False-Positive HIV RNA Results Are Uncommon Among Injectable PrEP Users in Real-World Data

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Aniruddha Hazra, MD[1,2]; Tommy Schafer[1]; Andrew Crone[1]; Avelle Bailey[1]; Michelle DallaPiazza[1]; Catherine Creticos[1]
[1]Howard Brown Health, Chicago, IL, USA, [2]University of Chicago Medicine, Chicago, IL, USA
ahazra2@bsd.uchicago.edu

BACKGROUND

- Accurate HIV testing is critical as oral and long-acting injectable (LAI) PrEP use expands
- HIV RNA testing is used in some PrEP monitoring strategies to detect acute infection
- Emerging data suggest RNA testing may increase false-positive results
- False positives can lead to:
  - Patient anxiety
  - Unnecessary PrEP interruption
  - Increased clinical burden
- Real-world data on false-positive HIV results, especially among LAI PrEP users, are limited
- **Aim to assess the frequency and correlates of false-positive HIV test results by testing modality, PrEP use, and PrEP type in a large urban PrEP program**

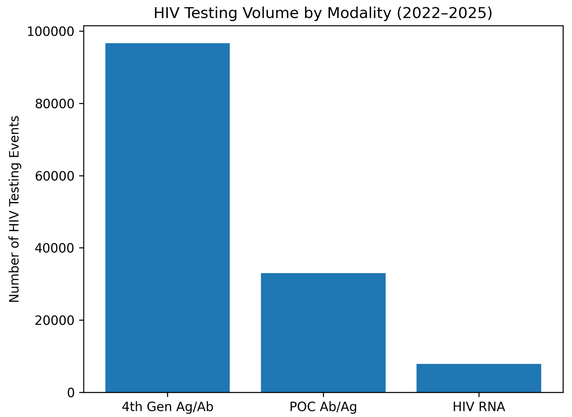
METHODS

- Retrospective analysis of all HIV testing events at Howard Brown Health
- Study period: September 22, 2022 – August 31, 2025
- Testing modalities:
  1. Point-of-care (POC) Ag/Ab
  2. Laboratory-based 4th-gen Ag/Ab
  3. HIV RNA assay
- False positive defined as initially reactive test not confirmed by supplemental or follow-up testing
- Exclusions: recalled test lots, repeat false-positive episodes in the same individual
- All false positives confirmed by chart review
- Assessed associations with PrEP use, PrEP type (oral vs LAI), & testing modality

RESULTS

HIV Testing Events

- A total of 104,088 HIV testing events occurred during the study period.
  - 96,691 (92.9%) included laboratory-based fourth-generation assays
  - 32,962 (31.7%) included POC Ag/Ab tests
  - 7,843 (7.5%) included HIV RNA testing
- Overall, 64,016 (61.5%) testing events occurred among individuals using PrEP



False Positive HIV Results

- Across all testing events, **156 false positive HIV results** were identified (**0.15%**).
- No significant difference of false positive rates by PrEP use
- False positives were most common with lab-based fourth-generation assays (**145/156; 93%**)
- HIV RNA false positives were uncommon (**4/156; 2.56%**)

Testing Groups	Total HIV Tests	False Positives (n)	False Positive Rate
PrEP Users	64,016	88	**0.14%**
Non-PrEP Users	40,072	68	**0.17%**
All Tests	104,088	156	**0.15%**

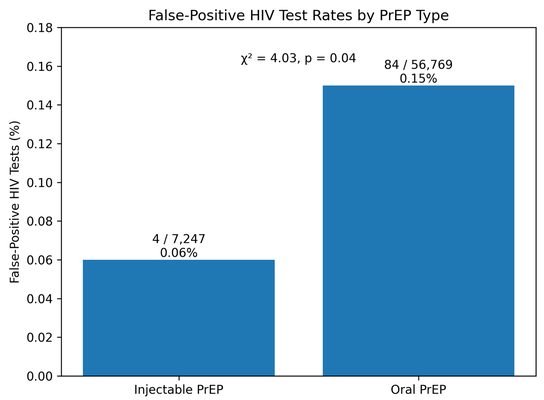
PrEP Use and False Positive HIV Results

Among all individuals on PrEP (n = 64,016 tests):

- LAI PrEP users had a lower false positive HIV testing rate than oral PrEP users
  0.06% vs 0.15% ($\chi^2 = 4.03$, **p = 0.04**)
- Among 4,856 HIV RNA tests performed in LAI PrEP users, **no false positive RNA results were observed**

Among false positive results for PrEP users (n = 88)

- Most false positives occurred with lab-based fourth-generation assays (**79/88; 89%**)
- No other significant associations with PrEP use or testing modality



DISCUSSION

- False-positive HIV test results were rare across a large, real-world PrEP program
- The majority of false positives occurred with 4th-generation Ag/Ab assays, consistent with prior reports
- LAI PrEP was associated with a lower false-positive frequency compared with oral PrEP
- No false-positive HIV RNA results were observed among LAI PrEP users
- HIV RNA testing was not associated with increased false-positive risk in this setting
- Provides reassurance regarding false positive HIV testing as LAI PrEP use expands
- These findings support continued refinement of HIV testing algorithms to balance early detection with minimizing unintended harms

PLAIN LANGUAGE SUMMARY: Using data from over 100,000 HIV tests in a large PrEP program, we found that false-positive HIV results were uncommon. People using long-acting injectable PrEP had fewer false positives than those using oral PrEP, and none of the HIV RNA tests in injectable PrEP users were falsely positive.

ACKNOWLEDGMENTS

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False-positive HIV test results were rare overall; none were observed with HIV RNA assays among individuals receiving LAI PrEP.