

S16 Real-Time Stability of Plasma Using ViveST™, a Revolutionary Ambient Temperature, Storage and Transportation Device

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Introduction

Infectious disease monitoring often requires collection sites to ship specimens to reference testing laboratories. These samples require careful temperature control and special packaging as specimens are subjected to harsh shipment conditions. This study evaluated the stability of infectious plasma samples stored on ViveST™, a second generation dried ambient transportation matrix, and analyzed with the Abbott RealTime HCV and HIV-1 viral load assays.

Methods

- To evaluate the stability of HCV infectious plasma stored on the ViveST device (ViveBio LLC, Alpharetta, GA), 21 sets of plasma samples (1.0 mL each) were prepared, loaded onto ViveST, dried overnight and stored for up to 2 months. Each set contained twenty 1.0 mL aliquots of HCV infectious plasma (4 levels, 5 replicates each) and 1 negative control. Seven sets were stored at each of three different conditions (ambient temperature, 4°C and 40°C/75%RH). One set was removed from each storage condition at Days 1, 3, 7, 10, 14, 21 and 62 for analysis. The plasma was recovered from ViveST using 1.0 mL of recovery buffer and analyzed with Abbott's RealTime™ HCV assay (Abbott Laboratories, Illinois, USA). For comparative purposes, identical 1.0 mL aliquots (4 levels, 5 replicates each) of frozen plasma were analyzed.

- To evaluate the stability of HIV-1 infectious plasma stored on the ViveST device, 21 sets of plasma samples (1.1mL each) were prepared, loaded onto ViveST, dried overnight and stored as described above. The plasma was recovered from ViveST using 1.1 mL of recovery buffer and analyzed with Abbott's RealTime™ HIV-1 assay (0.6 mL application, Abbott Laboratories, Illinois, USA). For comparative purposes, identical 1.1 mL aliquots (4 levels, 5 replicates each) of frozen plasma were analyzed.

Results: HCV Stability

For HCV infectious plasma stored on ViveST for a 62 day period (ambient temperature), the maximum reduction recorded when compared to frozen plasma was 0.58 LOG IU/mL (See Table 1). When stored at 4°C and 40°C/75% RH, the maximum reduction recorded when compared to frozen plasma was 0.43 LOG IU/mL and 1.37 LOG IU/mL, respectively (data not shown). The Standard Deviation across all levels/all test points/all storage conditions ranged from 0.01 to 0.17 (data not shown). 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 1, ambient storage only).

Table 1. Mean Results: ViveST (ambient storage) Analyzed with Abbott RealTime HCV (LOG IU/mL)

Target HCV titre (LOG IU/mL)	Mean Results - Ambient Storage (Days)							
	Frozen	1	3	7	10	14	21	62
4.67	4.64	4.42	4.39	4.21	4.27	4.18	4.16	4.06
4.38	4.38	4.09	4.09	3.95	3.91	3.87	3.93	3.80
4.07	4.07	3.75	3.63	3.66	3.61	3.60	3.60	3.58
3.77	3.77	3.39	3.41	3.33	3.38	3.35	3.30	3.24

Figure 1. Linear Regression: ViveST Processed HCV Plasma Ambient Storage through 62 days

