MULTISURE HCV ANTIBODY ASSAY

Instructions For Use

FOR RESEARCH USE ONLY
NOT FOR USE IN DIAGNOSTIC PROCEDURES.

REVISION DATE: 2016-05
MDR0012-ENG-2

REF 43132-020 (20 tests)

TRADE NAME AND INTENDED USE

The **MP Diagnostics MULTISURE HCV ANTIBODY ASSAY** is a qualitative immunochromatographic assay for the rapid detection of antibodies to HCV in human serum, plasma, finger-pricked whole blood or whole blood with anti-coagulants.

INTRODUCTION

HCV has been identified as the major cause of parenteral transmitted non-A, non-B (NANB) hepatitis.

The **MP Diagnostics MULTISURE HCV ANTIBODY ASSAY** is a rapid test, developed to detect antibodies specific to HCV core, NS3, NS4 and NS5 antigens, similar to an Immunoblot. The test can detect the structural and non-structural proteins and the resulting band pattern can offer information such as the possible phase of the Hepatitis C infection.

CHEMICAL AND BIOLOGICAL PRINCIPLES OF THE PROCEDURE

The **MP Diagnostics MULTISURE HCV ANTIBODY ASSAY** is an indirect solid-phase immunochromatographic assay, in which antibodies in the test sample (serum, plasma or whole blood) form antibody-antigen complexes with immobilized HCV recombinant antigens on a nitrocellulose membrane in the test viewing window as the test sample migrates upward from the sample well. The bound antibody-antigen complexes are subsequently detected by a dye conjugated to anti-human IgG carried by chase buffer migrating downward giving a pink-purplish color. The control line contains protein A which binds with human IgG from the test sample and anti-human IgG-dye conjugate. The appearance of control line serves as an indication of proper sample addition and migration.

DESCRIPTION OF SYMBOLS USED

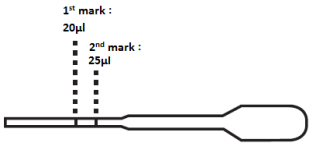
The following are symbols used in or found on MP Diagnostics' products and packaging. These symbols are the most common ones appearing on medical devices and their packaging.

	Use by	LOT	Batch Code *Synonyms for this are:* *Lot Number* *Batch Number*
REF	Catalogue Number *Synonyms for this are:* *Reference Number* *Reorder Number*		Temperature Limitation

	Caution		Manufacturer
	Consult Instructions for Use	Σ	Contains sufficient for <n> tests
	Do not reuse		

KIT COMPONENTS

DEVICE	MP Diagnostics MULTISURE HCV ANTIBODY ASSAY Device Incorporated with HCV recombinant proteins. Packed in individually sealed pouches with desiccant. Store at 2°C - 28°C	20 devices
APPLICATOR	SAMPLE APPLICATOR With marking of 20µl and 25µl.	20 pieces
BUFFER	CHASE BUFFER Contains sodium azide as preservative, Store at 2°C - 28°C	1 bottle (5ml)
	INSTRUCTIONS FOR USE	1 copy
	INTENSITY SCALE	1 copy



HEALTH AND SAFETY INFORMATION

1. In case of an accident or contact with eyes, rinse immediately with plenty of water and seek medical advice.
2. Consult a physician immediately in the event that contaminated materials are ingested or come in contact with open lacerations, or other breaks in the skin.
3. Wipe any spills of sera, plasma or blood promptly with 1% sodium hypochlorite solution.
4. Autoclave all used and contaminated materials at 121°C, 15 p.s.i. for 30 minutes before disposal. Alternatively, decontaminate materials in 5% sodium hypochlorite solution for 30-60 minutes before disposal in biohazard waste-bags.

