

**Objectives** The objective of this study was to evaluate the cobas<sup>®</sup> HSV 1 and HSV 2 Test using clinician-collected swab specimens from external anogenital lesions as part of a large multicenter clinical trial.

**Methods** Two swabs were collected from patients with possible HSV infection at 8 geographically diverse sites. The first swab was used for the Quidel Lyra<sup>™</sup> Direct HSV 1+2/VZV on the Cepheid SmartCycler II System and the second for the cobas<sup>®</sup> HSV 1 and 2 Test. The Quidel Lyra<sup>™</sup> Direct HSV 1+2/VZV test was performed at a reference laboratory and the cobas<sup>®</sup> HSV 1 and HSV 2 Test was performed at 3 sites. Discrepant analysis included HSV culture using the ELVIS<sup>®</sup> HSV ID and D<sup>3</sup> Typing Test, a second FDA-cleared nucleic acid amplification test (BD ProbeTec<sup>™</sup> Herpes Simplex viruses [HSV 1 and 2] Q<sup>x</sup> Amplified DNA Assays) and Sanger sequencing. The sensitivity and specificity were calculated by comparing cobas<sup>®</sup> HSV 1 and HSV 2 Test results with the Quidel Lyra<sup>™</sup> Direct HSV 1+2/VZV test following discrepant analysis using the majority result from the three comparator tests.

**Results** There were 229 HSV positive subjects, with 73 HSV-1 (44 female, 29 male) and 157 HSV-2 (78 female, 79 male) positive subjects, among 409 evaluable participants (205 female, 204 male). The sensitivity and specificity of the cobas<sup>®</sup> HSV 1 and HSV 2 Test compared to the Quidel Lyra<sup>™</sup> Direct HSV 1+2/VZV following discrepant analysis for HSV-1 was 98.6% (72/73) and 97.0% (326/336), respectively, and for HSV-2 was 100% (157/157) and 92.9% (234/252), respectively.

**Conclusion** The cobas<sup>®</sup> HSV 1 and 2 Test, on the automated cobas<sup>®</sup> 4800 system, displayed excellent performance compared Quidel Lyra<sup>™</sup> Direct HSV 1+2/VZV Test combined with discrepant analysis. The test is highly suitable to detect HSV in clinician-collected anogenital swab specimens from patients with suspected HSV infection.

**Disclosure of interest** This clinical trial study was supported by Roche Molecular Diagnostics.

#### P07.26 EVALUATION OF A NOVEL TRANSCRIPTION MEDIATED AMPLIFICATION ASSAY FOR THE DETECTION OF HERPES SIMPLEX VIRUS FROM CLINICAL SAMPLES

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**Introduction** This study compared the performance, using routine clinical samples, of the Aptima Herpes Simplex Viruses 1 and 2 Assay (AHSV) to our current RT-PCR assay developed in-house.

**Methods** 512 prospective routine samples in VTM from male and female patients were tested with the RT-PCR and AHSV assays. Samples were submitted for HSV detection (243), VZV detection (76) or both (193) from genital (127) extragenital (309) and unspecified (76) sites. The RT-PCR assay is a multiplex in-house assay based on published sequences for HSV-1, HSV-2 and VZV. The AHSV assay is a real-time Transcription Mediated Amplification assay that detects mRNA for HSV-1 and HSV-2 and an internal control. Within 3 days of collection, a 500  $\mu$ L aliquot of VTM was transferred to Aptima Sample Transport Media and tested with AHSV on the Panther instrument.

**Results** Of 512 samples, 510 had valid results in both assays. The RT-PCR and AHSV assays detected HSV-1 in 76 and 64 samples respectively. For HSV-2, there were 25 samples detected positive by RT-PCR and 24 by AHSV. 54 samples were positive for VZV. No samples positive by RT-PCR for VZV were positive with AHSV. All RT-PCR positive, AHSV negative samples had a high crossing point.

**Conclusions** For HSV-1, the percent total agreement and kappa value were 97.7% and 0.90 (very good agreement), while for HSV-2, these values were 99.8% and 0.98 (very good agreement). The AHSV assay workflow on the Panther instrument was very efficient. The AHSV assay has not yet been released as an IVD assay.

