organisms. Analytical sensitivity was determined using titered, purified CT elementary bodies and cultured NG cells.

Results The Xpert CT/NG assay detects all CT serovars, new variant CT, and 48 geographically diverse NG strains.

The CT primers and probes do not cross-react with DNA or RNA from non-trachomal species. All non-gonococcal *Neisseria* species yielded negative results, including N. mucosa and N. cinerea, because both NG targets must be PCR positive for a "NG DETECTED" result.

The LoDs for the Xpert CT/NG Assay for CT serovar D in male urine and vaginal swab matrix respectively were 75 and 84 Eb/mL; for CT serovar H, LoDs were 134 and 161 Eb/mL. In both matrices, the LoD for two NG strains was approximately 2 cfu/mL.

Conclusion The Xpert CT/NG assay is highly specific and sensitive. The ease of use and fast time to result could lead to reduced time to treatment of CT and NG infections.

P2.015 EVALUATION OF THE TRIPLEX REAL-TIME PCR ASSAY FOR DETECTION OF CHLAMYDIA TRACHOMATIS AND NEISSERIA GONORRHOEAE IN URINE AND VAGINAL SWABS

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Background Chlamydia trachomatis and Neisseria gonorrhoeae are among the most common causes of sexually transmitted bacterial infections worldwide. Infection with these organisms is mostly asymptomatic, however serious complications are also observed. Screening of the diseases is necessary to identify, treat and control the infection. In this study, we evaluated the performance of the triplex real-time PCR assay with internal control for detection of C. trachomatis and N. gonorrhoeae infections in urine and vaginal swabs.

Methods The performance of TaqMan probe-based triplex real time PCR targeting the cryptic plasmids of C. trachomatis (pCHL1) and N. gonorrhoeae (pJD1) and beta-globin gene as an internal control was assessed using 188 urine specimens and 118 vaginal swabs. The triplex real time PCR was compared with the Roche COBAS AMPLICOR CT/NG assay. The urine specimens were further tested using real-time PCR targeting the N. gonorrhoeae porA pseudogene.

Results For urine specimens, the sensitivity and specificity of the triplex real time PCR were 100% and 97.6%, respectively, for C. trachomatis, and 100% and 95.2%, respectively, for N. gonorrhoeae. For vaginal swabs, the sensitivity and specificity were 100% and 100%, respectively, for C. trachomatis, and 100% and 98.1%, respectively, for N. gonorrhoeae. There were 5 (2.84%) from 176 urine specimens that were negative for cryptic plasmid, but positive for N. gonorrhoeae porA pseudogene.

Conclusion The performance of the triplex real time PCR assay was comparable to that of the Roche COBAS AMPLICOR CT/NG assay. This assay is easy to perform and the results can be achieved in 3–4 hours, including sample preparation. The estimated cost of triplex real time PCR was less than 20 USD. Taken together with using non-invasive urine sampling, this assay is convenient and suitable for epidemiological studies in screening large number of samples.

P2.016 COMPARISON OF THREE REAL-TIME PCR TESTS FOR THE DETECTION OF CHLAMYDIA TRACHOMATIS AND NEISSERIA GONORRHOEAE IN YOUNG PREGNANT WOMEN

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At the Bordeaux University Hospital, among pregnant women aged less than 25 years-old the prevalence of C. trachomatis (CT) and N. gonorrhoeae (NG) is 12.5% and 2.4%, respectively for those requesting abortion by using the Abbott m2000 CT/NG test, and 7.9% and 0%, respectively, for those consulting for monitoring pregnancy by using the Roche Cobas 4800 CT/NG test.

The objective of this study was to evaluate and compare the performances of both of these tests along with a third one, the Cepheid GeneXpert CT/NG, for the detection of CT and NG in vaginal swabs collected from pregnant women consulting for abortion or for monitoring pregnancy. A patient was considered infected if at least two tests were positive.

Among 304 pregnant women included, from September 2012 to January 2013, 34 were infected, leading a prevalence of 11.7% (26/222) for patients requesting abortion and 9.7% (8/82) for patients consulting for monitoring pregnancy. There were two false CT-positive results with the Abbott m2000, one false negative result reported by Roche and the Cepheid GeneXpert. The sensitivity and specificity were 97% and 100% for the Roche and the Cepheid GeneXpert tests, and 100% and 99.3% for the Abbott assay. The positive predictive value ranged from 94.4% to 100% according to the test.

