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# HCV AND HIV TESTING USING A NOVEL DRIED AMBIENT SAMPLE COLLECTION AND TRANSPORT DEVICE, VIVEST

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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. 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. Herein we 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

•Thirteen HIV-1 plasma specimens were aliquoted into two 1 mL volumes. One aliquot was stored at -80°C, and one aliquot was loaded and dried onto ViveST devices overnight. The ViveST samples were reconstituted with molecular grade water. All specimens were subsequently assayed per FDA approved ViroSeq™ HIV-1 Genotyping System v2.0 package insert.

•Twenty HIV positive plasma samples were aliquoted into two 1 mL volumes. One aliquot was stored at -80°C and one aliquot was loaded and dried onto ViveST devices overnight. The ViveST samples were reconstituted with molecular grade water. HIV-1 viral load testing was performed on one frozen plasma aliquot and one ViveST recovered aliquot using Abbott's RealTime™ HIV-1 assay (Abbott Laboratories, Abbott Park, Illinois, U.S.A.).

•Nineteen HCV positive plasma samples were aliquoted into four 1 mL volumes. Two aliquots were stored at -80°C and two aliquots were loaded and dried onto ViveST devices overnight. The ViveST samples were reconstituted 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.).

## Results

ViveST processed samples had an 85% (11/13) genotyping success rate as compared to a 100% (13/13) success rate for frozen plasma samples using the HIV-1 ViroSeq Assay. [No repeat analysis was performed for the ViveST samples]. There was 91% (10/11) concordance between plasma recovered from ViveST compared to frozen plasma in identifying mutations associated with drug resistance. One sample (b1220) had a V75I mutation identified in the frozen plasma sample (based on unidirectional coverage) while no mutations were identified in the ViveST sample (See Table 1).

## Results (cont'd)

HIV-1 viral load results showed an average reduction of 0.59 log with a $R^2$ of 0.98 when recovered from ViveST using molecular grade water (Table 2 and Figure 1).

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 (data not shown). HCV viral load results showed an average reduction of 0.32 log for plasma recovered from ViveST compared to frozen plasma (Table 3 and Figure 2).

**Table 1. Comparative Analysis of Frozen Plasma versus ViveST using the HIV-1 ViroSeq Assay**

| bioMONTR ID | HIV-1 Viral Load: Frozen Plasma (LOG c/mL) | ViroSeq Results: Frozen Plasma | ViroSeq Results: Plasma Processed through ViveST |
|---|---|---|---|
| b1208 | 5.45 | NRTI: M41L, E44D, D67N, L74I/V, V118I, M184V, L210W, T215Y, K219N | NRTI: M41L, E44D, D67N, L74I/V, V118I, M184V, L210W, T215Y, K219N |
| | | NNRTI: V108I, Y181C/I | NNRTI: V108I, Y181C/I |
| | | PI: L10I, V32I, M46I, F53L, I54V, Q58E, A71V, V82A, L90M | PI: L10I, V32I, M46I, F53L, I54V, Q58E, A71V, V82A, L90M |
| b1210 | 3.46 | NRTI: M41L, E44D, D67N, K70R, M184V, L210W, T215Y, K219E | NRTI: M41L, E44D, D67N, K70R, M184V, L210W, T215Y, K219E |
| | | PI: L10I, I54V, V82A | PI: L10I, I54V, V82A |
| b1211 | 6.07 | NRTI: M41L, T215Y | NRTI: M41L, T215Y |
| b1213 | 5.09 | NRTI: M41L, E44D, L74V, L210W, T215Y | NRTI: M41L, E44D, L74V, L210W, T215Y |
| | | NNRTI: Y188L | NNRTI: Y188L |
| | | PI: M46I, A71T, I84V, L90M | PI: M46I, A71T, I84V, L90M |
| b1214 | 3.54 | NRTI: M41L, E44D, D67N, T69D, V118I, M184V, L210W, T215Y | NRTI: M41L, E44D, D67N, T69D, V118I, M184V, L210W, T215Y |
| | | PI: L90M | PI: L90M |
| b1215 | 3.16 | NRTI: M184V | No amplification |
| b1218 | 4.72 | NNRTI: K103N | NNRTI: K103N |
| b1219 | 4.17 | NRTI: T69D | NRTI: T69D |
| | | NNRTI: K103N | NNRTI: K103N |
| b1220 | 4.44 | NRTI: V75I | No mutations Identified |
| b1221 | 3.24 | NRTI: D67N, M184I, T215Y | NRTI: D67N, M184I, T215Y/C |
| | | NNRTI: K101Q, K103R, V179D, Y181C, G190A | NNRTI: K101Q, K103R, V179D, Y181C, G190A |
| | | PI: L10F, M46I, I54L, I84V, L90M | PI: L10F, M46I, I54L, I84V, L90M |
| b1222 | 4.18 | PI: A71V | PI: A71V |
| b1224 | 3.83 | No Mutations Identified | No amplification |
| b1225 | 4.19 | NRTI: D67N, L74V, V118I, M184V, T215F, K219Q | NRTI: D67N, L74V, V118I, M184V, T215F, K219Q |
| | | NNRTI: L100I, K103N | NNRTI: L100I, K103N |
| | | PI: L10I, G48V, I54V, A71V, V82A, L90M | PI: L10I, G48V, I54V, A71V, V82A, L90M |

