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Evaluation of the Performance of the HBsAb Rapid Test for Hepatitis B Antibody Detection

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Abstract

The Hepatitis B is a serious liver infection caused by the Hepatitis B Virus (HBV), remains a significant public health concern due to its global prevalence and related complications. The presence of HBsAg in whole blood, serum or plasma is an indication of an active Hepatitis B infection, either acute or chronic. As a result, vaccination against HBV was introduced to control the morbidity and mortality associated with the virus. As part of the World Health Organization program for control Hepatitis B. Many people, especially new born, receive vaccination. HBsAb, the antibody to HBsAg, can be detected after receiving the HBV vaccination, and will gradually decrease over time. The minimum standard titer of HBsAb is 10 mIU/mL for protective immunity to HBV. HBsAb ≥ 10mIU/mL indicates successful vaccination and immunity against the hepatitis B virus. Unfortunately, approximately 5-15% of healthy immune competent individuals either does not exhibit an antibody response to the existing recombinant vaccination or respond poorly.

This study evaluates the performance of the HBsAb rapid test, developed by Hangzhou AllTest Biotech Co., Ltd, in comparison to the Radio-Immuno Assay (RIA) method. Clinical trials, employing human whole blood, serum, plasma samples, aimed to ascertain the sensitivity, specificity, and accuracy of the HBsAb rapid test. The HBsAb Rapid Test Cassette (Whole Blood/Serum/Plasma) is a rapid test to qualitatively detect the presence of HBsAb in whole blood, serum or plasma specimen. The test utilizes a double antigen sandwich system to detect as low as 10 mIU/ml of HBsAb in whole blood, serum or plasma.

The HBsAb Rapid Test Cassette (Whole Blood/Serum/Plasma) demonstrated ultra-high sensitivity of 99.9% and a specificity of 99.4%, underscoring its accuracy and reliability in identifying HBsAb. Such performance metrics highlight the viability as a supplementary diagnostic tool in HBsAb detection and management.

Keywords: Hepatitis B; Hepatitis B surface antibody; Vaccination; Rapid test; Radio immune assay

Introduction

Viral hepatitis

Viral hepatitis refers to a group of infectious diseases characterized by inflammation of the liver caused by viral infections. Among the various types of viral hepatitis, Hepatitis B virus (HBV) is significant concern globally. Hepatitis B is an infectious disease caused by the Hepatitis B Virus (HBV) that affects the liver [1]. It can cause both acute and chronic infection.

A sizeable number of individuals have no symptoms during the early stage of infection, while others may exhibit symptoms within 30 to 180 days after becoming infected. These symptoms can manifest as a sudden onset of illness characterized by nausea, vomiting, yellowish discoloration of the skin, fatigue, dark-colored urine, and abdominal discomfort. Typically, the symptoms observed during the acute phase of infection persist for a duration ranging from a few weeks to as long as six months.

The virus is transmitted by exposure to infectious blood or body fluids. In regions with a high prevalence of the disease, the most common modes of acquiring hepatitis B are perinatal infection or contact with the blood of others during childhood. Conversely, in regions where the disease is less prevalent, intravenous drug use and sexual intercourse are the primary routes of infection. Additional risk factors include healthcare-related occupations, blood transfusions, dialysis, cohabitation with an infected individual, travel to countries with high infection rates, and residing in institutional settings. The detection of the infection can generally be made between 30 to 60 days after the exposure, and diagnosis typically involves testing the blood for specific viral components and antibodies associated with the virus [2].

It is estimated that in 2022 the global prevalence of chronic HBV infection was 3.2%, equivalent to 257 million cases of infection. It can lead to severe health consequences, including liver decompensation, cirrhosis, and Hepatocellular Carcinoma (HCC), resulting in high morbidity and mortality rates [3]. The highest prevalence of the

disease is founded in Africa, affecting around 7.5% of the continent's population, followed by the Western Pacific region with a prevalence of 5.9%. In Europe, the infection rate is approximately 1.5%, while in the Americas around 0.5%.

In order to effectively combat viral hepatitis and work towards its elimination, it is crucial to develop curative therapeutic treatments for chronic hepatitis B, implement preventive measures to reduce transmission, administer vaccines to prevent new infections, and prioritize early detection strategies.

