



XVth REGIONAL CONGRESS OF THE ISBT, ATHENS

RESULTS FROM THE PROCLEIX HIV-1/HCV AND HIV-1/HCV/HBV (PROCLEIX ULTRIO) ASSAYS FOR THE DETECTION OF HIV-1 RNA, HCV RNA AND HBV DNA IN BLOOD DONORS OF TWO BLOOD TRANSFUSION CENTERS OF SW GREECE

Author:	A. Mouzaki, University of Patras, Medical School, Patras, Greece
Co-author: (s):	S. Thymianou, University of Patras, Medical School, Patras, Greece E. Koutougou, University Hospital, Patras, Greece A. Petrou, University Hospital, Patras, Greece E. Theodori, Patras University Hospital, Patras, Greece

Introduction

The Procleix HIV-1/HCV assay is a high-throughput nucleic acid test for the simultaneous detection of human immunodeficiency virus type 1 (HIV-1) and hepatitis C virus (HCV) RNA during blood donor screening. The Procleix Ultrio HIV-1/HCV/HBV assay is a high-throughput nucleic acid test for the simultaneous detection of human immunodeficiency virus type 1 (HIV-1), hepatitis C virus (HCV) RNA and hepatitis B (HBV) DNA during blood donor screening, and has recently replaced the Procleix HIV-1/HCV assay.

AIM: To assess and compare the Procleix HIV-1/HCV (Procleix) and the Procleix Ultrio HIV-1/HCV/HBV (Ultrio) assays' ability to identify HIV-1-, HCV- and HBV-infected individuals in blood donors of a southwestern Greek area with about 450,000 inhabitants.

Method

Plasma samples were obtained and tested in the Procleix HIV-1/HCV assay and, if reactive, were then tested in the Procleix or Ultrio HIV-1, HCV and HBV discriminatory assays to differentiate the source of viral RNA or DNA. Conventional standard serological tests (ELISA) were run in parallel.

Results

15,080 blood donors were tested by the Procleix assay during the period between 18 Jan. 2003 and 26 Sept. 2004. Consecutively, 4,151 blood donors were tested by the Ultrio assay during the period between 27 Sept. 2004 and 9 Febr. 2005.

Of the 15,080 blood donors, 5 (0.033%) tested reactive in the Procleix HIV-1/HCV assay. In discriminatory assay testing, 3 out of 5 (60% of the positive, 0.020% of total) were reactive for HCV RNA only and 2 out of 5 (40% of the positive, 0.013% of total) were reactive for HIV-1 RNA only. None were positive for both HIV-1 and HCV. The standard serological assays gave the same results for the above positive samples. Two samples that tested positive by the standard serological assays tested negative in the Procleix HIV-1/HCV assay.

Of the 4,151 samples tested by the Ultrio assay, 21 (0.5%) tested reactive for HIV-1/HCV/HBV. In discriminatory assay testing, 1 out of 21 (4.76% of the positive, 0.024% of total) was reactive for HIV-1 RNA, 4 out of 21 (19% of the positive, 0.096% of total) were reactive for HCV RNA, and 16 out of 21 (76.2% of the positive, 0.38% of the total) were reactive for HBV DNA. All were single positive i.e. none tested positive for more than 1 virus. Three out of 16 positive samples for HBV DNA tested negative by the standard serological tests. The opposite was not observed.

Conclusion

The Procleix Ultrio assay is a definite improvement over the Procleix assay in a region with a high incidence of HBV carriers. Up until its use, it is obvious that HBV positive blood with very low antibody titers was transfused into patients. More results will show whether Procleix Ultrio can eventually replace the standard serological tests.