

TECHNICAL EVALUATION OF HCV LIAISON XL AND HCV MUREX ETI-MAX FOR HEPATITIS C VIRUS TOTAL ANTIBODY DETECTION

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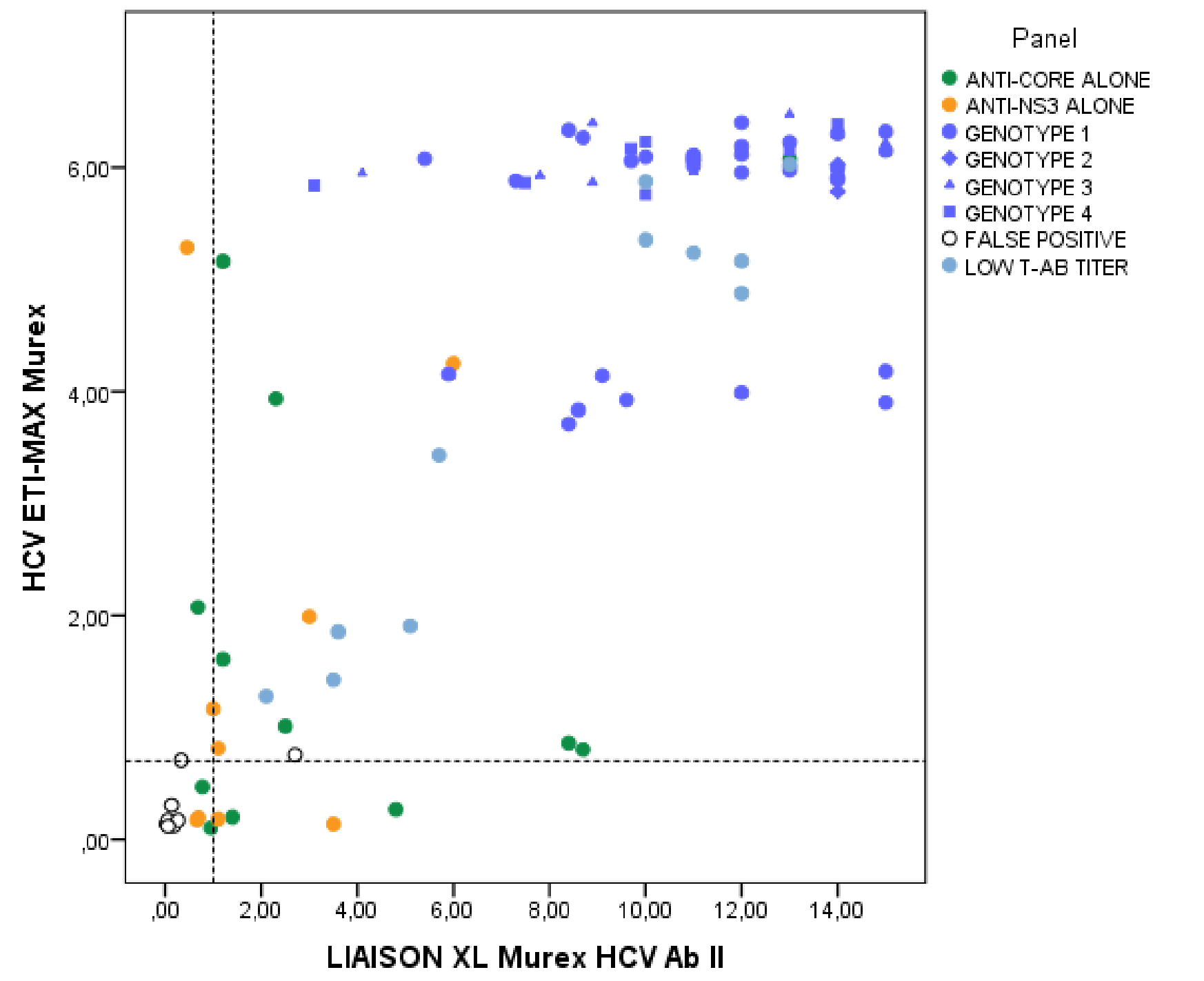
Introduction:
Hepatitis C virus (HCV) total-antibody (T-Ab) detection is useful as screening test, particularly nowadays when detection of unaware infection is one of the points of the strategic plans for HCV treatment. For this purpose, sensitive and specific screening methods are demanded and technical evaluations of them encouraged. **The aim of this study is the assessment of sensitivity and specificity of a new version of DiaSorin LIAISON XL Murex HCV Ab II and ETI-MAX Murex anti-HCV 4.0 for the detection of HCV T-Ab**

