

SIX MONTHS EXPERIENCE OF NAT IN THE BLOOD CENTER OF NORTHERN GREECE (P-271)

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Poster Session: 6.5 Blood Safety - Transfusion Transmitted Disease (TTD) - Nucleic Acid Amplification Technology (NAT)

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BACKGROUND

NAT can reduce the "window period" and detect occult hepatitis B. In June 2006, the Blood Center of Northern Greece, responsible for the screening of blood donations from 18 blood banks, implemented NAT testing to identify viraemic blood donors by use of the automated NAT Chiron PROCLEIX® TIGRIS® System.

AIM

The aim of the study is to present our experience with the NAT testing of blood donations (TMA-ULTRIO-Chiron screening and discriminatory test) during the first 6 months

STUDY DESIGN AND METHODS

All blood units have been tested with transcription-mediated amplification (TMA) methodology on individual donations. The screening test used was a multiplex assay (TMA-ULTRIO-Chiron) capable to detect human immunodeficiency virus type 1 (HIV-1), hepatitis C virus (HCV) and hepatitis B virus (HBV). This assay allows for large-scale blood screening of individual donations. A discriminatory test was subsequently performed on all reactive samples to identify the viral agent. All blood units were also tested by conventional serologic testing (MEIA) for anti-HIV, HBSAg and anti-HCV. All samples reactive by NAT were retested by ULTRIO as well as samples from the corresponding blood bag. In case of positive serologic testing but negative TMA, the initial tube and a sample from the blood bag were tested again by ULTRIO. If the results were not conclusive, the blood donors were invited to give a new sample immediately as well as three and six months later. Blood donors NAT-reactive, MEIA-positive were definitely deferred. Blood donors initially NAT-reactive, MEIA-negative, were retested after three and six months and if at that time they tested NAT-non reactive, they re-entered the blood donors' pool. Blood donors ULTRIO-NAT-reactive, discriminatory-HBV reactive, MEIA-negative, were tested for anti-HBc and anti-HBs to identify occult hepatitis B.

RESULTS

Between June and December 2006, 61,575 blood units have been tested.

- 149(0.24%) were found ULTRIO-NAT-reactive, discriminatory-HBV-reactive, HbsAg positive by MEIA.
- 6(0.01%) were ULTRIO-NAT-reactive, discriminatory-HBV reactive, HBsAg-negative, anti-HBc positive (occult hepatitis B).
- 3(0.05%) were ULTRIO-NAT-reactive, discriminatory-HBV-reactive, HbsAg negative (possibly occult hepatitis B, missing information about anti-HBc).
- 2(0.03%) were ULTRIO-NAT-reactive, discriminatory-non reactive, HbsAg negative, anti-HBc positive.
- 5(0.008%) were ULTRIO-NAT-reactive, discriminatory-non reactive, HbsAg positive.
- 27(0.044%) were ULTRIO-NAT-reactive, discriminatory-reactive for HCV, MEIA-positive for HCV and RIBA positive.
- 1(0.0016%) was ULTRIO-NAT-reactive, discriminatory-reactive for HCV, MEIA-negative, RIBA negative (donor in the window period for hepatitis C). Two months later, the donor was found MEIA-positive for HCV.
- 7(0.011%) were found ULTRIO-NAT-positive, discriminatory-reactive for HIV and MEIA anti-HIV positive.
- Finally 182 blood units (0.29%) were initially ULTRIO-NAT-reactive but negative upon repetition and negative by MEIA (possibly false-positive samples).

CONCLUSIONS-COMMENTS

These results confirm that NAT screening of all blood donations by the above described methodology improves blood safety. In six months time, 9 cases of HBV-infected donations were detected by NAT only (MEIA-negative). One HCV case in the window period (MEIA-negative) was also detected. Further investigations are needed to elucidate why the discriminatory was negative in five cases of certain HBV-infected blood (HBSAg+), and in two cases of possible HBV infection (anti-HBcore+) and the cause of the false-positive initial tests(0.29%).