

**Conclusion** Overall, from this limited evaluation, Artus® CT/NG is analytically highly sensitive and specific for the detection of *C. trachomatis* and *N. gonorrhoeae*. Further assessment with clinical samples would need to be done to fully assess the performance of this assay prior to clinical implementation.

**P5.065 EVALUATION OF THREE DIFFERENT DIAGNOSTIC SYSTEMS FOR THE DETECTION OF *CHLAMYDIA TRACHOMATIS* AND *NEISSERIA GONORRHOEA* FROM ORAL SPECIMENS**

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**Background** To assess the performance characteristics of the Abbott *m2000* (*m2000*), BD ProbeTec CT/GC Qx Amplified DNA Assay (Viper Qx), and COBAS 4800 (*c4800*) using oropharyngeal swabs (OP). This study may lead to additional diagnostic testing options for the identification of CT and GC using OP.

**Methods** De-identified, residual OP from a sequential convenience sample of patients attending an STD clinic for routine diagnostic testing was used for this comparison. Samples were collected using a BD culturette swab, and eluted into M4-equivalent culture medium (CTM) in the laboratory. Two-hundred  $\mu$ l of residual sample was added into each manufacturer's collection device, which was subsequently tested on the Viper Qx, *m2000*, and *c4800* systems per the package insert. A patient was considered infected if 2 of the 3 amplified test results were positive (PIS). The distribution of results across all three systems was assessed by Cochran's Q test and between systems by McNemar's chi-square. Agreement between each system and the PIS was assessed using Kappa statistics.

**Results** Two hundred and twenty one residual specimens were available for Viper Qx and *m2000* testing; 216 for *c4800*. There was no statistical difference in performance between the three systems for GC ( $p = 0.174$ ). For CT, there was a difference observed for both sensitivity and specificity when comparing all three systems ( $p = 0.018$ ). However, there were no statistical differences in the distribution of results between systems in pair-wise comparison (all  $p > 0.125$ ). Agreement was excellent for both CT and GC with  $\kappa$ -scores  $> 0.85$  for CT and  $\geq 0.95$  for GC.

**Conclusions** There was no statistical difference in performance between the three systems for the detection of CT or GC using OP. All systems had very good agreement with the PIS, are user friendly, and will provide additional testing options for OP.

**P5.066 EVALUATION OF COPAN FLOQSWAB FOR THE MOLECULAR DETECTION OF *CHLAMYDIA TRACHOMATIS* BY ABBOTT REALTIME CT PCR**

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Use of Copan FLOQSwab due to its stronger capillary action should result in better specimen collection and more effective release of collected material. The objective of the present study was to evaluate FLOQSwab next to the swab validated by manufacturer in Abbott RealTime CT PCR for the detection of *Chlamydia trachomatis*. In total 1084 couples of both types of swabs were collected during 21 months as a part of the female sex workers' screening programme. The study was divided in two arms according to the order of swab collection. If manufacturer's swab was collected first, 32 coupled samples were both positive, 459 - both negative and 36 - discordant. Among discordant samples 25 (69%) required retesting of FLOQSwab (IC failed-flagging in 16 (44%) cases) with the final negative

results. For 2 samples no result on FLOQSwab was available due to persistent inhibition while manufacturer's swab gave negative results by initial testing. Two samples gave FLOQSwab positive/manufacturer's swab negative results. When comparing analytical values of concordant positive samples, no statistical difference was observed ( $p$ -value 0.49). If FLOQSwab was taken first, 32 coupled samples were both positive, 483 - both negative and 42 - discordant. Twenty one (50%) of the discordant results represented retesting of FLOQSwab due to the IC failed-flagging with the final negative results. The result for 1 FLOQSwab could not be achieved while the manufacturer's swab was negative. Eight samples were positive only by FLOQSwab, 2 - only by manufacturer's swab. Analytical values of concordant positive samples did not differ statistically ( $p$ -value 0.22). Concluding, FLOQSwab can be used for Abbott RealTime CT PCR. Positivity in 10 additional samples by FLOQSwab was in low analytical range while technical problems led to retesting of 46 FLOQSwab's, for 3 FLOQSwab's no final result was achieved and 2 low positives were missed.

**P5.067 THE WAY TO GO FORWARD IN OPTIMIZATION OF STI MANAGEMENT IN EASTERN EUROPE: EASTERN EUROPEAN NETWORK FOR SEXUAL AND REPRODUCTIVE HEALTH (EE SRH)**

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**Background** The collapse of the Soviet Union resulted in large changes in the organisation of the health care in many newly independent countries belonging to the WHO European region. Unfortunately, STI management received a highly suboptimal attention. Accordingly, existing professional STI networks were disaggregated by country borders as well as differences in economic and political situations. Many became isolated by their own country and language barriers and financial limitations, and the evidence-based standards elaborated by "Western professional societies" were difficult to access, adhere to and, in general, discuss regarding their appropriateness for the EE countries.

**Methods** Establishment of the EE SRH; a professional network and bridge between the EE countries and Western European countries and expertise. Numerous of meetings, workshops and trainings to, using international evidence-based approaches, optimise and quality assure diagnosis, treatment and epidemiological surveillance of sexually transmitted and other genital tract infections, as part of the reproductive health disorders.

**Results** An international network of professionals in STI management was established in 2006 with participation of 15 EE countries. Using evidence-based international approaches, including those elaborated by the CDC, WHO, IUSTI and with the help of internationally acknowledged experts, consensus guidelines for the diagnosis of STIs have been elaborated and internationally published. Those guidelines have also been translated into the national languages and after adaptation published in the national languages and legalised as national STI diagnostic standards in many countries. Strict validation of locally-manufactured cost-effective diagnostic test systems has also been performed. Attempts to establish sustainable surveillance of antimicrobial resistance in gonococci in many of the EE countries is also ongoing.

**Conclusion** As the next steps, increased implementation of the EE SRH guidelines, establishment of laboratory networks (including STI reference laboratories), and strict monitoring of the achievements are imperative.