The relationship between HBsAb and HBV vaccination

The hepatitis B vaccines consist of a viral envelope protein, known as the Hepatitis B surface Antigen (HBsAg), which stimulates the immune system to produce antibodies against the Hepatitis B surface protein (anti-HB). These antibodies, along with the immunological memory of the immune system, enable the human body to defend against hepatitis B infection. The presence of HBsAb antibodies indicates clinical recovery and subsequent immunity to HBV infection. It is the last antibody to appear after HBV infection and is associated with the development of post-immunization immunity.

The Hepatitis B surface Antibody test (HBsAb) detects proteins that are made by the immune system (antibodies) in response to the Hepatitis B Virus (HBV). HBsAb test is used to find out if individuals are immune to the virus after natural exposure or vaccination.

A positive or "reactive" outcome of the HBsAb test indicates immunity to the hepatitis B virus. Conversely, a negative or "non-reactive" result suggests the absence of immunity to the virus. The HBsAb test is capable of detecting prior exposure to HBV and shows how recent it was. Moreover, the test can assess the results of vaccine protection. Results from the HBsAb test can determine whether an individual is considered successfully vaccinated or not regarding hepatitis B immunity. If the HBsAb level drops below the protective threshold, a booster vaccine may be necessary.

An anti-Hbs antibody level above 100 mIU/mL is deemed adequate, and occurs in about 85-90% of individuals. An antibody level between 10 and 100 mIU/mL is considered a poor response, and these people should receive a single booster vaccination at this time, but do not need further retesting [4-8]. People who fail to respond (anti-Hbs antibody level below 10 mIU/mL) should be tested to exclude current or past hepatitis B infection, and given a repeat course of three vaccinations, followed by further retesting 1-4 months after the second course.

Materials and Methods

Evaluation of AllTest HBsAb rapid test

Objective: The main purpose of this evaluation report was to assess the reliability and performance of the HBsAb Rapid Test Cassette in determining the level of HBsAb in whole blood, serum, or plasma samples to aid in assessing immunity to the hepatitis B virus following the vaccination.

Method: The evaluation involved a comprehensive analysis of the performance characteristics of the HBsAb Rapid Test Cassette. Clinical trials were conducted using human samples, including Whole Blood, Serum, and Plasma, to determine the sensitivity, specificity, and overall accuracy of the test. The performance of the HBsAb Rapid Test Cassette was assessed by comparing its results with those obtained from established reference methods, such as the Radioimmunoassay (RIA).

Principle: The HBsAb Rapid Test Cassette (Whole Blood/Serum/Plasma) is a qualitative, lateral flow immunoassay for the detection of HBsAb in whole blood, serum or plasma. The membrane is pre-coated with HBsAg on the test line region of the strip. During testing, the whole blood, serum or plasma specimen reacts with the particle coated with HBsAg. The mixture migrates upward on the membrane chromatographically by capillary action to react with HBsAg on the membrane and generate a colored line. The presence of this colored line in the test region indicates a positive result, while its absence indicates a negative result. To serve as a procedural control, a colored line will always appear in the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

Materials and directions for use: The HBsAb Rapid Test kit includes the following components: Test cassettes, droppers, and buffer. Additional materials required to conduct the experiment include specimen collection containers, centrifuge, and timer.

Prior to conducting the test, it is important to ensure that the test, specimen, buffer, and/or controls have reached room temperature (15-30°C). Therefore, it is recommended to allow them to equilibrate at room temperature before proceeding. To ensure accurate testing, place the cassette on a clean and level surface.

For serum or plasma specimens, hold the dropper in a vertical position and carefully transfer 3 drops (approximately 75 L) to the specimen well of the test cassette. Start the timer at this point. In the case of a venipuncture whole blood specimen, hold the dropper vertically and dispense 3 drops (approximately 75 L) of whole blood onto the designated specimen area. Then, add 1 drop of buffer (approximately 40 L) and initiate the timer.

When using a fingerstick whole blood specimen, there are two methods. Firstly, using a capillary tube, fill it with the fingerstick whole blood and transfer approximately 75 L onto the specimen area of the test cassette. Subsequently, add 1 drop of buffer (approximately 40 L) and start the timer. Alternatively, using hanging drops, allow 3 hanging drops of fingerstick whole blood (approximately 75 L) to fall onto the specimen area of the test cassette. Then, add 1 drop of buffer (approximately 40 L) and begin the timer.

