P1403
Poster Session V
Molecular and non-molecular diagnostics of viruses

EVALUATION OF THE NOVEL GEENIUS HIV 1/2 HIV CONFIRMATORY SYSTEM

A. Blaich[1], A. Geschke[2], T. Klimkait[3], K. Rentsch[2], H. Freidank[4], A. Buser[5], R. Frei[1]

[1]Division of Clinical Microbiology, University Hospital, Basel, Switzerland ; [2]Division of Clinical Chemistry, University Hospital, Basel, Switzerland ; [3]Department of Biomedicine, University of Basel, Basel, Switzerland ; [4]Division of Laboratory Medicine, University Hospital, Basel, Switzerland ; [5]Blood Transfusion Center, Swiss Red Cross, Basel, Switzerland

Objectives:
Highly sensitive HIV screening tests are prone to false-reactive results, which cause unnecessary concerns in patients waiting for confirmation. Therefore, a rapid and reliable confirmatory test is mandatory. The Geenius HIV 1/2 system (Bio-Rad Laboratories) is a novel immunochromatographic assay detecting separately and simultaneously antibodies against membrane-fixed antigens of HIV-1 (groups M and O): p31, gp160, p24, gp41, and of HIV-2: gp36 and gp140. The test can be performed with volumes of 15 µL whole blood, 5 µL serum, or 5 µL plasma. After a short 3-step procedure, the test results of the antigen bands are read, interpreted, and reported automatically. For interpretation, the system uses a validated algorithm, and each test report provides full traceability for the sample tested. Furthermore, the system offers the option for bidirectional interfacing with the laboratory information system. This study aimed at determining the performance of the Geenius HIV 1/2 confirmation system.
Methods:
A total of 88 well-defined sera comprising 30 HIV positive and 31 HIV negative samples as well as 27 challenging sera that tested repeatedly false-reactive in screening assays were included in this study. All samples came from patients of the University Hospital Basel and had been screened for HIV upon physicians` request with the Cobas HIV combi PT (Roche Diagnostics), the Architect HIV Ag/Ab combo (Abbott), and the Vidas HIV Duo Ultra (bioMérieux) assay. Non-reactive samples had further been confirmed by a line immunoassay (LIA, INNO-LIA HIV I/II, Innogenetics) as true HIV negatives. Samples reactive in one or more of the screening tests had been confirmed as false or true HIV-reactive by LIA and/or a quantitative PCR (COBAS AmpliPrep/TaqMan HIV-1 Test, version 2.0, Roche Diagnostics). All 88 samples were tested with the Geenius HIV 1/2 confirmatory assay.
Results:
All 31 true HIV negative samples were negative with the Geenius. 29 out of 30 true HIV positive samples were confirmed as HIV-1 positive by Geenius. One of these 30 samples was negative with the Geenius as well as the LIA; it represented a very early HIV infection prior to antibody seroconversion. All 27 false-reactive samples could be confirmed as HIV-negative with the Geenius. Two of these 27 samples tested doubtful in the first run and negative on repeat testing with the Geenius. No HIV-2 antibodies were present in our samples.
Conclusions:
The Geenius HIV 1/2 Confirmatory System reliably determined the presence or absence of HIV antibodies in all sera tested including those challenging samples that were false-reactive in screening assays. In the daily routine, samples tested doubtful with the Geenius should be analysed by additional confirmatory assays. Moreover, the Geenius is easy to handle, has a short hands-on-time of 2-3 minutes and a turn-around time of less than 30 minutes.