IVD_24 - Revalidation of HTLV positive serological panel intended for quality control of HTLV I/II diagnostic tests

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Introduction: Human T-lymphotropic viruses (HTLV) types I and II are human retroviruses, discovered in the early 1980s, affecting 5 to 10 million individuals worldwide, it is estimated that there are approximately 800,000 to 2.5 million individuals infected by HTLV-I in Brazil. To ensure the quality of diagnostic tests for HTLV-I/II detection is essential, as they are used both in laboratory routines and in Hemotherapy Services, where serological screening for HTLV became mandatory in Brazil following the Ordinance No. 1.376 of the Ministry of Health in 1993. The kits used in the serological diagnosis of the disease, in accordance to Resolution RDC No. 36/2015, belong to risk class IV, and are subject to prior laboratory analysis, one of the mandatory steps for granting registration with the National Health Surveillance Agency (ANVISA).

Objectives: The objective of this study was to revalidate the positive HTLV serological panel used to evaluate the sensitivity and clinical specificity of tests for HTLV I/II diagnosis in compliance with Resolution RDC 36/2015.

Methodology: A retrospective evaluation and selection of results obtained from January 2014 to December 2023 was carried out regarding samples from the HTLV panel initially consisting of 109 human serum/plasma samples characterized as true positive. Excel ® spreadsheets were created to assist in data analysis. As criteria for revalidation and inclusion in the panel, samples should be positive in 05 immunoenzymatic tests (ELISA), 04 chemiluminescence tests (CLIA), 01 Western Blot or Immunoblot (WB/Ib) in addition to a volume greater than or equal to 10 mL.

Results: From the panel made up of 109 samples, 78 (71%) samples were revalidated, meeting exactly all the criteria for revalidation, 15 (14%) were inconclusive and will be subject to additional testing and 16 (15%) did not meet the inclusion criteria established and excluded from the revalidated panel for presenting a volume of less than 10mL.

Conclusion: The 78 revalidated samples showed reproducible results in different methodologies and therefore constitute an essential tool to evaluate the performance of products for HTLV I/II detection and consequently for the safety of diagnosis and blood transfusions carried out in the country.

Keywords: HTLV; Serological Panel Revalidation; Health Surveillance