Methods An online survey was designed based on a large-scale in depth focus discussion study among STI experts and professionals and distributed via email to current IUSTI members. Conditional logistical regression modelling will be used for data analysis. We present preliminary data here.
Results To date, 142 subjects took the online survey with 123 completing it: 44% (n = 63) male and 56% (n = 79) female. Most subjects were from Oceana (35%) followed by Europe (18%), America (18%), Africa (15%) and Asia (14%). The majority (59%) of participants were from developed countries. Unreliability (17%) was the greatest barrier for use of POCTs, followed by being laboratory-driven (15%) and time- frame (13%). Perceptions of STI POCT differed significantly between developing and developed country participants. The majority (85%) of participants from developing countries thought test cost was more important versus 67% from developed countries ($p < 0.05$). Participants from developing countries ranked early HIV seroconversion as top priority for new STI POCT while those from developed countries chose chlamydia. Only 24% from developing countries preferred to prioritise the development of chlamydia POCT as compared to 57% from developed countries.(p value?) In addition, the majority (53%) of participants from developed countries preferred a POCT with higher sensitivity but longer turn-around-time and much more expensive but only 28% from developing countries preferred this POCT ($p < 0.05$).
Conclusion One STI POCT may not fit all. Industry should consider country identified needs in development of future acceptable, usable STI POCT.

P5.084 MULTIPLEX CAPABILITY OF A FULLY-INTEGRATED, LOW-COST, ULTRA-RAPID PCR DEVICE WITH POINT-OF-CARE APPLICATIONS

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Background We have developed a novel Point-of-Care molecular assay system, io™, comprising an assay-specific Cartridge and Reader. With a turnaround time of just 30 minutes the System has an initial focus on rapidly detecting sexually-transmitted infections (STIs). The System has been developed to run tests that simultaneously detect *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (NG), each run with an internal control (IC). The assays utilise a novel electrochemical method that demonstrates low copy number amplification and detection. Here, we have developed a CT/NG/IC triplex assay where each target analyte is co-amplified prior to being differentially detected.
Methods The assays were run using prototype PCR Cartridges in conjunction with an ultra-rapid thermocycler. All reagents necessary to perform the assay were deposited into the Cartridge. A sample was added to the Cartridge, DNA extracted, and the resulting eluate reconstituted dried amplification reagents. Amplified targets were detected using electrochemically-labelled target-specific probes and a double-stranded DNA-specific nuclease to release the electrochemical labels. Released labels were detected by applying a voltage to a screen-printed carbon electrode. Measurable current at specific oxidation potentials indicated the presence of targets in the sample.
Results Initial analytical sensitivity of the triplex CT/NG/IC assay was evaluated by testing each target analyte in combination with various concentrations of the other two (including negative controls). Electrochemical detection demonstrated clear differentiation between peaks generated by each cleaved label and showed a limit of detection of ten genome copies. Negative samples showed no significant peaks.
Conclusions The results showed that reliable, differentiated detection of three targets in a single sample was possible across a wide range of concentrations of the three targets. While demonstrated here for three analytes, the Atlas high-multiplex technology will allow expansion of the Atlas io™ test menu to detect multiple STIs in a single sample.

P5.085 TREPONEMA PALLIDUM ANTIBODIES DETECTION BY A POINT-OF-CARE TEST AND RPR AND TPHA TESTS IN MSM ATTENDING A COMMUNITY BASED HIV ANONYMOUS CENTER - CHECKPOINT LX

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Background When available, point-of-care tests are very useful in the screening of STIs. They have affordable prices, need minimal equipment and training, results are immediately available, allowing treatment with no delay.
Objectives We describe the prevalence of syphilis in an MSM population attending an HIV Anonymous Testing Center (ATC), who stated that they were never infected with *Treponema pallidum*, as evaluated with a rapid test. Positive results were confirmed with the RPR and TPHA tests.
Materials and Methods Nine hundred and forty four individuals attending the HIV ATC were tested with the Determine Syphilis TP test. Those who were found to have reactive results had blood taken for confirmation with RPR and TPHA tests.
Results The rapid test was reactive in 44 of the 944 (4.7%) individuals. Samples were further tested with the RPR and the TPHA tests; 34 showed to have antibodies against *T. pallidum* in both tests, although one sample was reactive only at the 1:2 dilution in the RPR and its TPHA titer was 1:640. Six samples were only reactive for the TPHA test, while four were non reactive in both tests. The FTA-ABS was performed in these four samples and it was non reactive.
Discussion and conclusion: In accordance with the results of the rapid test, the percentage of reactive samples was 4.7% (44/944). However, when confirmatory tests were performed in the samples received in the laboratory, the percentage of reactive samples decreased to 4.2% (40/944). Furthermore, in six of these samples only the TPHA was reactive, meaning that these patients probably had a treated past infection, which was not detected as such by the rapid test.

In conclusion, the Determine Syphilis TP test seems to be useful as a screening test for syphilis, although it does not differentiate between treated and active syphilis.

P5.086 DIAGNOSIS OF EXTRA-GENITAL CHLAMYDIA AND/OR GONORRHOEA INFECTIONS BY VERSANT CT/GC DNA 1.0

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Objectives Nucleic acid amplification testing (NAAT) has become the preferred method to detect *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (GC) infections. Anyway, no commercial test has been cleared so far for use with extra-genital swab samples.

In this study Versant CT/GC DNA 1.0 (Siemens) performances have been evaluated by testing ocular, rectal or pharyngeal secretions collected by Siemens collection devices.
Methods Study group. A prospective study was performed with 7 newborns with conjunctivitis, and 183 subjects attending the STD Outpatients Clinic of St. Orsola Hospital, Bologna. The latter ones were enrolled because having unsafe receptive anal and/or pharyngeal sex intercourses.

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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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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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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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.