Clinical Evaluation Report of Anti-HCV Reagent Kit

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ABSTRACT

Automatic qualitative in vitro detection of anti-HCV in human serum is clinically used to assist diagnosis of hepatitis C. It is also used as a screening test to prevent transmission of HCV in blood components, cells, tissues, or organs in the recipients.

The objective of this study was to evaluate the performance of Anti-HCV Reagent Kit VIRTUEDX CS Anti-HCV (Chemiluminescent Method).

This clinical study used cross-sectional design. The sample size was 80. The Anti-HCV test uses chemiluminescence immunoassay (CLIA).

Based on the test results, VIRTUEDX CS Anti-HCV had the sensitivity 100%, the specificity 100% and the accordance rate 100%. 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-HCV was good overall terms of sensitivity, specificity, accordance rate, and precision.

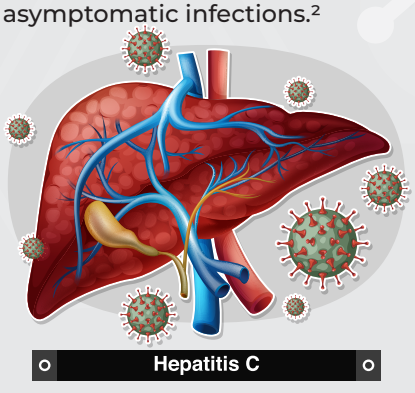
Keywords: anti-HCV, CLIA, hepatitis C, performance test

VERCENTRA CS-1500

BACKGROUND

Hepatitis C virus (HCV) and hepatitis B virus (HBV) cause serious problem in approximately 250 million people worldwide. Chronic HCV infection causes major health problems in later life including chirrosis, and hepatocellular carcinoma (HCC).[1]

In Indonesia, the prevalence of people with positive antibody of hepatitis C virus (anti-HCV) was 0.82% (of 11,762 samples), with peak incidence in the middle age groups.[1] Anti-HCV detection is the primary marker for screening and diagnosis of HCV infection. However, the detection of HCV infection is quite challenging because of the latent asymptomatic infections.[2]


Hepatitis C

Automatic qualitative in vitro detection of anti-HCV in human serum is clinically used to assist diagnosis of hepatitis C. It is also used as a screening test to prevent transmission of HCV in blood components, cells, tissues, or organs in the recipients. The principle of anti-HCV examination is immunoassay, one of which is chemiluminescence Immunoassay (CLIA).[3] The objective of this study was to evaluate the performance of Anti-HCV Reagent Kit VIRTUEDX CS Anti-HCV (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-HCV test uses chemiluminescence immunoassay (CLIA) which involves two-site immunoassay ("sandwich" principle) to determine the presence of Anti-HCV in human serum. The test reagent was VIRTUEDX CS Anti-HCV Reagent Kit (Table. 1)

	Test Reagent	Reference Reagent
Analyzer	VIRTUEDX CS Anti-HCV Reagent Kit	ARCHITECT Anti-HCV 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 Anti-HCV had the sensitivity 100%, the specificity 100% and the accordance rate 100% (Table 2.).

The within run test showed coefficient of variation (CV) of all negative and 4.38% (CV<8%). The between day test showed CV of all negative and 4.73% (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	0	40
negative	0	40	40
total	40	40	80
TPR	**sensitivity 100%**		
TNR	**specificity 100%**		
TTR	**accordance rate 100%**		

These study findings were similar to Li et al.[2] that showed the sensitivity and specificity of anti-HCV CLIA test were 100% and 99.75% respectively. Tsoi et al.[4] showed the CV ranged from 4.5 to 7.3% which means this study had similar CV.

CONCLUSION

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

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