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Evaluation of ViveST™ For HIV/HCV Testing Using Abbott's RealTime Assays

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Introduction

With the development of new direct-acting antiviral HCV and HIV drugs, global viral load and genotypic monitoring will become increasingly important in patient management. Such infectious disease monitoring often requires collection sites to ship patient samples to reference testing laboratories. These samples require careful temperature control and special packaging which is costly and labor intensive. This study compared the performance of ViveST, a novel dried ambient transportation matrix, to frozen plasma for use with commercially available HCV and HIV-1 viral load and genotypic assays.

Method

- Nineteen HCV positive plasma samples were aliquoted into four 1 mL volumes. Two aliquots were stored at -80°C and two aliquots were loaded onto ViveST devices and dried overnight. The ViveST samples were recovered with molecular grade water. HCV viral load testing was performed on one frozen plasma aliquot and one ViveST recovered aliquot using Abbott's RealTime™ HCV assay (Abbott Laboratories, Abbott Park, Illinois, U.S.A.). HCV Genotyping was performed on one frozen plasma aliquot and one ViveST recovered aliquot using Abbott's RealTime™ HCV Genotype II RUO assay (Abbott Laboratories, Abbott Park, Illinois, U.S.A.).
- Twenty HIV positive plasma samples were aliquoted into three 1 mL volumes. One aliquot was stored at -80°C and two aliquots were loaded onto ViveST devices and dried overnight. The ViveST samples were recovered with either molecular grade water or mLysis buffer (a component of Abbott's mSample Preparation System). HIV-1 viral load testing was performed on one frozen plasma aliquot, one ViveST water recovered aliquot and one ViveST mLysis buffer recovered aliquot using Abbott's RealTime™ HIV-1 assay (Abbott Laboratories, Abbott Park, Illinois, U.S.A.).

Results

HCV genotyping results demonstrated 100% concordance between plasma recovered from ViveST compared to frozen plasma with HCV genotypes 1, 1a, 1b, 2 and 3 being tested (Table 1). HCV viral load results showed an average reduction of 0.32 log for plasma recovered from ViveST compared to frozen plasma (Table 2 and Figure 1).

HIV-1 viral load results showed an average reduction of 0.26 log when plasma was recovered from ViveST using mLysis buffer (Table 3 and Figure 2) and an average reduction of 0.59 log when recovered from ViveST using water as the sample recovery buffer (Table 3 and Figure 3).

Results (cont'd)

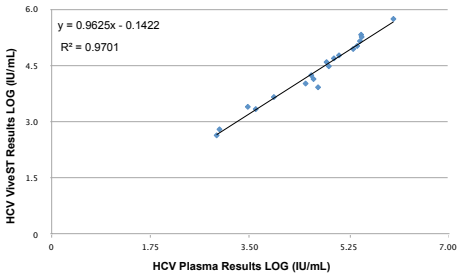
Table 1. Results of Comparative Analysis Using Abbott's RealTime HCV Genotype II RUO Assay

Sample ID	Fresh Plasma	ViveST Processed
b1169-1	2	2
b1170-2	1, 1a	1, 1a
b1171-3	1, 1a	1, 1a
b1172-4	1, 1a	1, 1a
b1173-5	1, 1a	1, 1a
b1174-6	1, 1a	1, 1a
b1175-7	1, 1a	1, 1a
b1176-8	1, 1a	1, 1a
b1177-9	1, 1a	1, 1a
b1169-10	2	2
b1179-11	3	3
b1180-12	1, 1a	1, 1a
b1184-13	3	3
b1178-14	3	3
b1172-15	1, 1a	1, 1a
b1185-16	1, 1a	1, 1a
b1186-17	1, 1b	1, 1b
b1172-18	1, 1a	1, 1a
b1187-19	1	1

Table 2. Results of Comparative Analysis using Abbott's RealTime HCV Assay (Fresh Plasma versus ViveST)

Fresh Plasma, Mean Viral Load LOG IU/mL (n = 19)	4.64
ViveST, Mean Viral Load LOG IU/mL (n = 19)	4.32
Mean Difference, LOG IU/mL (Fresh vs ViveST)	-0.32
Std Dev, LOG IU/mL	0.15
Correlation Coefficient (R)	0.98

Figure 1. Sample Correlation, HCV Viral Load: Fresh Plasma versus Samples Processed thru ViveST.



