Observation of Inconsistent HIV-1 Viral Load Results from Roche COBAS®/AmpliPrep/COBAS®/TaqMan® and Hologic Aptima HIV-1 Quant Assays

M. Shaktiyanova, J. Fu, R. Gu, M. Rasul, T. Ghattas, C. Mahle and J. Rakeman
New York City Department of Health and Mental Hygiene, Public Health Laboratory, New York, NY

BACKGROUND

The Hologic Aptima HIV-1 Quant Assay designed for the Panther system (Panther) has a relatively large specimen capacity, lower cost, and requires less hands-on and on-board testing time compared to the Roche COBAS®/AmpliPrep/COBAS®/TaqMan® HIV-1 Test (COBAS). The NYC Public Health Laboratory (PHL) performed HIV-1 viral load testing on both instruments at different times and observed discrepancies.

METHODS

The NYC PHL tested 945 patient specimens from June 2016 to December 2018. All specimens had been previously tested HIV-positive by the Alere Determine® HIV-1/2 Ag/Ab Combo or the INSTI® HIV-1/2 Rapid Antibody Test. In compliance with the HIV-1 Diagnostic Testing Algorithm (1) the same samples were tested at PHL by the Bio-Rad EVOLIStHM/HIV 4th Generation Combo Ab/Ag EIA (4th Gen Combo) assay and also by the ViroSeq HIV-1 Genotyping System Abbott (ViroSeq) for antiretroviral drug resistance and by the COBAS (COBAS) or Panther (Panther) instrument (see below) for HIV-1 Viral Load.

RESULTS

256 specimens from presumptively new HIV cases or known HIV-positive but treatment-naive patients were tested on the COBAS (June 1, 2016, to April 4, 2017), and 691 specimens from a similar cohort were tested on the Panther (May 8, 2016, to December 31, 2018). The comparison of these two assays is presented in Table 1. All 19 specimens with undetectable viral loads on the COBAS were also “non-reactive” when tested by the 4th Gen Combo assay, indicating that false positive results were obtained from the rapid screening test. Of 70 specimens with undetectable viral loads on the Panther, 50 were also “non-reactive”. However, 20 of 70 specimens (28.6%) were “Reactive” with the HIV-4th Gen Combo assay.

Table 1. Capacity of COBAS®/AmpliPrep/COBAS®/TaqMan® HIV-1 Test, v. 2.0 and Hologic Aptima HIV-1 Quant assay.

<table>
<thead>
<tr>
<th>Method</th>
<th>Detection range (copies/ml)</th>
<th>Assay time (min)</th>
</tr>
</thead>
<tbody>
<tr>
<td>COBAS®/AmpliPrep/COBAS®/TaqMan® HIV-1 Test</td>
<td>2-4,000,000 copies/ml</td>
<td>30-45 min</td>
</tr>
<tr>
<td>Hologic Aptima HIV-1 Quant assay</td>
<td>3-10,000,000 copies/ml</td>
<td>30-60 min</td>
</tr>
</tbody>
</table>

In comparison, the Panther assay has a lower detection limit (20 copies/ml) and a shorter turnaround time (20-30 minutes).

CONCLUSIONS

The less costly Aptima HIV-1 Quant Assay did not detect low viral loads in some specimens, which were detected by a similar assay on the COBAS system. Some of these specimens were successfully sequenced by ViroSeq genotyping assay. The discrepancy in viral load detection may result from unrecognized differences in the sensitivities of the COBAS and Panther assays.

REFERENCE

2. COBAS® AmpliPrep/COBAS®/TaqMan® HIV-1 Test, version 2.0 Package insert.