# Recency HIV Testing to Estimate HIV Incidence: Preliminary Results from South African sites in the INSIGHT Cohort

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# Summary

- Estimate background HIV incidence using recency testing (LAg avidity and viral load) among women screening out of multi-country PrEP study due to HIV-positive status
- Preliminary data from participants from 13 South African sites
  - Of 2365 women screened for the study, **109 (4.6%)** tested HIV positive at baseline
  - Recency testing available for 79 of 109 and will be completed by the end of year
- Study findings will inform ongoing and future HIV prevention trials on the use of recency assays to provide estimates of HIV incidence without placebo arm

# Background: Rationale for Recency assay

**High efficacy of approved interventions:** Existing PrEP regimens are highly effective in preventing HIV transmission.

**Ethical dilemma:** Given existing highly effective PrEP interventions (FTC/TDF and CAB-LA), comparing new candidate PrEP agents against a placebo is not ethical.

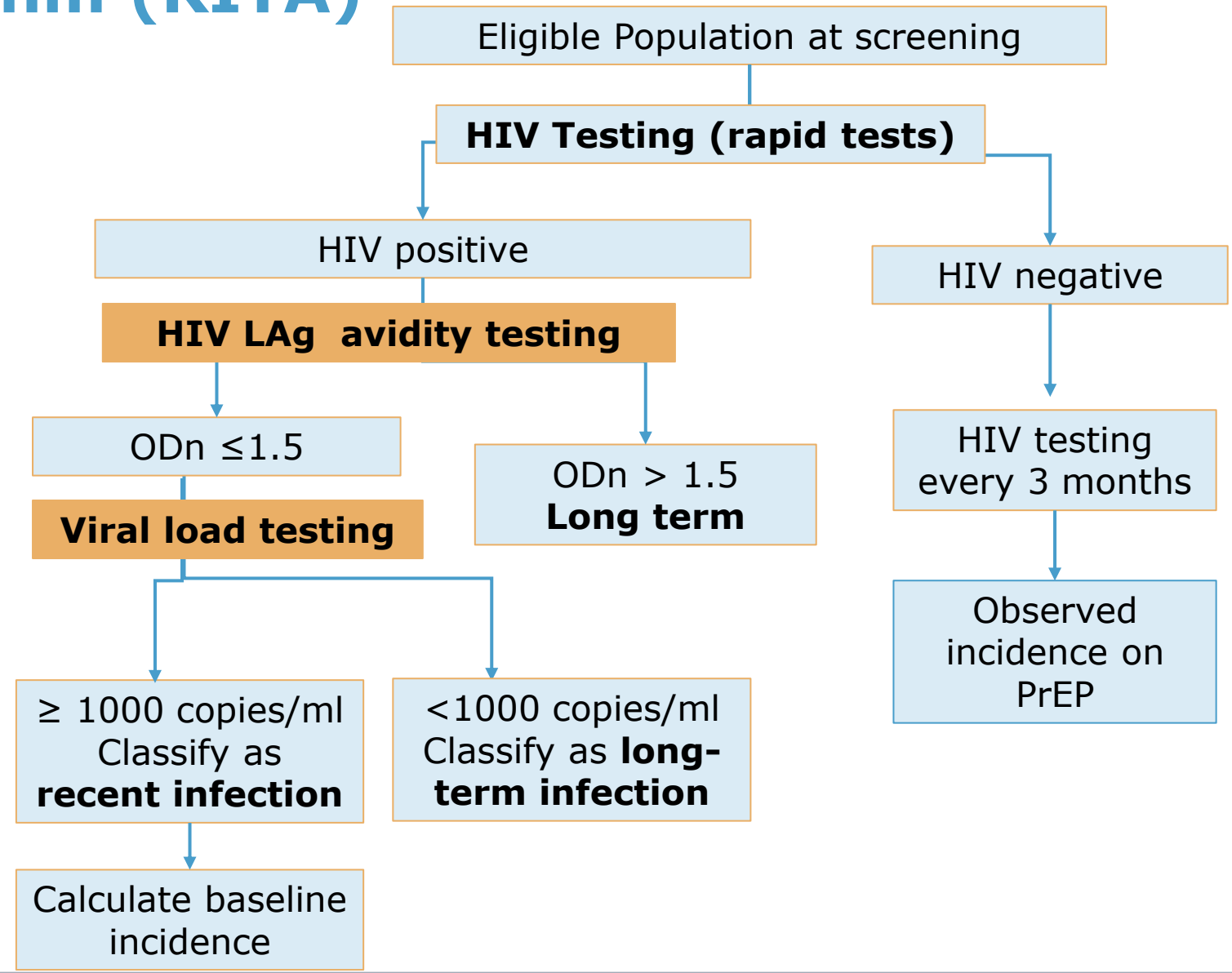
**Feasibility challenges:** Conducting active-controlled trials assessing superiority or non-inferiority requires prohibitively large sample sizes.

