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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