NAAT methods. All the specimens were tested by Versant CT/GC DNA 1.0.

In case of a Versant CT positive result, we collected the corresponding remnant DNA extract and used it as a template for *omp1* semi-nested-PCR. RFLP analysis of PCR-positive samples was carried out by using *AluI, HinfI* and *DdeI* as restriction enzymes, for genotyping.

All the specimens scored GC positive were retested by a "home-made" PCR assay, targeting *cppB* gene.

Results A total of 253 samples were obtained. In particular, we tested 14 conjunctival swabs, 155 pharyngeal swabs and 84 rectal swabs.

Versant assay scored as GC positive 13 pharyngeal and 7 rectal samples. All these specimens were confirmed reactive by *cppB* PCR. Regarding CT infections, Versant assay identified 2 ocular specimens as positive: one was further genotyped as E and the other one as F. Moreover, we found 4 positive pharyngeal specimens (genotypes E, F, J) and 12 rectal samples (genotypes E, H, J, L2).

Conclusions Versant CT/GC DNA 1.0 demonstrated to be a very good method to identify extra-genital infections due to chlamydia and/or gonorrhoea. Because of its performances, and the walk-away capability of the system, this assay can be considered an excellent choice for CT/GC diagnosis.

P5.087 EVALUATION OF THE MULTIPLEX AMPLISENS HCV/HBV/HIV-FRT REAL-TIME PCR FOR SIMULTANEOUS QUALITATIVE DETECTION OF HEPATITIS C RNA, HEPATITIS B DNA AND HIV RNA

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[1]**K Malm**, [1]M Unemo, [1]S Thulin Hedberg, [2]D Kireev, [1]S Andersson. *[1]Dept of Laboratory Medicine, Örebro, Sweden; [2]Central Research Institute for Epidemiology, Moscow, Russian Federation*

Background Human donors of tissues and organs are obliged to undergo analysis for several blood transmitted infections. Serological assays are used, but for ideal sensitivity particularly for early infections these assays are beneficially supplemented with a nucleic acid amplification test (NAAT). For this as well as other diagnostic purposes, we have evaluated the multiplex AmpliSens HCV/HBV/HIV-FRT real-time PCR for simultaneous qualitative detection of HCV RNA, HBV DNA and HIV RNA in clinical plasma samples.

Methods Clinical plasma samples with known concentrations (according to viral load assays from Roche Diagnostics) of HCV (n = 34; range: 25 – 4.9×10^6 IU/mL), HBV (n = 30; 20 – 7.6×10^4 IU/mL) and HIV (n = 32; 34 – 4.7×10^5 c/mL); and samples from virus-negative blood donors (n = 100) were tested. Nucleic acid was isolated from 1 mL plasma on the MagNA Pure Compact using its Total Nucleic Acid Isolation kit I-Large Volume (Roche Diagnostics). The multiplex AmpliSens HCV/HBV/HIV-FRT real-time PCR (Central Research Institute of Epidemiology, Moscow, Russia) was run on a Rotor-Gene Q PCR instrument (Qiagen).

Results To date, 96 samples with various viral loads of HCV (n = 34), HBV (n = 30) and HIV (n = 32), have been analysed. Only three samples with very low concentrations of HCV (< 25–59 IU/mL) were false negative, and no false positive samples have been found. Complete data of the study will be presented at the meeting.

Conclusion The multiplex AmpliSens HCV/HBV/HIV-FRT real-time PCR proved to be highly sensitive and specific. Accordingly, this rapid, technically simple and low cost assay might be effectively used for screening of human donors as well as for other diagnostic purposes

P5.088 CHLAMYDIA TRACHOMATIS AND NEISSERIA GONORRHOEA DIAGNOSIS BY NUCLEIC ACID AMPLIFICATION TESTS AMONG FEMALE ENTERTAINMENT WORKERS (FEWS) IN CAMBODIA

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[1]**J R Papp**, [2]M Chandara, [2]M Phalkun, [1]C Phillips, [1]C Farshy, [3]C Hy, [3]M Downer, [2]M Vun, [3]W Killam. *[1]CDC, Atlanta, GA, United States, [2]NCHADS, Phnom Penh, Cambodia, [3]CDC, Phnom Penh, Cambodia*

Background Accurate diagnosis of chlamydia and gonorrhoea infections followed by appropriate treatment are critical steps in preventing transmission and morbidity. Sex workers are a target population for lab-based screening. This study compared the performance of commercially available nucleic acid amplification tests (NAATs) to detect chlamydia and gonorrhoea infections among FEWs in Cambodia.

Methods In 2011, 2564 FEWs were recruited and consented into a national prevalence survey for sexually transmitted infections (STIs) in Cambodia. Two self-collected vaginal swab specimens were obtained from 2525 FEWs. One swab was placed in m2000 media for testing with m2000, and the other was placed in GeneLock media for testing with AC2 and GeneXpert. Specimens were tested for chlamydia and gonorrhoea with the Abbott m2000 and Aptima AC2 assays. Samples with discrepant results were tested with the Cepheid GeneXpert assay. The reference standard was defined as results from two of three assays being in agreement.