**Disclosure of interest statement** Hologic provided Aptima Herpes Simplex Viruses 1 and 2 Assays and Panther training for this study.

#### P07.27 PERFORMANCE OF HERPESELECT ELISA FOR DIAGNOSIS OF HSV-1 AND HSV-2 INFECTION IN A CLINICAL SETTING

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**Introduction** Focus HerpeSelect type specific ELISA is the most commonly used commercial assay for detection of HSV-1 and HSV-2 serostatus. We evaluated the accuracy of the HerpeSelect ELISA in patients who were seeking to confirm their serostatus with the University of Washington Western blot (UW WB).

**Methods** We reviewed charts of all persons who were tested for HSV antibody at the Westover Heights Clinic in Portland, OR between July 2010 and April 2014, and who were tested with both HerpeSelect ELISA and UW WB.

**Results** We evaluated test results on 442 persons, of whom 49% were women, with a median age of 36 (range 18–68). Overall, by UW WB, 61 persons tested HSV-2 seropositive only, 81 tested HSV-1 and HSV-2 seropositive, 170 were HSV-1 seropositive only, and 130 were seronegative for an overall HSV-2 prevalence of 32% and HSV-1 prevalence of 57%. Among 199 persons who tested HSV-2 positive on HerpeSelect ELISA according to manufacturer's cutoff of index value  $\geq 1.1$ , 58% confirmed by the UW WB. Among 131 persons with an index value 1.1–2.9, 50% confirmed; among 37 persons with an index value  $\geq 3$ , 81% confirmed with the UW WB ( $c^2$  test,  $p = 0.0007$ ). The risk of false positive HSV-2 results was similar among persons with and without HSV-1 antibody (44% vs 39%,  $c^2$  test,  $p = 0.41$ ). Among 156 persons who tested HSV-2 negative by ELISA, 2% were found UW WB positive. Among 143 persons who tested HSV-1 positive by ELISA, 133 (92%) confirmed by the UW WB. However, an additional 49 persons were HSV-1 seropositive by UW WB but negative by the ELISA, for a negative predictive value of 72%.

**Conclusion** HerpeSelect ELISA has poor positive predictive value for HSV-2 and poor negative predictive value for HSV-1 in clinical practice. More accurate commercially available tests are needed for HSV antibody diagnostics.

**Disclosure of interest statement** No pharmaceutical grants were received for this study.

**P07.28** **SYPHILIS TESTING IN ANTENATAL CARE: POLICIES AND PRACTICES AMONG LABORATORIES IN THE AMERICAS**

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**Introduction** The World Health Organization (WHO) recommends universal syphilis testing in pregnancy as part of basic maternal and child health services. Coupled with HIV testing, antenatal syphilis testing is fundamental for the regional initiative on elimination of mother-to-child transmission of HIV and congenital syphilis (EMTCT) in the Americas and globally. We conducted this survey of laboratory practices around syphilis testing to characterise syphilis testing in the Pan American Health Organisation (PAHO) member countries.

**Methods** A structured survey assessing syphilis laboratory testing practices in the 35 PAHO member states was administered electronically between March and August 2014. Leaders of national reference labs, large regional laboratories and a sample of local (e.g., large maternal hospitals, district hospitals) and private laboratories that conducted syphilis testing were recruited to participate. The survey collected data on laboratories tests used, testing algorithms applied in different clinical settings, testing volume and turnaround time, quality assurance strategies, and results reporting to national surveillance.

**Results** Data were obtained from 30 (86%) PAHO member states, including 36 national or regional reference laboratories and 33 lower level laboratories, primarily (94%) publicly funded. Of 69 laboratories reporting results, 41% used rapid syphilis tests (RSTs), of which 36% were lower level laboratories. Sixty-eight percent of reporting laboratories (83% of national/regional) participated in external quality control, and 36% reported surveillance data. Of the 69 laboratories, 49 (71%) reported using a national algorithm for syphilis testing in pregnancy, of which 5 involved RSTs. Of 54 (78%) laboratories that reported processing samples from antenatal clinics, approximately half experienced stock outs of at least one essential commodity during the previous 12 months.

