

IVD_09 - Adaptation and evaluation of point-of-care tests for infectious diseases in the telediagnosis system in Pernambuco - UBS

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Introduction: Given technological advances for the development and control of new diagnostic alternatives, some diseases persist as a public health problem in Brazil (HIV, Syphilis, Hepatitis B and C) and need to be diagnosed quickly, in the first access health service, such as the Basic Health Units (UBS). Driven by the new coronavirus pandemic in 2020, advances in diagnostics have brought a new way of providing *in vitro* diagnostic products, for example, tests that can be performed remotely with the help of a healthcare professional (telediagnostics). Telediagnosis was created to optimize the delivery of diagnosis to patients quickly and effectively, providing more agility in treatment and epidemiological mapping for health surveillance actions.

Objectives: This study aimed to adapt and develop conventional tests for HIV 1/2, Syphilis, Hepatitis B, and C for this remote system.

Methodology: For the initial adaptation studies, the rapid test strips were applied to a new "capsule" support (specific for the Hilab Flow equipment), and serum and whole blood were used to evaluate the reactivity of the strips. In the second stage of the study, specific calibration curves were created for each test, using the raw optical density (OD) data obtained from the images captured by the equipment, distinguishing between positive and negative results (compared by the intensity of the lines test and test control), using validation. After that, 100 tests were produced to diagnose each disease mentioned above and sent to UBS based in Caruaru–Pernambuco.

Results: All tests showed >95% sensitivity (30 positive samples) and specificity (50 negative samples). At UBS, the team received training on operating the device and carrying out the tests. As preliminary data, it was possible to verify that more Syphilis and HIV tests were applied (60 tests), with a higher incidence in women and those aged between 20-39 years. Furthermore, it was possible to verify that the loss of exams was around 8%.

Conclusion: Given the above, the point-of-care test is a valid alternative to be implemented in basic health units to assist in the clinical conduct of the SUS-Brasil.

Keywords: Digital Health; Digital technologies; Point-of-care