

# Is an HIV Antibody Rapid Test Sufficient to Monitor PrEP Effectiveness?

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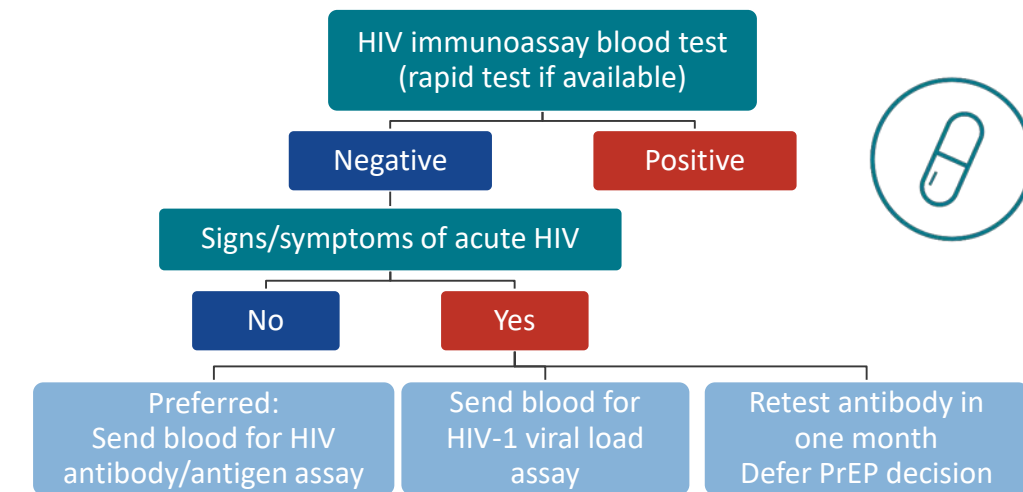
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## Background

- **Pre-exposure prophylaxis (PrEP)** significantly reduces HIV infection by up to 92% in people who are at high risk of infection
- Frequent HIV testing is required to ensure absence of breakthrough infections during PrEP

### Recommended HIV testing for determination of HIV Status for PrEP Provision<sup>1</sup>



1. Adapted from 2017 CDC HIV PrEP Guidelines

## Objective

We evaluated the strategy of using the **INSTI HIV-1/2 rapid antibody (INSTI) test** with fingerstick whole blood (FSWB) as a monitoring test for patients on PrEP. We compared results of the INSTI with plasma testing by an HIV-1 nucleic acid test, two Ag/Ab tests and another rapid antibody test.

## Stronger Together Study

- A randomized control trial designed to test the efficacy of couples-focused care for men in HIV serodiscordant male-male partnerships
  - » Each couple received lab-based testing for HIV infection, STDs, viral suppression, and adherence to anti-retroviral therapy
- At enrollment, HIV-negative participants were counseled on risk-reduction practices and PrEP use and then monitored every six months for up to two years with an INSTI FSWB test at each visit



