



XVth REGIONAL CONGRESS OF THE ISBT, ATHENS

TWO YEARS' EXPERIENCE OF NUCLEID ACID TECHNOLOGY (NAT) SCREENING OF SINGLE DONATIONS FOR HIV 1 RNA / RNA AND HIV 1 RNA / HCV-RNA / HBV DNA

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Objective

To study the implementation of NAT testing in the screening of single blood donations to increase safety and quality in blood transfusion medicine.

Materials and Methods

We present our experience in screening 65,442 single donations by the Procleix HIV 1/HCV RNAs assay and another 7169 single units by the Procleix HIV 1/ HCV/HBV assay (Ultrio). All blood units were initially screened for anti-HIV-1/2, anti-HCV and HBsAg using standard EIA procedures and routine confirmatory tests. The Procleix HIV 1/HCV/HBV assay is an NAT method for the simultaneous detection of HIV 1, HCV RNAs and HBV DNA in plasma. It utilizes three proprietary technologies - a target capture-based sample preparation, transcription mediated amplification (TMA) and a hybridization protection assay (HPA) - all carried out in the same sample. Samples initially reactive with this assay, were tested with the Procleix discriminatory assays to confirm the type of viral RNA or DNA present.

Results

The NAT yield was one HCV Ab-negative per 65,442 blood donations. Quantitative HCV RNA PCR showed 7000000 IU/ML while HCV genotyping revealed type 3a. The donor was male, 22 years of age, with possible history of drug use, who gave blood for the first time (Table 1). Other infectious markers and ALT in this donor were normal. HIV-WB and HCV-RIBA as well as EIA HBsAg positive samples were also confirmed positive with NAT. All 10 indeterminate HCV cases were negative with NAT as well as with qualitative PCR (Table 2).

Conclusions

Our results indicate that this new NAT assay is capable of detecting potentially infectious units that are missed by currently licensed immunological assays. The implementation of HIV 1/HCV/HBV NAT assay would reduce the residual risk of transfusion-transmitted HIV 1, HCV or HBV infection and provide immediate resolution of indeterminate results.

Table 1. Profile of a seronegative, NAT positive HCV donor

EIA HCV		HIV 1/HCV RNA	HCV RNA PCR
BIORAD	Negative	Procleix HIV 1/HCV Reactive RLU 412713 (1:16-1:96)	ROCHE
AxSYM	Negative		Positive
PRISM	Negative		7000000 IU/ML HCV genotype 3a

Table 2. Aggregate data: 65,442 blood units tested

EIA (RR)	HIV		EIA (RR)	HCV		HBV	
	WB (+)	NAT (+)		RIBA	NAT (+)	EIA* (RR)	NAT** (+)
37	5	5	115	Pos 21 Ind 10 Neg84	22	85	10
0.056 %	0.00 7%	0.00 7%	0.17 %	0.03% 0.01% 0.13%	0.03 %	0.11 %	0.14 %

* 72,611 units

** 7169 units