**Conclusions** Updating laboratory algorithms along with improving testing standards and quality assurance, supply distribution, and surveillance reporting could better advance EMTCT of syphilis and improve syphilis testing in various clinical settings in the Americas Region.

**Disclosure of interest** No grants or outside funding were received in the development of this study.

**P07.29** **POINT OF CARE TESTING (POCT) FOR HIV; CAN VENIPUNCTURE BE AVOIDED FOR SYPHILIS?**

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**Introduction** Point of Care Testing (POCT) for HIV potentially removes the need for venipuncture; however it is currently still required for syphilis and hepatitis B testing. Syphilis POCTs exist but most cannot be used for clients with a past history of

syphilis. Newcastle Sexual Health Service explored whether venipuncture could be avoided at the Hunter ACON outreach clinic.

**Methods** A list of MSM seen at Hunter ACON during 2014 was obtained from the clinic database. Data for the following parameters were obtained from laboratory and clinic records: numbers of individual clients, occasions of service, if they were first time presenters to the service, past history of syphilis and HBV status.

**Results** 105 MSM clients were tested for syphilis on 150 occasions during 2014 at Hunter ACON with 2 clients testing positive on the syphilis screening EIA. Both clients were known to have been previously diagnosed with syphilis. 71 clients attended as a first visit, 40 of these were of unknown hepatitis A or B status and hence may have required HBV testing. Further analysis of reported HBV status may reduce this number as NSW has been vaccinating MSM and school aged males for many years. Overall 108 of 150 (72%) HIV testing occasions could have avoided venipuncture through use of HIV and syphilis rapid testing.

**Conclusion** This data demonstrates that a syphilis POCT could be used for the overwhelming majority of MSM seen at the Hunter ACON outreach clinic. In at least 72% of occasion's venipuncture could be avoided when performing HIV/STI testing at the Hunter ACON clinic.

**Disclosure of interest statement** N/A.

**P07.30** **IMPACT OF EXPANDED SCREENING ON THE DETECTION OF HIV AND SYPHILIS IN WUXI, CHINA**

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**Introduction** HIV and syphilis shares same mode of transmission. In 2010 the Chinese government adopted expanded HIV and syphilis screening strategy (EHSS) across the country in order to timely detect people with these two infections. The impact of this strategy has not been well documented.

**Methods** HIV and syphilis surveillance data 2004–2014 in Wuxi, China were retrieved. Sources of surveillance data included general hospitals (GHs), sexual health clinics (SHCs), blood donation centres (BDCs), voluntary counselling and testing clinics (VCTs) and others in Wuxi. We used Poisson distribution events test to compare number of HIV and syphilis testing, Chi-squared test to compare HIV and syphilis positive rates and proportions of source of HIV and syphilis notification, between the period before EHSS (Period I, 2004–2009) and the period after EHSS (Period II, 2010–2014).

**Results** Comparing Periods I and II, 586,000 vs 1,423,000 person-times were screened for both HIV and syphilis ( $P < 0.001$ ); HIV positive rates were 0.08% (476) vs 0.13% (1,854) ( $<0.001$ ); syphilis positive rates were 0.37% (2,172) vs 0.63% (8,955) ( $P < 0.001$ ). In Period I, 18.8%, 10.9%, 7.1%, 14.2% and 49.0% of all HIV positive cases were from GHs, SHCs, BDCs, VCTs and other sources, respectively. This compared to 25.8%, 7.4%, 9.0%, 16.5% and 41.3% in Period II ( $P < 0.001$ ). In Period I, 42.0%, 13.7%, 7.8%, 1.5% and 35.0% of all syphilis positive cases were from GHs, SHCs, BDCs, VCTs and other sources, respectively. This compared to 26.7%, 28.0%, 17.7%, 1.7% and 25.9% in Period II ( $P < 0.001$ ).

**Conclusion** Both the number of HIV and syphilis testing and positive rate increased as a result of EHSS. More HIV infections were detected from GHs compared to syphilis from SHCs in