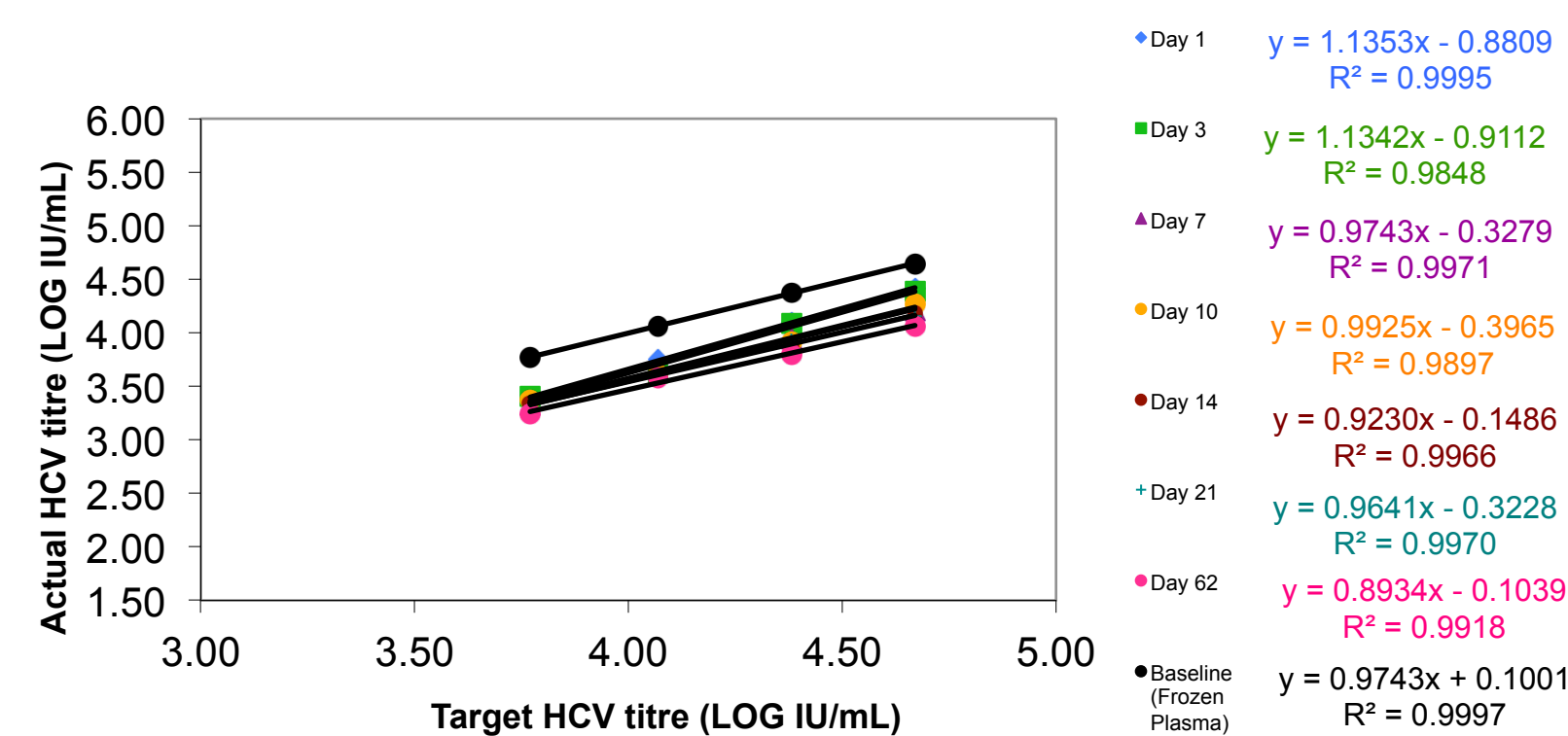