For NG, 297 specimens were negative and 7 were positive using the three tests. All results were concordant, leading to a sensitivity and specificity of 100% for all the assays. The prevalence of NG among pregnant women requesting abortion was 2.7% (6/222) and 1.2% (1/82) for those consulting for monitoring pregnancy.

In the populations studied, all three assays have similar performances for CT/NG detection.

P2.017 CLINICAL EVALUATION OF THE PELVOCHECK® CT/NG FOR THE DETECTION OF CHLAMYDIA TRACHOMATIS AND NEISSERIA GONORRHOEAE

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Background In the present study the performance of the PelvoCheck® CT/NG, a microarray-based nucleic acid amplification assay for the detection of Chlamydia trachomatis (CT) and Neisseria gonorrhoeae (NG), was evaluated in single and pooled urine specimen of young women.

Methods A total of 1649 female urine specimens were collected and examined for urogenital chlamydia infections. Because of a low prevalence (2.12%), 50 CT-negative urine specimens were enriched with CT reference material mimicking the natural chlamydial distribution in female urine. The results were compared to those of the Roche COBAS® TaqMan® CT assay as the first and the Abbott RealTime CT/NG assay as the second reference method.

Similarly, NG pre-screened female urine specimens (60 NG-positive and 60 NG-negative specimens) were analysed with the PelvoCheck® CT/NG test and compared to a validated in-house Q-PCR method and the Abbott RealTime CT/NG assay.

Furthermore, the PelvoCheck® CT/NG assay was tested for pooled urine specimens (52 CT-negative and 55 CT-positive specimens). Each pool consisted of either five individual CT-negative specimens or four CT-negative and one CT-positive individual specimens.

Results For the detection of CT the overall positive agreement (sensitivity) and overall negative agreement (specificity) of the PelvoCheck® CT/NG were 98.8% and 100%, for the detection of NG 98.3% and 98.2%, respectively.

The comparison of data obtained with the PelvoCheck® CT/NG for pooled urine specimens resulted in a positive agreement of 90.9% and a negative agreement of 100%. Four CT-positive pooled specimens with final CT-concentrations of 0.05 – 0.13 IFU/ml were not detected.

Conclusion In summary, we show that the PelvoCheck® CT/NG assay is a highly sensitive and highly specific method for the detection of CT and NG. To our knowledge, this is the first commercial CT/NG test system validated for the analysis of pooled urine specimens.

P2.018 CRYPTOSPORIDIOSIS AND CYCLOSPORIDIASIS, TWO MAJOR INFECTIONS IN HIV POSITIVE PATIENTS, IN BUKAVU, D.R.CONGO

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Background There are little data on the prevalence and clinical outcomes of coccidian parasites infection in HIV positive patients in Africa.
Methods We conducted a cross-sectional study at the Opportunistic Infections Clinic of the Provincial Hospital of Bukavu, from April 2010 to October 2011. HIV patients attending the clinic, aged 15 years and above were included after obtaining their consent, the CD4 count and patient details were recorded, stool samples were collected according to the WHO procedure. A single stool sample was collected and conserved in formalin - ether 10% and transported to the Provincial Laboratory of Bukavu for analysis. A consecutive sample of 108 patients was collected.

Smears were stained according to the modified ziehl neelsen procedure and examined at x100 magnification using an oil immersion microscope. Data were analysed with EPI-INFO 3.5. Differences with P-values < 0.05 were considered significant.
Results 58.3% were female. Mean (±SD) age 40 ± 15.7 years old. Stools were diarrheic in 66.7%. Overall prevalence of Cryptosporidium spp was 57.9% (95% CI: 41.8 – 76.1), Cyclospora cayetanensis 31.6% (95% CI: 19.3 – 47.5). 63.9% of patients were on antiretroviral therapy. Patients with CD4 counts < 50cells/μL, presented with a higher prevalence of either Cryptosporidium spp (62.1%) or Cyclospora cayetanensis (27.6%) (P = 0.0000). In diarrheic stools we recorded 59.6% (28/47) Cryptosporidium spp (P = 0.0001), 27.7% (13/47) Cyclospora cayetanensis. Dual infections were more noted in the CD4 count range of < 100 cells/μL, 63.4% (26/41) for CD4 count < 50cells/μL and 36.6% (15/41) for CD4 50 – 100cells/μL (P = 0.0000). On ARV, only subjects with100 – 200 cells/μL of CD4, had a good clinical evolution (P = 0.0000).
Conclusions Cryptosporidium parvum and Cyclospora cayetanensis are highly prevalent in HIV patients with advanced diseases and major causes of chronic diarrhoea. Dual infection is related to very low CD4 count.