Observe the test cassette for the appearance of colored lines. Results should be showed after 15 minute. It is important not to interpret the result after 20 minutes, as it may lead to inaccurate conclusions.

Results and Discussion

Performance characteristics

Sensitivity: The sensitivity of the HBsAb Rapid Test Cassette (Whole Blood/Serum/Plasma) has been evaluated using a comprehensive sensitivity panel encompassing a range from 1 mIU/ml to 40 mIU/ml. The results of the evaluation demonstrated that the test can reliably detect HBsAb at a concentration as low as 10 mIU/ml within just 15 minutes (Table 1).

Method		RIA	Total	
HBsAb Rapid Test Cassette (Whole Blood/Serum/Plasma)	**Results**	**Positive**	**Negative**	**Results**
	Positive	189	2	191
	Negative	0	341	341
Total Results		189	343	532

Table 1: HBsAb rapid test cassette *vs*. RIA. Relative

sensitivity: >99.9% (95%CI*: 98.4%-100%) Relative

specificity: 99.4% (95%CI*: 97.9%-99.9%)

Accuracy: 99.6% (95%CI*: 98.6%-100%); *: Confidence intervals

Specificity: The HBsAb Rapid Test Cassette (Whole Blood/Serum/Plasma) incorporates an antigen that demonstrates a high level of specificity for the detection of HBsAb in whole blood, serum, or plasma samples. This antigen is carefully selected and designed to specifically a target and bind with HBsAb, ensuring accurate and reliable test results. To validate the specificity of the HBsAb Rapid Test Cassette, comparative assessments have been conducted, including the comparison with a widely recognized and established method, the Radioimmunoassay (RIA).

Precision

Intra-assay: Within-run precision has been determined by using 15 replicates of three specimens containing negative, low positive and high positive. 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 specimens of negative, low positive and high positive of HBsAb in 15 independent assays. Three different lots of the HBsAb Rapid Test Cassette (Whole Blood/Serum/Plasma) has been tested over a 3-day period using negative, low positive and high positive specimens. The specimens were correctly identified 99% of the time.

Cross-reactivity: The HBsAb Rapid Test Cassette (Whole Blood/Serum/Plasma) has been tested by HAMA, Rheumatoid factor (RF), HAV, Syphilis, HIV, H. Pylori, MONO, CMV, Rubella and TOXO positive specimens. The results showed no cross-reactivity.

Interfering substances: The HBsAb Rapid Test Cassette (Whole Blood/Serum/Plasma) has been tested for possible interference from visibly hemolyzed and lipemic specimens. No interference was observed. additionally, no interference was observed in specimens containing up to 2,000 mg/dL Hemoglobin, 1000 mg/dL Bilirubin, and 2000 mg/dL human serum Albumin.

In summary, the HBsAb Rapid Test Cassette (Whole Blood/Serum/Plasma) demonstrates high sensitivity, specificity, precision, and minimal interference, making it a reliable and efficient tool for the detection of HBsAb in clinical settings.

Conclusion

The HBsAb Rapid Test Cassette (Whole Blood/Serum/Plasma) demonstrates a remarkably high sensitivity of 99.9% and a specificity of 99.4%, highlighting its accuracy and reliability in detecting HBsAb. These performance measures emphasize its potential as an adjunct diagnostic tool for HBsAb detection and management. The test's sensitivity was evaluated using a comprehensive panel spanning concentrations from 1 mIU/ml to 40 mIU/ml, and the results confirm its ability to reliably detect HBsAb even at a low concentration of 10 mIU/ml within a rapid 15-minute timeframe.

However, while these findings bring hope, it should be noted that more extensive evaluations in different real-world settings may provide further insights. Future research could focus on understanding the utility and acceptance of this diagnostic tool among diverse healthcare professionals. Additionally, ongoing studies indicate room for improvement, particularly in detecting HBsAb levels below 10 mIU/ml in samples. These results strongly suggest the inclusion of HBsAb Rapid Test in broader screening programs. The comparative study presented in this report indicates that the HBsAb rapid test developed by Hangzhou AllTest Biotech Co., Ltd., in comparison to the RIA results. Demonstrating ultra-high specificity, sensitivity, and accuracy.

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