Pursuant to EC regulation 1272/2008 (CLP), hazardous components are classified and labelled as follows:

Component:	Chase Buffer
Signal Word:	Warning
Pictogram:	
Hazard Statements:	H319 Causes serious eye irritation.
Precautionary Statements:	P264 Wash hands thoroughly after handling. P280 Wear protective gloves/protective clothing/eye protection/face protection.
Supplemental Statements:	EUH 210 Safety Data Sheet is available on request
Contains:	1% Triton X-100z

ANALYTICAL PRECAUTIONS:

1. For research use only.
2. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when samples are assayed.
3. Handle all samples as if they contain infectious agents. Observe established precautions against microbiological hazards throughout all procedures and follow the standard procedures for proper disposal of samples.
4. Optimal assay performance requires **STRICT ADHERENCE** to the assay procedure described in this Instruction For Use. Deviations from the procedure may lead to aberrant results.
5. Do not interchange reagents between kit lots.
6. Do not use kit components beyond the expiry date printed on the kit box.
7. The chase buffer reagent contains sodium azide as a preservative. Handle reagent carefully to avoid spills on work surface. Clean up spills with absorbent paper and water.
8. Reagents supplied should not present a hazard to health if used in accordance to the instructions stated.
9. For best results, allow all reagents and samples to reach room temperature (25°C ± 3°C) before use.
10. Humidity and temperature can adversely affect results.
11. Store the intensity scale away from light.
12. DO NOT use the test device if the seal of the pouch is broken.
13. DO NOT use the test device if the pull tab is not fully inserted, i.e. pre-pulled.

STORAGE

1. Store the kit and its components at 2ºC - 28ºC.
2. Do not freeze the kit and its components.
3. The test device must remain in the sealed pouch until use.
4. Do not use after the expiry date printed on the pouch.

MATERIAL REQUIRED BUT NOT PROVIDED

1. Timer
2. Lancet
3. Alcohol swabs

SPECIMEN COLLECTION

Whole blood can be collected in anti-coagulant containing tubes and used as outlined in the assay procedure immediately or stored at 2°C to 8°C for not more than 72 hours before use. The presence of 5 anti-coagulants, K-Oxalate, Acid Citrate Dextrose (ACD), Ethylenediaminetetraacetic acid (EDTA), Sodium Citrate (Na Citrate) or Heparin (Hep), were found to have no effect on the performance of MULTISURE HCV Antibody Assay

Serum / plasma samples should be stored at 2°C to 8°C if the test is to be run within 7 days of collection or frozen at -20°C or colder if the test is to be delayed for more than 7 days. Clear, non-hemolyzed samples are preferred. Lipemic, icteric or contaminated (particulate or bacterial) samples should be filtered (0.45µm) or centrifuged before testing.

Samples can be inactivated but this is not a requirement for optimal test performance.

Inactivate as follows:

1. Loosen cap of sample container.
2. Heat-inactivate sample at 56°C for 30 minutes in a water bath.
3. Allow sample to cool down before retightening cap.
4. Sample can be stored frozen until analysis.

Repeated freeze-thawing of the sample is not recommended.

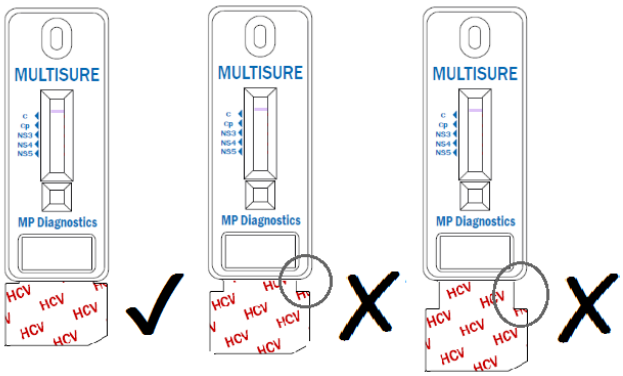
ASSAY PROCEDURE

IMPORTANT: Strict adherence to the assay procedure will ensure optimal performance. Deviations from the procedure may lead to aberrant results.

