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P1905 Alere Determine HIV-1 ag/ab combo rapid test and Multisure test efficacy in acute HIV infection, established HIV infection and HIV-2 infection

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Background: Using methods that have higher sensitivity and specificity, faster results in the diagnosis, and decrease in the indeterminate results could be achieved. In this study, the efficacy of two rapid tests in the detection of acute, defined HIV infection was investigated.

Materials/Methods: 897 serum samples and 20 external quality control samples (EQC) were included in the study. All samples were tested according to the CDC HIV diagnostic algorithm. In addition, the samples were also tested with Alere Determine™ HIV1/2 Ag/Ab Combo. Samples were screened with ELISA (HIV ½ duo ultra, BioMerieux, France). Repeatedly reactive tests were subjected to confirmation test (HIV1/2 differentiation test, Geenius, BioRad, USA). Positive values obtained by the confirmation test were interpreted as HIV positive. When negative or indeterminant results were obtained, HIV RNA (artus HIV1 RNA, Qiagen, Germany) and p24 antigen test (VIDAS, BioMerieux, France) was performed and evaluated for acute HIV infection.
Results: According to the HIV confirmation algorithm 711 (79.3%) positive and 186 (20.7%) negative result were detected. Of 631 samples identified as HIV1 positive, 603 showed antibody positivity and six were weak positive with Alere. Of the 181 HIV-negative samples, 22 were false positive. Of the 631 HIV-positive samples, 24 were for p24 antigen positive (also 6 were faintly positive). When Multisure was used in 215 samples, all 11 negative samples were negative with Multisure, and of the 204 positive samples, 187 were positive and four were indeterminant. Except for the P24 antigen test, all of the EQC samples were correctly identified by Alere and Multisure. Sensitivity and specificity values were determined as 93.6% for Multisure, 100% for Alere Ab, 96.5%, 86.7% for Alere Ab, 97.7% and 85.6% for Alere Ag and Ab together.
Conclusions: The high sensitivity values obtained with the Alere Determine Combo test and the Multisure test show that the tests can be used safely for screening purposes. The 100% specificity value obtained with Multisure suggests that it may be an alternative to the HIV1/2 differentiation test. However, more extensive studies are required to better understand the efficacy of the tests.