

The history of the development and implementation of the Brazilian nucleic acid testing (NAT) platform to detect and discriminate among human immunodeficiency virus (HIV), hepatitis C virus (HCV), and hepatitis B virus (HBV) infections in blood donors is described here” Rocha et al (2018).

Abstract:

**BACKGROUND:** The history of the development and implementation of the Brazilian nucleic acid testing (NAT) platform to detect and discriminate among human immunodeficiency virus (HIV), hepatitis C virus (HCV), and hepatitis B virus (HBV) infections in blood donors is described here. The results for the sensitivity, reproducibility, and NAT yield of the platform since program implementation are provided.

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**STUDY DESIGN AND METHODS:** The Brazilian NAT HIV, HCV, and HBV kit was developed and evaluated with regard to analytical sensitivity, specificity, intralot and interlot reproducibility, interfering substances, and genotype and diagnostic sensitivity. Additionally, a sample of identified NAT-yield cases was characterized with regard to viral load.

**RESULTS:** The 95% limits of detection for HIV, HCV, and HBV were 68.02, 102.35, and 9.08 IU/mL, respectively. All replicates were detected with reproducibility assays between the acceptable values. A total of 13,610,536 blood donors was screened from 2010 to 2016, and 63 HIV-yield cases and 28 HCV-yield cases were detected. Among 5,795,424 blood donors screened for HBV from 2014 to 2016, 42 yield cases were found.

**CONCLUSION:** The Brazilian NAT HIV, HCV, and HBV kit is an automated NAT system suitable for routine blood donor screening in a completely traceable process. The analytical sensitivity as well as the diagnostic sensitivity fulfilled all requirements set by the health ministry for blood donor screening. A significant number of transmission cases were prevented by the implementation of this important program.

Reference:

Rocha, D., Andrade, E., Godoy, D.T., Fontana-Maurell, M., Costa, E., Ribeiro, M., Ferreira, A.G.P., Brindeiro, R., Tanuri, A. and Alvarez, P. (2018) The Brazilian experience of nucleic acid testing to detect human immunodeficiency virus, hepatitis C virus, and hepatitis B virus infections in blood donors. *Transfusion*. January 30th. .

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