nos.	1 No.	1No.
AVHCV3SP-30	30 Tests	30 Nos.	2 Nos.	1 No.
AVHCV3SP-50	50 Tests	50 Nos.	3 Nos.	1 No.

MATERIALS

1. Materials Provided

Each kit contains :

a) Individually packed test device
b) Buffer
c) Sample Dropper
d) Product insert

2. Materials Required But Not Provided

- Specimen collection containers
- Centrifuge (For serum/plasma separation)
- Stop Watch

PRECAUTIONS

1. For professional in vitro diagnostic use only. Do not use after expiration date.
2. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
3. Do not eat, drink or smoke in the area where the specimens or kits are handled.
4. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing and follow the standard procedures for proper disposal of specimens.
5. The used test should be discarded according to local regulations.
6. Humidity and temperature can adversely affect results.

SPECIMEN COLLECTION AND PREPARATION

1. The HCV One Step Test Device (Serum/Plasma) can be performed using either Serum/Plasma.
2. Separate the serum or plasma from blood as soon as possible to avoid hemolysis. Only clear, non-hemolyzed specimens can be used.
3. Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Specimens may be stored at 2-8°C for up to 3 days. For long term storage, specimens should be kept below -20°C.
4. 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.
5. If specimens are to be shipped, they should be packed in compliance with federal regulations for transportation of etiologic agents.

TEST PROCEDURE

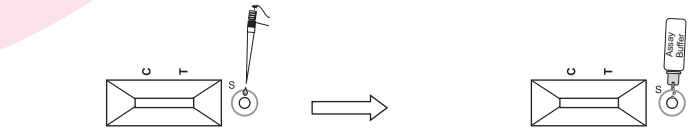
Allow test device, specimen, buffer and/or controls to equilibrate to room temperature (15-30°C) prior to testing.

1. Remove the test device from the foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.
2. Place the test device on a clean and level surface. Transfer the specimen by a pipette or a dropper:
3. Add 1 drop or 20 µL of Serum/ Plasma to the specimen well (S) of the test device and after absorbing the sample.
4. Add 1 drop of assay buffer (apporximately 35 µL) and start the timer. Avoid trapping air bubbles in the specimen well (S).

See illustration below.

INTERPRETATION OF RESULTS

Use Only Serum/Plasma



One drop or 20 µl Serum/Plasma

Add 1 Drop of Assay Buffer

*** Special Instruction ***

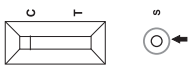
20µl Serum/Plasma
and
1 Drop of Assay Buffer

5 - 20 mins

Interpretation of Result

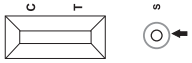
Negative

One bands appears in Window "C" Region



INVALID

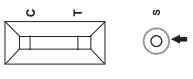
No bands appears in Window Region. The Result is considered invalid



POSITIVE Result

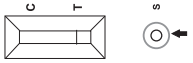
Positive

Two bands appears in Window "C" and "T" Region



INVALID

The result should also be considered invalid if only test band appears and no control band appears in window region.



Wait for the coloured line(s) to appear. The result should be read at 5-20 minutes. Do not interpret the result after 20 minutes.

QUALITY CONTROL

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

EXPECTED VALUES

The HCV Rapid Test (Serum/ Plasma) has been compared with a leading commercial HCV test, demonstrating an overall accuracy greater than or equal to 99.7%.

PERFORMANCE CHARACTERISTICS

110 positive and 535 negative sample are tested with MaxLINE HCV test and compared with commercially available ELISA kit. The result are given below:-

Type of Specimen	Observation				
	MaxLINE HCV Test		HCV ELISA		Total Results
	Positive	Negative	Positive	Negative	
Positive	110	0	110	0	110
Negative	01	534	0	535	535

On the basis of above internal evalutions,
The Sensitivity is 100%
The Specificity is 99.8%

Precision

Intra-Assay

Within-run precision has been determined by using 10 replicates of four specimens: a negative, a low positive, medium positive and a high positive. The negative, low positive, medium positive and high positive values were correctly identified >99% of the time.

Inter-Assay

Between-run precision has been determined by 10 independent assays on the same four specimens: a negative, a low positive, medium positive and a high positive. Four different lots of the HCV One Step Test Device (Serum/Plasma) have been tested over a 3-month period using negative, low positive, medium positive and high positive specimens. The specimens were correctly identified 99.8% of the time.

INTERFERING SUBSTANCES

The following potentially interfering substances were added to HCV negative and positive specimens.

Acetaminophen:	20 mg/dL	Caffeine:	20 mg/dL
Acetylsalicylic Acid:	20 mg/dL	Gentisic Acid:	20 mg/dL
Ascorbic Acid:	2g/dL	Albumin:	2 g/dL
Creatin:	200 mg/dL	Hemoglobin	1.1 mg/dL
Bilirubin:	1g/dL	Oxalic Acid:	600mg/dL

None of the substances at the concentration tested interfered in the assay.

LIMITATION

1. The HCV One Step Test Device (Serum/Plasma) is for *in vitro* diagnostic use only. This test should be used for the detection of antibodies to HCV in human Serum/Plasma specimen.
2. The HCV One Step Test Device (Serum/Plasma) will only indicate the presence of antibodies to HCV in the specimen and should not be used as the sole criteria for the diagnosis of Hepatitis C viral infection.
3. As with all diagnostic tests, all results must be considered with other clinical information available to the physician.
4. If the test result is negative and clinical symptoms persist, additional follow-up testing using other clinical methods is recommended. A negative result at any time does not preclude the possibility of Hepatitis C Virus infection.

DISCLAIMER:

The manufacturer has take every precaution to ensure the diagnostic ability and accuracy of this product, the product is used outside of the control of the Manufacturer and Distributor and the result may accordingly be affected by user error and/or environmental factors. A person who is the subject of the diagnosis should consult a clinician for further confirmation of the result.

WARNING:

The Manufacturer and Distributors of this product shall not be liable for any losses, liability, claims, costs or damages whether direct or indirect or consequential arising out of or related to an incorrect diagnosis, whether positive or negative, in the use of this product.

REFERENCE

1. Choo, Q.L., G. Kuo, A.J. Weiner, L.R. Overby, D.W. Bradley, and M. Houghton. Isolation of a cDNA clone derived from a blood-borne non-A, non-B viral hepatitis genome. Science 1989; 244:359

Symbols Used on Pack

REF	Catalogue Number		Warning/Caution
LOT	Batch No.	IVD	In vitro diagnostic device
	Manufacturing Date		Storage Limit
	Expiry Date		Consult instruction for use
	Manufacturer		Keep away from sunlight
	Keep Dry		Do not use if package is damaged
	Do Not Reuse		Contains sufficient no. of test

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GMP 5th Schedule MDR 2017

Manufactured in India by :
AVECON Healthcare Pvt. Ltd.
Transforming Research into Innovations
Plot No.: 338, Sector-2, Industrial Growth Centre, Saha, Ambala, Haryana (INDIA)-133104
E-mail : helpdesk@aveconhealthcare.com, Website : www.aveconhealthcare.com
Customer Care No. : +91 93065 12576, CIN No.: U24230HR2006PTC118875

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