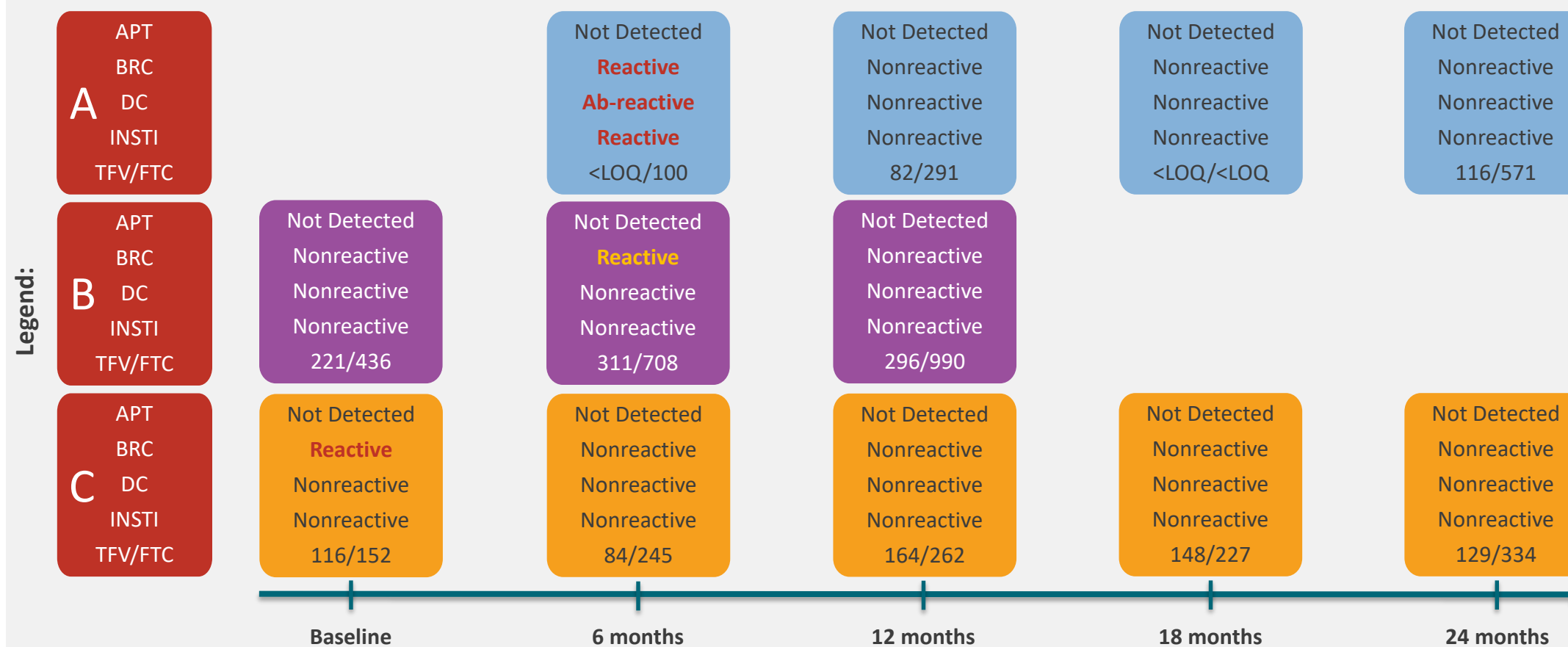
## Methods

- 130 INSTI (FSWB)-nonreactive plasma specimens from 35 participants with 3 to 5 longitudinal samples were available
- Each specimen was tested with:
  - » Hologic Aptima HIV-1 Quant Assay (APT)
  - » Bio-Rad GS HIV Combo Ag/Ab (BRC) test
  - » Determine HIV-1/2 Ag/Ab Combo (DC) rapid test
  - » INSTI
- All initially reactive test results were repeated
- BRC-repeatedly reactive samples were tested with Geenius HIV-1/2 supplemental test
- The presence of tenofovir (TFV) and emtricitabine (FTC) was measured by tandem liquid chromatography-mass spectrometry [Limit of quantification (LOQ)= 10 ng/mL]
  - » For each participant, the average drug level for each drug was calculated (5 ng/mL was used when the drug level was <LOQ)
  - The mean was calculated of the drug averages for participants that had non-reactive or reactive HIV tests and compared

## Results

- All 130 samples were target not detected on the APT-Quant (LOQ=30 copies/mL)
- HIV test specificities:
  - BRC: 97.7% (95% CI 92.94% - 99.41%)
  - INSTI and DC: 99.24% (95% CI 95.19% - 99.96%)
- 20% of participants had at least one instance of low adherence to PrEP (drug level <10 ng/mL)
- Three participants (A, B, C) had seroreactivity at one time point (Fig)
  - » All three had detectable levels of at least one PrEP drug at each time point, except for participant A at 18 months
  - » All three samples remained negative at all subsequent follow-ups up to 24 months

Figure: Timeline of testing for reactive specimens including molecular and serological testing and drug levels (ng/ml)



## Results Continued

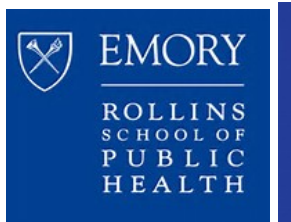
- Average of drug levels for:
- 32 participants without a reactive HIV test (n=118):
    - » TFV 148 ng/mL (standard deviation (SD): 94.21 ng/mL)
    - » FTC 465 ng/mL (SD: 394.27 ng/mL)
  - 3 participants with at least one reactive HIV test (n=12):
    - » TFV 152 ng/mL (SD: 113.94 ng/mL)
    - » FTC 399 ng/mL (SD: 270.47 ng/mL)
  - Drug levels were similar in both groups

## Conclusions

- Our results indicate that PrEP in combination with HIV risk reduction counseling protected a high-risk population from HIV-1 infection
- The ease of INSTI use with FSWB makes it a good option for monitoring infection status
- The absence of detectable breakthrough infections in our cohort and lack of longer term follow-up are limitations in this study
- Seroreactivity in three persons may indicate rare false-reactivity, but seroreactivity due to HIV exposure under potent chemoprophylaxis cannot be discounted
- Cases of rare, possible false-immunoreactivity and reports of ambiguous HIV test results suggest that diagnostic performance with PrEP use requires further investigation.<sup>2</sup>

2. Smith D et al OFID 2018

## Affiliates / Partners



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