ABSTRACT

Background: Conﬁrmatory assays for HIV diagnosis are not well implemented in limited income settings, impairing an early HIV diagnosis and, consequently, delaying the prescription of antiretroviral treatment in the infected population. Bio-Rad Geenius™ HIV 1/2 Confirmatory Assay is an immunochromatographic test for the conﬁrmation of HIV-1 and HIV-2 infection using dried blood spots. This test can serve as a ﬁrst line assay in areas where the population has limited access to health systems.

Objective: To evaluate, for the ﬁrst time, the HIV-1 and HIV-2 diagnostic performance of Bio-Rad Geenius™ HIV 1/2 Conﬁrmatory Assay using dried blood specimens from 70 HIV-infected women from Equatorial Guinea previously diagnosed as HIV positive using one to three rapid tests.

Results: Geenius™ HIV 1/2 (Bio-Rad) successfully conﬁrmed the HIV infection using DBS in all 70 tested women from Equatorial Guinea previously diagnosed as HIV positive using one to three rapid tests (New Lav Blot I, Bio-Rad) using the same elution volume. Test cassette using dried blood spots was a simple and rapid performance procedure and a clear result interpretation. Geenius™ HIV 1/2 Conﬁrmatory Assay can be used for the screening and conﬁrmation of HIV-1 and HIV-2 in developing areas.

Conclusion: Geenius™ HIV 1/2 Conﬁrmatory Assay for the conﬁrmation of HIV can be used in semi-remote settings when plasma is difﬁcult to collect and in remote in settings from limited resourced countries and in mobile population, as an alternative test for the HIV-1 and HIV-2 infection.

INTRODUCTION

The diagnosis of the HIV infection in adults and children over 18 months of age is usually made using a serological screening test based on the detection of HIV-1 antibodies or the simultaneous detection of HIV-1 and HIV-2 antibodies. In developed areas, the use of immunodiagnostics tests (IPTs) can serve as ﬁrst line assays. Reactive samples always need to be conﬁrmed by serological conﬁrmatory tests such as western blot.

Due to their simplicity, cost and rapid turn-around time, WHO recommends the use of IPTs for the HIV detection in resource limited settings. Different IPTs are commercially available, including immunochromatographic (lateral-ﬂow tests) and immunofluorescence (ﬁxation-based tests) formats that use different antigens depending on the assay: ﬁngerstick/capillary whole blood, whole venous blood, serum, plasma or oral ﬂuid.

In Equatorial Guinea, due to an HIV prevalence over 5% (32% in the population aged 15-49 years), WHO recommends the conﬁrmation of the HIV infection in reactive samples using a different second test and the same specimen if it is plasma or serum. If the specimen is ﬁngerstick whole blood or dried blood on ﬁlter paper, WHO recommends the collection of a new sample.

Dried blood specimens (DBS) are an appropriate alternative for the diagnosis and conﬁrmation of the HIV infection in areas where the population has limited access to health systems.

Bio-Rad Geenius™ HIV 1/2 Conﬁrmatory Assay is a single-use immunochromatographic test for the conﬁrmation of HIV infection in whole blood, serum and plasma samples.

RESULTS

Conclusions:

- This is the ﬁrst study using the Bio-Rad Geenius™ HIV 1/2 Conﬁrmatory Assay for the simultaneous detection of HIV-1 antibodies using DBS.
- Reactive samples were detected in 70 DBS specimens from infected women in Equatorial Guinea and the HIV-1 infection was conﬁrmed by western blot in all cases.
- No HIV-2 infection was found in the 6748 samples.
- Antibodies reactive to 4 or 3 HIV-1 antibodies were found in 32 (45.7%) specimens.
- Most (95.7%) specimens presented reactivity to 2 Env proteins, 92.8% to Gag and 46.8% to Pol.

Table 2: Percentage of test bands and band proﬁles in the sample panel

<table>
<thead>
<tr>
<th>Test line 1 (gp120)</th>
<th>Test line 2 (gp140)</th>
<th>Test line 3 (p24)</th>
<th>Test line 4 (HIV-1 Group O Peptide)</th>
<th>Test line 5 (p24)</th>
<th>Test line 6 (gp41)</th>
<th>Test line 7 (Proliferation control)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Negative HIV-1</td>
<td>Negative HIV-1</td>
<td>Negative HIV-1</td>
<td>Negative HIV-1</td>
<td>Negative HIV-1</td>
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<td>HIV-1 bands</td>
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<td>Negative HIV-1</td>
</tr>
</tbody>
</table>

Table 3: Interpretation of results

- Test line 1 (gp120) envelope peptide
- Test line 2 (gp140) envelope peptide
- Test line 3 (p24) envelope peptide
- Test line 4 (HIV-1 Group O Peptide)
- Test line 5 (p24) envelope peptide
- Test line 6 (gp41) envelope peptide
- Test line 7 (Proliferation control proteins)

ACKNOWLEDGMENTS

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CONCLUSIONS

Geenius™ HIV 1/2 Conﬁrmatory Assay can be used for the screening and conﬁrmation of HIV-1 and HIV-2 using two drops of dried blood. It requires minimum laboratory infrastructure following a simple and rapid performance procedure and a clear result interpretation.

The use of DBS is a practical alternative to plasma or venous whole blood collected by veno- puncture in limited resource settings for the HIV serological diagnosis in adults and children over 18 months of age.

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