

Title: Excellent sensitivity of a rapid 4th generation HIV test (DetermineHIV-1/2 Ag/Ab) – based on a blinded evaluation in chronically HIV infected women and men.

Background: Rapid point-of-care HIV testing is an essential screening tool for widespread detection of HIV infection and thus an important contribution to HIV prevention. Recently, a 4th generation test with the ability to detect p24-antigen and HIV-antibodies has become available. Pavie et al challenged the use of this test by reporting an unacceptably low sensitivity at the 2009 IAS meeting. We are currently re-evaluating sensitivity of this assay.

Methods: A prospective blinded evaluation of the 4th generation HIV test (Determine HIV-1/2), is conducted in chronically HIV infected women and men at our HIV clinic. Recruited patients had all been confirmed HIV positive. The control group were blood donors routinely tested with ELISA Combo and PCR. Upon written informed consent, all participants provided as recommended a whole blood drop, obtained through finger prick.

Results: So far, 109 HIV positive women (n=41) and men (n=68), and 10 control women (n=5) and men (n=5) were tested. Sensitivity was 100%. None of the chronically infected patients tested false negative and none of the controls tested false positive. As reported previously, a high rate of invalid test results (only in HIV positive individuals) were observed, missing a control line but a strong HIV-positive band (9.8 %).

Conclusions: Point-of care HIV testing with the “Determine rapid HIV Ag/Ab” test showed a high reliability and ability to identify HIV infection in our cohort. Due to a high rate of invalid test results, we propose evaluation of additional test material, with 2-3 whole blood drops or optimization of the chase buffer.