Evaluation of a novel Geenius HIV 1/2 Confirmatory System

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Introduction

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 and of HIV-2 (figure).

Figure: Geenius cartridge of a HIV-1 and HIV-2 double-positive control serum

HIV-2:
Band 1 gp36 (envelope peptide)
Band 2 gp140 (envelope peptides)

HIV-1:
Band 3 p31 (polymerase peptide)
Band 4 gp160 (envelope recombinant protein)
Band 5 p24 (core recombinant protein)
Band 6 gp41 (group M and O, envelope peptides)

Band C Control Band (Protein A)

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 automatically read, interpreted, and reported. 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.

Materials and Methods

A total of 89 well-defined sera comprising 30 confirmed HIV positive and 31 HIV negative samples as well as 28 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). The Geenius HIV 1/2 confirmatory assay was performed according to the manufacturer`s instructions.

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.

27 out of the 28 false-reactive samples could be confirmed as HIV-negative with the Geenius (table). However, 3 of these 28 samples tested doubtful in the first run. Two of these 3 samples were negative on repeat testing and only one sample tested doubtful also on repeat.

No HIV-2 antibodies were present in any of our samples.

	Test					
Sample	Cobas HIV combi PT	Architect HIV Ag/Ab Combo	Vidas HIV Duo Ultra	INNO-LIA HIV I/II	Cobas Ampli-Prep/TaqMan qPCR	Bio-Rad Geenius HIV1/2
1	reactive	negative	negative	negative	negative	negative
2	reactive	negative	negative	negative	negative	negative
3	reactive	negative	negative	negative	negative	negative
4	reactive	negative	negative	negative	negative	negative
5	reactive	negative	negative	negative	negative	negative
6	reactive	negative	negative	negative	negative	negative
7	reactive	negative	negative	negative	negative	negative
8	reactive	negative	negative	negative	negative	negative
9	reactive	negative	negative	negative	negative	negative
10	reactive	negative	negative	negative	negative	negative
11	reactive	negative	negative	negative	negative	negative
12	reactive	negative	negative	negative	negative	negative
13	reactive	negative	negative	negative	negative	negative
14	reactive	negative	negative	negative	negative	negative
15	reactive	negative	negative	negative	negative	negative
16	reactive	negative	negative	negative	negative	negative
17	reactive	negative	negative	negative	negative	negative
18	reactive	negative	negative	negative	negative	negative
19	reactive	negative	negative	negative	negative	negative
20	reactive	negative	negative	negative	negative	negative
21	reactive	negative	negative	negative	negative	negative
22	reactive	negative	negative	negative	negative	negative
23	doubtful	negative	negative	negative	negative	negative
24	negative	reactive	negative	negative	negative	negative
25	negative	reactive	negative	negative	negative	negative
26	negative	reactive	negative	negative	negative	negative
27	negative	reactive	negative	negative	negative	negative
28	negative	reactive	negative	negative	negative	doubtful

Table: HIV screening and confirmation results of the 28 false – reactive sera

Conclusions

The Geenius HIV 1/2 Confirmatory System reliably determined the presence or absence of HIV-1 antibodies in all sera tested including those challenging samples that were false-reactive in screening assays, except in one serum which showed a doubtful result. In the daily routine, samples tested doubtful with the Geenius should be analysed by alternative 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.

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