

Specificity of Two HIV Screening Tests of the 4th Generation

Annette Blaich¹, Andreas Buser², Hans H. Hirsch³, Ralf Beyrau⁴, Thomas Klimkait³, Reno Frei¹

¹ Division of Clinical Microbiology, University Hospital Basel, ² Blood Transfusion Center, Swiss Red Cross, Basel, ³ Division Infection Diagnostics, Department Biomedicine, University of Basel, ⁴ Division of Clinical Chemistry, University Hospital Basel, Basel, Switzerland

Introduction

We have previously shown that the Cobas HIV combi test (Roche Diagnostics) has a limited specificity with a positive predictive value (PPV) of 55% (ref 1). It has also been reported that this test has a lower specificity than the Architect HIV Ag/Ab Combo assay (HIVA, Abbott) (ref 2).

The Cobas HIV combi assay has recently been replaced by its successor, the Cobas HIV combi PT (HIVCPT, Roche Diagnostics). The HIVCPT was developed to allow earlier detection of HIV-infection and to have increased sensitivity and improved specificity (ref 3).

This study aimed at assessing the specificity of the new HIVCPT in comparison to the HIVA on a large number of patient samples in a tertiary care hospital.

Materials and Methods

A total of 3998 unselected sera, on which a HIV screening had been requested by the clinicians, were tested with the HIVCPT and the HIVA between December 2011 and December 2012. Reactive samples with the HIVA or HIVCPT were confirmed once by repeat, and then retested with the Vidas HIV Duo Ultra (HIVDU, bioMérieux), with the 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.

Cobas HIV combi PT (Roche) is an electro-chemiluminescence immunoassay.

Architect HIV Ag/Ab Combo (Abbott) is a chemiluminescent magnetic microparticle immunoassay.

Vidas HIV Duo Ultra (bioMérieux) is an enzyme-linked fluorescence assay.

All three assays are of the 4th generation detecting simultaneously HIV-1 p24 antigen and antibodies to HIV-1 and HIV-2.

Results

A total of 46 of 3998 sera were repeatedly reactive with either the HIVCPT or the HIVA or both. 28 out of these 46 sera (from 46 patients) were reactive with all three HIV screening systems and were confirmed as true HIV positive. 18 of these 46 sera could be confirmed as negative and were also negative with the HIVDU (table). 11 out of these 18 non-confirmed sera were only reactive with the HIVCPT and 7 only reactive with the HIVA (table). Thus, the specificity and the PPV is 99.7% and 71.8% of the HIVCPT as well as 99.8% and 80% of the HIVA, respectively.

| Sample | Test | | | | |
|--------|--------------------|---------------------------|---------------------|-------------------|------------------------------|
| | Cobas HIV combi PT | Architect HIV Ag/Ab Combo | Vidas HIV Duo Ultra | INNO-LIA HIV I/II | Cobas Ampli-Prep/TaqMan qPCR |
| 1 | reactive | negative | negative | negative | negative |
| 2 | reactive | negative | negative | negative | negative |
| 3 | reactive | negative | negative | negative | negative |
| 4 | reactive | negative | negative | negative | negative |
| 5 | reactive | negative | negative | negative | negative |
| 6 | reactive | negative | negative | negative | negative |
| 7 | reactive | negative | negative | negative | negative |
| 8 | reactive | negative | negative | negative | negative |
| 9 | reactive | negative | negative | negative | negative |
| 10 | reactive | negative | negative | negative | negative |
| 11 | reactive | negative | negative | negative | negative |
| 12 | negative | reactive | negative | negative | negative |
| 13 | negative | reactive | negative | negative | negative |
| 14 | negative | reactive | negative | negative | negative |
| 15 | negative | reactive | negative | negative | negative |
| 16 | negative | reactive | negative | negative | negative |
| 17 | negative | reactive | negative | negative | negative |
| 18 | negative | reactive | negative | negative | negative |

Table: HIV screening and confirmation results of the 18 false - reactive sera

Conclusions

- Our data show that the Cobas HIV combi PT assay has an improved specificity and positive predictive value (PPV) compared to its predecessor, the Cobas HIV combi, but still a lower PPV than the Architect HIV Ag/Ab Combo test (71.8% versus 80%).
- For lowering the rate of false-reactive results, the Architect HIV Ag/Ab Combo may be the better HIV screening test.
- Our data also demonstrate that a testing algorithm involving the Vidas HIV Duo Ultra as second method is able to distinguish true HIV positive sera from false-reactive sera.

References

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