Results By reference standard, chlamydia and gonorrhoea were detected in 21.2% and 7.0% of samples respectively. The m2000 and AC2 assays detected chlamydia in 499 specimens, and discordant results were found in 127 specimens. When compared to the reference standard, the m2000 sensitivity and specificity for chlamydia was 99.1% and 95.8% respectively. The sensitivity and specificity of AC2 for chlamydia was 94.4% and 99.6%. Gonorrhea was detected by both assays in 134 specimens while 110 yielded discordant results. The m2000 was 97.7% and 97.3% sensitive and specific for gonorrhoea while sensitivity and specificity of AC2 was 78.0% and 99.9% respectively.

Conclusions Chlamydia and gonorrhoea are prevalent STIs among Cambodian FEWs. Both NAATs had high sensitivity and specificity for chlamydia, and high specificity for gonorrhoea, but the AC2 sensitivity for gonorrhoea was low. Given high sensitivity and specificity of the assays, cost and usability will be important factors for ongoing programmatic use.

P5.089 CONFIRMATION OF HIGH SPECIFICITY OF AN AUTOMATED ELISA TEST FOR SEROLOGICAL DIAGNOSIS OF SYPHILIS - RESULTS FROM CONFIRMATORY TESTING AFTER SYPHILIS SCREENING AND SENSITIVITY ANALYSIS IN THE ABSENCE OF A GOLD STANDARD

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[1,2]L van Dommelen, [3,4,2]**C J P A Hoebe**, [1,2]F H van Tiel, [1,2]C Thijs, [1,2]V J Goossens, [1,2]C A Bruggeman, [1,2]I H M van Loo. *[1]Maastricht University Medical Centre, Maastricht, The Netherlands; [2]CAPHRI School of Public Health and Primary Care, Maastricht, The Netherlands; [3]Public Health Service South Limburg, Geleen, The Netherlands; [4]Maastricht University Medical Centre, Maastrich, The Netherlands*

Background In clinical microbiology laboratories, serological diagnostic assays are usually implemented after evaluation using a selected sample collection. We have previously evaluated the performance of the Bioelisa Syphilis 3.0 compared with the *Treponema pallidum* Particle Agglutination (TPPA) in a selected collection of serum samples (syphilis positivity rate 44%) and found a sensitivity and specificity of both 100%. In the current study we have compared the specificity of Bioelisa Syphilis 3.0 after clinical implementation as a syphilis screening test with the specificity found in the previous evaluation to assess whether the high specificity would stand up in clinical practise.

Methods We included 14,622 sera (positivity rate 0.9%) sent to the laboratory for syphilis serology in the period between October 2007 and February 2010.

Results We confirm the initially reported specificity and further narrow down its confidence interval (specificity 99.5%, 95% CI 99.4–99.6%), and show that this high specificity is valid across diverse patient categories. Here we demonstrate that differences in positive predictive values between patient categories reflect the prevalence of syphilis in these categories, and are not due to differences in specificity. In addition, in a sensitivity analysis we show that these conclusions are robust for several assumptions.
Conclusion Our analysis shows that the high specificity found in the initial study, stands up after implementation in a population with a low syphilis prevalence (0.9%). Using a selected serum sample collection is therefore a valid manner in the evaluation of syphilis serological diagnostic assays. Confirmatory syphilis testing remains mandatory in low prevalence populations, even when the screening test has a very high specificity.

P5.090 EVALUATION OF A DOUBLE RAPID TEST FOR SYPHILIS AND HIV: SD BIOLINE HIV/SYPHILIS DUO

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[1]**M A Chiappe**, [1]L Lopez-Torres, [1]C Carcamo, [1]P Garcia, [2]R Peeling. *[1]Universidad Peruana Cayetano Heredia, Lima, Peru; [2]Clinical Research Unit, ITD London School of Hygiene & Tropical Medicine, London, UK*

Background Although syphilis and HIV are primarily transmitted through sexual intercourse, they can also be transmitted from mother to child during pregnancy or at delivery. Testing pregnant women for syphilis and HIV is an important public health measure to prevent vertical transmission. Several countries have included screening of pregnant women using rapid HIV testing, and recently also rapid syphilis testing. Screening pregnant women for both diseases with one test is not only desirable but could also be very convenient. We present the results of the laboratory-based evaluation of a new test: the SD Bioline HIV/Syphilis Duo.
Methods We used archived serum specimens characterised as positive or negative for HIV and/or Syphilis. The gold standard positive for HIV was EIA (Vironostika® HIV Uni-Form II Ag/Ab, bioMérieux) with confirmation using Western blot. The reference standard positive for syphilis was the Rapid Plasma Reagin test (RPR, bioMérieux) with confirmation using the *Treponema pallidum* Particle Agglutination (TPPA) assay (Fujireibio, Japan). Reference standard negatives were EIA negative and RPR negative for HIV and syphilis respectively. For Syphilis we used a total of 665 samples, including 198 positives, and for HIV we used 662 samples including 91 positives. There were 42 samples positive for both HIV and syphilis. The samples were tested with the SD Bioline HIV/Syphilis Duo by a laboratory technician blinded to the gold standard results.
Results For Syphilis we observed a sensitivity of 100% (198/198) and a specificity of 99.57% (465/467). The two RPR negative/Bioline positive samples were negative for TPPA. For HIV, both the sensitivity and specificity were 100% (91/91 and 571/571 respectively).
Conclusions The SD Bioline HIV/Syphilis Duo test has a good performance in archived sera. Its high sensitivity suggests that this dual test would be of use in screening programmes for syphilis and HIV.

