A key component of molecular infectious disease testing centers around the preservation of biological samples during shipping and storage. Typically samples are collected at one site and shipped to a central laboratory for testing requiring careful temperature control and special packaging to minimize effects of harsh shipping conditions. Time elapses between sample collection and analysis; therefore, it is imperative to have a shipping and storage process that is efficient and preserves sample integrity over time.

The current standards require dry ice, special packaging, and ultra-cold storage, all of which is expensive and laborious. This study evaluated the stability of HIV-1 plasma samples shipped and stored on ViveST®, a transformational dried ambient temperature storage and transportation device (ViveBio LLC, Alpharetta, GA, USA).

Methods

- To evaluate effects of shipping, 4 sets of HIV-1 plasma samples were prepared, loaded onto ViveST, dried overnight at room temperature (RT), and capped. Each set contained twenty 1.15 mL aliquots of HIV-1 plasma (4 levels, 5 replicates each) and 1 negative control.
- 1 set was stored frozen (-80°C) and 3 sets were each packaged in standard cardboard boxes and shipped via FedEx from bioMONTR Labs in North Carolina to 1 of 3 distinct geographic locations across the continental United States (Northeast, Southwest and West Coast). The 3 sets were returned (via FedEx) to bioMONTR Labs for analysis.
- All samples were recovered using 1.15 mL of molecular grade water and analyzed with Abbott’s RealTime HIV-1 assay (0.6 mL protocol, Abbott Laboratories, Illinois, USA).
- One-Way Omnibus ANOVA in R was used to evaluate the variance between replicates shipped to 3 sites.
- Four sets were each stored at one of three storage conditions (RT, 4°C, and 40°C/75% RH). The 4 sets were set contained twenty 1.1 mL aliquots of HIV-1 plasma (4 levels, 5 replicates each) and 1 negative control.
- Seven sets were stored at each of the three different conditions (RT, 4°C, and 40°C/75% RH). One set was removed from each storage condition at days 1, 3, 7, 10, 14, 21, and 28 and analyzed.
- All samples were recovered using 1.1 mL of molecular grade water and analyzed with Abbott’s RealTime HIV-1 assay (0.6 mL protocol, Abbott Laboratories, Illinois, USA). For comparative purposes, identical 1.1 mL aliquots (4 levels, 5 replicates each) of frozen plasma were analyzed.
- Linear Regression Analysis was performed to evaluate effects of storage at different conditions over time.

For HIV-1 plasma shipped on ViveST, the average reduction in viral load when compared to frozen plasma was 1.07 LOG c/mL (See Table 1). A linear fit (R²>0.99) was retained across all levels/all sites (See Figure 1).

The omnibus ANOVA test results indicate NO significant differences between the measurements shipped to the 3 sites (P-Value = 0.9897). Box Plot of viral load results demonstrate that the data from the three sites are equivalent (See Figure 2).

For HIV-1 plasma stored on ViveST for a 62-day period (ambient temperature), the maximum reduction recorded when compared to frozen plasma (data not shown) was 0.91 LOG c/mL, 0.84 LOG c/mL (4°C), and 1.09 LOG c/mL (40°C/75%RH).

A linear fit (R²>0.8) was retained over the course of the 62-day study as indicated by linear regression analysis (See Figure 3, ambient storage only).

The data demonstrated that samples stored on ViveST over a 62-day period at RT, 4°C, and 40°C/75% RH yielded reproducible results. (See Figure 2).

Table 1. Summary of Abbott RealTime HIV-1 Assay Data, ViveST Shipping Study

<table>
<thead>
<tr>
<th>Level</th>
<th>Replicate</th>
<th>Process</th>
<th>Storage</th>
<th>Avg c/mL</th>
<th>Amplicon</th>
<th>Std Deviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1</td>
<td>Freeze</td>
<td>RT</td>
<td>0.96</td>
<td>0.03</td>
<td>0.02</td>
</tr>
<tr>
<td>2</td>
<td>1</td>
<td>Freeze</td>
<td>RT</td>
<td>0.95</td>
<td>0.05</td>
<td>0.02</td>
</tr>
<tr>
<td>3</td>
<td>1</td>
<td>Freeze</td>
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<tr>
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<td>Freeze</td>
<td>RT</td>
<td>0.96</td>
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<td>0.02</td>
</tr>
</tbody>
</table>

Results Cont.

Figure 1. Linear Regression: ViveST Shipping Study

Figure 2. Boxplot: ViveST Shipping Study

Figure 3. Linear Regression: ViveST Processed HIV-1 Plasma Ambient Storage Through 62 Days

Conclusions

- There is no significant difference between the HIV RNA levels of samples recovered from ViveST after shipping to 3 different sites. (P Value = 0.9897).
- The linear responses over time coupled with the high degree of precision and reproducibility observed with ViveST imply application of a conversion factor could be utilized to account for any reduction of viral RNA recovery to convert ViveST values to frozen values.
- ViveST provides significant cost savings as compared to dry ice shipments and can enhance access to healthcare globally while significantly reducing the cost burden associated with frozen samples.
- ViveST exhibits great potential for shipping and storing samples for viral load testing worldwide.

Acknowledgments

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