Clinical Evaluation Report of Anti-HBs Reagent Kit

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ABSTRACT

Automatic quantitative in vitro detection of anti-HBs in human serum is clinically used to assist diagnosis, monitor the progression of the disease, monitor individual recovery from hepatitis B, and evaluate the protective benefit of hepatitis B vaccination. The objective of this study was to evaluate the performance of Anti-HBs Reagent Kit VIRTUEDX CS Anti-HBs (Chemiluminescent Method). This clinical study used cross-sectional design. The sample size was 80. The Anti-HBs test uses chemiluminescence immunoassay (CLIA). Based on the test results, VIRTUEDX CS Anti-HBs had the sensitivity 97.5%, the specificity 95% and the accordance rate 96.3%. The within run and between day precision tests showed coefficient of variation (CV) were both appropriate. This study confirmed the performance of VIRTUEDX CS Anti-HBs was good overall terms of sensitivity, specificity, accordance rate, and precision.

Keywords: anti-HBs, CLIA, 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).[1]

In Indonesia, the prevalence of people with positive antibody of hepatitis B surface antigen (anti-HBs/ HbsAb) was 0.6 % (of 16,904 samples).[1] Hepatitis B surface antigen (HBsAg) is the primary marker for screening and diagnosis of HBV infection. However, the presence of anti-HBs shows both natural infection and vaccine-induced immunity.[2]

Automatic quantitative in vitro detection of anti-HBs in human serum is clinically used to assist diagnosis, monitor the progression of the disease, monitor individual recovery from hepatitis B, and evaluate the protective benefit of hepatitis B vaccination. The principle of anti-HBs examination is immunoassay, one of which is chemiluminescence Immunoassay (CLIA).[3] The objective of this study was to evaluate the performance of Anti-HBs Reagent Kit VIRTUEDX CS Anti-HBs (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 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 Anti-HBs test uses chemiluminescence immunoassay (CLIA) which involves two-site immunoassay ("sandwich" principle) to determine the presence of Anti-HBs in human serum. The test reagent was VIRTUEDX CS Anti-HBS Reagent Kit (**Table. 1**)

Table 1. Test and reference reagent kits

	Test Reagent	Reference Reagent
Analyzer	VIRTUEDX CS Anti-HBS Reagent Kit	ARCHITECT Anti-HBS Reagent Kit
Manufacturer	PT. Virtue Diagnostics Indonesia	Abbott
Methodology	sandwich two-step	sandwich two-step
Storage	2-8°C	2-8°C
Measurement Range	5-1000 mIU/mL	2.5-1000 mIU/mL
Testing Equipment	VERCENTRA CS-1500	ARCHITECT i2000 SR

RESULT AND DISCUSSION

Based on the test results, VIRTUEDX CS Anti-HBs had the sensitivity 97.5%, the specificity 95% and the accordance rate 96.3% (**Table 2.**).

The within run test showed coefficient of variation (CV) of 2.42% (all negative) and 5.52% (CV<8%). The between day test showed CV of 3.25% (all negative) and 1.82% (CV<10%). These CVs were appropriate based on their cut offs.

Table 2. Performance of the test kit

Virtue	Abbott		total
	positive	negative	
positive	40	2	42
negative	1	38	39
total	41	40	81
TPR	**sensitivity 97,5%**		
TNR	**specificity 95%**		
TTR	**accordance rate 96,3%**		

These study findings corresponded to Raven et al.4 that compiled anti-HBs assay from various kits including Architect, Vidas, ADVIA Centaur, Roche, AxSYM, and Access. Sensitivity and specificity ranged respectively from 64%–100% and 95%–100%. Raven et al.4 showed the CV ranged from 17% to 57% which means this study had lower CV.

CONCLUSION

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

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