**Table 2. Comparative Analysis of Frozen Plasma versus ViveST using Abbott's RealTime HIV-1 Assay**

| | |
|---|---|
| Frozen Plasma, Mean Viral Load LOG c/mL (n = 20) | 3.74 |
| ViveST, Mean Viral Load LOG c/mL (n = 20) | 3.15 |
| Mean Difference, LOG c/mL (Frozen vs. ViveST) | -0.59 |
| Std Dev, LOG c/mL | 0.15 |
| $R^2$ | 0.98 |

## Results (cont'd)

Figure 1. HIV-1 Viral Load Correlation of Frozen Plasma vs. ViveST

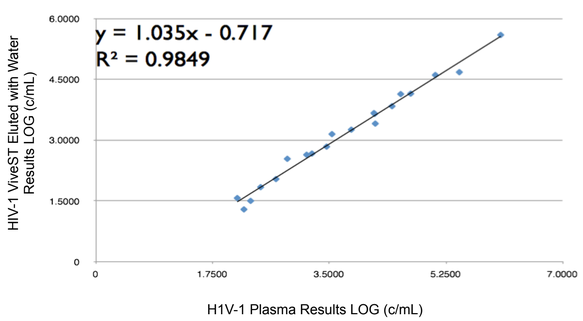
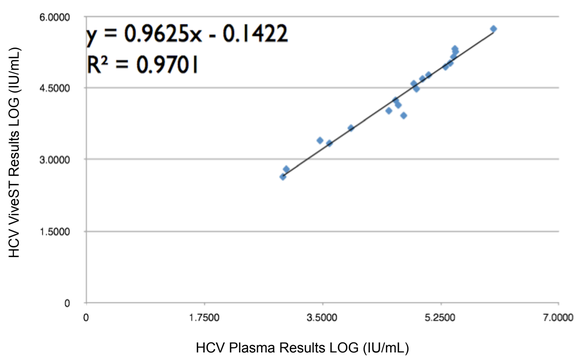



**Table 3. Comparative Analysis of Frozen Plasma versus ViveST using Abbott's RealTime HCV Assay**

| | |
|---|---|
| Frozen 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 (Frozen vs. ViveST) | -0.32 |
| Std Dev, LOG IU/mL | 0.15 |
| $R^2$ | 0.97 |

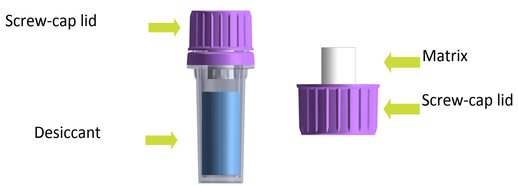
Figure 2. HCV Viral Load Correlation of Frozen Plasma vs. ViveST




## Conclusions

- Plasma recovered from ViveST yielded comparable results to frozen plasma for sequence analysis of viral RNA.
- HCV and HIV-1 viral load results, using plasma recovered from ViveST, demonstrated generally lower RNA values, but were within criteria established by the HHS Panel on Antiretroviral Guidelines.[2]
- Plasma recovered from ViveST is viable for use in Abbott RealTime and ViroSeq Drug Resistance Assays without requiring additional processing for use following standard protocols.[3]
- 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.[4]

Figure 4. The ViveST Sample Storage and Transportation Device




## References

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2. Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the use of antiretroviral agents in HIV-1 infected adults and adolescents. Department of Health and Human Services. October 14, 2011; 1-167.
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4. E. Lehotzky, J. Zhang., et.al. Evaluation of SampleTanker, a Resource-limited-Setting Friendly Sample Collection Device for HIV-1 Drug Resistance Genotyping Analysis. 17th Conference on Retroviruses and Opportunistic Infections. San Francisco, CA. February 2010.

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