Clinical Evaluation Report of HBsAg Reagent Kit

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ABSTRACT

Automatic qualitative in vitro detection of HBsAg in human serum is clinically used to assist diagnosis, monitor the progression of the disease, and monitor individual recovery from hepatitis B. HBsAg detection is also important because its function as a screening test to prevent transmission of HBV to blood components, cells, tissues, and organs in recipients. The objective of this study was to evaluate the performance of HBsAg Reagent Kit VIRTUEDX CS HBsAg (Chemiluminescent Method). This clinical study used cross-sectional design. The sample size was 80. The HBsAg test uses chemiluminescence immunoassay (CLIA). Based on the test results, VIRTUEDX CS HBsAg had the sensitivity 100%, the specificity 97.5% and the accordance rate 98.75%. The within run and between day precision tests showed coefficient of variation (CV) were both appropriate. This study confirmed the performance of VIRTUEDX CS HBsAg was good overall terms of sensitivity, specificity, accordance rate, and precision.

Keywords: CLIA, HBsAg, hepatitis B, performance test

BACKGROUND

Hepatitis B virus (HBV) approximately infected 2 billion people worldwide with 240 million are chronic carriers. This condition causes major health problems in later life including liver failure, chirrosis, and hepatocellular carcinoma (HCC). In Indonesia, the prevalence of people with positive hepatitis B surface antigen (HBsAg) was 9.4% (of 10,391 samples). There has been a decreased prevalence of HBsAg in 2013, indicating that Indonesia has moved from high to moderate HBV infection endemicity.[1]

HBsAg is the key primary marker for screening and diagnosis of HBV infection.[2] Automatic qualitative in vitro detection of HBsAg in human serum is clinically used to assist diagnosis, monitor the progression of the disease, and monitor individual recovery from hepatitis B. HBsAg detection is also important because its function as a screening test to prevent transmission of HBV to blood components, cells, tissues, and organs in recipients. The principle of HBsAg examination is immunoassay, one of which is chemiluminescence Immunoassay (CLIA).[3] The objective of this study was to evaluate the performance of HBsAg Reagent Kit VIRTUEDX CS HBsAg (Chemiluminescent Method).

METHODS

This clinical study used cross-sectional design. This study corresponded to the ethical guidelines of the Declaration of Helsinki, clinical trial research norms, and regulations. This study was approved by the Ethics Committee of Universitas Indonesia Hospital (Number: S-059/KETLIT/RSUI/VIII/2023).

Minimum sample size was 80 (around half are negative and half are positive) using test and reference reagents for a single determination. The samples were grouped in a synchronous blinded control group.

Inclusion criteria : Sample was serum with volume not < 0.8 mL.

Exclusion criteria : Sample that was freezed and thawed more than twice, stored at room temperature for > 24 hours; at 2-8° C for > one week; or at -20° C for > three months, not mixed well, with severe hemolysis, lipemia, fibrin, or other particulate matter, with obvious flocculent or microbial contamination, with oil slick from separation gel, with blood clot, with unclear mark or specially treated, or from ruptured blood vessels.

The HBsAg test uses chemiluminescence immunoassay (CLIA) which involves two-site immunoassay ("sandwich" principle) to determine the presence of HBsAg in human serum. The test reagent was VIRTUEDX CS HBsAg qualitative Reagent Kit (Table. 1)

Table 1. Test and reference reagent kits

	Test Reagent	Reference Reagent
Analyzer	VIRTUEDX CS HBsAg Qualitative	ARCHITECT HBsAg Qualitative Reagent Kit
Manufacturer	PT. Virtue Diagnostics Indonesia	Abbott
Methodology	sandwich two-step	sandwich two-step
Storage	2-8°C	2-8°C
Testing Equipment	VERCENTRA CS-1500	ARCHITECT i2000SR

RESULT AND DISCUSSION

Based on the test results, VIRTUEDX CS HBsAg had the sensitivity 100%, the specificity 97.5% andthe accordance rate 98.75% (Table 2.).

Table 2. Performance of the test kit

Virtue	Abbott		total
	positive	negative	
positive	40	1	41
negative	0	39	39
total	40	40	80
TPR	**sensitivity 100%**		
TNR	**specificity 97,5%**		
TTR	**accordance rate 98,75%**		

The within run test showed coefficient of variation (CV) of all negative and 3.05% (CV<8%). The between day test showed CV of all negative and 5.35% (CV<10%). These CVs were appropriate based on their cut offs.

These study findings were similar to Khadem-Ansari et al.[3] that showed HBsAg assay with CLIA principle had sensitivity and specificity respectively from 96% and 100%, respectively. Wu et al.[4] showed that the CV of HBsAg test kit was 7.07% which means this study had lower CV.

CONCLUSION

This study confirmed the performance of VIRTUEDX CS HBsAg qualitative was good overall in terms of sensitivity, specificity, accordance rate, and precision.

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