# Development and Clinical Use Case of a Urine Tenofovir Adherence Test

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## Background

- Pre-exposure prophylaxis (PrEP) effectively prevents HIV infection when taken consistently[1]
- Poor adherence limits PrEP's effectiveness
- Current adherence monitoring methods are limited
- A Liquid Chromatography Mass Spectrometry (LC-MS/MS) urine test for Tenofovir (TFV) was developed and used clinically[2]
- This poster describes:
  1. Early adherence results using the LC-MS/MS test
  2. Ongoing efforts to develop a point-of-care (POC) urine test for TFV

## Objectives

1. To evaluate initial results from utilization of novel adherence monitoring test
2. To develop a prototype POC urine test for TFV to assess non-adherence within the last 48 hours

## 1 LC-MS/MS Test

### Methods

- Urine samples were collected from PrEP patients in Broward County, Florida
- The LC-MS/MS test quantified levels of the TFV in urine
- Adherence results were reported to providers and patients through an online portal
- De-identified data was collected for quality improvement purposes

### Results

- Over ten weeks, samples from 271 individuals were tested
- Participants ranged from 20-69 years old with an average age of 35.2 years old
- Urine TFV testing demonstrated:
  - 14 individuals were non-adherent in the previous 7-10 days
  - 17 individuals were inconsistently adherence in the previous 7-10 days
- 11.4% of individuals and 22.2% of women were sub-optimally adherent

## 2 POC Test

### Results

- The antibody performance in the ELISA format showed 100% sensitivity and 94.67% specificity to TFV *(Table 1)*

***Table 1:*** *Results from antibody's performance in ELISA format*

| mAB Sensitivity and Specificity of ELISA | | |
|---|---|---|
| | LC-MS (+) | LC-MS (-) |
| Antibody (+) | 50 | 8 |
| Antibody (-) | 0 | 140 |

- An initial dose response curve was developed for the LFIA prototype *(Figure 1)*

***Figure 1:*** *Nitrocellulose strip demonstrating dose response curve*

| Dilution | [TFV] (ng/mL) | Visual Grade | Photograph |
|---|---|---|---|
| none | 2000 | 1 | |
| | 1000 | 2 | |
| | 250 | 4 | |
| | 125 | 5 | |
| | 50 | 6 | |
| | 25 | 7 | |
| | 10 | 8 | |
| | 0 | 8 | |

## Conclusions

### 1 *LC-MS/MS:*

- For the first time, an objective adherence test was used commercially in a clinic setting
- PrEP navigators and specific counselling were targeted to those individuals with sub-optimal adherence
- Adherence rates in the small sample of female patients was substantially lower

### 2 *POC:*

- A POC LFIA could promote adherence and patient engagement to PrEP
- This performance may also be applicable to monitoring first line ART adherence, especially in resource-limited settings

## References

1. Kearney BP, Flaherty JF, Shah J. Tenofovir disoproxil fumarate: clinical pharmacology and pharmacokinetics. Clin Pharmacokinet. 2004;43(9):595–612

2. Koenig, H. C., Mounzer, K., Daughtridge, G. W., Sloan, C. E., Lalley-Chareczko, L., Moorthy, G. S., Conyngham, S. C., Zuppa, A. F., Montaner, L. J., … Tebas, P. (2017). Urine assay for tenofovir to monitor adherence in real time to tenofovir disoproxil fumarate/emtricitabine as pre-exposure prophylaxis. *HIV medicine*, 18(6), 412-418.