

# HIV Testing in the US PrEP Demonstration Project: rEIA vs. Antigen/Antibody vs. RNA

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## Introduction

- Ensuring individuals are HIV-uninfected prior to pre-exposure prophylaxis (PrEP) initiation and continuation is critical to minimize the risk of developing drug resistance
  - The optimal HIV testing algorithm for PrEP is not yet known
  - US CDC recommends, at minimum, documenting a negative blood EIA within the week before starting or restarting PrEP, and every three months during PrEP continuation; persons with suspected acute HIV infection should receive additional HIV testing
  - To compare the performance of rapid blood enzyme immunoassay (rEIA), lab-based p24 antigen/antibody (4<sup>th</sup> generation), and RNA tests in detecting HIV infection at PrEP screening, initiation, and follow-up
- CROI 2016

## Methods

- From September 2012 to January 2014, 635 HIV-uninfected men who have sex with men (MSM) and transgender women (TGW) attending STI clinics in San Francisco and Miami and a community health center in Washington, DC were screened for The Demo Project
  - The 557 enrolled participants were offered up to 48 weeks of open-label emtricitabine/tenofovir
  - All participants were HIV tested at screening, PrEP Initiation, and follow-up (weeks 4, 12, 24, 36, 48) with rEIA and 4<sup>th</sup> generation tests. Pooled RNA was performed at all visits in San Francisco, with quantitative or qualitative RNA only at enrollment in DC and Miami, respectively. Any positive test was confirmed using local testing algorithms
- ### Results
- 18 of 20 HIV infections were detected during Screening and PrEP Initiation (**Figure 1**): 15 (75%) at Screening and 3 (15%) at Initiation. Prevalence of HIV infection at screening was 15/635 or 2.4%

- Rapid EIA detected 14/15 infections at screening; Ag/Ab testing detected 13/13 infections at screening (**Table 1**)
- At PrEP initiation, 3 participants had HIV infection: all were rEIA (-), 4<sup>th</sup> generation (-) and RNA (+), with viral loads of 120, 3343, and 51 copies/mL (all pre-treatment); all RNA tests were detectable on repeat testing
- 2 participants started ART as soon as the first (+) RNA was known
- All participants found to be infected at initiation had been HIV-negative at screening within the prior 7-45 days

## Results

Figure 1: Visit Schedule and HIV Testing Results in PrEP DEMO

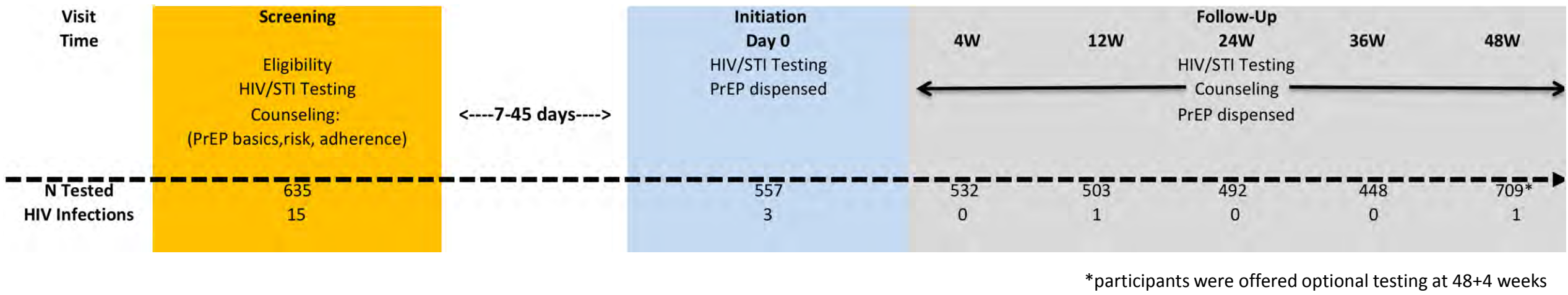


Table 1. HIV Infections at Screening, Enrollment, and during Follow-up

	Pt	First visit at which HIV infection diagnosed	Rapid EIA	4 <sup>th</sup> Gen Ag/Ab	RNA	Final Status
SF	1	SCR	reactive	reactive	pool positive	infected
	2	SCR	reactive	reactive	pool positive	infected
	3	initiation	nonreactive	nonreactive	pool positive <sup>1</sup>	infected
	4	initiation	nonreactive	nonreactive	pool positive <sup>2</sup>	infected
	5	W12	reactive	reactive	8,671,733 c/mL	infected
MIAMI	6	SCR	reactive	reactive	n/a	infected
	7	SCR	reactive	reactive	n/a	infected
	8	SCR	reactive	reactive	n/a	infected
	9	SCR	reactive	reactive	n/a	infected
	10	SCR	nonreactive	reactive	n/a	infected
	11	SCR	reactive	reactive	n/a	infected
	12	SCR	reactive	reactive	n/a	infected
	13	SCR	reactive	reactive	n/a	infected
	14	SCR	reactive	reactive	n/a	infected
	15	SCR	reactive	n/a	n/a	infected
	16	SCR	reactive	reactive	n/a	infected
	17	SCR	reactive	reactive	n/a	infected
	18	initiation	nonreactive	nonreactive	reactive <sup>3</sup>	infected
DC	19	SCR	reactive	--	n/a	infected
	20	W48	reactive	reactive	79,540 c/mL	infected

1: RNA=120 c/mL  
2: RNA=3343 c/mL  
3: qualitative RNA; quantitative RNA at confirmation was 51 c/mL