Methods:
LIAISON XL Murex HCV Ab II and Murex anti-HCV (4.0) on ETI-MAX were performed according to manufacturer’s instructions. Serum panels samples were selected according to MP HCV Blot 3.0 (MP) results as follows:
 ✓ Assessment of sensitivity:
 ▪ 50 HCV infections RNA positive corresponding to genotypes 1 to 4 [1a (n=15); 1b (n=16); 2a, 2i, 2j (n=3); 3a (n=8); 4a (n=2) and 4d (n=6)].
 ▪ 21 HCV infections with incomplete HCV Ab by MP but positive criteria: anti-Core alone panel (n=12) and anti-NS3 alone panel (n=9).
 ▪ 11 HCV infections with low Ab titer, obtained through dilution (1:10; 1:100; 1:1000, 1:10000 and 1:100000)
 ✓ Assessment of specificity: False positive panel (n=8). Including: negative samples with MP but reactive to other test an one anti-streptavidin Ab.

Results:
Table below shows sensitivity and specificity results by both ETI-MAX MUREX and LIAISON XL with all assayed panels.

Scatter plot graphic of LIAISON XL Murex HCV (S/CO) and ETI-MAX Murex (O.D.) results according to sample panel. Lines indicate established cut/off values

		ETI-MAX MUREX anti-HCV 4.0	LIAISON XL Murex HCV Ab II	
ASSESSMENT OF SENSITIVITY	CHRONIC INFECTIONS RNA POSITIVE CORRESPONDING TO GENOTYPES 1 TO 4	100% (50*/50)	100% (50*/50)	
	HCV INFECTIONS WITH INCOMPLETE AB BY MP BUT POSITIVE CRITERIA	ANTI-CORE ALONE	66,6% (8/12)	75,0% (9/12)
		ANTI-NS3 ALONE	55,5% (5/9)	66,7% (6/9)
	CHRONIC INFECTIONS WITH LOW AB TITER	100% (11/11)	100% (11/11)	
ASSESSMENT OF SPECIFICITY	FALSE POSITIVE PANEL (NON-REACTIVE/TOTAL)	75% (6/8)	87,5% (**7/8)	
SENSITIVITY (REACTIVE/TOTAL)		90,2% (74/82)	92,7% (76/82)	
SPECIFICITY (NON-REACTIVE/TOTAL)		75% (6/8)	87,5% (7/8)	



* No differences in optical density or S/CO values by genotype (ANOVA). ** Non-reactive result in sample with anti-streptavidin Ab.

CONCLUSIONS:

- LIAISON XL Murex HCV Ab II and ETI-MAX Murex anti-HCV 4.0 sensitivity was optimal (100%) for detecting T-Ab in positive RNA HCV chronic infections, even after titration and without differences by genotype.
- LIAISON XL Murex HCV Ab II showed better sensitivity than Murex anti-HCV 4.0 in HCV infections with incomplete Ab pattern (75.0% for anti-Core alone and 66.7% for anti-NS3 alone). When an early infection is suspected, the combined use of T-Ab test with MP HCV Blot 3.0, would increase sensitivity.
- LIAISON XL Murex HCV Ab II showed an excellent specificity (7 non-reactive from 8), even in the sample with confirmed anti-streptavidin antibodies.

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