Correlation between a confirmatory test and S/CO values in the initial HCV antibody assay

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Background: Testing for HCV infection begins with an assay for HCV antibody in serum. A nonreactive test result excludes the presence of HCV antibodies. A reactive result indicates one of the following: 1) current HCV infection, 2) past HCV infection that has resolved, or 3) false positivity. A reactive result should be followed by NAT for HCV RNA. If HCV RNA is detected, that indicates current HCV infection. If HCV RNA is not detected, that indicates either past, resolved HCV infection, or false HCV antibody positivity. To distinguish between true and false positivity for HCV antibody, testing may be done with a second HCV antibody confirmatory assay.

The aim of this study is to analyze the correlation between S/CO values obtained in the HCV antibody screening test and a confirmatory test. Study period: 1/1/2015 to 30/9/2015.

Methods: Confirmatory test is performed to all the new diagnosed cases and to patients with known positivity for HVC antibodies without a previous confirmatory test or previous positive viral load. Initial antibody testing for HVC is made by means of (Architect, Abbott), confirmatory assay HVC (INNOLIA HCV Score, Fujirebio Europe, Gent, Belgium) and viral load (detection limit: 15 IU/mL) (Cobas AmpliPrep-Taqman/VHC, Roche, Mannheim, Germany).

Results: During the study period 10.970 serum samples were analyzed for HVC antibodies. There were 256 positive screening tests. 154 (60.16%) out of them had previous confirmatory or positive viral load. Therefore the confirmatory test was performed for the remaining 102 samples. Table 1 shows the relationship between the different cut-off points of screening HCV antibodies and the results of confirmatory assay.

10/102 (9.80%) samples from 9 patients had indeterminate results in the confirmatory test. 5 patients out of them had undetectable viral load and 1 had detectable viral load (log 4.94). In 3 cases there were no samples for determining viral load. These 8 patients with inconclusive results continue on study and undergoing clinical and serological monitoring.

Table1. Results of HVC antibody assay and confirmatory assay.

Screening S/CO Value	Confirmatory assay INNOLIA					
	POSITIVE		INDETERMINATE		NEGATIVE	
	n	%	n	%	n	%
<2.5	8	21.62	3	8.11	26	70.00
2.5-4.9	7	41.18	4	23.53	6	35.29
TOTAL <5	**15**	**27.78**	**7**	**12.96**	**32**	**59.26**
5-9.99	9	75.00	2	16.67	1	8.00
>10	35	97.22	1	2.78	0	0
TOTAL >5	**44**	**91.67**	**3**	**6.25**	**1**	**2.08**

Conclusions:

1. The result of the S/CO value is useful to determine the true positives: 27.78% ≤ 5 are true positives; however when S/CO is >5 91.67% are true positives. With S/CO values >10, 97.22% are true positives.
2. Performing on the same serum sample the confirmatory test has the advantage of avoiding possible false positive reports and reporting the true positives without delay. 9.80% of the samples have indeterminate results in the confirmatory test and require monitoring over time.

References: Testing for HCV Infection: An Update of Guidance for Clinicians and Laboratorians. MMWR May 10, 2013 / 62(18);362-365