BACKGROUND
- Rapid point of care testing (R-POC) has been widely implemented and accepted by healthcare workers and populations at high-risk for HIV infection.
- R-POC are affordable and easy-to-perform tests with reported high sensitivity and specificity.
- Most screening programs are based on 3rd generation R-POC technology, with an unknown amount of false negatives.
- High-risk populations in Lima are requested to be regularly tested using rapid tests but these are not always available.
- 4th generation EIA assays available could diminish the HIV infection window period.

METHODS
- We are conducting an observational cohort study to understand the syphilis and HIV epidemic among men who have sex with men (MSM) in Lima, Peru.
- Recruited participants (N=400) included MSM and TW who are 18 years old or older, live in Lima or Callao and have at least 3 of the following inclusion criteria:
  - have had syphilis in the past 2 years, are HIV positive, have been sexually active for 5 or more years, have had 5 or more sex partners in the past 3 months, have had an STI diagnosis in the past 6 months, have current STI symptoms, or have had 5 unprotected sex acts in the past 6 months.
- Blood samples were collected and tested for HIV infection using two following algorithms:
  - Initial 3rd generation HIV R-POC (Determine, Alere Medical Co., Japan).
  - All samples were re-screened using a 4th generation Ag/Ab HIV EIA serum test (Genscreen ULTRA HIV Ag-Ab, Bio Rad, Redmond, WA)
- Any R-POC or EIA positive results were confirmed using Western Blot (WB) (Genetic Systems HIV-1 Western Blot, Bio Rad, Redmond, WA).
- Participants are returning every 3 months for 2-year follow-up testing.
- R-POC results were provided to participants along with post-test counseling and referral the same day of testing, and EIA screening and WB confirmatory results were delivered after two weeks.

RESULTS
- Of 400 participants tested for HIV, 124 (31%) were positive using the 3rd generation R-POC HIV test and 129 (32%) were positive using the 4th generation EIA test.
- There were five discordant results between the R-POC and the HIV-EIA during the baseline assessment. All 5 were EIA positive and R-POC negative.
  - 1 indeterminate for WB, the remaining four were WB negative.
- HIV EIA testing increases HIV case detection by 3.9% when used as a second screening test.

| Table 1. Sensitivity and Specificity for rapid point care test* |
|----------------------|------------------|
|                     | EIA + | EIA - |
| R-POC +             | 1.19  | 0.00  |
| R-POC -             | 5.00  | 259.00|
| Point Estimate(%)   | 95% C |
| Sensitivity         | 96%   | (90.4 - 98.5) |
| Specificity         | 100%  | (98.1 - 100.0) |

*Gold standard: 4th generation HIV ELISA

- In longitudinal follow-up: Among the 11 individuals who were EIA positive and WB negative or indeterminate at baseline:
  - 4 retested EIA positive and WB positive
  - 2 were EIA negative at subsequent testing
  - 5 have not yet returned for follow-up (not shown in tables)

Table 2: Test Results Among R-POC, EIA, and WB at follow-up visits

<table>
<thead>
<tr>
<th>HIV positive at follow-up visit</th>
<th>Participant</th>
<th>R-POC1</th>
<th>EIA1</th>
<th>WB1</th>
<th>R-POC2</th>
<th>EIA2</th>
<th>WB2</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>-</td>
<td>+</td>
<td>-</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>2</td>
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<td>+</td>
<td>-</td>
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<td>+</td>
<td>+</td>
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<td>4</td>
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<td>+</td>
</tr>
</tbody>
</table>

Revert to EIA negative at follow-up visit

<table>
<thead>
<tr>
<th>Participant</th>
<th>R-POC1</th>
<th>EIA1</th>
<th>WB1</th>
<th>R-POC2</th>
<th>EIA2</th>
<th>WB2</th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td>-</td>
<td>+</td>
<td>-</td>
<td>-</td>
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<td>NA</td>
</tr>
<tr>
<td>6</td>
<td>-</td>
<td>+</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>NA</td>
</tr>
</tbody>
</table>

DISCUSSION
- Among High-risk populations, samples tested for HIV antibodies based on 3rd generation R-POC assays should be also screened using a 4th generation HIV EIA assay to avoid false negatives.
- R-POC and EIA discordant results are explained by the differences in the target markers detected by each test. While the R-POC detects only antibodies, the HIV-EIA used also detects antigen, this increases the detection of recent infections.
- New confirmatory algorithms are needed when R-POCs are used.
- Number and prevalence of false positive EIA for HIV is within known limits (0.4 – 1%) (Table 2).
- We will continue to monitor discordances between the R-POC and EIA tests too see if discordant participants become HIV positive.

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We would also like to thank:
- Picasso program staff.
- Picasso participants.

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- In subsequent study visits, there were an additional 4 discordances between R-POC and EIA.
  - Among these:
    - 1 reverted to EIA negative.
    - 3 have not returned for additional follow-up, 1 of whom was WB indeterminate.
  - The majority of WB discrepancies with EIA from the baseline go on to be HIV positive in later visits.

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