
SENSITIVITY ANALYSIS OF THE PROCLEIX® ULTRIO® ASSAY ON THE PROCLEIX® TIGRIS® SYSTEM FOR NUCLEIC ACID TESTING IN A SPANISH TRANSFUSION CENTER (P-294)

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BACKGROUND

Between March and April 2006, the Transfusion Center of Valencian Community carried out a Technical Validation of PROCLEIX ULTRIO Assay (Chiron Corp) in the automated PROCLEIX TIGRIS System for the simultaneous detection of RNA-HCV, RNA-HIV1 and DNA-HBV in human plasma. This study was performed before the introduction of this technology for the screening of the individual blood units in our center in July 2006. The aim of this work is to analyze the sensitivity of the PROCLEIX TIGRIS System using serial dilutions of standards for RNA-HCV, RNA-HIV1 and DNA-HBV detection levels.

METHODS

Chiron Corporation provided the World Health Organization (WHO) Standards for HIV1-RNA, HCV-RNA and HBV-DNA that were diluted by Acrometrix to different concentrations. These concentrations were: 30, 15, 7.5, 3.75, 1.8, 0.94, 0.47 and 0.23 IU/mL for RNA-HCV; 100, 50, 25, 12.5, 6.25, 3.13, 1.56 and 0.78 IU/mL for RNA-HIV1; 40, 20, 10, 5, 2.5, 1.25, 0.63 and 0.31 IU/mL for DNA-HBV. The WHO standard Panels were configured in sets of 8 replicates of each dilution of each WHO Standard (HIV1-RNA, HCV-RNA and HBV-DNA) for the total of 192 tubes per panel set. Three sets of WHO Standard Panel were delivered for the total of 576 tubes (3 sets x 192 tubes per set). The WHO Standards Panel samples were stored in 1.5 mL aliquots and frozen at -20°C before performing PROCLEIX ULTRIO Assay testing. One operator tested one panel of 192 tubes one day and two panels of 192 tubes in other day for a total of 576 results (24 replicates for each dilution for HIV1, HCV and HBV). One TIGRIS Instrument was utilized in this study.

RESULTS

HBV-DNA: 0.31 IU/mL (3/24) 13%; 0.63 IU/mL (4/23) 17%; 1.25 IU/mL 29%; 2.5 IU/mL (18/25) 75%; 5 IU/mL (18/24) 75%; 10 IU/mL (22/24) 92%; 20 IU/mL (24/24) 100%; 40 IU/mL (24/24) 100%.
HCV-RNA: 0.23 IU/mL (3/24) 13%; 0.47 IU/mL (7/24) 29%; 0.94 IU/mL (11/24) 46%; 1.8 IU/mL (13/24) 54%; 3.75 IU/mL (21/23) 91%; 7.5 IU/mL (24/24) 100%; 15 IU/mL (24/24) 100%; 30 IU/mL (24/24) 100%.
HIV1-RNA: 0.78 IU/mL (3/24) 13%; 1.56 IU/mL (5/24) 21%; 3.13 IU/mL (9/24) 38%; 6.25 IU/mL (19/24) 79%; 12.5 IU/mL (20/24) 83%; 25 IU/mL (24/24) 100%; 50 IU/mL (24/24) 100%; 100 IU/mL (24/24) 100%.
Probit analysis: HBV-DNA: 50% positive: 1.71 (1.26-2.27) IU/mL and 95% positive: 12.24 (7.90-23.82) IU/mL; HCV-RNA: 50% positive: 1.01 (0.75-1.33) IU/mL and 95% positive: 6.38 (4.16-12.47) IU/mL; HIV1-RNA: 50% positive: 3.41 (2.58-4.43) IU/mL and 95% positive: 18.95 (12.69-35.28) IU/mL.
Conclusions.1) The sensitivity of this technology is very high for the three viral genomic markers and better than the FDA/EMEA requirements for individual blood donation testing. 2) The introduction of PROCLEIX TIGRIS System for nucleic acid testing on individual blood donations would allow to diminish the window period of the different virus and to detect silent HBV carriers with very low viral load.