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Diagnostic Effectiveness of All Test HBsAg Rapid Test Kit Compared with ELISA Serology

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Abstract

Background: HBsAg Rapid Diagnostic Tests (RDT) has been developed for the detection of hepatitis B surface antigen (HBsAg). They represent a promising alternative to enzyme immunoassays and a powerful tool for large-scale screening and diagnosis of HBV infection, especially in regions without access to serological and molecular testing (3).

Objective: This study aimed to evaluate the effectiveness of the AllTest HBsAg Rapid Test Kits for the qualitative detection of Hepatitis B Surface Antigen (HBsAg) in whole blood, serum or plasma to aid in the diagnosis of hepatitis B virus (HBV) infection.

Method: A rapid in vitro diagnostic test device for detection of HBsAg in Whole Blood, Serum or Plasma was evaluated and compared with ELISA serology. Sensitivity (Se) and specificity (Sp) were used to estimate test performance.

Results: The relative Se and Sp (lower bound of 95% CI) were as follows: >99.9% and 99.6% for serum or plasma specimens; and >99.9% and 99.5% for whole blood specimens.

Conclusion: The All Test HBsAg Rapid Test Kit could be considered an ideal method for HBV screening, given the ease of use, fast testing time, and high accuracy. The test utilizes a combination of monoclonal and polyclonal antibodies to selectively detect elevated levels of HBsAg in whole blood, serum or plasma.

Keywords: Antenatal care; Ethiopia; Gondar city; Perceived Stress

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Introduction

Hepatitis B virus (HBV), a DNA virus with a human-only reservoir, is a worldwide public health issue [5]. In Far-East Asia and tropical Africa, chronic carriers of the HBV represent 10% or more of the population and chronic active hepatitis and liver cirrhosis are major causes of mortality (6). Moreover, epidemiological studies have clearly shown the importance of HBV in hepatocellular carcinoma (HCC), one of the most common cancers in the world [1, 7]. In China, between 500,000 and one million new cases appear every year. HBV is one of the few viruses known to be involved in human cancer [1, 8]. Viral hepatitis is a systemic disease primarily involving the liver. Most cases of acute viral hepatitis are caused by hepatitis A virus, hepatitis B virus or hepatitis C virus. The complex antigen found on the surface of HBV is called HBsAg. Previous designations included Australia or Au antigen [2]. The presence of HBsAg in whole blood, serum or plasma is an indication of an active HBV infection, either acute or chronic. In a typical hepatitis B infection, HBsAg will be detected 2 to 4 weeks before the ALT level becomes abnormal and 3 to 5 weeks before symptoms or jaundice develop. HBsAg has four principal subtypes: adw, ayw, adr and Ayr. Because of antigenic heterogeneity of the determinant, there are 10 major serotypes of the HBV.

HBV Prevention

More than two billion people have been infected worldwide, and of these, more than 350 million suffer from chronic HBV infection [7]. The incidence of HBV infection and patterns of transmission vary greatly throughout the world in different population subgroups [7]. In Western countries, chronic HBV infection is relatively rare and acquired primarily in adulthood, whereas in Asia and most of Africa, most infections occur from infected mother to child, from child-to-child contact in household settings, and from the reuse of unsterilized needles and syringes.

Due to the often silent nature of the disease, testing for HBV is imperative for public health, particularly for blood screening.

Chronic carriers with undetected acute infection and low levels of viremia are vulnerable to HBV transmission [3]. Studies also show that early diagnosis and treatment can reduce the risk of the development of long-term complications and prevent further transmission [4]. The World Health Organization (WHO) aims to contribute to the global prevention and control of viral hepatitis infections by [5-7]

• Recommending that hepatitis B vaccine be included in routine immunization services in all countries. The goal for the future is the establishment of national immunization programs for hepatitis B in all countries where such are not yet in place or are not completely implemented. The Global Alliance for Vaccines and Immunization (GAVI) created in 1999 is a unique coalition of public and private institutions that provide support for the 74 low-income countries to reinforce their national vaccine programs and introduce hepatitis B, yellow fever, and Hemophilic influenza type b vaccines into their national immunization programs. As of now, a total of 147 countries have implemented mass vaccination of newborns and infants [8].

• Promoting safe injection techniques that are essential for reducing the global HBV-related morbidity and mortality.

• Raising the awareness of HBV infection among health care providers, policymakers, and the public.

• Collaboration with patient support groups to improve health education, prevention efforts, and treatment compliance.

• Stressing the potential impact of preventive strategies.

