Development and validation of a point-of-care, urine assay to measure adherence to PrEP and ART

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Background

- PrEP and ART are highly effective at preventing new infections and suppressing HIV, but only when taken consistently[1]
- Adherence to PrEP and ART is sub-optimal and current monitoring methods are inadequate to reach global scale[2]
- **UrSure developed a qualitative, visually-read, point of care urine test which can measure adherence to tenofovir (TFV)**, a metabolite of tenofovir disoproxil fumarate (TDF) and tenofovir alafenamide (TAF), prodrugs of most ART and all PrEP regimens
- The test uses lateral flow immunoassay, and has been validated with clinical samples against a LC-MS/MS machine

Methods

- We synthesized a novel derivative of TFV, conjugated that to BSA, and use that to develop and screen for an anti-TFV antibody
- Our anti-TFV monoclonal antibody yielded 100% sensitivity, and 97% specificity, with minimal cross-reactivity
- LFIA strip was optimized to the device's cut off, based off internal analysis
- TFV concentrations above or below the cutoff were tested on the POC LFIA for 199 urine samples and validated against a LC-MS/MS test
- Storage and temperature stability tests were carried out to ensure integrity of the LFIA at +25% and -50% of the cutoff

Results

UrSure developed a POC LFIA prototype (Figure 1), which tests for TFV concentrations in urine at a set cutoff. **The prototype has 100% sensitivity and 100% specificity** against a urine LC-MS/MS TFV test. (Figure 2) We saw no changes in the performance of the LFIA with storage at room temperature, 45ºC, and 55ºC for up to 21 days. (Figure 3)

Figure 1. UrSure's Rapid Tenofovir Test Prototype, ready for investigational use

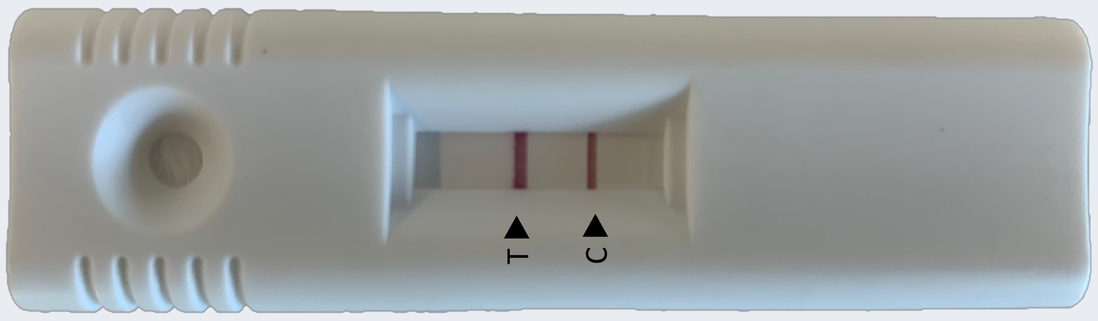
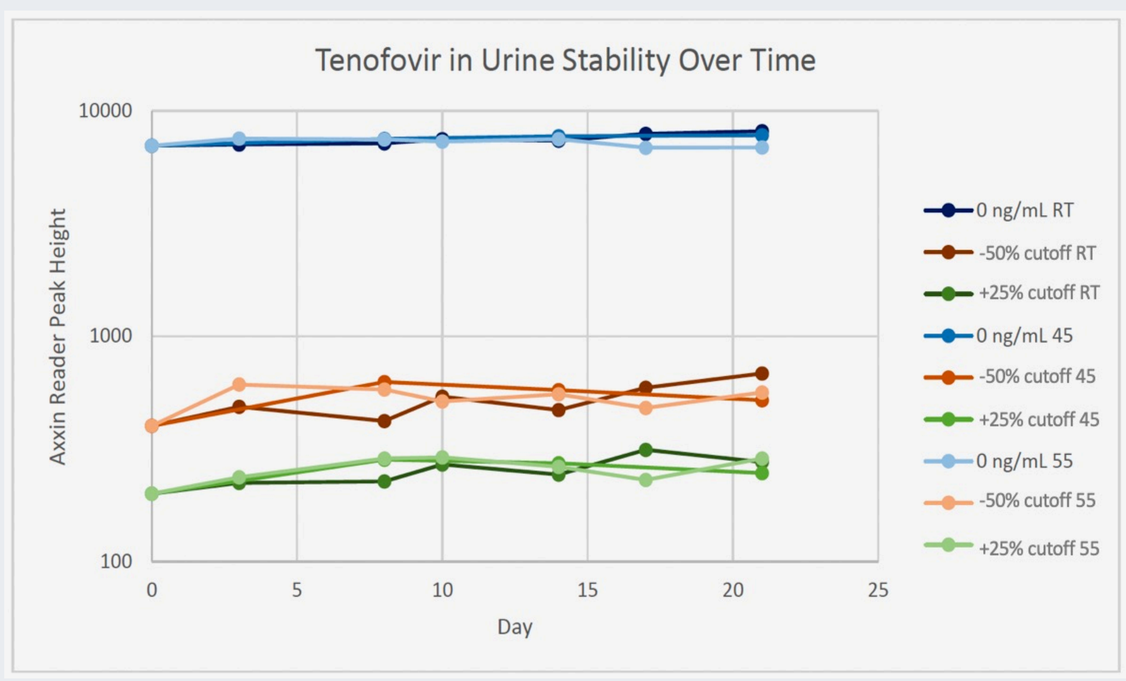


Figure 2. Sensitivity, Specificity, of UrSure LFIA prototype

	LC-MS (+)	LC-MS (-)
LFIA (+)	37	0
LFIA (-)	0	162

Figure 3. Stability results in time and temperature study



Conclusions

- We have developed the first-ever urine TFV LFIA prototype with 100% sensitivity and specificity, available for investigational use.
- **UrSure's POC TFV Test can inexpensively facilitate real-time monitoring of adherence to PrEP and TFV-based ART, helping providers to optimally allocate adherence resources**
- Due to the routine collection of urine in visits, the test is non-invasive, and seamlessly fits into clinical workflow.
- Enhanced adherence support can prevent seroconversions and improve outcomes for PrEP and ART patients

Next Steps

- Our prototype is currently going through further validation testing to ensure stability, precision, reproducibility and integrity in the presence of potentially interfering substances.
- UrSure's Rapid Tenofovir Test will be used in over ten planned field settings for research studies around the world.

Acknowledgements

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References

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2. Iacob, S., et al. (2017). "Improving the Adherence to Antiretroviral Therapy, a Difficult but Essential Task for a Successful HIV Treatment—Clinical Points of View and Practical Considerations."