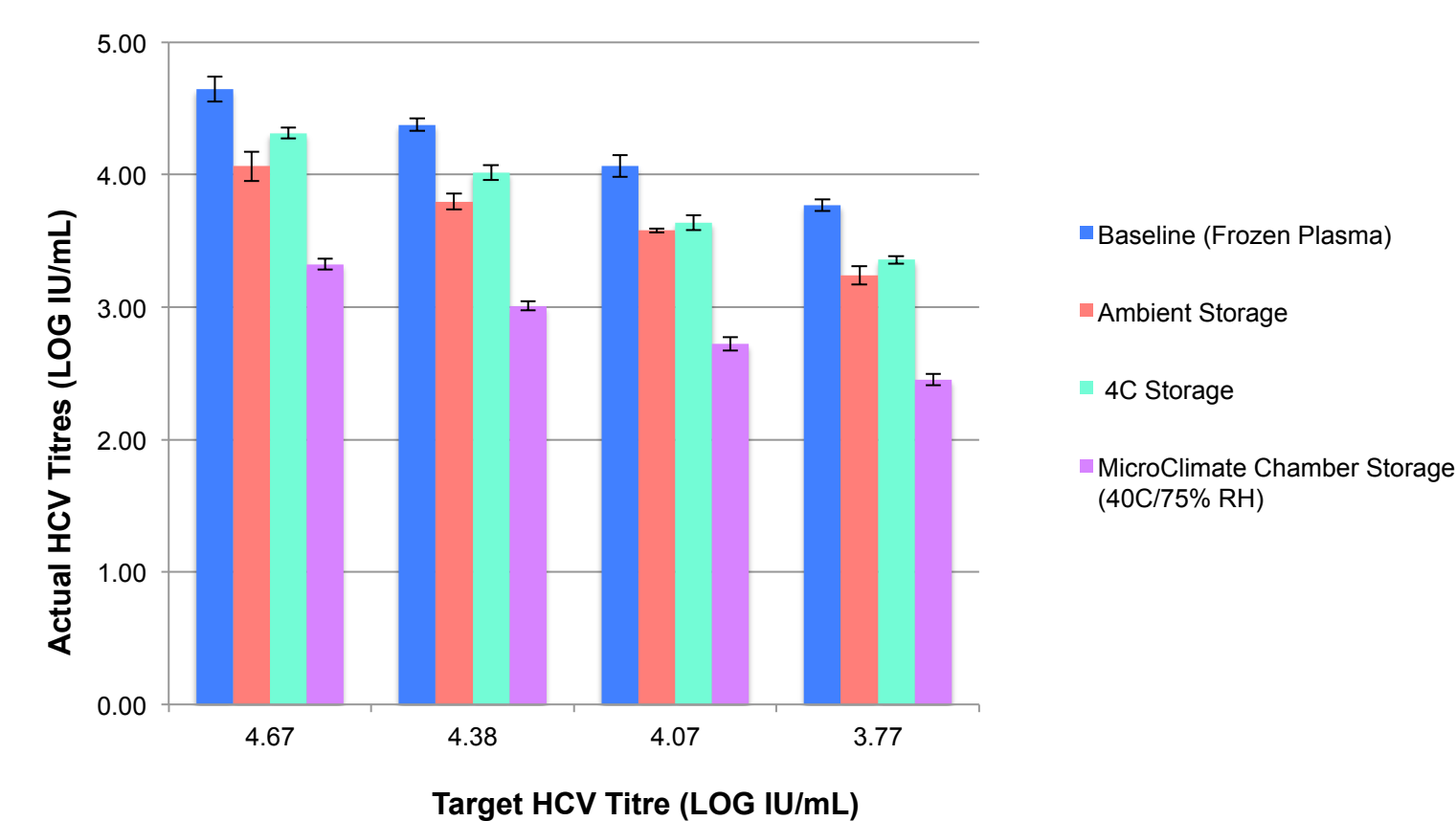


