AMBIENT TEMPERATURE SHIPPING AND STORAGE FOR MOLECULAR INFECTIOUS DISEASE TESTING: ViveST®

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Introduction

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 (-80ºC) 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.
- To evaluate stability of HIV-1 plasma stored on the ViveST device, 21 sets of HIV-1 plasma were prepared, loaded onto ViveST, dried overnight and stored for up to 2 months. Each 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, 4ºC, and 40ºC/75% RH). One set was removed from each storage condition at days 1, 3, 7, 10, 14, 21, and 62 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.

Results

- 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 (R^2>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 (4ºC), and 1.69 LOG c/mL (40ºC/75%RH).
- A linear fit (R^2>0.98) 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, 4ºC, and 40ºC/75% RH yielded reproducible results. (See Figure 4).

Table 1. Summary of Abbott RealTime HIV-1 Assay Data_ViveST Shipping Study

Level	Replicate	Frozen	Shipping - Ambient Conditions		
			Site 1	Site 2	Site 3
		Log c/mL	Log c/mL	Log c/mL	Log c/mL
1	A	6.05	4.84	4.81	4.89
	B	5.98	4.87	4.83	4.83
	C	5.95	4.82	4.84	4.86
	D	5.95	4.82	4.83	4.89
	E	6.03	4.90	4.80	4.88
	Mean	**5.99**	**4.85**	**4.82**	**4.87**
	Std deviation	**0.05**	**0.03**	**0.02**	**0.03**
	% CV	**0.06**	**0.04**	**0.02**	**0.03**
2	A	4.81	3.75	3.76	3.87
	B	4.93	3.73	3.68	3.78
	C	4.93	3.71	3.75	3.81
	D	4.93	3.69	3.72	3.84
	E	4.90	3.73	3.75	3.76
	Mean	**4.90**	**3.72**	**3.73**	**3.81**
	Std deviation	**0.05**	**0.02**	**0.03**	**0.04**
	% CV	**0.07**	**0.03**	**0.04**	**0.06**
3	A	3.78	2.88	2.86	2.96
	B	3.92	2.86	2.81	2.85
	C	3.86	2.88	2.88	2.9
	D	3.92	2.84	2.87	2.68
	E	3.88	2.82	2.95	2.85
	Mean	**3.87**	**2.86**	**2.87**	**2.85**
	Std deviation	**0.06**	**0.03**	**0.05**	**0.10**
	% CV	**0.07**	**0.03**	**0.06**	**0.13**
4	A	2.99	1.80	2.06	2.03
	B	2.91	1.73	2.13	2.01
	C	2.82	2.18	1.84	1.22
	D	2.95	1.84	1.99	2.13
	E	2.75	1.58	2.00	2.11
	Mean	**2.88**	**1.83**	**2.00**	**1.90**
	Std deviation	**0.10**	**0.22**	**0.11**	**0.38**
	% CV	**0.12**	**0.28**	**0.13**	**0.48**

NOTE: Highlighted cells indicate samples where m2000rt results were reported as <1.60 LOG c/ml (<40 c/mL). Results were manually calculated using the calibration curve.

Results Cont.

Figure 1. Linear Regression: ViveST Shipping Study

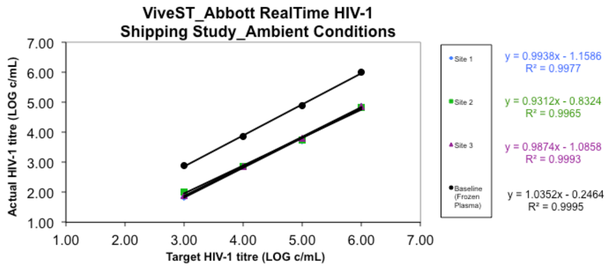


Figure 2. Boxplot: ViveST Shipping Study

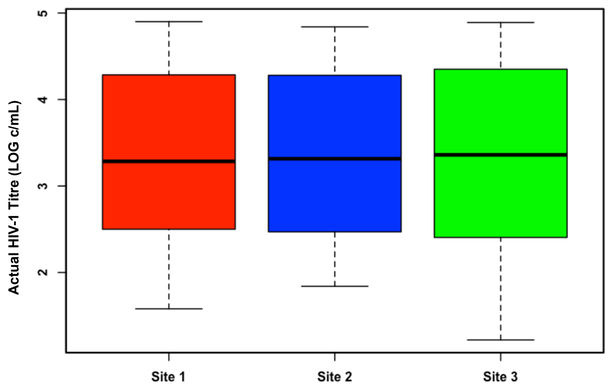
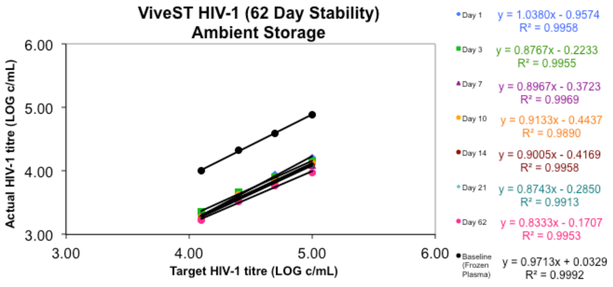
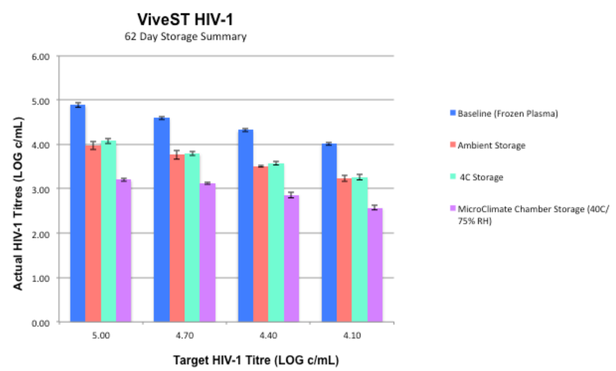


Figure 3. Linear Regression: ViveST Processed HIV-1 Plasma Ambient Storage through 62 Days



Results Cont.

Figure 4. ViveST Processed HIV-1 Plasma: Comparison Across All Storage Conditions (62 Days Storage)



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.

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