

SIMULTANEOUS DETECTION OF THREE VIRAL GENOMES IN BLOOD DONOR SCREENING WITH THE USE OF A SINGLE MOLECULAR ASSAY (P-289)

E. Perna, M. D'Onofrio, L. Paesano, E. D'Agostino, G. Ciardiello, F. Ferruzzi, S. Formisano (Naples, Italy)

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BACKGROUND

In last years, introduction of nucleic acid testing (NAT) for HIV-1 and HCV RNA and HBV DNA improved blood safety by reducing the window period between infection and serologic detection.

AIMS

In this study, we have evaluated the prevalence of viral genomic replication in blood donors after the introduction of the PROCLEIX® ULTRIO® Assay, investigational nucleic acid test designed for the simultaneous detection of human immunodeficiency virus type 1 (HIV-1) RNA, hepatitis C virus (HCV) RNA and hepatitis B virus (HBV) DNA in human plasma.

METHODS

This molecular assay utilizes three proprietary technologies: a target capture-based sample preparation, transcription mediated amplification (TMA) and hybridation protection assay (HPA). Samples initially and repeatedly reactive with this assay are tested with the PROCLEIX® HIV 1, HCV and HBV Discriminatory Assay to confirm the type of viral RNA or DNA present. The assay detects all known HIV-1 subtypes and HCV and HBV genotypes and is highly reproducible.

RESULTS

We have analyzed 19.786 blood units collected in the period between 2005 and 2006. After confirming test, 79 samples resulted positive to NAT Screening. Using the discriminatory assay, we have identified 16 donors only positive for HCV, 5 only for HIV and 58 only for HBV. None were positive for more than one virus. The routine serological assays showed the same results for all positive samples.

CONCLUSIONS

Our data showed that the PROCLEIX ULTRIO Assay has a very good sensitivity and specificity. In fact, literature data affirm that this test has a specificity $\geq 99.5\%$ in healthy donor blood specimens while assay sensitivity is $>95\%$ in detection of 100copies/mL, 30IU/mL, and 15IU/mL for respectively HIV-1, HCV and HBV. This assay is capable of detecting potentially infectious units that could be missed by currently sero-immunological assays. Using this combination of molecular tests, blood safety can be furtherly improved and the multiplex format enhances blood screening efficiency. The throughput capability of this assay is compatible with large volume processing and the chemistry is adaptable to full automation. This assay is a necessary improvement in a region with a high incidence of HBV carriers. The ability of the NAT technique for rapid use, reliability, sensitivity, specificity, in simultaneously detecting three viruses, indicates its use in screening of blood donors. This technique is useful to prevent transmission of infectious agents, reducing the post-infection window-periods, respect to serologic tests, and decreasing the residual risk of transfusion transmitted infections. At the end this assay provides immediate resolution of indeterminate results.