HCV viral load and HIV-1 drug resistance monitoring are key tools for accessing response to antiviral therapy and are critical tests for patient management. Transportation of frozen plasma has tremendous logistic and cost limitations which limit global access to these tests. Herein we describe the performance of a transformational ambient storage and transport device, ViveST™, for use with viral load and drug resistance assays.

Methods

- For proof of concept, plasma from an HCV infected patient ( genotype 1a, IL28B genotype CT) was analyzed prospectively prior to and during therapy (PEG/Interferon, Ribavirin and Telaprevir). Baseline, week 2, week 4, week 12, and week 24 time points were analyzed using Roche COBAS TaqMan assay ( frozen plasma only) and Abbott RealTime HCV assay (frozen and plasma processed ViveST).

- To assess ViveST performance for HCV viral load testing, HCV infectious plasma (1 mL) was loaded onto ViveST, dried and stored at ambient temperature. Samples were recovered with 1 mL recovery buffer and analyzed using the Abbott RealTime HCV Assay (Abbott Molecular, Des Plaines, IL). For inter- and intra-assay precision, specimens with varying viral loads (low, mid, high) were analyzed in triplicate (n = 21 total). To assess analytical measurement range, a high titer viral load of 37.5 IU/mL were detected using the Abbott RealTime HCV Assay. For the recovered samples, the average calculated viral load was 5 IU/mL (0.61 LOG IU/mL). The range was 1 IU/mL – 10 IU/mL (0.14 – 1.00 LOG IU/mL). Two of the recovered samples were not detected (See Table 1).

- Testing diluted samples from 1.3 to 6.6 LOG IU/mL demonstrated a direct proportional relationship between the dilution factor and number of HCV copies reported ($R^2 = >0.99$). See Figure 2.

HIV-1 drug resistance mutations demonstrated 100% concordance for 10/10 pairs between frozen plasma and ViveST processed plasma samples. Per bioMONTR bioConT sequence analysis tool, there was >99% concordance at the nucleotide level comparing ViveST versus frozen plasma for Protease and Reverse Transcriptase regions (See Table 3). Sequence quality from ViveST processed plasma was comparable to that obtained from frozen plasma (See Figure 3).

Conclusions

- ViveST sample transportation and storage device demonstrates utility for transporting plasma obtained from HIV positive samples for Abbott RealTime HCV Assay.

- Plasma samples recovered from ViveST yielded reproducible results with a standard deviation of <0.10 LOG IU/mL (intra-assay) and <0.07 LOG IU/mL (inter-assay). The 95% CI were <±0.11 (intra-assay) and <±0.04 (inter-assay).

- When stored on ViveST, 91% of samples (21 of 23) with a viral load of 37.5 IU/mL were detected using the Abbott RealTime HCV Assay.

- HCV patient specimens processed through ViveST and tested produced viral load profiles similar to frozen plasma.

- Plasma samples stored on ViveST yielded equivalent genotypic data as compared to frozen plasma; confirming ViveST utility for transporting plasma obtained from HIV-1 positive individual for HIV-1 resistance testing.

- ViveST has great potential to offer a global solution for infectious disease testing and reduce costs in both developed and developing countries.

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