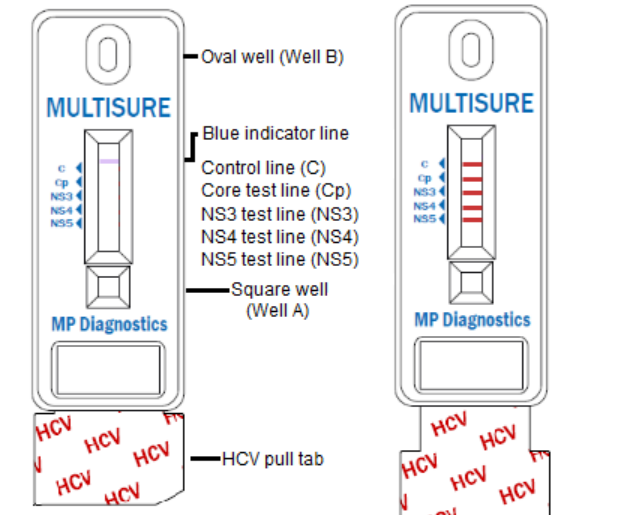
Note:

- Allow the kit to warm to room temperature before running the assay.
- Chase buffer with crystallization may affect test results.
- In order to prevent crystallization in chase buffer, it is highly recommended that the chase buffer to be stored at 18°C - 28°C.
- Check the chase buffer carefully. If crystals are present in the chase buffer, make sure that they are fully dissolved before use. Warming at 37°C helps to expedite the dissolving process.

1. Open the pouch by tearing at the tear notch on the right side of the pouch to avoid accidental pulling of pull tab.
2. Discard the device if the pull tab is not fully inserted into test device. Refer to diagrams below.



3. Label the test device with the sample name.
4. Proceed with the assay procedures as shown in the diagrams below.



Assay procedures for serum/plasma

Step 1:
Add 25 µl sample to square well A. Go to step 2.

Step 2:
Sample will start wicking up the membrane. When the sample front reaches the blue line, add 3 drops of Chase Buffer into oval well B. Go to Step 3.
(Caution: Do not allow sample front to flow out of Test Viewing Window.)

Step 3:

Pull out the Pull Tab until resistance is felt. Add 1 drop of Chase Buffer into square well A. Start timing, read result at 15 minutes. Do not read the results after 15 minutes.

Assay procedures for whole blood

Step 1:
Add 25 µl sample to square well A followed by 1 drop of chase buffer to the same well. Go to step 2.

Step 2:
Sample will start wicking up the membrane. When the sample front reaches the blue line, add 4 drops of Chase Buffer into oval well B. Go to Step 3.
(Caution: Do not allow sample front to flow out of Test Viewing Window.)

Step 3:
Pull out the Pull Tab until resistance is felt. Add 1 drop of Chase Buffer into square well A. Start timing, read result at 15 minutes. Do not read the results after 15 minutes.

QUALITY CONTROL

The control line is an internal procedure control. Absence of control line indicates insufficient/improper sample volume or incorrect assay technique used. The procedure should be reviewed before repeating with a new device.

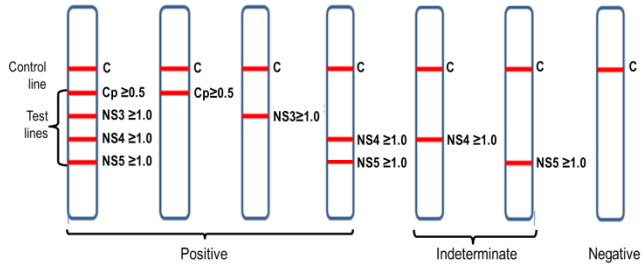
Positive and negative controls are not provided with this kit. However, it is recommended that controls be used as good laboratory practice to verify proper assay technique and performance.

INTERPRETATION OF RESULTS

The intensity of the visible band should be measured using the intensity scale provided in the kit. The intensity score should be graded as follow:

Intensity	Description
3.0	≥ 3
2.5	≥ 2.5, < 3
2.0	≥ 2, < 2.5
1.5	≥ 1.5, < 2
1.0	≥ 1, < 1.5
0.5	≥ 0.5, < 1

Any band with intensity < 0.5 should be considered as '0' and thus non-visible band.