HBsAg Rapid Test Kit Materials and Method

The AllTest HBsAg Rapid Test Kit (Whole Blood/Serum/Plasma) is a new rapid immunochromatographic test for the qualitative detection of HBsAg that is performed manually. The single test kit consists of a test cassette, a dropper, a buffer and a package insert. The membrane is pre-coated with anti-HBsAg antibodies on the test line region of the cassette. During testing, the whole blood, serum or plasma specimen reacts with the particle coated with anti-HBsAg antibodies. The mixture migrates upward on the membrane chromatographically by capillary action to react with anti-HBsAg antibodies on the membrane and generate a colored line. The presence of this colored line in the test region indicates a positive result, while the absence of the colored line indicates a negative result. To serve as a procedural control, a colored line will always appear in the control line region indicating that the proper volume of specimen has been added and membrane wicking has occurred.

The HBsAg Rapid Test Kits can be performed using whole blood (from venipuncture or finger stick), serum or plasma. The three specific operation methods are as follows:

For Serum or Plasma specimen

The first step is to separate serum or plasma as soon as possible to avoid hemolysis. The instructions note to only use clear non-hemolysis specimens. Next, three drops of serum or plasma (approximately 75 µl) are added to the specimen area and start the timer.

For Venipuncture Whole Blood specimen

Three drops of whole blood (approximately 75 µl) are added to the specimen area and then one drop of buffer solution (approximately 40 µl).

For Finger stick Whole Blood specimen

Fill the capillary tube and transfer approximately 75 µl of finger stick whole blood specimen to the specimen area and then one drop of buffer solution (approximately 40 µl). The intensity of the color in the Test line region (T) will vary depending on the concentration of HBsAg present in the specimen. Therefore, any shade of color in the Test line region (T) should be considered a positive result. A colored line will always appear at the Control (C) location on the cassette to indicate that the assay worked correctly. The test result is obtained in 30 minutes or less.

The AllTest HBsAg Rapid Test Kit correctly identified specimens of a seroconversion panel and was compared to ELISA, which served as the gold standard. The results show that the relative sensitivity of the HBsAg Rapid Test Kit to plasma and serum specimens is >99.9% and the relative specificity is 99.6%. The relative sensitivity of the HBsAg Rapid Test Kit to whole blood specimens is >99.9% and the relative specificity is 99.5%. (See Table 1 &2: AllTest HBsAg Rapid Test Compared to ELISA HBsAg Test Kit) Within-run precision was determined by using 10 replicates of six specimens containing 0ng/ml, 1ng/ml, 2ng/ml, 5ng/ml, 12ng/ml, and 20ng/ml of HBsAg. The negative and positive values were correctly identified >99% of the time. Between-run precision was determined by using the same six specimens of 0ng/ml, 1ng/ml, 2ng/ml, 5ng/ml, 12ng/ml, and 20ng/ml of HBsAg in 3 independent assays. Three different lots of the HBsAg Rapid Test Cassette (Whole Blood/Serum/Plasma) have been tested using negative, low positive and high positive specimens. The specimens were correctly identified >99% of the time (**Tables 1 and 2**).

Table 1. All Test HBsAg Rapid Test Compared to ELISA HBsAg Test Kit Serum or plasma specimens.

Method		ELISA		Total Results
HBsAg Rapid Test (WB/Serum/Plasma)	Results	Positive	Negative	
	Positive	180	2	182
	Negative	0	550	550
Total Results		180	552	732

Relative Sensitivity: ＞99.9% (95%CI: *98.3%-100%)
Relative Specificity: 99.6% (95%CI: *98.7%-99.9%)
Overall accuracy: 99.7% (95%CI: *99.0%-99.9%)

Table 2. AllTest HBsAg Rapid Test Compared to ELISA HBsAg Test Kit Whole Blood specimens.

Method		ELISA		Total Results
HBsAg Rapid Test (WB/Serum/Plasma)	Results	Positive	Negative	
	Positive	180	1	181
	Negative	0	200	200
Total Results		180	201	381

Relative Sensitivity: ＞99.9% (95%CI: *98.3%-100%)
Relative Specificity: 99.5% (95%CI: *97.3%-99.9%)
Overall accuracy: 99.7% (95%CI: *98.5%-99.9%)

Compared to conventional testing methods, rapid tests can be performed directly at the point-of-care (POC) and produce results in 15-30 minutes, enabling healthcare providers to quickly share results with patients. Therefore, in the last 20 years, the availability and use of POC tests have markedly increased and expanded to all fields of medicine. In the setting of infectious diseases, most existing POC tests consist of immunoassays, including agglutination or immunochromatographic strips (strip tests). These methods can be used to accurately detect HBsAg.

Summary

In conclusion, the AllTest HBsAg Rapid Test kit is a simple, fast, easy-to-run and highly sensitive assay that can be used in both high- and low-risk populations for the diagnosis of HBsAg carriage with 99.7% accuracy. As many studies indicate, rapid diagnostic tests appear as promising new tools for large-scale screening and diagnosis of HBV infection in clinical settings [3]. However, the laboratory evaluation could differ from test performance outside of a laboratory due to factors such as limited sample size and staff training. From the results of the tested samples, it presents that the HBsAg Rapid Test Kit developed by Hangzhou AllTest Biotech Co., Ltd meets the requirements of intended use.

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