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 D1 TYPING TEST AND SANGER SEQUENCING**

1: Young, 2: Van Der Pol, 3: Taylor, 4: Fife, 5: Hock, 6: Patel, 7: Ding, 8: Hemyari, 9: Duncan, 10: Liesenfeld, 11: Osiecki*, 12: Lewinski. 1: TrcCore Reference Laboratories, Albuquerque, NM, USA; 2: University of Alabama at Birmingham, Birmingham, AL, USA; 3: Louisiana State University School of Medicine, New Orleans, LA, USA; 4: Indiana University School of Medicine, Indianapolis, Indiana, USA; 5: Royal South Hants Hospital, Southampton, England, UK; 6: Roche Molecular Diagnostics, Pleasanton, CA, USA

**Abstracts**

**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 publicly 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 ompA 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 ompA 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 publicly 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**

1: Young, 2: Van Der Pol, 3: Taylor, 4: Fife, 5: Hock, 6: Patel, 7: Ding, 8: Hemyari, 9: Duncan, 10: Liesenfeld, 11: Osiecki, 12: Lewinski*. 1: TrcCore Reference Laboratories, Albuquerque, NM, USA; 2: University of Alabama at Birmingham, Birmingham, AL, USA; 3: Louisiana State University School of Medicine, New Orleans, LA, USA; 4: Indiana University School of Medicine, Indianapolis, Indiana, USA; 5: Royal South Hants Hospital, Southampton, England, UK; 6: Roche Molecular Diagnostics, Pleasanton, CA, USA

**Introduction** The P05.25 direct HSV 1+2/VZV, BD ProbstecTM HSV 1/2 QX assay and Sanger sequencing using clinician-collected anogenital lesion swabs showed excellent predicted inclusivity and specificity.