Introduction

The current diagnosis of HCV infection relies primarily on the detection of HCV specific antibodies and/or clinical symptoms not attributed to Hepatitis A, B, D or E. The transmission of HCV has been reported to be via transfusion of contaminated blood or blood products as well as shared needles and close personal contact with an infected individual.

The MPD ASSURE® HCV Rapid Test Device is a rapid test to qualitatively detect the presence of antibodies to Hepatitis C Virus in serum or plasma.

Chemical and Biological Principles of the Procedure

The MPD ASSURE® HCV Rapid Test utilizes a combination of protein A coated particles and recombinant HCV proteins to selectively detect antibodies to HCV in serum or plasma. The recombinant HCV proteins used in the test kit are encoded with the genes for both structural (nucleocapsid) and non-structural proteins.

The availability of a rapid, simple test for HCV will enable HCV testing in urgent situations such as transplant and grafting procedures. Such a test will also allow small private laboratories to perform the assay in-house rather than referring the sample to the reference centre. The ASSURE® HCV Rapid Test may also be utilized by large reference centres or blood transfusion centres as a second assay when they are required to perform two methods on each reactive sample.

Interpretation of Results

Positive: If two distinct red lines appear. One line is in the control region and the other in the test region.

As titer of HCV antibodies varies from sample to sample, any shade of red on the test line should be read as positive.

Negative: If only one red line in the control region appears. No red or pink line is seen in the test area.

Invalid: No red line in the Control region. No line is present or a Test line is present alone without a Control line. If this occurs, the assay should be repeated using a new device.

SAFETY PRECAUTIONS

- For professional in vitro diagnostic use only.

Material Required but not Provided

- Timer

Kit Components

Component Description | Quantity
--- | ---
1. HCV Test Device | 20 sachets
20 test devices in individually sealed foil pouches.
Store at 2°C - 30°C.
2. Buffer | 3 ml
3. Sample applicators | 20 Pieces
In a plastic zip lock bag
4. Instruction Manual | 1 copy

Safety Precautions

- Do not use kit components beyond the expiry date.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when samples are assayed.
- 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.
- Humidity and temperature can adversely affect results.

Storage Instructions

- Store the kit and its components at 2°C - 30°C when not in use.
- Do not freeze the kit and its components.
- The test device must remain in the sealed pouch until use.
- Do not use after the expiry date printed on the pouch.

Sample Collection and Preparation

- The test can be performed using either serum or plasma.
- Separate the serum or plasma from whole blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed samples.
- Use fresh samples. If samples are not immediately tested, they may be stored at 2°C - 8°C for up to 3 days. For long-term storage, they should be kept at -20°C or below.

Assay Procedure

Ensure that test device and sample are brought to room temperature (15°C - 30°C) before testing. Remove device from foil pouch and use within one hour. Place device on a clean and level surface.

1. Hold the sample applicator vertically and draw the sample up to the Fill Line as shown in the illustration below (approximately 5 µl). Transfer the sample to Sample well (S) of test device.
2. Then add 2 full drops of buffer (approximately 80 µl). Avoid air bubbles in the specimen well.
3. Start the timer and read the results at 10 minutes. Do not read the results after 20 minutes.

Diagrammatic Procedure: 5 µl of Serum or Plasma
2 drops of buffer

The C and T in the diagram indicate the (C)ontrol line and the (T)est line.
QUALITY CONTROL

The control line is an internal procedure control. Absence of control line indicates insufficient 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.

LIMITATIONS OF THE PROCEDURE

The MPD ASSURE® HCV Rapid Test is for in vitro diagnostic use and for detection of HCV antibodies in serum or plasma samples only. This test is not for determining the quantitative value or the rate of increase in HCV antibodies.

The MPD ASSURE® HCV Rapid Test will only indicate the presence of HCV antibodies in the sample. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the qualified practitioner after all the clinical and laboratory findings have been evaluated and should not be used as the sole criteria for the diagnosis of HCV infection. 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 HCV infection.

PERFORMANCE CHARACTERISTICS

Sensitivity
The MPD ASSURE® HCV Rapid Test Device has been tested with a seroconversion panel and compared with leading commercial HCV EIA test using clinical samples.

Specificity
The recombinant antigens used for the MPD ASSURE® HCV Rapid Test Device are encoded by genes for both structural (nucleocapsid) and non-structural proteins. The MPD ASSURE® HCV Rapid Test Device is highly specific for antibodies to Hepatitis C Virus compared with a leading commercial HCV EIA test.

<table>
<thead>
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<th>Method</th>
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<td>TOTAL RESULTS</td>
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<td>1908</td>
<td>2003</td>
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</tbody>
</table>

Relative Sensitivity: 96.8%
Relative Specificity: 99.0%
Accuracy: 98.9%

PRECISION

Intra Assay
The intra-run precision has been determined by using 15 replicates of three samples containing a negative, a low positive and a high positive sample. The negative and positive values were correctly identified 98% of the time.

Inter Assay
The inter-run precision has been determined by 15 independent assays on the same three samples of negative, low positive and high positive. Three different lots of ASSURE® HCV Rapid Test were tested over a 3-month period using negative, low positive and high positive samples. The samples were correctly identified 98% of the time.

REFERENCES


LIMITED EXPRESSED WARRANTY DISCLAIMER

The manufacturer makes no express warranty other than that the test kit will function as an in vitro diagnostic assay within the specifications and limitations described in the product Instruction Manual when used in accordance with the instructions contained therein. The manufacturer disclaims any warranty expressed or implied, including such 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 expiry date.
2. Retain the kits and the results that were obtained.
3. Contact the nearest MP Biomedicals office or your local distributor.

Head Office:
MP Biomedicals Asia Pacific Pte. Ltd.
85 Science Park Drive
#04-01, The Cavenish
Singapore Science Park
Singapore 118259
Tel. No.: +65 6775 0008
Fax No.: +65 6775 4536
Email: enquiry_sp@mpbio.com

Regional Offices:
MP Biomedicals Suisse S.A.
Halle de Fret/Aeroport,
P.O. Box 1015
1211 Geneva 5
Switzerland
Tel No.: (4122) 788-1908
Fax No.: (4122) 788-1986
Email: mpbiosuisse@mpbio.com

MP Biomedicals Asia Pacific Pte Ltd (Shanghai Rep office)
Room 1009, Pine City
No 8 Dong An Road
Shanghai 200032
Tel No.: (86-21) 64746202
Fax No.: (86-21) 64746210
Email: mpbio_sh@mail.online.sh.cn

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