- Use of counterfactual estimate of background HIV incidence recommended as an external comparator[1]
- Recency assays are one method to derive a counterfactual estimate of HIV incidence

[1] *Facilitating Next-Generation Pre-Exposure Prophylaxis Clinical Trials Using HIV Recent Infection Assayshttps://pubmed.ncbi.nlm.nih.gov/36550769/*

# Recency Testing Algorithm (RITA)

- Limiting Antigen Avidity Enzyme Immunoassay (LAg) used
- Normalized optical density(ODn) used to measure recency
- Results incorporated into recency testing algorithm with viral load
- The LAg avidity and viral load results[1,2] :
  - ODn ≤1.5 + VL≥ 1000 copies/ml classify as recent infections
  - ODn > 1.5 + VL < 1000 copies /ml classify as long-term infections





1. Duong YT et al. Recalibration of the limiting antigen avidity EIAhttps://europepmc.org/backend/ptpmcrender.fcgi?accid=PMC4339840&blobtype=pdf
2. https://www.sediabio.com/wp-content/uploads/2021/05/LN-6039-09PackageInsertLAgAvidityEIA.pdf
3. Oliver et al ; Validation of the Limiting Antigen Avidity Assay in Rakai, Uganda: https://doi.org/10.1089/aid.2018.0207

# INSIGHT STUDY:
## Insights to advance PrEP discovery and delivery for African women

- **Background/Rationale**: Study of PrEP uptake, adherence, persistence and preferences for PrEP product attributes and PrEP delivery among young cisgender women, which was initiated after the FDA hold on islatravir in December 2021
- **Approach***:* Prospective cohort with open-label offer of daily TDF-based PrEP among cisgender women ages 16-30 years old from 20 sites in 6 African countries (South Africa, Eswatini, Kenya, Malawi, Uganda, Zambia)
- **Objectives**:
    - **Estimate HIV incidence using recency algorithm on samples from women who screen out due to HIV**
    - Assess the characteristics of women who initiate PrEP compared to those who do not
    - Evaluate young women's preferences for attributes of long-acting PrEP formulations using a Discrete Choice Experiment(DCE)
    - Assess bacterial STI prevalence and incidence and high-risk HPV prevalence
    - Assess the acceptability of a patient-facing decision support tool to provide informed choice about PrEP options

# Eligibility criteria and recruitment for recency testing

- **Eligibility at Screening:**
  - Women ages 16-30 years
  - Written informed consent (parental assent obtained for <18 years  if required)
  - Recently sexually active (having had vaginal intercourse at least once in the previous 3 months)
  - Interested in PrEP for HIV prevention
- **Recruitment:**
  - Prescreening was limited to finding people interested in PrEP; did not ask about HIV status
  - Sites used a variety of recruitment approaches tailored to local settings, including community and facility-based approaches
  - Screening and enrollment between Sept-Dec 2022
- **Sample size:**
  - 3000 HIV uninfected women ages 16-30 in a prospective cohort (150 per site)

# Results: Participant characteristics

- Data from 13 South African sites are included in this presentation
- **Demographics:**
  - 2365 participants screened at the study entry
  - Median age was 24 years  (IQR 21.0 - 27.0)
  - Most in a partnership/relationship (97%)
  - Almost all have at least secondary education (97%)
  - 2/3 (68%) were unemployed
- **Clinical:**
  - 12% had previously used PrEP for HIV prevention
  - 31% had at least one of 4 curable STIs (syphilis, gonorrhoea, chlamydia, trichomoniasis)