Results (cont'd)

Table 3. Results of Comparative Analysis using Abbott's RealTime HIV-1 Assay (Fresh Plasma versus ViveST)

Fresh Plasma, Mean LOG c/mL (n = 20)	3.74	
	Recovery with mLysis	Recovery with Water
ViveST, Mean LOG c/mL (n = 20)	3.48	3.15
Mean Difference, LOG c/mL (Fresh vs ViveST)	-0.26	-0.59
Std Dev, LOG c/mL	0.31	0.15
Correlation Coefficient (R)	0.96	0.99

Figure 2. Sample Correlation, HIV-1 Viral Load: Fresh Plasma versus Samples Processed thru ViveST (Recovery with mLysis).

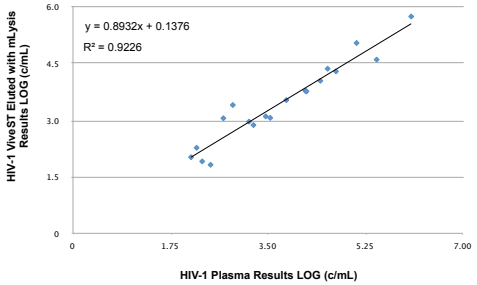
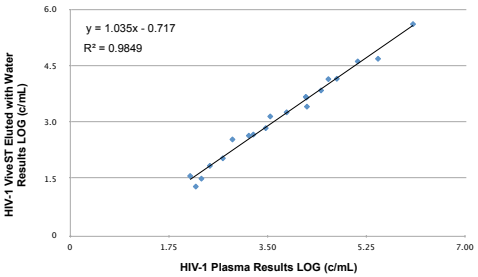


Figure 3. Sample Correlation, HIV-1 Viral Load: Fresh Plasma versus Samples Processed thru ViveST (Recovery with Water).



Conclusions

- ViveST sample transportation and storage device shows great potential for use in transporting plasma obtained from HCV and HIV-1 positive patients for viral load and genotypic testing.
- HCV and HIV-1 viral load results using plasma recovered from ViveST produced slightly lower RNA values compared to frozen plasma, but generally within accepted variation for replicate samples.
- Plasma recovered from ViveST can be directly utilized in the Abbott Real-time assays; no additional processing is required and standard protocols can be followed.[2]
- The use of ViveST can enhance the access to HCV and HIV-1 viral load and genotypic testing in resource-limited countries and significantly reduces the burden associated with shipping frozen samples.[3,4]

Figure 4. The ViveST™ Sample Storage and Transportation Device

References

1. R.M. Lloyd Jr. D.A. Burns, J.T. Huong, et. al. Dried-Plasma Transport Using a Novel Matrix and Collection System for Human Immunodeficiency Virus and Hepatitis C Virus Virologic Testing. Journal of Clinical Microbiology. May 2009, Vol. 47, No. 5, p. 1491-1496.
2. Package Inserts for Abbott RealTime HCV Genotype II RUO (List No. 8K24-86), Abbott RealTime HCV (Ref # 1N30-90) and Abbott RealTime HIV-1 (Ref # 6L18-90).
3. Evaluation of SampleTanker, a Resource-limited-Setting Friendly Sample Collection Device for HIV-1 Drug Resistance Genotyping Analysis. E. Lehotzky, J. Zhang., et.al., 17th Conference on Retroviruses and Opportunistic Infections. San Francisco, CA. February 2010.
4. Cost Effectiveness of International Shipment of Dried Plasma for HIV Resistance Testing. Lloyd, et. al., 5th IAS Conference on HIV Pathogenesis, Treatment and Prevention. Cape Town, South Africa. July 2009.

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