



# URINE POINT-OF-CARE TFV TEST SHOWS STRONG PREDICTIVE CLINICAL AND RESEARCH UTILITY

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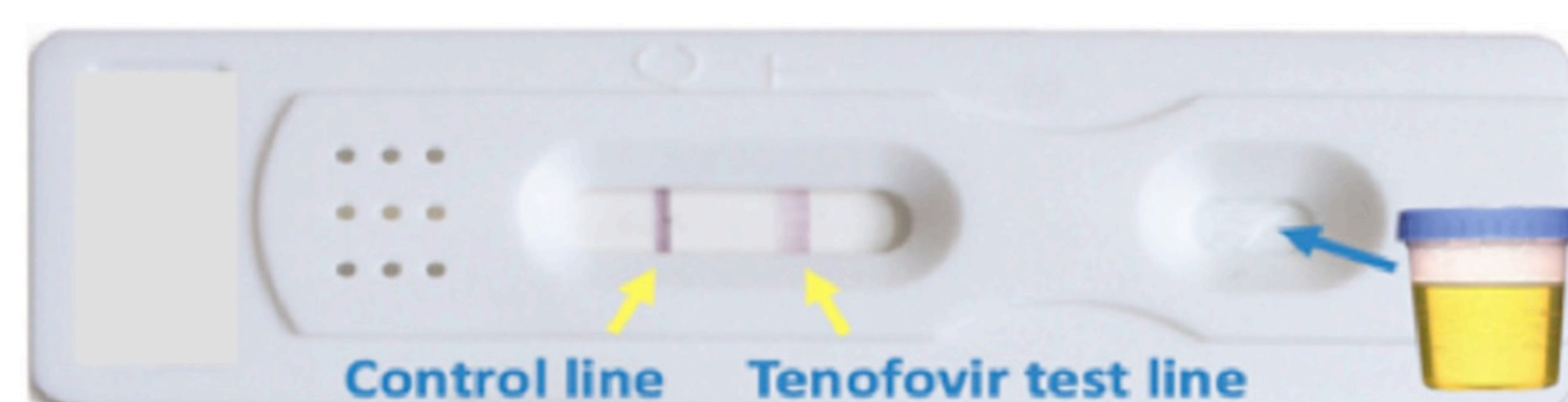
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## BACKGROUND

- We calculated predictive values of a urine point-of-care tenofovir (POC TFV) test against self-reported recent PrEP use and TFV-diphosphate levels in dried blood spots (DBS) to inform alternative options of measuring PrEP adherence in clinical and research settings.
- Although self-reported PrEP adherence may lack accuracy, self-report is the most frequent metric used in clinical and research settings due to cost and time constraints. Pharmacologic measures of PrEP adherence are objective, but settings may lack the resources and infrastructure needed to implement these tools.
- Urine POC testing has excellent sensitivity and specificity, provides rapid results, does not require specialized training, and is projected to be low-cost.
- Urine POC TFV testing can serve as an alternative to self-reported adherence, DBS, or electronic adherence monitors, which suffer from respective disadvantages, including inaccuracy, the need for expensive equipment, or having longer turnarounds for results.

## METHODS

- Participants were current PrEP users in the RADAR community-cohort study of young men who have sex with men.
- Participants completed a survey of daily PrEP use in the prior 7 days and provided DBS and urine samples once a month for three months. 73 PrEP-users contributed 126 observations.
- DBS samples were tested for TFV-DP to estimate average dosing over the prior month and emtricitabine-triphosphate (FTC-TP) to assess recent dosing (past 2-3 days).
- A urine POC TFV test qualitatively assessed recent adherence (past 4-7 days; See Gandhi et al. 2018).



Self-reported metrics of PrEP adherence are suboptimal, but used in clinical and research settings due to cost and time constraints. We calculated predictive values of a urine point-of-care tenofovir test against self-reported recent PrEP use and dried blood spots (DBS) PrEP levels among current PrEP users in a community-cohort study of young men who have sex with men.

Self-reported adherence was over-reported, versus objective urine and DBS sample results. **In multivariable logistic regression analyses, the urine assay was a significant predictor of DBS tenofovir adherence (OR = 30.2, p < .0001).**

Urine POC assays can serve as a tool for PrEP adherence measurement in both clinical and research settings.

## RESULTS

- Self-reported adherence was over-reported (87% for 4+ doses in last 7 days), versus urine TFV (69%), DBS FTC-TP (68%), and DBS TFV-DP (67%) concentrations.
- Urine TFV and DBS FTC-TP performed similarly well in predicting longer term adherence via DBS TFV-DP (see table for predictive values). Self-report did not perform as well due to overreporting.
- In multivariable logistic regression analyses, the urine assay was a significant predictor of DBS TFV-DP (OR = 30.2, p < .0001); self-report did not add significantly to prediction.

	DBS TFV-DP (average dosing over prior month)		DBS FTC-TP (recent dosing in past 2-3 days)	
	Positive predictive value	Negative predictive value	Positive predictive value	Negative predictive value
DBS FTC-TP	94%	93%	-	-
Urine	91%	87%	97%	95%
Self-report (4+ doses in prior 7 days)	75%	88%	-	-
Self-report (1+ dose in prior 2 days)	-	-	76%	88%

## CONCLUSIONS

- The urine POC TFV assay had excellent predictive values for adherence in a real-world cohort, while self-reported adherence did not add significantly to prediction.
- Given the likely low cost of the urine POC TFV test, the test may be particularly useful as an adherence assay for clinical and research purposes.
- In terms of clinical applications, when no TFV is detected, urine POC testing could spur a conversation between a patient and provider about the importance of adherence, with provision of additional resources for potentially co-occurring mental health conditions, substance use, or support for other adherence barriers as indicated.
- Switch to a long acting PrEP agent (e.g. cabotegravir) may help with adherence difficulties identified by the urine POC TFV test.
- Our study provides additional information on the utility of the urine POC TFV test in real-world settings to help eventually move the test into clinical use.

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## REFERENCES

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