

IVD_01 - Detection of *Plasmodium* spp. in asymptomatic blood donors at Brazilian blood centers by the NAT PLUS HIV/HBV/HCV/MALARIA Bio-Manguinhos kit

Beatriz Vasconcello de Souza Barreto¹; Daniele Ramos Rocha¹; Elisabete Ferreira de Andrade¹; Marisa de Oliveira Ribeiro¹; Elaine Motta Costa¹; Marcela Fontana do Carmo Machado Maurell¹; Alexandre Frederico¹; Pedro Henrique Cardoso¹; Monica Barcellos Arruda¹; Patrícia Alvarez Baptista¹.

¹Fiocruz/Bio-Manguinhos

Introduction: Malaria is a vector-borne disease caused by protozoan parasites, genus *Plasmodium*. Five species of *Plasmodium* can infect humans: *P. falciparum*, *P. vivax*, *P. malariae*, *P. ovale*, and *P. knowlesi*. Brazil reported 139.211 cases of Malaria in 2021, where more than 99,9% of the transmission occur in Amazonian Region. The number of *P. vivax* (83.0%) cases were the most frequent. The parasite spreads by the bite of female *Anopheles mosquitoes*, but can also be transmitted by blood transfusion, organ transplantation and other ways. As a blood parasite, it is emphasized that transfusion-transmitted malaria (TTM) is a public health problem. With the aim to improve the Brazilian NAT platform, the detection of the Malaria target was included. The nucleic acid extraction technology and Real-time PCR reaction were adapted to this new target. The named NAT PLUS HIV/HBV/HCV/Malaria Bio-Manguinhos Kit was registered in March 2022.

Objectives: We reported for the first time, in the world, detections of *Plasmodium spp* in asymptomatic blood donors at the city of Rio de Janeiro (HEMORIO) and Manaus (HEMOAM) by the Brazilian NAT PLUS kit, recently implemented at the Blood Centers.

Methodology: The NAT PLUS has an automated platform for nucleic acid extraction and amplification and detection of targets. The kit is a qualitative and discriminatory multiplex test that uses the RT-PCR technique (Taqman). The kit targets the C-terminal domains of integrase region (HIV-1), 5'UTR (HCV), S (HBV), and 18S rRNA (*Plasmodium spp*) and the assay is divided into two triplex reactions: HIV/HBV/IC and HCV/Malaria/IC.

Results: HEMORIO started using the NAT PLUS Kit in September/2022 and had 2 positive samples for *Plasmodium spp*. The first sample being confirmed by thick blood film and rapid test and the second negative for both tests. Samples were sequenced and classified as *P. vivax* and *P. malariae*, by phylogenetics analysis. HEMOAM started using the test in January/2023 and had 1 positive sample for *Plasmodium spp.*, then it was confirmed by thick blood film. The sample was sequenced and discriminated as *P. vivax*.

Conclusion: These preliminary results and due to its relevance in the public health context, the inclusion of Malaria detection in the Brazilian NAT Kit demonstrated to be essential to prevent TTM and to guarantee transfusion safety, especially in endemic areas. Malaria screening in blood donors throughout the national territory will allow a better understanding of the epidemiological situation in Brazil. The NAT PLUS Kit is being one of the main examples of the affirmative public health policy of the Ministry of Health.

Keywords: Malaria, bloodcenters, NAT