P5.091 HEAD-HEAD COMPARISON OF REACTIVITY AND SIGNAL STRENGTH VALUE FOR REACTIVITY AMONG SEVEN TREPONEMAL ASSAYS: A PRELIMINARY REPORT

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[1]**Y F Fakile**, [1]H Jost, [1]S Kikkert, [1]K W Hoover, [2]J M Schapiro, [3]S M Novak-Weekley, [4]J M Chow, [4]I U Park. *[1]Centers for Disease Control and Prevention, Atlanta, GA, United States, [2]Regional Laboratory, Kaiser Permanente Northern California, Berkeley, CA, United States, [3]SCPMG Regional Reference Laboratories, North Hollywood, CA, United States, [4]CA Dept of Public Health-STD Control Branch, Richmond, CA, United States*

Background Automated immunoassays (AI) for detection of *T. pallidum* antibodies are increasingly used for syphilis screening in the United States. These assays demonstrate fast performance, reduced labour requirements, and high throughput with walk-away capability. Limited data are available about the relative seroreactivity among commercial treponemal assays, especially in low risk populations. Additionally, it is unknown to what extent the AI signal strength values, used to assess reactivity, are associated with non-AI treponemal reactivity. We compared concordance of seroreactivity among 7 treponemal tests and assessed AI signal strength values associated with reactivity.
Methods Previously identified reactive and nonreactive sera (n = 566) were obtained from Kaiser Northern and Southern California regional laboratories. All sera were tested with AIs: BioPlex 2200 Syphilis IgM/IgG (BioRad), treponemal LIAISON (DiaSorin), Advia-Centaur syphilis (Siemens), and non-AIs (INNOLIA syphilis score (INNOGENETICS), TrepSure (Phoenix Biotech), Treponemal Pallidum Particle Agglutination (TP-PA) (Fujirebio), and Fluorescent Treponemal Antibody-Absorption (FTA-ABS) (Zeus Scientific) tests. Reactivity was interpreted according to manufacturers' instructions.
Results Seroreactivity ranged from 40.5 – 43.9% for AIs, and 33.0–42.2% for non-AIs. In all 7 tests, 30% (167/566) were reactive, and positive agreement among assays was 82.3%. The overall seroreactivity among AIs was 38.9% (220/566) and positive agreement was 92.6%. Minimum signal strength values of 11.72 (Centaur, range: 1.1–45), 4.4 (BioPlex, range: 1.1–8) and 9.4 (Liaison, range: 1.1–70) correlated 100% with TPPA reactivity. The proportion of AI-seroreactive specimens that were also TP-PA reactive were: 86.5% (198/229) for BioPlex, 85.2% (202/237) for ADVIA-Centaur, and 81.6% (200/245) for LIAISON.
Conclusion Although there is some variation in seroreactivity among the 7 tests, there is good correlation. A large proportion of AI tests with a minimal signal-to-cutoff ratio were associated with a positive TP-PA, suggesting that a second treponemal test may not be necessary to confirm AI-reactive, RPR-nonreactive sera.

P5.092 EVALUATION OF A LABORATORY DEVELOPED TEST FOR THE DETECTION OF *TRICHOMONAS VAGINALIS* USING A MODIFICATION OF THE ABBOTT *M*2000 REALTIME SYSTEM

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[1]**J A Williams**, [1]L Eddleman, [1]A LeMonte, [1,2]B Van Der Pol. *[1]Indiana University School of Medicine, Indianapolis, IN, United States; [2]Indiana University School of Public Health, Bloomington, IN, United States*

Background Assays for the detection of *Trichomonas vaginalis* (TV) are available on certain commercial platforms. The objective of this study was to assess the performance characteristics of a new laboratory developed test (LDT) for the detection of TV from urine, and swab samples, when tested on the Abbott *m*2000 platform; a platform widely used for the detection of *C. trachomatis* (CT) and *N. gonorrhoeae* (NG).
Methods Residual swab samples that had been previously eluted into CT transport medium and urine were placed into Abbott transport tubes. Testing for CT/NG was performed on the *m*2000 platform per package insert; the remaining residual extracted DNA was used for TV testing on the *m*2000 platform. TV specific primers, probe, and thermal cycling conditions were optimised in our laboratory. Residual DNA from each sample was manually transferred to an amplification plate containing master mix. Real-time PCR was performed on the *m*2000 platform in open mode with the TV LDT results being compared to an LDT for TV that has been validated and used in our laboratory for more than a decade. Assay agreement was assessed using Kappa statistics.