Objectives The objective of this study was to evaluate the **cobas**® 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™ Direct HSV 1+2/VZV on the Cepheid SmartCycler II System and the second for the **cobas**® HSV 1 and 2 Test. The Quidel Lyra™ Direct HSV 1+2/VZV test was performed at a reference laboratory and the **cobas**® HSV 1 and HSV 2 Test was performed at 3 sites. Discrepant analysis included HSV culture using the ELVIS® HSV ID and D^3 Typing Test, a second FDA-cleared nucleic acid amplification test (BD ProbeTec™ Herpes Simplex viruses [HSV 1 and 2] Q^x Amplified DNA Assays) and Sanger sequencing. The sensitivity and specificity were calculated by comparing **cobas**® HSV 1 and HSV 2 Test results with the Quidel Lyra™ 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**® HSV 1 and HSV 2 Test compared to the Quidel Lyra™ 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**® HSV 1 and 2 Test, on the automated **cobas**® 4800 system, displayed excellent performance compared Quidel Lyra™ 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

T Sadlon*, M Turra, T Hahesy, G Higgins. *Microbiology & Infectious Diseases, SA Pathology, Adelaide, South Australia*

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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 μL 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

[1]Q Le, [2]T Warren*, [1]S Selke, [1]A Magaret, [1]A Wald. [1]*University of Washington, Seattle, WA, USA*; [2]*Westover Heights Clinic, Portland, OR, USA*

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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 ^{3}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 ≥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.