



ASSURE[®] HBsAg Rapid Test

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Note Changes Highlighted

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TRADE NAME AND INTENDED USE

The MPD Diagnostics (MPD) ASSURE[®] HBsAg Rapid Test assay is a rapid chromatographic immunoassay for the qualitative detection of Hepatitis B surface antigen (HBsAg) in whole blood, serum or plasma.

INTRODUCTION

In 1964, Blumberg and his associates discovered Hepatitis B surface antigen (HBsAg). The discovery of HBsAg was a major step towards the understanding and differential diagnosis of viral hepatitis. This antigen has proved to be an important marker of Hepatitis B virus (HBV) infection.

The antigen reactivity of HBsAg is associated with the outer coat of 42 nm diameter virion (dane particle) which encloses the inner viral nucleocapsid HBcAg and nucleic acid (HBV-DNA).

Analysis has revealed that one antigen designated "a" is common to all HBsAg preparations. In addition, there are two sets of mutually exclusive determinants, "d" or "y and "w" or "r". This results in four principal subtypes of HBsAg: adw, ayw, adr and ayr. Because of antigenic heterogeneity of the "w" determinant, there are 10 major serotypes of HBV.

The MPD ASSURE[®] HBsAg Rapid Test is a rapid test to qualitatively detect the presence of HBsAg in whole blood, serum or plasma sample. The test utilizes a combination of monoclonal and polyclonal antibodies to selectively detect elevated levels of HBsAg in whole blood, serum or plasma.

CHEMICAL AND BIOLOGICAL PRINCIPLES OF THE PROCEDURE

The MPD ASSURE[®] HBsAg Rapid Test is a qualitative, lateral flow immunoassay based on the immunochromatographic sandwich principle.

Particles conjugated to monoclonal anti-HBsAg antibody (anti-HBsAg) are coated on the test strip between the sample well and test region. When whole blood, serum or plasma sample is added to the sample well, HBsAg present in the sample binds with the particle conjugated monoclonal anti-HBsAg antibody to form an "antigen-antibody complex". The "antigen-antibody complex" migrates to the test region where it is trapped by an immobilized polyclonal anti-HBsAg antibody, forming a sandwich, which is detected as a red line indicating the presence of HBsAg in the sample.

MPD ASSURE[®] HBsAg Rapid Test also provides an integral quality check. Appearance of a red line in the control region indicates that the test has been performed properly and the test device is in good working condition.

KIT COMPONENTS

Component Description	Quantity
1. HBsAg Test Device 20 test devices with sample applicators in individually sealed foil pouches. The sample applicator is provided for Serum, Plasma or Venipuncture blood only. Store at 2°C - 30°C.	20 sachets
2. Buffer (For whole blood only)	3 ml
3. Instruction Manual	1 copy

MATERIAL REQUIRED BUT NOT PROVIDED

- Timer
- Specimen collection container
- Lancets (for finger prick whole blood only)
- Disposable heparinized capillary tubes and dispensing bulb (for finger prick whole blood only)

SAFETY PRECAUTIONS

- For professional *in vitro* diagnostic use only.
- 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. The test device must remain in the sealed pouch until use.
- Do not freeze the kit and its components.

SAMPLE COLLECTION AND PREPARATION

- The test can be performed using whole blood (from venipuncture or finger prick), 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. Whole blood collected by venipuncture should be stored at 2°C - 8°C if the test is to be run within 2 days of collection. Do not freeze whole blood specimens. Whole blood collected by finger prick should be tested immediately.
- Bring samples to room temperature prior to testing. Frozen samples must be completely thawed and mixed well prior to testing.

ASSAY PROCEDURE

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

For Serum or Plasma sample

1. Hold the sample applicator vertically and squeeze 3 full drops of serum or plasma (approximately 75µl) into the Sample well (S) of test device.
2. Start timer and read the result at 15 minutes. Do not read the result after 20 minutes.

