CD4/CD8 ratios decreased over the course of clinical observation. HIV viral load was at the highest on the 1st visit and declined afterwards. The HIV virus had a genotype of CRF 01_AE.

Conclusion In clinical practice, a combination of HIV antigen-antibody tests is required for early detection of HIV infections.

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P07.18 EASE AND COMFORT OF A NOVEL HERSWAB™ VAGINAL SELF-SAMPLING DEVICE FOR THE DETECTION OF SEXUALLY TRANSMITTED INFECTIONS

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Introduction Eve Medical Inc. (Toronto, Canada) has developed a novel HerSwab™ device for self-collection of vaginal samples for STI screening. The objective of this study was to survey opinions on ease and comfort from women using the HerSwab™.

Methods A total of 189 women with infection prevalence of 10.6% for *C. trachomatis* and 2.6% for *N. gonorrhoeae* by Aptima Combo 2 assay testing signed consent for a physician-collected sample with a vaginal swab and a self-obtained vaginal sample using the HerSwab™ device. The order of collection was randomised. A research coordinator demonstrated steps for proper self-sampling following instructions in the HerSwab™ package. Following self-collection, each participant completed a 5-point Likert Scale questionnaire indicating ease (5 steps) and comfort (3 steps) of self-collection. Additional questions included: whether the instructions were easy to follow; whether there was anything that participants would change about the device; whether participants preferred physician or self-collection and why; and whether participants would consider self-sampling at home.

Results The majority of women experienced high levels of ease and comfort. Instructions were easy to follow for 97.1% (169/175); 80.9% (140/173) preferred self-collection over physician-collection; and 79.7% (137/172) would consider self-collection at home. Reasons for preferring self-collection included convenience, privacy, confidentiality, an opportunity for self-education of own body, greater access for people with disabilities, comfort, and a reduction of physical and psychological stress. Suggestions to improve ease and comfort included making the brush bristles softer and including arrows on the handle of the device to better indicate the direction of turning.

Conclusion Vaginal self-sampling with the HerSwab™ device demonstrated high levels of ease and comfort. The majority of women found the instructions easy to follow, preferred self-sampling over physician sampling and would consider self-collection at home. Organisers of STI screening programs should benefit from this personal feedback on vaginal self-collection.

Disclosure of interest statement Dr. Chernesky has received research funding from Eve Medical Inc.

P07.19 ADDED VALUE OF A NOVEL DUAL TREPONEMAL/ NONTREPONEMAL RAPID DIAGNOSTIC TEST FOR SYPHILIS AMONG PREGNANT WOMEN

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Introduction In resource-limited settings, syphilis rapid diagnostic tests (RDTs) aide in the prevention of congenital syphilis. However, most syphilis RDTs detect only treponemal antibodies which persist after treatment. Consequently, treatment may be provided unnecessarily to pregnant women with past infection. We estimated the potential reduction of over-treatment by comparing a new RDT detecting both treponemal and non-treponemal antibodies, with a treponemal RDT (T-RDT).

Methods A prospective descriptive study among pregnant women in antenatal care was conducted in Déou, Burkina Faso. The women were included if they were eligible for routine syphilis screening and provided informed consent. *DPP Screen and Confirm assay* (Chembio) and T-RDT (SD Bioline) were performed on whole blood specimens by a trained laboratory technician. Plasma was tested in an international reference laboratory by *T. Pallidum* Particle Agglutination (TPPA) and quantitative Rapid Plasma Reagin, (RPR). Presumptive active syphilis was defined as both TPPA and RPR were reactive.

Results A total of 242 pregnant women were included: 91 (37.6%) had a presumptive active syphilis and one-in-five (19.8%) had high RPR titres ≥1:8. The DPP did not reduce the number of incorrectly treated cases (over-treatment) compared to the T-RDT (0.0% vs. 2.5%; $p = 0.218$). In addition, the DPP led to a higher proportion of under-treatment compared to the T-RDT (18.2% vs. 0.8%; $p < 0.001$). Therefore, 48.4% of women requiring treatment (including 16% with high RPR titres) would not have been treated using DPP against 2.2% using T-RDT.

Conclusion This study was the first evaluation of DPP in pregnant women. DPP showed no added value in reducing the proportion of women unnecessarily treated. Conversely, it underestimated women needing treatment. Our study population may not have been representative as the surprising high seroprevalence may suggest presence of other treponemal infections in the area. Accordingly, additional studies are required to evaluate the potential benefits of DPP.

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P07.20 FIELD EVALUATION OF A DUAL RAPID DIAGNOSTIC TEST FOR HIV INFECTION AND SYPHILIS IN PORT-AU-PRINCE, HAITI

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Introduction Congenital syphilis is responsible for over 500,000 adverse pregnancy outcomes globally every year, including

stillbirth, fetal loss, neonatal death, low birth weight, preterm birth and syphilis infection in the infant. In Haiti, 90% of pregnant women report at least one antenatal visit. We evaluated the field performance of the SD BIOLINE HIV/Syphilis Duo test in a high-risk setting in Port-au-Prince, Haiti using whole blood fingerprick specimens.

Methods GHESKIO (Haitian Study Group for Kaposi's sarcoma and Opportunistic Infections) clinic attendees 18 years of age or older were invited to participate. Venipuncture blood specimens were used for reference testing: for HIV, Murex HIV-1.2.0 (DiaSorin S.p. A.) or Determine HIV-1/2 (Alere Inc). Positive results were confirmed with the HIV(1+2) Rapid Test Strip (KHB Shanghai Kehua Bioengineering Co. Ltd). For *Treponema pallidum* (Tp) antibody comparison, *Treponema Pallidum* Hemagglutination Assay (TPHA) (Human Gesellschaft fur Biochemica und Diagnostica mbH) was used. For 21 TPHA indeterminate results, specimens were retested using a Tp enzyme-linked immunosorbent assay test (ELISA) (Architect Syphilis Tp, Abbott Laboratories). Sensitivity and specificity were calculated and the exact binomial method was used to determine 95% confidence intervals (CI).

