The POC Alere q HIV-1/2 Detect test for detection and quantification of HIV-2

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BACKGROUND:

Rapid point-of-care (POC) nucleic acid testing (NAT) that can detect, differentiate and quantify HIV-1 and HIV-2 RNA/DNA has the potential to improve the cascade of care and antiretroviral therapy monitoring. In addition, FDA-approved confirmatory HIV-2 NAT assays currently available.

AIMS:

To evaluate the Alere q HIV-1/2 Detect for detection and quantification of HIV-2 plasma RNA

METHODS:

We compared the ability of the Alere q HIV-1/2 Detect test with 25µL of sample input and the University of Washington (UW)-Abbott m2000 HIV-2 viral load assay (Chang et al. JCV 2012) and the Abbott RealTime HIV-1 assay (Abbott Molecular) to detect and differentiate between HIV-1 and HIV-2. Under a “research use only” protocol, the Alere q HIV-1/2 platform was used to quantify HIV-2 plasma RNA viral load. Clinical samples from HIV-1, HIV-2 and HIV-1/2 dually-infected patients from Senegal and the US (ART-naïve and ART experienced) were tested, along with the WHO HIV-2 international standard and HIV-2 reference strains (HIV-2 ROD and HIV-2 EHO). All testing was performed in the CLIA-certified UW Clinical Retrovirology Laboratory using 4 Alere q HIV-1/2 Detect devices (picture below).

RESULTS:

Alere q detection rates in HIV-1, HIV-2, HIV-1/2 & HIV-negative plasma

<table>
<thead>
<tr>
<th>HIV serological status</th>
<th>Number of plasma samples</th>
<th>Alere q HIV-1</th>
<th>Alere q HIV-2</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIV-1 seronegative</td>
<td>4</td>
<td>0</td>
<td>4</td>
</tr>
<tr>
<td>HIV-1 seropositive</td>
<td>22</td>
<td>5</td>
<td>17</td>
</tr>
<tr>
<td>HIV-2 seropositive</td>
<td>111</td>
<td>0</td>
<td>57</td>
</tr>
<tr>
<td>HIV-1 and HIV-2 seropositive</td>
<td>8</td>
<td>5</td>
<td>3</td>
</tr>
</tbody>
</table>

We found that the Alere q HIV-1/2 Detect test detected HIV-2 RNA in all positive samples with high sensitivity and specificity. The results were consistent with those of the UW-Abbott m2000 HIV-2 assay and the Abbott RealTime HIV-1 assay. The Alere q HIV-1/2 Detect assay has the potential to be a rapid and simple device that detects HIV-2 RNA in clinical samples and differentiates between HIV-1 and HIV-2 with a high level of specificity. It is designed to use small samples (finger prick, 25µL) of whole blood and plasma and has the potential for use as a rapid HIV-2 NAT-based diagnostic and a viral load monitoring device in resource-limited settings, as well as providing confirmation of HIV-2 infection in the new CDC algorithm for HIV testing.

CONCLUSIONS:

The Alere q HIV-1/2 Detect test is a novel, rapid and simple device that detects HIV-2 RNA in clinical samples and differentiates between HIV-1 and HIV-2 with a high level of specificity. It is designed to use small samples (finger prick, 25µL) of whole blood and plasma and has the potential for use as a rapid HIV-2 NAT-based diagnostic and a viral load monitoring device in resource-limited settings, as well as providing confirmation of HIV-2 infection in the new CDC algorithm for HIV testing.

Additional data and references are included in the full manuscript.