

HBsAg Rapid Test Cassette

HBsAg Rapid Test Device Package Insert

SP-216

Specimens: Whole Blood/Serum/Plasma For professional in vitro diagnostic use only

INTENDED USE

The HBsAg Rapid Test Device (Whole Blood/Serum/Plasma) is a rapid visual immunoassay for

the qualitative presumptive detection of HBsAg in human whole blood, serum, or plasma

specimens. This kit is intended to be used as an aid in the diagnosis of HBV infection

INTRODUCTION

Hepatitis B virus (HBV) is the prototypic member of the hepadnaviruses. In the lipid envelope of

this small DNA virus the hepatitis B surface antigen (HBsAg) is located. During the replicative

phase of the virus this surface antigen is produced in excess and detectable in the blood of

infected person. The antigens HBcAg and HBeAg are parts of the nucleocapsid. The incubation

period of HBV is 6 weeks to 6 months.

PRINCIPLE

The HBsAg Rapid Test Device (Whole Blood/Serum/Plasma) has been designed to detect the

 $\ensuremath{\mathsf{HBsAg}}$ through visual interpretation of color development in the strip. The membrane was

immobilized with anti-HBsAg antibodies on the test region. During the test. the specimen is

allowed to react with colored anti-HBsAg antibodies colloidal gold conjugates, which were

precoated on the sample pad of the test. The mixture then moves on the membrane by a capillary

action, and interact with reagents on the membrane. If there were enough HBsAg in specimens, a

colored band will from at the test region of the membrane. Presence of this colored band indicates

a positive result, while its absence indicates a negative result. Appearance of a colored band at the

control region serves as a procedural control. This indicates that proper volume of specimen has

been added and membrane wicking has occurred.

KIT COMPONENTS

1 Package insert 40 Individually packed test devices 40 Disposable pipettes 40 Alcohol pads 40 Lancet

MATERIALS REQUIRED BUT NOT PROVIDED

Specimen collection container

For specimens collection use.

Timer

For timing use. For preparation of clear

Centr i fuge

specimens

PRECAUTIONS

- · For professional in vitro diagnostic use only.
- · Do not use after expiration date indicated on the package. Do not use the test if its foil pouch

is damaged. Do not reuse tests.

This kit contains products of animal origin. Certified knowledge of the origin and/or sanitary

state of the animals does not totally guarantee the absence of transmissible

agents. It is therefore, recommended that these products be treated as potentially infectious.

and handled observing the usual safety precautions (do not ingest or

 ${\boldsymbol{\cdot}}$ Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.

- · Read the entire procedure carefully prior to performing any tests.
- · Do not eat, drink or smoke in the area where the specimens and kits are handled. Handle all

specimens as if they contain infectious agents. Observe established precautions against

microbiological hazards throughout the procedure and follow the standard procedures for

proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable

gloves and eye protection when specimens are assayed.

- $\cdot\ \ \,$ Do not interchange or mix reagents from different lots.
- · Humidity and temperature can adversely affect results.
- · The used testing materials should be discarded in accordance with local, state and/or federal regulations

STORAGE AND STABILITY

- · The kit should be stored at 2-30°C until the expiry date printed on the sealed pouch.
- · The test must remain in the sealed pouch until use.
- · Do not freeze.
- · Cares should be taken to protect components in this kit from

contamination. Do not use if

there is evidence of microbial contamination or precipitation. Biological contamination of

dispensing equipments, containers or reagents can lead to false results.

SPECIMEN COLLECTION AND STORAGE

· The HBsAg Rapid Test Device (Whole Blood/Serum/Plasma) is intended only for use with

human whole blood, serum, or plasma specimens.

· Only clear, non-hemolyzed specimens are recommended for use with this test Serum or

plasma should be separated with soonest possible opportunity to avoid

· Perform the testing immediately after the specimen collection. 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.

· Bring specimens to room temperature prior to testing. Frozen specimens must be completely

thawed and mixed well prior to testing. Avoid repeated freezing and thawing of specimens.

- ${\boldsymbol \cdot}$ $\,$ Pack the specimens in compliance with applicable regulations for transportation of etiological agents, in case they need to be shipped.
- · Icteric, lipemic, hemolysed, heat treated and contaminated sera may cause erroneous results.

PROCEDURE

Bring tests, specimens and/or controls to room temperature (15 - 30° C) before use.

1. Remove the test from its sealed pouch, and place it on a clean, level

with patient or control identification. To obtain a best result, the assay should be performed

within one hour.

Transfer 2 drops of serum/plasma to the specimen well of the device with a disposable

pipette provided in the kit and then start the timer.

Transfer 2 drop of whole blood to the specimen well of the device with a

provided in the kit, then add 1 drop of buffer and start the timer.

OR

Allow 2 hanging drop of fingerstick whole blood specimen to fall into the center of the

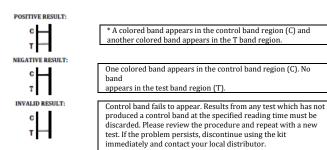
specimen well (S) on the device, then add 1 drop of buffer and start the timer $\,$

Avoid trapping air bubbles in the specimen well (\$), and do not drop any solution in observation window.

As the test begins to work, you will see color move across the membrane. **2.** Wait for the colored band(s) to appear. The result should be read at 15 minutes. Do not

interpret the result after 20 minutes.

INTERPRETATION OF RESULTS



diagnostic use, and should be used for the qualitative detection of HBsAg only.

2. The HBsAg Rapid Test Device (Whole Blood/Serum/Plasma) will only indicate the presence of

HBsAg in the specimen and should not be used as the sole criteria for the diagnosis of

Hepatitis B viral infection.

 ${\bf 3.}$ If the test result is negative and clinical symptoms persist, additional testing using other

clinical methods is recommended. A negative result does not at anytime rule out the existence

of HBsAg in blood, because the HBsAg may be absent or below the minimum detection level of

the test.

4. Like with all diagnostic tests, a confirmed diagnosis should only be made by a physician after

all clinical and laboratory findings have been evaluated.

PERFORMANCE CHARACTERISTICS

NOTE:

 $\begin{tabular}{ll} \textbf{1.} The intensity of the color in test region (T) may vary depending on the concentration of aimed \\ \end{tabular}$

substances present in the specimen. Therefore, any shade of color in the test region should be $\,$

considered positive. Besides, the antibodies level can not be determined by this qualitative

 ${\bf 2.}\ Insufficient\ specimen\ volume,\ incorrect\ operation\ procedure,\ or\ performing\ expired\ tests\ are$

the most likely reasons for control band failure.

QUALITY CONTROL

 \cdot Internal procedural controls are included in the test. A colored band appearing in the control

 $region \ (C) \ is \ considered \ an \ internal \ positive \ procedural \ control. \ It \ confirms \ sufficient \ specimen$

volume and correct procedural technique.

• External controls are not supplied with this kit. It is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify

LIMITATIONS OF THE TEST

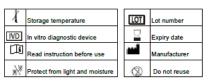
proper test performance.

1. The HBsAg Rapid Test Device (Whole Blood/Serum/Plasma) is for professional in vitro

LITERATURE REFERENCES

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







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