**Background**

- The effectiveness of TDF/FTC taken as HIV pre-exposure prophylaxis (PrEP) is limited by poor adherence.
- A previously validated liquid chromatography/tandem mass spectrometry (LC-MS/MS) test measures tenofovir (TFV) levels in urine to monitor adherence to PrEP.
- Urine samples for this test were previously stored and shipped at -80°C.
- We determined the stability of TFV in urine at different temperatures to assess ease of incorporation into variable clinical settings.

**Methods**

- Two temperature control tests were conducted on urine samples collected from patients receiving daily PrEP with TDF/FTC at a community-based clinic.

**Temp Stability Test 1: Proof of Concept**

- TFV calibration curve in human urine over a concentration range of 10 to 1000 ng/mL. A known concentration of TFV was injected into a human urine sample (x axis) and measured using LC-MS/MS (y axis). [TFV] = Measured [TDF] concentration of TDF was 1000 ng/mL.

**Temp Stability Test 2: 14 day study**

- This assay determines TFV concentrations in log10 categories between 0 ng/mL to > 10,000 ng/mL.
- TFV was detected over 7 days later in urine after one dose of TDF/FTC.
- Urine TFV is cleared in a log-linear fashion, with a direct correlation of urine levels to time since last dose.
- Urine assay is 2 logs more sensitive than serum over 7d.

**Results**

- **Urine was obtained from 10 total study participants.**
- **60 1.5ml aliquots analyzed.**
- **Bold test labels represent standard of care practices, where samples were frozen immediately at -80°C.**
- **Urine TFV concentrations in both studies were 100% concordant at all temperatures and times.**

**Conclusions**

- TFV is stable in urine samples for up to 14 days at RT and with standard refrigeration.
- Urine PrEP adherence monitoring is accessible to providers with minimal laboratory facilities and shipping capabilities worldwide.

**Future Steps**

- Will real-time adherence monitoring with urine TFV lead to clinically significant and sustained increase in adherence to PrEP?
- Will the availability of simple and reliable adherence monitoring techniques influence worldwide PrEP uptake?
- Can the urine assay be further developed into a point of care test?

**References**

2. Prospective Use of Urine Tenofovir Assay to Monitor Adherence to PrEP. 11th International Conference on HIV Treatment and Prevention Adherence, May 2016.