

# Technical expertise of the Turklab Toyo anti-HCV rapid test

Stéphane Chevaliez, PharmD, PhD  
Jean-Michel Pawlotsky, MD, PhD

French National Reference Center for Viral Hepatitis B, C and delta  
Department of Virology & INSERM U955  
Henri Mondor Hospital  
Creteil, France

The National Reference Center for Viral Hepatitis B, C and delta (Director: J-M Pawlotsky) has assessed the analytical performance of the rapid anti-HCV test in fresh clinical specimens, i.e. unfrozen sera kept at 2-8°C for less than one week.

A total of 150 clinical specimens, including 100 HCV-seronegative and 50 HCV-seropositive samples as assessed by 3rd generation EIA assay [Vitros ECI™, Ortho-Clinical Diagnostics (Rochester, New-York)] were tested by means of the Toyo anti-HCV rapid test.

The Toyo anti-HCV rapid test is a rapid immunochromatographic test for the qualitative detection of total anti-HCV antibodies (Abs) performed manually with a visual readout. A double reading was made after 15 minutes. The development of a purple line in the test line region indicates the presence of total anti-HCV Abs in the clinical specimen. The absence of a colored line indicates the absence of total anti-HCV Abs or the presence at a concentration below the limit of detection of the test. Each test strip also incorporates a built-procedural control for reagent stability and test functionality, and indicates that the full reagents have properly flowed up the test strip.

The results are presented in Table 1.

. The specificity of the Toyo anti-HCV rapid test was assessed by testing 100 fresh HCV-seronegative clinical specimens. All of them tested anti-HCV negative with the Toyo anti-HCV rapid test. Specificity was 100% (95% confidence interval (95%CI), 96.3%-100.0%).

. The clinical sensitivity of the Toyo anti-HCV rapid test was assessed by testing 50 fresh clinical specimens from HCV-infected patients. All of them tested positive for total anti-HCV Abs by the Toyo anti-HCV rapid test. Sensitivity was 100% (95%CI, 92.9%-100.0%).

Table 1. Specificity and sensitivity of the Toyo anti-HCV rapid test

Toyo anti-HCV rapid test		Anti-HCV EIA (Vitros ECI HCV)	
		Positive	Negative
	+	50	0
	-	0	100

In conclusion, our study, based on a relatively small number of samples tested, shows that the Toyo anti-HCV rapid test is a simple, rapid, specific and sensitive test for freshly collected serum samples from HCV-seronegative and -seropositive patients.

Dr. Stéphane Chevaliez  
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