

# Evaluation of the INNOTEST™ HCV Ab IV at a Peruvian blood transfusion center: Comparison with third generation EIAs

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## Introduction

Blood screening for HCV antibodies in the blood transfusion setting is currently performed with third generation enzyme immunoassays (EIA). Such EIAs are principally based on antigens derived from genotype 1.

Several studies have nevertheless indicated that lower serological reactivity could be found in such EIAs with non-type 1-infected samples(1,2).

The INNOTEST™ HCV Ab IV is a fourth generation assay incorporating carefully selected antigens derived from the most prevalent HCV genotypes (1a, 1b, 2 and 3a).

In many countries, there are significant numbers of non-genotype 1 infected HCV patients. In Peru significant numbers of HCV genotype 2 and 3 infected patients are found, as well as genotype 1(3).

## Aims

Evaluation of the INNOTEST™ HCV Ab IV at a Peruvian Blood Transfusion Center.

Comparison of repeatedly positive samples on the INNOTEST™ HCV Ab IV with results from two third generation HCV screening assays: Ortho® HCV 3.0 Enhanced SAvE and Murex® anti-HCV 4.0.

## Materials and methods

- Between December 2000 and March 2001, 8603 blood donations were analyzed with a 4<sup>th</sup> generation assay.

INNOTEST™ HCV Ab IV

- Repeat positive samples were further analyzed with 3<sup>rd</sup> generation assays:

Murex® anti-HCV 4.0

Ortho® HCV 3.0 Enhanced SAvE

- Discrepant samples were further analyzed with the INNO-LIA™ HCV Ab III update confirmatory assay and qualitative PCR.

- VERSANT® HCV Genotype Assay (LiPA) was performed on PCR positive samples.

## Results

Forty-two repeatedly positive samples were screened with INNOTEST™ HCV Ab IV. These positive samples were analyzed with Ortho® HCV 3.0 Enhanced SAvE and Murex® anti-HCV 4.0.

Twenty-eight samples were reactive and 14 samples were non-reactive on the Murex® anti-HCV 4.0. Twenty-two samples were reactive and 20 samples were non-reactive on the Ortho® HCV 3.0 Enhanced SAvE.

19 discrepant samples were available in sufficient quantities for further testing with the INNO-LIA™ HCV Ab III update confirmatory assay, in-house qualitative PCR and genotyping.

Of the 19 INNOTEST™ positive samples, 8 were positive and 11 were non-reactive on the Murex® assay, whereas 2 were positive and 17 were non-reactive on the Ortho® assay.

With the INNO-LIA™ confirmation assay, 6 samples scored positive, 6 indeterminate, and 7 negative. In 3 cases, samples were confirmed positive by the INNO-LIA™ while being negative on both 3<sup>rd</sup> generation EIAs. Additionally, 2 LIA™-positive samples were positive on INNOTEST™ and Ortho® while negative on Murex®; 1 LIA™-positive sample was positive on INNOTEST™ and Murex® and negative on Ortho®.

Six samples were PCR-positive and could be genotyped using the VERSANT® HCV Genotype Assay (LiPA) (see Table).

Nr	INNOTEST™	Murex®	Ortho®	INNO-LIA HCV	PCR	HCV genotype VERSANT®
	S/N	S/N	S/N	result	result	result
1	2.5	4.53	0.01	POS	POS	6
2	2	0.32	0.01	NEG	POS	6
3	3.6	2.74	0.04	IND	POS	1a
4	5.4	0.40	5.34	POS	POS	6
5	5	0.38	4.74	POS	POS	1a
6	3.7	0.17	0.01	POS	POS	(1/4) co-infection

Three out of 6 proved to be non-genotype 1. Of these 6 samples, 2 could also be detected by the Murex® assay (type 1a, 6), whereas another 2 were detected by the Ortho® assay (type 1a, 6). The remaining 2 samples were exclusively detected by INNOTEST™ HCV Ab IV (type 1/4, 6).

## Conclusions

**These results confirm the results of an earlier comparative study in dialysis patients(4) and indicate that a 4<sup>th</sup> generation HCV screening assay such as the INNOTEST™ HCV Ab IV might well be more suitable for the screening of blood donors in a transfusion setting due to its careful selection of antigens from multiple genotypes.**

## References

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3. Sanchez JL et al. Am J Trop Med Hyg 2000; 63(5-6):242-248

4. Bassit L et al. Eur J Clin Microbiol Infect Dis 2002 May; 21(5): 404-406