

## **Evaluation of SampleTanker® for Collection, Storage and Transport of Dried Plasma from a Resource-limited Setting (R-LS) to a Resource-Rich Setting (R-RS) for HIV-1 Genotypic Analysis.**

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**BACKGROUND:** Storage and transport of plasma for HIV-1 genotypic resistance and VL to support clinical care in R-LS is prohibitively expensive. This has resulted in different strategies for 'virological support' of those on ART in R-LS. To simulate an R-LS environment, we established a temporary low-technology, 'laboratory tent' for evaluation of the SampleTanker® (ST) bio-matrix for collection, storage and transport of dried plasma to an R-RS for HIV-1 genotypic analysis.

**METHODS:** A 'laboratory tent' containing a bench, seat, portable refrigerator, plastic box, waste bins and pipettes was established in our laboratory. Temperature and humidity were monitored. Consecutive whole blood samples were allowed to sediment for >4 hours and 1mL of plasma was loaded onto the ST, air-dried overnight using a modified 9v computer fan in a plastic box, and shipped ambient to Atlanta, USA using first class mail. ST specimens were reconstituted and genotypic analysis performed using TRUGENE HIV-1 Genotyping and results compared with paired frozen plasma from the same site. Subtype analysis was performed using 4 analytical web tools for a consensus result.

**RESULTS:** 108/135 (80%) ST extracts analysed were successfully genotyped. Of the 27 negative extracts, 17 were found to have VL<1000c/mL giving an adjusted yield of 108/118 (91.5%). A comparison between frozen plasma and ST sequencing showed mean similarity scores of >99% and >98% concordance at nucleic acid and amino acid level. The subtype B:NB ratio was 1:2 with representation of all subtypes A-G (C:37%, B:33%, A:6%), and recombinant forms AG(10%), AE (6%), BC, AD, and BD (<5% frequency). The laboratory temperature ranged from -5 to +35 degrees centigrade and humidity ranged from 21%-89%. Relative transport costs for 25 samples were \$86 for ST tubes and \$426 for frozen plasma.

**CONCLUSIONS:** ST provided a highly flexible means of storing and transporting samples from our site, with 91.5% rates of genotyping, and >98% similarity with paired frozen plasma. Further, we demonstrated its utility in a low-technology laboratory setting with an 80% reduction in transport costs. ST provides a tool to examine an 'alternative pathway' to deliver patient – specific virological care to those in R-LS.