RapidTech HBsAg Test Strip

INTENDED USE:
The RapidTest HBsAg Test is an one step qualitative test for the detection of hepatitis B surface antigen (HBsAg) in human serum as an aid in the diagnosis of hepatitis B infection. Test results are read visually without any instrument.

This test is intended primarily as an initial screening test. Any specimen found to be repeatedly reactive should be confirmed by neutralization procedures utilizing human anti-HBs.

SUMMARY
The discovery of Australian antigen by Blumberg, et. al., and its subsequent identification as the surface antigen of hepatitis B virus (HBsAg) represents a significant break through in the understanding of the disease, serum hepatitis.

The chemical composition of the HBsAg consists of lipid, carbohydrate, and protein. The protein moiety of HBsAg contains several polypeptides, ranging from 23,000 to 97,000 molecular weight. The antigenic determinants on the protein moiety of the HBsAg determine the specific characteristics of the different serotypes of the virus and is the basis of the immunoassay. The antigenic reactivity of HBsAg is also associated with the surface of spherical or tubular particles. Other particles have also been observed, called Dane particles, which have two different antigenic sites: a superficial one, identifiable as HBsAg and an inner one, identifiable as the core. It has also been suggested that HBsAg is a fragment of the viral lipoprotein capsid and the Dane particle could be the real virus.

HBsAg has an antigenic heterogeneity. The principal determinant is called a (a1, a2, a3) and is common to all the different serotypes of HBsAg. Two couples of subspecific determinants have also been identified, that is d/y (1y, 2y, 3y) and w/r which seems to be mutually exclusive. Therefore the following combinations are possible: adw, adr, ayw, ayr.

Specimens non-reactive by RapidTech One Step HBsAg test are considered negative for HBsAg and need not be tested further. A reactive specimen should be retested. A specimen which is found to be repeatedly reactive should be confirmed by neutralization procedures utilizing human anti-HBs. If the specimen is neutralizable in the confirmatory test, the specimen is considered positive for HBsAg and need not be tested further.

PRINCIPLE
This assay is a chromatographic immunoassay (CIA), containing filter membrane coated with anti-HBs antibodies and colored gold colloidal reagents labeled with anti-HBs.

There are two regions, test region and control region, on the membrane of the test strip. The test line (T), a purple color band in the test region of membrane, will be developed rapidly (from 30 seconds to 10 minutes) when HBsAg is present in the specimen. If HBsAg is below 2 ng/mL or not present, no T line will be developed in the test region. The control line (C), a purple color band in the control region of the test, should always appear regardless of the presence of HBsAg, serving as an internal qualitative control of the test system.

REAGENTS AND MATERIALS PROVIDED:
1. Test strips (Each strip for one single test)

STORAGE CONDITIONS
The test should be stored at refrigeration or room temperature (8º to 30º C) in the sealed pouch with a desiccant packet for the duration of the shelf life. Freezing or expose the kit to temperatures over 30ºC may cause malfunction.

PRECAUTIONS
1. For in vitro diagnostic use only.
2. Do not use test kit beyond expiration date.
3. Do not open the test strip foil pouch until you are ready to perform the test.
4. Icteric, lipemic, haemolyzed, heat treated and contaminated sera may cause erroneous results.

SPECIMEN COLLECTION
Serum and plasma (heparin, citrate, or EDTA) specimens may be used.

HBsAg is thermo-labile. Specimens containing particulate matter or red blood cells may give inconsistent results and should be centrifuged before testing (recommended 8,000-10,000 RCF* x 10 minutes). Specimens which are not tested within 24 hours should be removed from the clot or red blood cells.

If the assay will be performed within 5 days after collection, the specimen should be stored at 2º to 8ºC. If testing will be delayed more than 5 days, the specimen should be stored frozen. Mix thoroughly after thawing to ensure consistency in the results. For optimal product performance, samples stored frozen should be centrifuged prior to use to remove particulate matter. Avoid repeated freezing and thawing. Do not use heat inactivated specimens.

All specimens should be centrifuged (recommended 8,000-10,000 RCF* x 10 minutes) prior to any repeat or confirmatory testing.
*RCF = Relative Centrifugal Force

TEST PROCEDURE
Test strips together with patient sample, control or reference materials should be brought to room temperature (18º to 25ºC) prior to testing.

1. Tear open pouch, remove strip from package. Label the strip with patient or control identification.
2. Immerse the strip into the serum with the arrows on the strip pointing upwards.
   **Do not immerse the “MAX” line.**

   You may leave the strip in the serum or you may take the strip out after a minimum of 5 seconds and lay the strip flat on a clean, dry, non-absorbent.

3. Read results in 15 minutes. **Do not interpret results after 30 minutes.**

INTERPRETATION OF RESULTS
1. **Negative:** Only one colour band appears on the control region. No apparent band on the test region.
2. **Positive:** Distinct colour bands appear on the control and test region. Colour intensity of the test bands may vary.
3. **Invalid:** No visible band at all or no visible band at the control region. Repeat test.

![Control Test Diagram](image-url)
PROCEDURE LIMITATIONS
1. This test is not for blood transfusion screening.
2. For diagnostic purposes and in order to differentiate acute HBV infection from chronic HBV infection, the detection of HBsAg should be correlated with patient symptoms and other hepatitis B viral serological markers.
3. Although the association of infectivity and the presence of HBsAg is strong, it is recognized that presently available methods for HBsAg detection are not sensitive enough to detect all potentially infectious units of blood or possible cases of hepatitis.

EXPECTED VALUES
In random blood donor populations, the number of specimens found repeatedly reactive for HBsAg by this test has typically been less than 0.5%.

REFERENCES
14. Epidemiological Notes and Reports, Hepatitis B Contamination.

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