Results Of 298 study participants, 61 (20.5%) were male. Of 237 females, 49 (20.7%) were pregnant. For the HIV component, sensitivity and specificity were 99.2% (95% CI: 95.8%, 100%) and 97.0% (95% CI: 93.2%, 99.0%), respectively. All 21 TPHA indeterminate results were Tp ELISA reactive. For the Tp component, sensitivity and specificity were 96.5% (95% CI: 91.2%, 99.0%) and 90.8% (95% CI: 85.7%, 94.6%), respectively. In pregnant women, the HIV component sensitivity and specificity were 93.3% (95% CI: 68.0%, 99.8%) and 94.1% (95% CI: 80.3%, 99.3%), respectively; and for the Tp component were 100% (95% CI: 81.5%, 100%) and 96.8% (83.3%, 99.9%), respectively.

Conclusion The HIV antibody component of the Duo test shows excellent performance. The *Treponema pallidum* antibody component showed high sensitivity, and slightly lower specificity. Amongst pregnant women the test performed very well.

Disclosure of interest statement The study was supported in part by Standard Diagnostics.

P07.21 SERUM CYTOKINE ANALYSIS AMONG PATIENTS WITH AND WITHOUT EARLY SYPHILIS INFECTION

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Introduction Current diagnostic technology for syphilis is over 100 years old and relies on detection of either reagins or treponemal antibodies. The development of new tests formulated on the basis of host cellular response may allow for improved diagnosis and clinical management. We aimed to pilot an evaluation of sera cytokine profiles as a means to better understand the pathogenesis of early infections.

Methods Participants included men who have sex with men and transgender women with and without early syphilis recruited at two sexual health clinics in Lima, Peru. Median fluorescence intensity (MFI) of 63 cytokines in serum collected on day of diagnosis was measured using Luminex (eBioscience). We calculated the relative change in MFI between those with active (RPR titer ≥1:32, TPPA+) versus no syphilis infection (TPPA-) and compared groups using a two-sample t-test.

Results Among 5 participants with active syphilis infections and 5 without there were 11 cytokines that differed between the groups with a p-value <0.1. The relative change (ratio) in MFI between syphilis infected and syphilis uninfected specimens was 1.535 for interleukin-7 (p = 0.012), 2.062 for inducible protein-10 (p = 0.054), 2.390 for leptin (p = 0.067), 1.960 for vascular endothelial growth factor (p = 0.067), 1.712 for granulocyte-macrophage colony-stimulating factor (p = 0.069), 1.947 for interleukin-10 (p = 0.070), 3.479 for vascular endothelial growth factor D (p = 0.074), 0.687 for Eotaxin (p = 0.082), 2.532 for macrophage inflammatory protein-1beta (p = 0.090), 1.493for monocyte chemotactic protein-3 (p = 0.093), and 2.526 for platelet-derived growth factor-BB (p = 0.097).

Conclusion Cytokines associated with cellular immune response might be useful in differentiating those needing treatment for active syphilis from those not requiring treatment. All of the cytokines presented here are higher in the active syphilis group versus syphilis uninfected except for Eotaxin. Larger sample size and longitudinal data are required to characterise cytokine profiles associated with treatment response and cure. Identifying cytokine changes may provide a new opportunity for diagnostic testing for syphilis infection.

Disclosure of interest statement None.

P07.22 PERFORMANCE CHARACTERISTICS OF AN AUTOMATED ASSAY ON THE COBAS® 4800 SYSTEM TO DETECT HERPES SIMPLEX VIRUS FROM GENITAL LESION SPECIMENS WITH THE COBAS® HSV 1 AND 2 TEST

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Introduction Herpes simplex viruses occur worldwide and laboratory confirmation is recommended using methods that directly demonstrate presence of the virus in genital specimens. This study was conducted to establish performance characteristics for the **cobas**® HSV 1 and 2 Test by evaluating genital lesion samples compared to standard of care viral isolation.

Methods This evaluation study was conducted using 193 clinical swab specimens from active lesions of suspected herpes simplex collected at the DSC Clinic during the period of April 2014 through October 2014. The results of the **cobas**® HSV 1 and 2 Test were compared with those obtained from viral isolation. Samples with discordant results for HSV-1 and HSV-2 were confirmed with an in-house HSV PCR performed at Singapore General Hospital.

Results Of the 193 samples tested for HSV-1, 27 were positive and 159 were negative with both the **cobas**® HSV 1 and 2 Test and viral isolation. Of the samples evaluated, 7 were positive by the **cobas**® HSV 1 and 2 Test but not in viral isolation. The overall agreement of the **cobas**® HSV 1 and 2 Test and viral isolation for HSV-1 was 96.4%. Of the 193 samples tested for HSV-2, 57 were positive and 113 were negative with both the **cobas**® HSV 1 and 2 Test and viral isolation. There were 23 samples found to be positive with the **cobas**® HSV 1 and 2 Test but not in viral isolation. The overall agreement of the **cobas**® HSV 1 and 2 Test and viral isolation for HSV-2 was 88.1%. Further testing of discrepant samples revealed 20/23 were detected by an in-house HSV PCR assay.