Conclusions Both CT MAMEF assays demonstrated moderate sensitivity and high specificity when using dry-shipped vaginal swabs. The cryptic plasmid assay was more sensitive than the 16S rRNA assay. MAMEF is an ultra-rapid platform with results in less than 10 minutes making it ideal as a point-of-care test.

P5.062 AN EASY TO USE REAL TIME PCR TEST FOR CHLAMYDIA TRACHOMATIS AND NEISSERIA GONORRHOEAE PROVIDING RESULTS THAT CAN GUIDE TREATMENT CHOICES BEFORE THE PATIENT LEAVES THE CLINIC

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Background New diagnostics for *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (NG) that can provide accurate, rapid, and timely results are urgently needed so that patients can be treated at the time they visit a clinic. The Cepheid GeneXpert® (Xpert) CT/NG assay is a rapid nucleic acid amplified test (NAAT) assay that can be performed in on-site laboratories. The assay detects DNA of CT and NG from female endocervical, patient-collected vaginal, and urine specimens, and in male urine from symptomatic and asymptomatic individuals.
Methods The Xpert test is a modular, cartridge-based, "walk-away" platform for testing which requires no manipulation from specimen loading until results are available (90 minutes). We compared results from the Xpert assay to results from two currently approved nucleic acid amplification assays (Aptima Combo2 and ProbeTec) in 1,722 females and 1,387 males. Results included a specimen adequacy control result and an amplification control result. The targets were two highly conserved, non-contiguous NG-unique chromosomal targets for NG and a chromosomal CT target.
Results Compared to patient-infected-status (PIS), the Xpert results for chlamydia demonstrated sensitivities for endocervical, vaginal, and urine samples of 97.4%, 98.7%, and 97.6%, respectively, in females and in male urine a sensitivity of 97.5%. All specificity estimates were ≥ 99.4%. Results for gonorrhoea demonstrated sensitivities for endocervical, vaginal, and urine samples of 100.0%, 100.0%, and 95.6%, respectively, in females, with specificities > 99.9%. In male urine, the sensitivity for gonorrhoea was 97.50% and the specificity was 99.9%.
Conclusions The GeneXpert® System is a closed, self-contained, fully-integrated, automated platform for CT/NG testing that demonstrated excellent sensitivities and specificities in women and men. This relatively rapid short-turn-around-time test can provide results to guide treatment decisions before patients leave the clinical setting. Such rapid treatment could potentially improve chlamydia and gonorrhoea control efforts.

P5.063 INFLUENCE OF TEMPERATURE, MEDIUM AND STORAGE DURATION ON *CHLAMYDIA TRACHOMATIS* DNA DETECTION BY POLYMERASE CHAIN REACTION

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Background *Chlamydia trachomatis* (Ct) is the most prevalent bacterial sexually transmitted microorganism worldwide. Many researchers conveniently use stored samples for Ct research. We assessed the impact of four different temperature conditions, six different types of medium and five increasing lengths of duration of storage, on Ct DNA detection.
Methods Phosphate buffered saline (PBS), 2-sucrose-phosphate (2-SP) medium, COBAS Amplicor medium and urine samples were spiked with the same amount of Ct serovar D elementary bodies and were stored in at room temperature (RT), 4°C, –20°C and –80°C. Clinical Ct positive urine samples and Ct positive swabs in COBAS Amplicor medium were collected, pooled and stored at the same 4 temperatures. Samples (136 clinical and 287 spiked samples) were tested in triplicate on day 0 and subsequently after 1, 7, 14 and 30 days of storage and two years hereafter for the presence of Ct DNA. Approximately 3000 plasmids were available per PCR reaction and each sample was thawed only once. Cycle thresholds were analysed using generalised linear models, controlling for repeated measurements.
Results Ct could be detected in all clinical samples and spiked media and cycle thresholds were stable over time with few exceptions. For Ct DNA detection in spiked COBAS Amplicor medium, cycle thresholds increased within the first month at –20°C and –80°C (both $p < 0.01$), but decreased in the samples frozen after two years of storage. In spiked urine and pooled clinical urine samples, the cycle threshold decreased within the first month ($p < 0.01$), including all but one (4°C, $p = 0.09$) of the studied temperatures, but increased after two years in the frozen samples.
Conclusion Our results demonstrate that storage conditions and duration hardly affect Ct DNA detection by PCR in a negative manner, although frozen urine samples, stored for prolonged periods (more than two years), could become Ct negative.

P5.064 PRELIMINARY ANALYTICAL EVALUATION OF ARTUS® CT/NG, FOR SIMULTANEOUS DETECTION OF *NEISSERIA GONORRHOEAE* AND *CHLAMYDIA TRACHOMATIS*

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Introduction Currently there are a number of molecular amplification assays for detection of *Neisseria gonorrhoeae* and *Chlamydia trachomatis*. Prior to introduction of any new assay, it should be thoroughly evaluated for potential false positive and false negative results due to cross reaction with other species, and potential mutations and genetic exchanges with other closely related organisms. Artus® CT/NG is currently a research use only kit (with the fully automated version to be released later this year)for simultaneously detection of *C. trachomatis* and *N. gonorrhoeae*. We performed preliminary analytical evaluation of this assay.
Method This study evaluated the Artus® CT/NG assay with 290 characterised culture isolates obtained from the Neisseria Reference Laboratory at the World Health Organization Collaborating Centres for Sexually Transmitted Disease (STD) in Sydney and WHO Collaborating Centre for Gonorrhoea and other STIs in Örebro, Sweden. Strains included 148 *N. gonorrhoeae* isolates, 130 isolates of non-gonococcal *Neisseria* species, 12 isolates of other species closely related to *Neisseria* and 16 *C. trachomatis* strains of different serovars (including LGV and nvCT strains).
Results All *C. trachomatis* and *N. gonorrhoeae* isolates were detected. A detection sensitivity of 10 genome copies per reaction was obtained with all *C. trachomatis* serovars as well as a representative *N. gonorrhoeae* control strain. All 142 non-gonococcal isolates were negative on the assay.

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 GONORRHOEAE* FROM ORAL SPECIMENS

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Background To assess the performance characteristics of the Abbott *m*2000 (*m*2000), BD ProbeTec CT/GC Q^x Amplified DNA Assay (Viper Q^x), 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 ul of residual sample was added into each manufacturer's collection device, which was subsequently tested on the Viper Q^x, *m*2000, 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 Q^x and *m*2000 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 κ-scores > 0.85 for CT and ≥ 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 devided 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 oberved (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.