

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 für Biochemia 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  $\geq 1:32$ , 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), 1.493 for monocyte chemoattractant 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.