1. **Positive for HCV antibody**

   A test is positive if it meets any of the following criteria:

   (i) Control line (C) appears and Core test line visible at intensity ≥ 0.5 (with or without other visible test lines)

   (ii) Control line (C) appears and NS3 test line visible at intensity ≥ 1.0 (with or without other visible test lines)

   (iii) Control Line (C) appears and both NS4 & NS5 test lines visible at intensity ≥ 1.0 (with or without other visible test lines)

2. **Indeterminate for HCV antibody**

   A test is indeterminate if it meets any of the following criteria:

   (i) Control line (C) appears and single NS4 test line visible with intensity ≥ 1.0

   (ii) Control line (C) appears and single NS5 test line visible with intensity ≥ 1.0

   (iii) Control line (C) appears and any other pattern which does not meet criteria for POSITIVE OR NEGATIVE

3. **Negative for HCV antibody**

   A test is negative if it meets any of the following criteria:

   (i) Control line (C) appears and Test line(s) are not visible

   (ii) One or more Test line(s) visible at the following intensities:

   Core <0.5
   NS3 <1.0
   NS4 <1.0
   NS5<1.0

4. **Invalid**

   A test is invalid if Control line (C) is absent. The assay should be repeated using a new device.

LIMITATIONS OF THE PROCEDURE

The **MP Diagnostics MULTISURE HCV ANTIBODY ASSAY** is for research use and for detection of HCV antibodies in serum, plasma finger-pricked whole blood or whole blood with anticoagulants only. This test is not for determining the quantitative value or the rate of increase in HCV antibodies.

Optimal assay performance requires the strict adherence to the assay procedure described. Deviation from the procedure may lead to aberrant results.

REFERENCES

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

2. Kuo, G., Q.L. Choo, H.J. Alter, and M. Houghton. An assay for circulating antibodies to a major etiologic Virus of human non-A, non-B hepatitis. Science 1989; 244:362

3. Van der Poel, C. L., H.T.M. Cuypers, H.W. Reesink, and P.N.Lelie. Confirmation of hepatitis C Virus infection by new four-antigen recombinant immunoblot assay. Lancet 1991; 337:317

4. Wilber, J.C. Development and use of laboratory tests for hepatitis C infection: a review. J. Clin. Immunoassay 1993; 16:204.

5. L.I. Nikolaeva, N.P. Blokhina, N.N. Tsurikova, N.V. Voronkova, M.L. Miminoshvili, D.M. Braginsky, O.N. Yastrebova, O.B. Booynitskaya, O.V. Isaeva, M.I. Michailov and A.I. Atrchakov . Virus-specific antibody in different phases of hepatitis C virus infection. Jour of Vir Hep 2002, 9, 429-437.

LIMITED EXPRESSED WARRANTY DISCLAIMER

The manufacturer makes no express warranty other than that the test kit will function as RUO (for research use only) assay within the specifications and limitations described in the product

Instructions for Use, when used in accordance with the instructions contained therein. The manufacturer disclaims any warranty expressed or implied warranty with respect to merchantability, fitness for use or implied utility for any other purposes. The manufacturer is limited to either replacement of the product or refund of the purchase price of the product. The manufacturer shall not be liable to the purchaser or third parties for any damage, injury or economic loss howsoever caused by the product in the use or in the application thereof.

TECHNICAL PROBLEMS / COMPLAINTS

Should there be a technical problem / complaint, please do the following:

1. Note the kit lot number and the expiration date.
2. Retain the kits and the results that were obtained.
3. Contact the nearest MP Biomedicals office or your local distributor.

MP Biomedicals Asia Pacific Pte. Ltd.
2 Pioneer Place
Singapore 627885
Tel. No.: + 65 6775 0008
Fax. No.: + 65 6775 4536
Email: enquiry_ap@mpbio.com

MP Biomedicals, LLC
29525 Fountain Parkway
Solon, OH 44139
Tel No.: 800-854-0530
Fax No.: 800-334-6999