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Abstract (poster session)

Specificity of two HIV screening tests of the 4th generation

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Objectives: We have previously shown that the Cobas HIV combi test (Roche Diagnostics) has a limited specificity with a positive predictive value (PPV) of only 55%. In literature, it has been demonstrated that this test has a lower specificity than the Architect HIV Ag/Ab combo (HIVA, Abbott). The Cobas HIV combi has been recently replaced by its successor, the Cobas HIV combi PT (HIVCPT, Roche Diagnostics). This study aimed to assess the specificity of the new HIVCPT in comparison to the HIVA on a large number of patients in a tertiary care hospital. Methods: A total of 3057 unselected sera on which a HIV screening had been requested by the clinicians were investigated with the HIVCPT and the HIVA between December 2011 and September 2012. Repeatedly reactive samples with the HIVA or HIVCPT were subjected to the Vidas HIV Duo Ultra (HIVDU, bioMérieux) and the results were confirmed by a line immunoassay (LIA, INNO-LIA HIV I/II, Innogenetics) and a quantitative PCR (qPCR, COBAS® AmpliPrep/TaqMan® HIV-1 Test, version 2.0, Roche Diagnostics). All tests were performed according to the manufacturers` instructions. Results: 38 of 3057 sera were repeatedly reactive with either the HIVCPT or the HIVA, or both. 23 out of these 38 sera were reactive with all three HIV screening systems and were confirmed as true HIV positive. 15 of these 38 sera could be confirmed as negative and were also negative with the HIVDU. 9 out of these 15 false-reactive sera were only reactive with the HIVCPT and 6 only reactive with the HIVA. Thus, the specificity and the PPV is 99.7% and 71.9% of the HIVCPT as well as 99.8% and 79.3% of the HIVA, respectively. Conclusion: Our data show that the HIVCPT has an improved PPV compared to its precursor, the Cobas HIV combi, but still a lower PPV than the HIVA. For lowering the rate of false-reactive sera, the HIVA may be the better HIV screening test. An algorithm involving the HIVDU as a second method is able to distinguish provisorily true HIV positive sera from false-reactive sera.