

## Evaluation of Fourth-Generation HIV Screening Assays to Detect One Case of Human Immunodeficiency Virus-1 During Seroconversion Window (SP197)

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**Background:** The prevalence of HIV-1 in Brazilian blood donors is unknown and represents a challenge, in particular for the early detection of HIV infection using nucleic acid amplification tests (NAT) and serological assays. The aim of this study was to evaluate the sensitivity of two commercially available fourth-generation HIV Ag/Ab enzyme immunoassays (EIAs) for the detection of primary infection in one blood donor tested positive only by HIV-1 NAT.

**Methods:** One case of primary infection during pre-seroconversion window was detected by HIV-1 NAT (TMA, Chiron Corporation) in individual blood donation at the Blood Bank of Hospital Sao Rafael (Salvador, Brazil). The antibody screening using the third-generation EIA anti-HIV 1/2 (Ortho HIV 1/2 Ab Capture) was nonreactive. To evaluate the sensitivity of two available fourth-generation HIV Ag/Ab EIAs, the HIV-1 NAT positive sample was simultaneously tested by Genscreen Plus HIV Ag/Ab (Biorad) and by Vironostika HIV Uni-Form II Ag/Ab (Biomerieux).

**Results:** The antibody screening using 3<sup>rd</sup> generation Ortho HIV 1/2 Ab Capture was nonreactive (OD/CO=0,068). Evaluating the 4<sup>th</sup> generation EIAs assays, a nonreactive result (OD/CO=0,32) was also observed with Genscreen Plus HIV Ag/Ab. However, when Vironostika HIV Uni- Form II Ag/Ab was used, this sample showed repeat reactive with a OD/CO>1,8. The S/CO of HIV-1 NAT was 23,03.

**Discussion:** New technologies for HIV screening have been developed to reduce risks to a minimal levels. Among them, 4<sup>th</sup> generation EIAs and NAT have improved the safety of blood supply worldwide. The results of this evaluation showed that some commercially available HIV combined Ag/Ab assays could not detect an infected donor during preseroconversion window. This reinforces that only 4<sup>th</sup> generation assays with a high sensitivity in antigen detection, should be used for blood donor screening process in lower income countries who may not be able to afford NAT. A combination of NAT and 4<sup>th</sup> generation HIV assays should be studied to evaluate the effectiveness of this protocol in the prevention of transfusion-transmitted HIV and the influence of virus subtypes.