

counselling and partner notification. Combination POCTs for HIV and syphilis are particularly beneficial for pregnant women and key populations as treating these infections early reduces vertical and community transmission.

**Methods** We evaluated Standard Diagnostics' Duo HIV and Syphilis Test (SD bioline) among female sex-workers (FSW) in the inner-city of Johannesburg. SD bioline was conducted on-site using whole blood according to manufacturer's instructions and compared to Genscreen HIV 1/2 V2 – 3<sup>rd</sup> and Vironostika Ag/Ab – 4<sup>th</sup> generation assays for HIV and to the *T. pallidum* particle agglutination (TPPA) test for syphilis. A Rapid Plasma Reagin (RPR) test was conducted in the laboratory to assist with classification of treponemal disease. Sensitivity, specificity, positive predictive values (PPV) and negative predictive values (NPV) were calculated

Participants with HIV were referred to HIV services and those with syphilis were managed according to national guidelines. The study received ethics approval.

**Results** We recruited 263 FSW, 14 (5.3%) declined an HIV test and were excluded. Among the remaining 249 FSW 187 (75.1%) women were HIV positive and 51 (20.5%) had evidence of syphilis with 7 (2.8%) having active syphilis. For HIV sensitivity was 98.9% (95% CI: 95.8–99.8), specificity was 100% (95% CI: 92.7–100), PPV was 100% (95% CI: 97.5–100%) and NPV was 96.9% (95% CI: 88.2–99.5). For treponemal antibody detection, sensitivity was 66.7% (CI: 52.0–78.9), specificity was 98.0% (CI: 94.5–99.3), PPV was 89.5 (CI: 74.3–96.6) and NPV was 91.9% (CI: 87.2–95.1). Sensitivity increases to 85.7% for active syphilis (RPR > 1:4).

**Conclusion** Although the SD bioline performs well for HIV diagnosis, the assay has lower sensitivity for syphilis detection in our field setting compared to published laboratory evaluations. Using the test in screening programmes will detect both HIV and active syphilis but will result in overtreatment for syphilis.

**Disclosure of interest statement** The study was funded by USAID/PEPFAR and AIDS Fonds. SD bioline tests were provided by SD diagnostics.

#### 002.5 EVALUATION OF FIVE RAPID POINT-OF-CARE TESTS FOR SYPHILIS: TWO TREPONEMAL ONLY, AND THREE DUAL TREPONEMAL/HIV ASSAYS

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**Background** Traditional syphilis and HIV screening strategies require laboratory capacity which is often limited in resource-poor settings. Affordable rapid point-of-care tests (RPOCT) with high sensitivity and specificity would allow same-day testing and referral for treatment of syphilis and HIV in pregnant women. This would allow a decrease in adverse outcomes as a result of mother-to-child transmission (MTCT). We compared test performance of two RPOCT treponemal tests and three combination treponemal/HIV tests for detection of treponemal antibodies in sera; and we also examined test performance of the three RPOCT treponemal/HIV tests for detection of HIV antibodies in sera.

**Methods** We tested banked sera previously characterised for syphilis (n = 1186), from San Francisco Department of Public Health, Kaiser Permanente Northern and Southern California, and 437 known HIV-positive samples (CDC HIV), according to manufacturer's insert with 3 dual HIV/Syphilis RPOCT: SD BIOLINE HIV Syphilis Duo (Standard Diagnostics), Multiplo TP/HIV (MedMira) and DPP HIV-syphilis Assay (Chembio), and 2 treponemal-only tests: SD Syphilis 3.0 (Standard Diagnostics), Determine SyphilisTP (Alere). Positive agreement across tests was determined and RPOCT results were compared to prior test results.

**Results** The 5 assays had concordant positive result of 84% (1362/1623) for treponemal antibodies, and 96.6% (1569/1623) for HIV antibodies. Compared to previously reported results, treponemal tests had sensitivities and specificities of; SD 3.0 – 72%, 97.2%; SD DUO- 72.2%, 97.2%; Multiplo- 80.7%, 88.7%; Chembio – 82.5%, 96.4%; DetermineTP- 89.3%, 97.5%. The 3 treponemal/HIV assays sensitivity was 100% for 437 known HIV-positives compared to standard assays.

**Conclusion** Positive agreement was greater for HIV antibodies than for treponemal antibodies; Using banked sera could have affected performance of treponemal assays. Further prospective studies need to be performed in the field to better characterise performance of RPOCT treponemal tests. Findings from this study will provide data to guide countries' selection of RPOCTs for syphilis and HIV screening.

**Disclosure of interest statement** The reagents/kits for this study, were donated by the various manufacturers (Standard Diagnostics, MedMira, Chembio, and Alere).

#### 002.6 A LOW-COST MOBILE NAAT PLATFORM FOR CHLAMYDIA TRACHOMATIS

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We report the development of a low-cost mobile nucleic acid analysis platform (mobiLab) utilising a smartphone-enabled microfluidic device for streamlined analysis of biological samples. Using magnetic particles as a mobile solid phase for nucleic acid capture and transport, fluidic processing is simplified to particle translocation on a robust and scalable cartridge.

Process integration facilitated by Bluetooth-enabled microcontrollers enables full control of the instrument by the user with a smartphone application. Each cartridge costs less than \$2 using off-the-shelf reagents and materials, an order of magnitude cheaper than \$9.98/test for a GeneXpert cartridge. The instrument utilises a microcontroller which controls the rotary bead manipulator, thermal incubation and Bluetooth-based communication with the smartphone application. Each assay consumes approximately 10% of the battery capacity, allowing up to 10 assays to be performed consecutively without access to a power outlet.

We designed a single-stream loop-mediated isothermal amplification (LAMP) assay to operate in tandem with the mobiLab platform. We tested the single-stream assay using plasmid targets and were able to capture and amplify 10<sup>3</sup> copies of gene targets. Absence of cross-reactivity with human genomic DNA or other vaginal flora was verified.