Conclusion The **cobas**® HSV 1 and 2 Test, run on the fully automated **cobas**® 4800 system, demonstrated excellent performance for detecting HSV 1 and 2 from clinical specimens when compared with viral isolation.

Disclosure of interest statement The Department of Sexually Transmitted Infections Control Clinic, Singapore collaborated with Roche Molecular Systems on the presentation of the outcomes of this evaluation study.

P07.23 EVALUATION OF THE COBAS® HSV 1 AND 2 TEST FOR THE DETECTION OF HSV FROM CLINICIAN-COLLECTED ANOGENITAL LESION SWAB SPECIMENS COMPARED WITH ELVIS® HSV ID AND D³ TYPING TEST AND SANGER SEQUENCING

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Introduction Diagnosis of anogenital herpes is definitively established by testing anogenital lesion specimens from symptomatic patients by culture or molecular methods. 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 conducted in the United States of America.

Methods Two swabs were collected from patients with possible HSV infection at 8 geographically diverse sites. The first swab was used for culture by the ELVIS® HSV ID and D³ Typing Test (Diagnostic Hybrids, Inc., Athens, OH) and PCR followed by Sanger sequencing for HSV-1 and HSV-2. The second swab was for the **cobas**® HSV 1 and 2 Test. Sensitivity and specificity were calculated compared to the combined results of culture and Sanger sequencing using the "any positive rule". The positive (PPA) and negative percent agreement (NPA) were calculated compared with culture.

Results There were 243 HSV positive subjects, with 84 HSV-1 (51 female, 33 male) and 167 HSV-2 (85 female, 82 male) positive subjects, among 408 evaluable participants (205 female, 203 male). The sensitivity and specificity of the **cobas**® HSV 1 and HSV 2 Test compared the Reference Method for HSV-1 was 92.9% (78/84) and 98.8% (320/324), respectively, and for HSV-2 was 97.0% (162/167) and 94.6% (228/241), respectively. The PPA and NPA of the **cobas**® HSV 1 and HSV 2 Test compared to the culture for HSV-1 was 100% (67/67) and 93.9% (199/212), respectively, and for HSV-2 was 99.2% (128/129) and 83.2% (232/279), respectively.

Conclusion The **cobas**® HSV 1 and 2 Test displayed excellent performance compared to the combined results of culture and Sanger sequencing. The test is highly suitable to detect HSV in clinician-collected anogenital swab specimens from patients with suspected HSV infection.

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

P07.24 PREDICTED INCLUSIVITY AND SPECIFICITY OF THE COBAS® 4800 CT/NG TEST THROUGH GLOBAL SURVEILLANCE MONITORING

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Introduction Nucleic acid amplification tests rely on conserved sequences for identification of specific targets, which may evolve, requiring global surveillance monitoring. An analysis of sequence heterogeneity within the primer and probe target region for the **cobas**® 4800 CT/NG Test was performed with publically available and in-house sequences to determine predicted inclusivity and specificity.

Methods To determine predicted inclusivity, analysis of the sequence heterogeneity within the primer and probe binding regions used in **cobas**® 4800 CT/NG Test were compared with the most current sequence information in NCBI's public sequence database supplemented with sequences generated by the Roche Global Surveillance Program. By design of the redundant nature of target amplification and detection for these assays (multiple copies of DR9 in NG and dual targets of *omp*A and cryptic plasmid in CT), mismatches in multiple sequences are required to affect assay inclusivity. For predicted specificity, the analysis of the potential generation of false-positive signals due to detection of non-target sequences was evaluated by interrogating the most current sequence information in NCBI's public sequence database.

Results For predicted inclusivity, a total of 56 cryptic plasmid and 373 *omp*A sequences from *Chlamydia trachomatis* and 357 sequences from 119 different strains of *Neisseria gonorrhoeae* covering the primer/probe binding region showed no predicted critical mismatches. For predicted specificity, extensive search identified no non- CT or NG target sequences that fit the broad criteria for potentially generating a false-positive signal based on the binding of two primers in the proper orientation, having a sequence that may bind one of the probes and generating a signal for an amplicon size of less than 3,000 base pairs.

Conclusion Global surveillance of publically available and in-house generated sequences shows the **cobas**® 4800 CT/NG Test is a reliable molecular method for detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae*, displaying excellent predicted inclusivity and specificity.

Disclosure of interest The authors are employees of Roche Molecular Diagnostics which supported this study.

P07.25 COMPARISON OF COBAS® HSV 1/2 TEST, QUIDEL LYRA™ DIRECT HSV 1+2/VZV, BD PROBETECTM HSV 1/2 QX ASSAY AND SANGER SEQUENCING USING CLINICIAN-COLLECTED ANOGENITAL LESION SWABS

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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

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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

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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.