

HBsAg Rapid Test Device

A direct monoclonal based immunochromatographic immunoassay for the visual detection of Hepatitis B Surface Antigen in serum

Catalog #:ID1001C

INTRODUCTION

The discovery of Australia antigen and subsequent identification as the surface antigen of Hepatitis B virus (HBsAg) represents a significant breakthrough in the understanding of the disease. Screening of blood donors for the presence of this antigen in serum has significantly reduced the incidence of Hepatitis B in blood transfusion recipients. Furthermore, anti-HBsAg determination can be used to: a) monitor the progress of patients recovering from Hepatitis B viral infection; b) indicate if the patient has had prior immunological exposure to HBsAg; and c) study the epidemiological factors associated with transmission of HBsAg.

SUMMARY AND PRINCIPLE OF THE TEST

This HBsAg-Card is a rapid, qualitative, one-step immunoassay employing a unique combination of monoclonal-dye conjugate (colloidal gold) and polyclonal solid phase antibodies to selectively identify HBsAg of Hepatitis B viral infection with a high degree of sensitivity. In this test, whole blood, plasma or serum specimen is added directly to the sample pad. As the test sample flows through the sample pad, the labelled antibody-dye conjugate binds to HBsAg forming an antibody-antigen complex. The pad is in contact with a chromatographic test strip which contains a region of immobilised polyclonal anti-HBsAg antibody in the test line. The antibody-antigen complex moves by capillary action along the strip forming a line of immobilised complex by the zone of antibody in the test line, indicating the presence of HBsAg in the sample (pink line). If no antigen is present, the test line will remain clear. The appearance of a pink line in the control line shows that the test has been carried out correctly.

REAGENTS AND MATERIALS

HBsAg Card: 50tests/kit

PRECAUTION FOR USERS

1. For in-vitro diagnostic use only.
2. Handle all specimens as if they contain infectious agents. When the assay procedure is completed, dispose of specimens carefully after autoclaving for at least one hour. Alternatively, treat with a 0.5 or 1% solution of sodium hypochlorite for one hour before disposal.
3. Wear protective clothing (laboratory coats and disposable gloves) when assaying samples.
4. Do not eat, drink or smoke in areas where specimens and kit reagents are handled.
5. Avoid contact between hands and eyes or nose during specimen collection and testing.

SPECIMEN COLLECTION AND PREPARATION

The HBsAg-Card is performed on human serum. Patient samples are best performed if tested immediately. HBsAg is thermolabile. Specimens should be refrigerated at 2-8°C, immediately following collection, for up to 3 days. If testing within 3 days is not possible, the specimens should be frozen (-20°C). If specimens are to be shipped, they should be packed in compliance with regulations covering the transportation of etiologic agents. Specimens containing precipitate may give inconsistent results. Such specimens should be clarified prior to assay.

STORAGE OF TEST KIT

The HBsAg-Card can be stored at any temperature between 4-30°C. **Do not freeze.** The stability of the kit under these storage conditions is 18 months. Use up the reagents as soon as possible after the kit is unpacked.

ASSAY PROCEDURES

1. Allow all reagents to reach room temperature before use.
2. Add 3-4d serum specimen into the small plastic well.
3. Wait for 10-20 minutes and read results. Do not read results after more than 25 minutes.

INTERPRETATION OF RESULTS

Negative: One pink line appears in control line, showing the test has been carried out correctly. There will be no line in test region

Positive: In addition to a pink colored control line, a distinct pink colored band will also appear in the test region.

Invalid: A total absence of color in both regions is an indication of procedure error and/or that the test reagent has deteriorated. The test should be repeated using a new strip.

LIMITATIONS OF THE ASSAY

HBsAg-Card is for in vitro diagnostic use only. The test will only indicate the presence or absence of Hepatitis B Surface Antigen in the specimen, and should not be used as the only basis for the diagnosis of Hepatitis viral infection. False positive results can occur in about 1% of cases because of the presence of other antigens. Additional follow up testing using other clinically available methods is required if the result is negative and clinical symptoms persist.

TEST PERFORMANCE

HBsAg-Card was compared with leading commercial RIA and EIA test for Hepatitis B. There was 98% overall agreement between RIA and this HBsAg-Card, and 97% agreement between EIA and HBsAg-Card. Typically, HBsAg-Card will detect any level of HBsAg greater than or equal to 1.5 ng/ml. Usually this level of sensitivity appears 20 to 30 minutes after addition of the sample

SPECIFICITY

All 10 HBsAg subtypes (ayw1, ayw2, ayw3, ayw4, ayr, adwr, adw4, adrg, ady4 and adr) produced positive results in the HBsAg-Card assay. Specificity of the HBsAg-Card was also tested with laboratory strains of Hepatitis A and Hepatitis C. They all gave negative results.

SENSITIVITY

HBsAg-Card was tested with a sensitivity panel ranging from 0 to 300 ng/ml (0, 0.5, 1, 2, 5, 100 and 300). Typically, concentrations higher than 5ng/ml appear positive within 10 minutes. However, to detect concentrations below 5ng/ml, and to confirm negative results, the test should be read at the end of 15 to 20 minutes.

ACCURACY

Intra-assay:

Within-assay precision was determined using 10 replicates of three specimens containing 0, 1 and 5 ng/ml of HBsAg. The negative and positive values were correctly identified in 100% of cases.

Inter-assay:

Between-run precision was determined using the same three specimens of 0, 1 and 5 ng/ml of HBsAg in 10 independent assays and with three different batches of HBsAg-Card test strip over a 6 month period. Again, the negative and positive values were correct in 100% of cases.

RELATED READING MATERIALS

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