Figure 2. ViveST Processed HCV Plasma: Comparison Across All Storage Conditions (62 Days Storage)



Results: HIV-1 Stability

For HIV-1 infectious plasma stored on ViveST for a 62 day period (ambient temperature), the maximum reduction recorded when compared to frozen plasma was 0.91 LOG c/mL (See Table 2). When stored at 4°C and 40°C/75% RH, the maximum reduction recorded when compared to frozen plasma was 0.84 LOG c/mL and 1.69 LOG c/mL, respectively (data not shown). The Standard Deviation across all levels/all test points/all storage conditions ranged from 0.02 to 0.13 (data not shown). 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).

Table 2. Mean Results: ViveST (ambient storage) Analyzed with Abbott RealTime HIV-1 (LOG c/mL)

Target HIV-1 titre (LOG c/mL)	Mean Results - Ambient Storage (Days)							
	Frozen	1	3	7	10	14	21	62
5.00	4.89	4.21	4.15	4.09	4.12	4.10	4.07	3.98
4.70	4.59	3.94	3.90	3.87	3.82	3.79	3.83	3.77
4.40	4.32	3.63	3.67	3.57	3.63	3.57	3.61	3.51
4.10	4.01	3.28	3.35	3.30	3.27	3.27	3.27	3.23

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

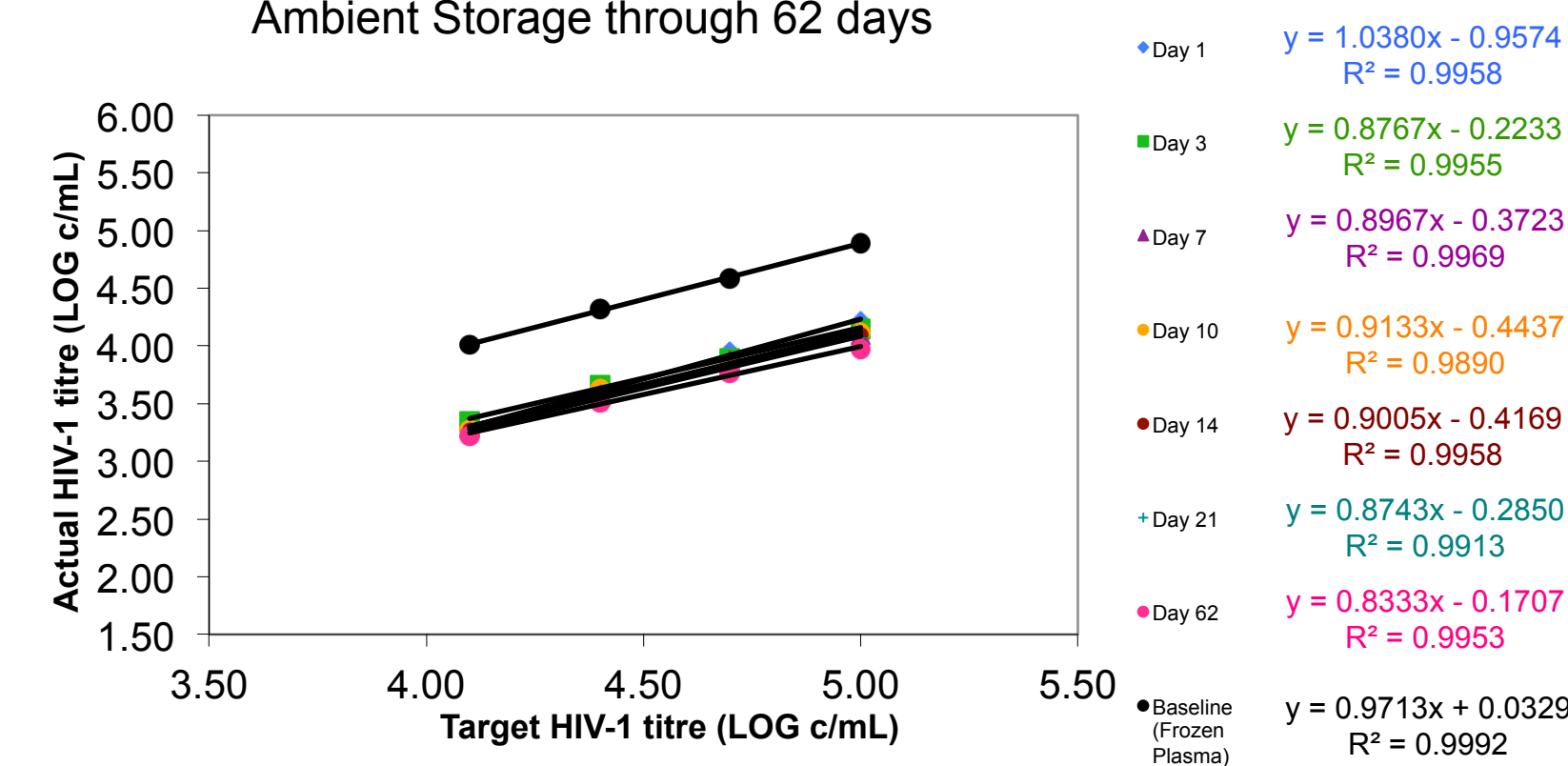
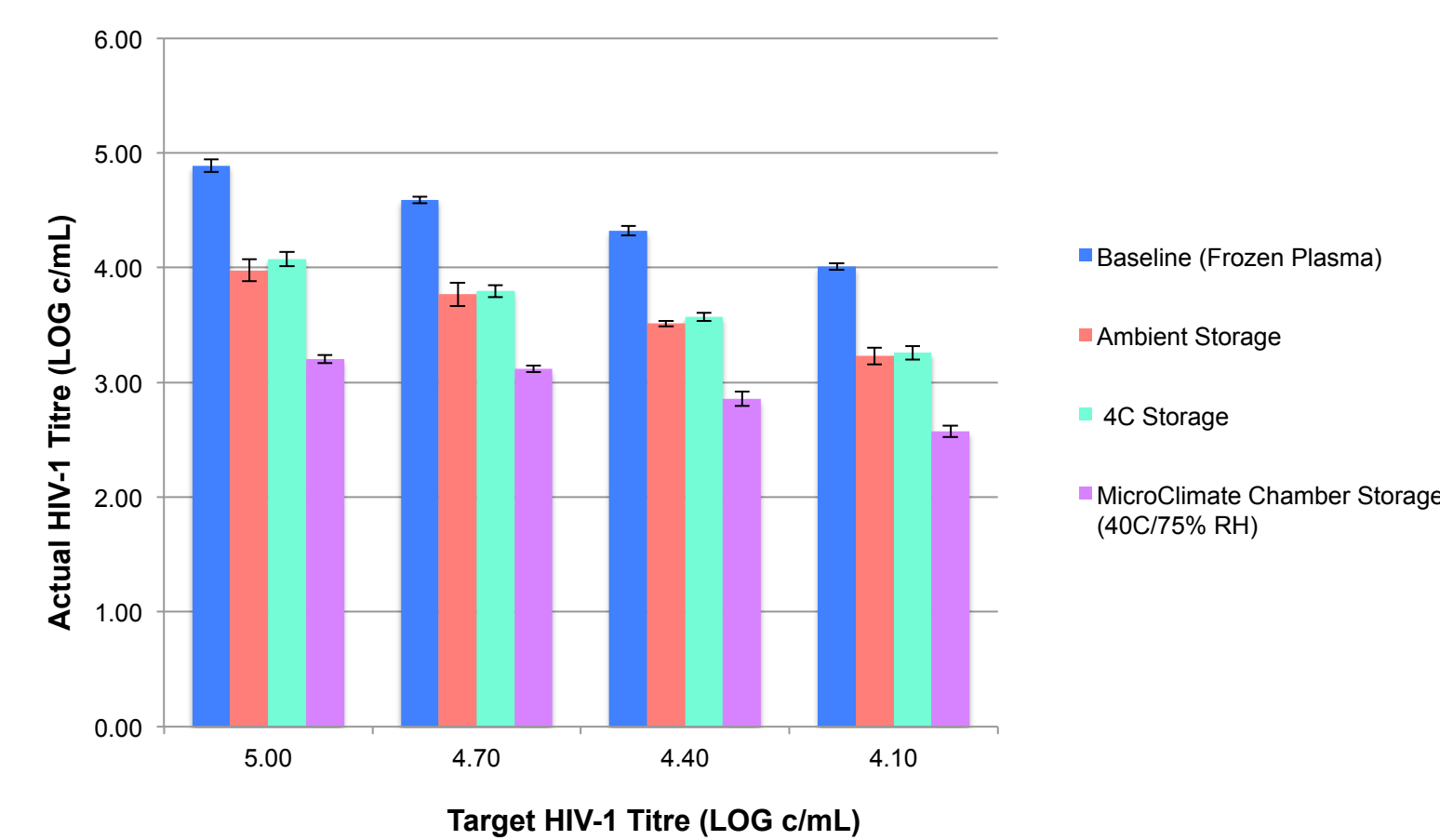


Figure 4. ViveST Processed HIV-1 Plasma: Comparison Across All Storage Conditions (62 Days Storage)



Conclusions

- This study confirms that ViveST sample transportation and storage device demonstrated excellent stability, accuracy and reproducibility at RT, 4°C and 40°C/75%RH (Fig 2 and Fig 4).
- Maximum reduction for HCV RNA was 0.58 log and for HIV-1 RNA was 0.91 log at RT for 2 months demonstrating excellent recovery of viral RNA.
- 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 ST values to frozen values.
- ViveST exhibits great potential for storing and viral load testing plasma obtained from HCV and HIV-1 positive patients worldwide.
- The use of the ViveST device can offer a global solution to expanding access to healthcare and significantly reduce healthcare costs.³

References

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