**Comparison of Viral Load and Resistance Genotyping Between Frozen Plasma and a Novel Dried Plasma Transportation Medium (SampleTanker™) on Treated Patient Samples.**

**Background**

HIV-1 rapid test and drug resistance testing are primary tools for antiretroviral treatment strategies. Both viral load and resistance testing have strong correlation with response to or resistance of antiretroviral therapy. Reference laboratories and clinical trial operations require patient plasma to be shipped to testing facilities under certain conditions, which is expensive and cumbersome. Dried blood spots on filter paper have shown promise as a method of sample collection for DNA/RNA extraction, PCR tests and quantitative assays. Although filter paper has potential as a collection medium, stability and sensitivity remain questionable. This study evaluates a novel dried plasma collection medium, SampleTanker.*

**Methods**

**Virion RNA extraction and genotyping:** HIV-1 and HIV-2 were collected using either the spin-based UltraTaq MPUniversal HIV-1/2 RIBOTEST kit (Hologic Diagnostics, Madison, WI), VERSANT HIV-1 3.0 assay (Siemens Medical Solutions Diagnostics, Deerfield, IL). Total virion RNA for all samples was extracted using the QIAamp Viral RNA Mini Kit (Qiagen, Valencia, CA). Viral RNA was genotyped using either the UltraTaq MPUniversal HIV-1/2 RIBOTEST kit (Hologic Diagnostics, Madison, WI) or the Ultrasound MPUniversal HIV-1/2 RIBOTEST kit (Hologic Diagnostics, Madison, WI).

**SampleTanker (Dried plasma) general methodology:** The SampleTanker method (Figure 1) has a resistance capacity of 1°C. A 1°C volume of plasma was added to each matrix, allowed to air-dry in a laboratory at 1°C until dry, then packaged in the SampleTanker cage and stored at a shelf at elevated temperature. Dried sample matrices were in tydipped in the appropriate volume of Renalux buffer to recover 147 of the reniduced plasma.

**Angiography dried plasma-extraction reproducibility using SampleTanker:** Three matrices were prepared for each of the six randomly selected HIV-1 positive plasma samples (18). The matrices were reconstituted and recovered in 1°C post preparation and were used to examine the intra-test day reproducibility of the UltraTaq MPUniversal viral load assay.

**Viral load dried plasma-extraction reproducibility using SampleTanker:** Five matrices were prepared for each of six randomly selected HIV-1 positive plasma samples (18). The matrices were reconstituted and recovered in 1°C post preparation and were used to examine the intra-test day reproducibility of the UltraTaq MPUniversal viral load assay.

**HIV-1 RNA genotyping:** 3.0 assay (Siemens Medical Solutions Diagnostics, Deerfield, IL). Total virion RNA for all samples was extracted using the QIAamp Viral RNA Mini Kit (Qiagen, Valencia, CA). Viral RNA was genotyped using either the UltraTaq MPUniversal HIV-1/2 RIBOTEST kit (Hologic Diagnostics, Madison, WI) or the Ultrasound MPUniversal HIV-1/2 RIBOTEST kit (Hologic Diagnostics, Madison, WI).

**HIV-1C resistance (Co-relation with UltraTaq MPUniversal):** For each of these HIV-1C-extracted plasma samples, a single metric for each plasma sample was used by an HIV-1C resistance genotyping method described above. The resistance metric was calculated based on a 6.5-fold increase for the UltraTaq MPUniversal HIV-1C resistance genotyping method compared with the resistance metric generated from the UltraTaq MPUniversal HIV-1/2 RIBOTEST kit.

**Pharmacokinetics:** Plasma samples were collected from treated SampleTanker and frozen plasma HIV-1/2C-coordinated samples were submitted for pharmacokinetic analysis.

**Results**

**SampleTanker Characterization:** The SampleTanker contains two matrices for the preparation of plasma samples and a device for storage and temperature control. The device is an advanced instrument that allows for maintenance of plasma samples during storage or transportation.

**Conclusions**

The study demonstrates the feasibility of using SampleTanker for the transport of HIV-1 and HIV-2 plasma samples using the standard UltraTaq MPUniversal HIV-1 and UltraTaq MPUniversal HIV-1/2 assay. The assay proved to be highly reproducible and reliable under the conditions tested. The results indicate that SampleTanker can be used as a reliable method for transporting HIV-1 and HIV-2 plasma samples for extended periods of time.

**References**