P2.019 ANALYTICAL SPECIFICITY AND SENSITIVITY OF THE APTIMA COMBO 2 AND APTIMA GC ASSAYS FOR DETECTION OF *NEISSERIA GONORRHOEAE* ON THE GEN-PROBE PANTHER INSTRUMENT AND VERIFICATION OF SPECIMENS POSITIVE FOR *N. GONORRHOEAE* USING OTHER COMMERCIAL DIAGNOSTIC NAATS

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Objectives Nucleic acid amplification tests (NAATs) have rapidly replaced culture for the detection of *Neisseria gonorrhoeae* in many countries worldwide. Several commercial gonococcal NAATs have received US FDA clearance, including the APTIMA Combo 2 assay (AC2) and APTIMA GC assay (AGC) (Gen-Probe, San Diego, CA, USA). In this study, the analytical specificity and sensitivity of AC2 and AGC were evaluated on the Gen-Probe PANTHER instrument and specimens positive for *N. gonorrhoeae* using commercial diagnostic NAATs were verified by AGC.
Methods Samples spiked with 503 bacterial isolates (298 non-gonococcal Neisseria isolates and 205 gonococci) were tested. All initially equivocal and false-positive/false-negative results were verified according to a strict algorithm for confirmatory testing. Furthermore, 92 selected specimens tested positive for *N. gonorrhoeae* on Abbott RealTime PCR CT/NG (Abbott Laboratories) (n = 19), COBAS 4800 CT/NG (Roche Molecular Systems Inc.) (n = 34), or BD ProbeTec ET/Qx *Chlamydia trachomatis* and *Neisseria gonorrhoeae* Amplified DNA (Becton Dickinson) assays (n = 39) were examined for confirmation with AGC. For discrepancy analysis, a gonococcal diagnostic duplex PCR (targeting the *porA* pseudogene and *opa* genes) was used.
Results Both AC2 and AGC had 100% analytical specificity and sensitivity. Moreover, the verification of positive specimens from other commercial NAATs showed that all (100%; 19/19) specimens from Abbott RealTime PCR CT/NG, 94% (32/34) from COBAS 4800 CT/NG, and 51% (20/39) from BD ProbeTec ET/Qx *Chlamydia trachomatis* and *Neisseria gonorrhoeae* Amplified DNA could be verified as true positive in AGC (AGC results were confirmed in the gonococcal duplex PCR).
Conclusion The analytical specificity and sensitivity of AC2 and AGC were substantially challenged, and both assays displayed 100% specificity and sensitivity. This study also shows that AGC can be used for confirmatory testing as well as emphasises the importance of verifying particularly *N. gonorrhoeae* specimens that are low-positive or from extragenital sites with an alternative NAAT target.

P2.020 DIAGNOSTIC ACCURACY OF RAPID TESTS FOR C. TRACHOMATIS, N. GONORRHOEA AND SYPHILIS AT THE POINT OF CARE IN WOMEN WITH SYMPTOMS OF LOWER GENITAL TRACT INFECTION

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Objective Evaluate the diagnostic accuracy of rapid tests (RTs) for C. trachomatis (CT), N. gonorrheae (NG), and syphilis at the point of care for management of women with symptoms of lower genital tract infection (LGTI).

Materials and Methods: Diagnostic validity study assembled in a cohort study of sexually active women 14 to 49 years old, consulting with symptoms of LGTI at three outpatient facilities in Bogotá, Colombia in 2010, after ethics board approval. Exclusion criteria: hysterectomy, pregnancy, or receiving antibiotics in the 7 previous days. Sampling: sequential. RTs evaluated: Acon® duo and Acon plate® (Acon, San Diego, CA, USA) for NG. Acon® Plate, Acon Duo and QuickVue® (Quidel Corporation, San Diego, CA, USA). for CT They were compared against polymerase chain reaction (PCR) AMPLICOR C.trachomatis/N. gonorrhoeae test (Roche Diagnostic Systems, Inc., Branchburg, N.J.). Bioline® Syphilis 3.0 (Standard Diagnostics, Inc., Kyunggi-do, South Korea) and ACON® Syphilis for syphilis and were compared to a positive RPR and TPHA. Sensitivity (S), specificity (Sp), positive and negative likelihood ratios LR (+), LR (-) were calculated.
Results 1410 subjects recruited. The prevalence of NG and CT with PCR was 1.4% (19/1376) and 9.6% (133/1379) respectively.