Detection of Low Level HCV RNA In Room Temperature Stored Samples Using ViveST™, a Transformational Storage and Transport Device

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Introduction

With the advent of new potent direct-acting antivirals for HCV treatment, viral load testing will increase dramatically. Of particular importance is monitoring patient response during drug therapy when the ability to detect low level HCV RNA is necessary to ensure correct therapy duration.

The storage of HCV patient plasma typically requires careful temperature control and the use of special equipment. This study evaluates the storage of low titer HCV plasma using ViveST, a transformational dried sample storage and transport device, in combination with the Abbott RealTime HCV assay.

Methods

- To evaluate the performance of ViveST for storage of low titer HCV plasma, a custom panel of HCV plasma samples (Genotype 1b in EDTA plasma) was obtained from Qnostics (Glasgow).
- To confirm the RNA concentration of the HCV samples, 1 mL aliquots (n = 45) were analyzed using the Abbott RealTime HCV assay (FDA approved 0.5 mL protocol).
- 1 mL aliquots were loaded onto ViveST (n = 180), dried overnight, and stored at room temperature pending recovery and analysis. Of the 180 samples, 45 were recovered from ViveST after 3, 4, 5, and 7 days storage using 1 mL molecular grade water.
- Immediately after recovery, samples were analyzed using the Abbott RealTime HCV assay.

Figure 1. Loading of Plasma onto ViveST Matrix

Results

Figure 2. Scatter Plot of ViveST Processed Samples (n=180)_Abbott RealTime HCV Assay

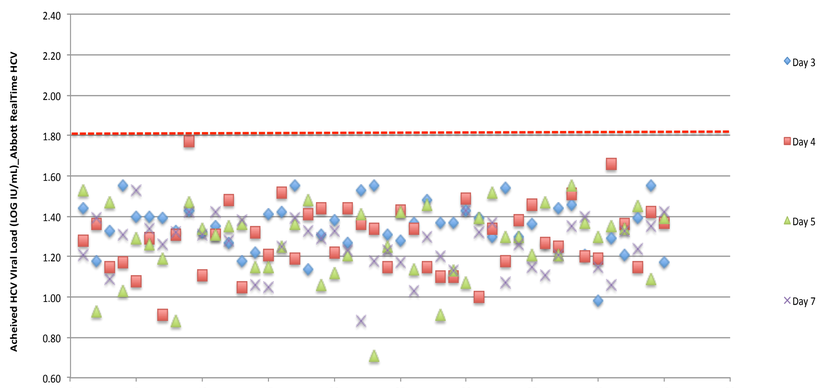
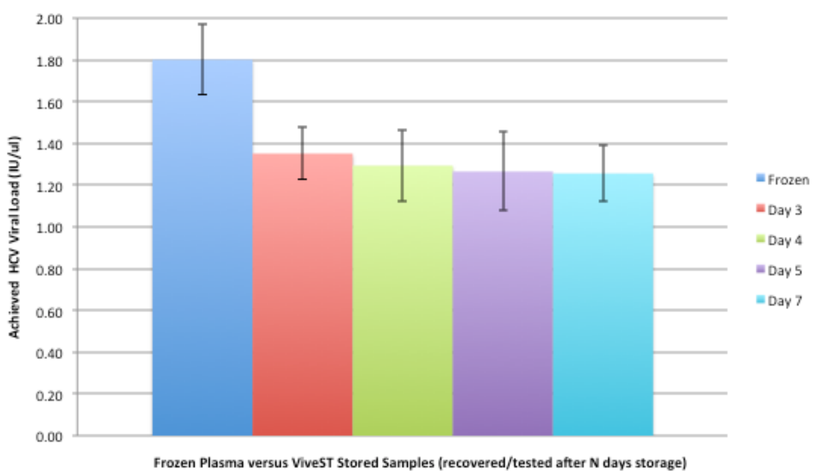


Figure 3. Achieved HCV Viral Load: Frozen versus ViveST Stored Samples (n = 45 samples each test point)



Results (cont'd)

- The average HCV RNA viral load (VL) of the Qnostics panel samples based on testing 45 frozen samples was 1.80 LOG IU/mL (69 IU/mL) with a range of 1.56 -2.20 LOG IU/mL (37-158 IU/mL).
- All samples recovered from ViveST were detected and exhibited an average HCV VL of:
  - 1.35 LOG IU/mL (3 days storage)
  - 1.29 LOG IU/mL (4 days storage)
  - 1.27 LOG IU/mL (5 days storage)
  - 1.26 LOG IU/mL (7 days storage)
- When compared to frozen plasma, the average reduction in HCV RNA for samples stored on ViveST (3, 4, 5, and 7 days respectively) was 0.45 LOG IU/mL, 0.51 LOG IU/mL, 0.53 LOG IU/mL, and 0.54 LOG IU/mL.

Conclusions

- While there is some reduction in HCV RNA, the recovery of HCV plasma from ViveST is accurate and reproducible regardless of storage time.
- These data support the use of a normalization factor of 0.5 LOG IU/mL to align the viral load results with values that would be expected from frozen plasma.
- These studies demonstrate ViveST's utility for storage of low titer HCV plasma and it's unique reproducibility profile for monitoring HCV viral load during drug therapy.
- ViveST eliminates the need for costly temperature control during sample shipment and storage.

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