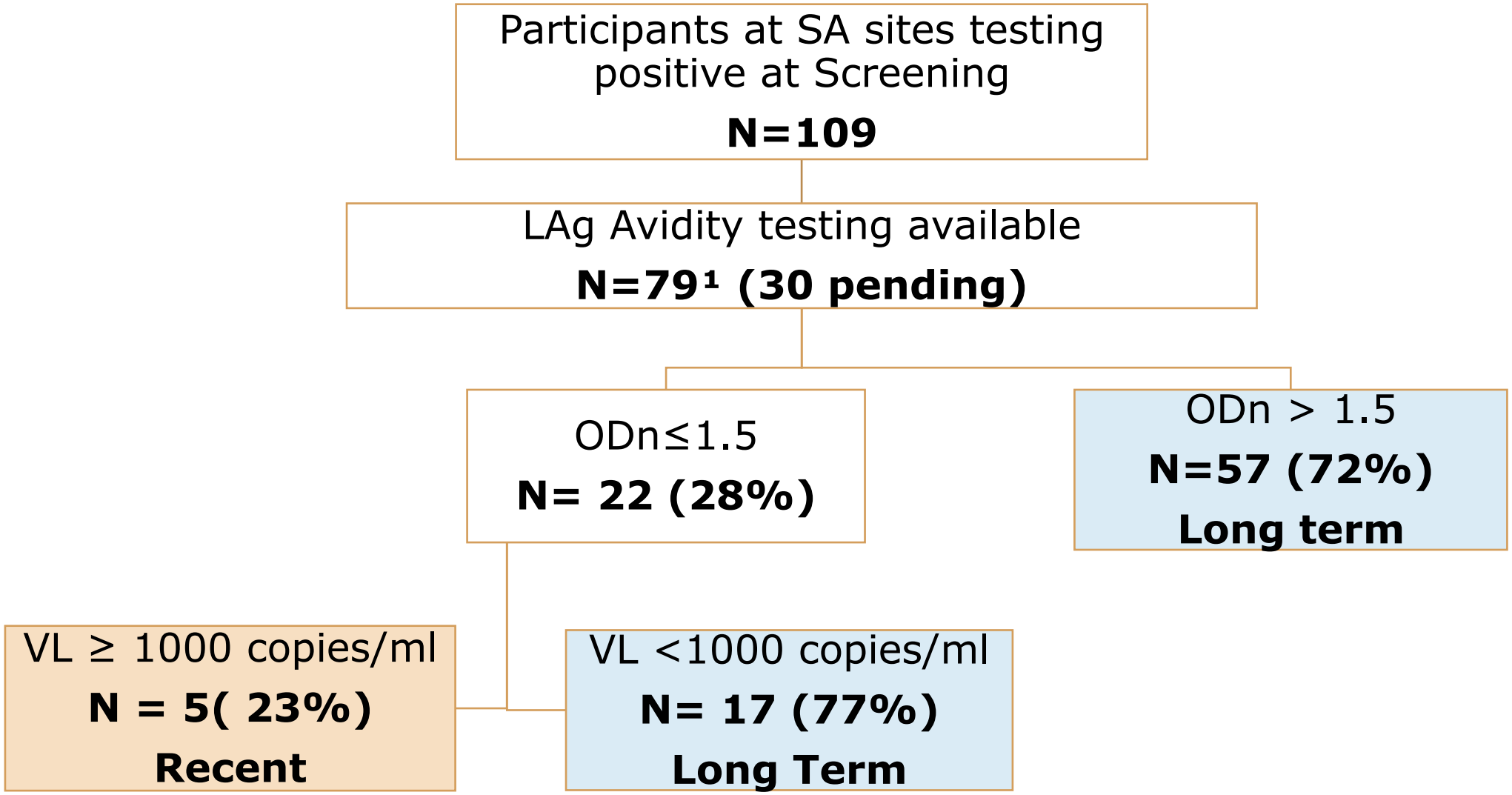
# Results: HIV positivity at screening

- **109/2365 (4.6%)** screened positive at study entry
- Of the 109, **18(17%)** had prior knowledge of HIV-positive status
- Among those reporting prior knowledge of having HIV, **8 (8%)** reported knowing this for 2 years or less

| Characteristic | N(%) |
|---|---|
| **Participants living with HIV** | **109 (4.6%)** |
| **Prior knowledge of HIV positive status** | |
| Yes | 18 (17%) |
| No | 91 (83%) |
| **Date when participant first knew of HIV positive status**[1] | |
| < 6 months | 4 (4%) |
| 6 months – 2 years | 4 (4%) |
| > 2 years | 9 (8%) |
| Did not know before study | 91 (84%) |

[1] 1 participant did not disclose when she first learned that she was living with HIV.

# Results: Recency Testing Algorithm(RITA)




[1]Lag avidity testing is ongoing

# Results: Viral load and ART use

| | LAg ≤1.5 ODn N = 22 | LAg >1.5 ODn N=57 |
|---|---|---|
| **Self-reported ART Use** | | |
| Yes Current | 1 (17%) | 5 (83%) |
| No, never taken ART | 1 (33%) | 2 (67%) |
| Taken in past but not currently | 0 (0%) | 2 (100%) |
| Did not know of infection | 20 (29%) | 48 (71%) |
| **Viral load** | | |
| <1000 copies/mL[a] | 16 (42%) | 22 (58%) |
| 1000-5000 copies/mL | 1 (6%) | 17 (94%) |
| >5000 copies/mL | 4 (22%) | 14 (78%) |
| Not tested | 1 (20%) | 4 (80%) |
| **Viral load and current ART[1]** | | |
| <1000 copies/mL on ART [a] | 1 (25%) | 3 (75%) |
| <1000 copies/mL not on ART [a] | 15 (44%) | 19 (56%) |
| ≥ 1000 copies/mL on ART | 0 (0%) | 2 (100%) |
| ≥ 1000 copies/mL not on ART | 5 (15%) | 29 (85%) |

*[1]excludes not tested for viral load*
*[a]Includes undetected viral loads*

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