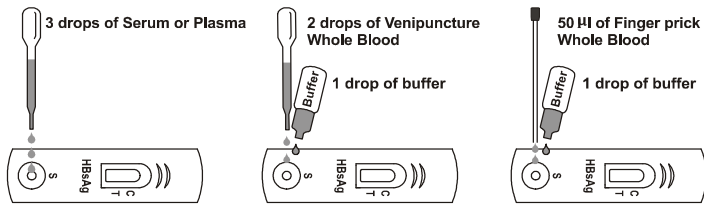
For Venipuncture whole blood sample

1. Hold the sample applicator vertically and squeeze 2 drops of venipuncture whole blood (approx. 50µl) to the Sample well (S) of the test device then add 1 drop of buffer (approximately 40µl). See diagram below.
2. Start timer and read the result at 15 minutes. Do not read the result after 20 minutes.

For Finger prick Whole Blood sample

1. Fill the capillary tube (not provided) and transfer the finger prick whole blood (approximately 50µl) into the Sample well (S) of test device, then add 1 drop of buffer (approximately 40µl). See diagram below.
2. Start timer and read the result at 15 minutes. Do not read the result after 20 minutes.

Diagrammatic Procedure:



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

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 Hepatitis B surface antigens 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. Insufficient sample volume or incorrect procedural techniques are the most common reasons for invalid test. If this occurs, the assay should be repeated using a new device.



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 a positive control (containing 10 ng/ml HBsAg) and a negative control (containing 0 ng/ml HBsAg) be tested as a good laboratory practice to verify proper assay technique and performance.

LIMITATIONS OF THE PROCEDURE

The MPD ASSURE® HBsAg Rapid Test is for *in vitro* diagnostic use and for detection of HBsAg in whole blood or serum or plasma samples only. The MPD ASSURE® HBsAg Rapid Test will only indicate the presence of HBsAg 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. Therefore this test should not be used as the sole criteria for the diagnosis of Hepatitis B infection. The MPD ASSURE® HBsAg Rapid Test can not detect less than 1 ng/ml of HBsAg in samples. 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 B infection.

PERFORMANCE CHARACTERISTICS

Sensitivity

The MPD ASSURE® HBsAg Rapid Test has been tested with a sensitivity panel ranging from 0 to 300 ng/ml. All 10 HBsAg subtypes produced positive results on the ASSURE® HBsAg Rapid test. The test can detect 1ng/ml of HBsAg in whole blood, serum or plasma in 15 minutes.

Specificity

Antibodies used for the MPD ASSURE® HBsAg Rapid Test were developed against whole Hepatitis B antigen isolated from Hepatitis B virus. Specificity of the ASSURE® HBsAg Rapid Test was also tested with laboratory strains of Hepatitis A and Hepatitis C. They all yielded negative results.

HBsAg Reference Method

Method	EIA		Total
	Positive	Negative	
ASSURE® HBsAg Rapid Test	200	3	203
	0	1062	1062
Total	200	1065	1265

Relative Sensitivity: > 99.0%
Relative Specificity: 99.7%
Accuracy: 99.8%

PRECISION

Intra-Assay

Within-run precision has been determined by using 15 replicates of three samples containing 0 ng/ml, 1 ng/ml and 5 ng/ml of HBsAg. The negative and positive values were correctly identified 99% of the time.

Inter-Assay

Between-run precision has been determined by using the same three samples of 0 ng/ml, 1 ng/ml and 5 ng/ml of HBsAg in 15 independent assays. Three different lots of the HBsAg test Devices have been tested over a 3-month period using negative, low positive and high positive samples. The samples were correctly identified 99% of the time.

REFERENCES

Blumberg, B.S. *The Discovery of Australian Antigen and its relation to viral hepatitis*. Vitro. 1971; 7: 223



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.

 Use by
Synonym for this :
Expiry Date
  In vitro diagnostic medical device

 Batch Code
Synonyms for this are:
Lot Number
Batch Number
  Catalogue Number

 Temperature Limitation
  Attention. See Instruction for Use

 Manufacturer
  Do not reuse



Contains
sufficient for
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