IVD_02 - Kit NAT PLUS HIV/HBV/HCV/Malária Bio-Manguinhos: Innovation and technological upgrade for NAT assay

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Introduction: Infections transmitted by blood transfusion are one of the biggest problems related to transfusional safety. NAT in blood donor screening has been implemented in many countries to reduce this risk. NAT detects and discriminates against infections caused by the HIV, HCV and HBV viruses, reducing the period of the immunological window. The NAT HIV/HCV/HBV Bio-Manguinhos (BM) Kit emerged in response to a demand by the Coordenação Geral de Sangue e Hemoderivados and, in 2010, it started to be used in 14 Brazilian public blood centers. Until 2022, more than 32 million blood bags were analyzed and approximately 343 samples in window period were detected for the targets. In March 2022, a second version of the Brazilian NAT Kit was registered in ANVISA and was designed with the aim of further improving the sensitivity of HIV, HCV and HBV, incorporating the identification of *Plasmodium spp.* and to update the equipment platform, with a more modern one, with magnetic bead extraction.

Objectives: Show the results of the validation of the NAT PLUS HIV/HBV/HCV/Malária Kit and upgrade on the implementation in the Brazilian Blood Centers.

Methodology: The NAT PLUS Kit is composed of liquid handling and nucleic acid extractor (Chemagic Prime), real-time PCR (QS Dx) and a software (BioLaudos) integrated for analysis and issue of results. The Kit is a qualitative and discriminatory multiplex test that is divided into two triplex reactions: HIV/HCV/IC and HBV/Malaria/IC.

Results: The estimated analytical sensitivity, for 95% positivity, was 36,43 copies/mL for the HIV, 14,81 IU/mL for HBV, 20.19 IU/mL for HCV and 39,77 copies/mL for *Plasmodium spp*. Accuracy, precision, linearity and specificity data were within the expected standards. Furthermore, the test was able to identify all HIV-1, HBV, HCV genotypes and malaria parasite species analyzed. In August/22, the implementation of NAT PLUS began and by March/23, 11 platforms had already been installed, in a total of 5 blood centers. BM has already produced more than 200,000 NAT PLUS Kit reactions. And, until now, 3 positive samples for *Plasmodium spp.* were detected, confirmed by thick blood film and sequencing.

Conclusion: The NAT PLUS HIV/HBV/HCV/Malária Kit further increases transfusion safety, representing an example of an innovative product for the Brazilian Health Industrial Complex, contributing to consolidate technological competences in the area of immunobiologicals and molecular diagnosis at FIOCRUZ, meeting the demand of strategic products from the Ministry of Health to the SUS.

Keywords: NAT, Virus, Malaria