from urine specimens prepared by adding 4.5 ml to 4.5 ml of cobas® PCR media, and from swabs discharged in 1.0 ml of the same media. The cobas® 4800 system loaded extracted DNA, controls and amplification reagents into 96-well amplification plates. Plates were then covered and placed into the cobas® z480 real-time PCR instrument. Retesting in both cobas® 4800 and TaqMan 48 assays was performed to further investigate specimens providing discrepant results.

Results A total of 708 clinical specimens (293 male urines and 415 swab specimens, of which 356 self-collected vaginal swabs, 45 swabs from cervix and 14 swabs from male urethra) were analysed. The results were concordant in 98.5% of cases (697/708). Out of 708 samples, 50 provided positive results (17 men, 33 women). Three urine specimens and eight vaginal swabs provided discrepant results. Out of five specimens providing positive results in the reference CT assay, four were false-negative in the cobas® 4800 CT test. Out of six positive results by the cobas® 4800 assay, five were false-positive. After discrepancy analysis, the prevalence of the CT infection was 7.7% (55/708). The sensitivity and specificity of the cobas® 4800 CT/NG test were 92.7% (urine specimens 94.1%, swab specimens 92.1%) and 99.2%, respectively. The three false-negative results in swabs could be explained by the procedure not consistent with the manufacturer's instructions. Indeed, swabs were not inserted directly into the cobas® media vials.

Conclusion The cobas® 4800 CT/NG test is suitable for high through-put identification of the *C trachomatis* infection.

P3-S1.15 THE MOLECULAR DIAGNOSIS OF RECTAL GC AND CT INFECTIONS USING THE FTA ELUTE CARD FOR SPECIMEN COLLECTION AND THE REAL-TIME MULTIPLEX PCR FOR DETECTION

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Background To evaluate the potential use of the Whatman Indicating FTA Elute Micro Card for collection, transport, and storage of rectal swab specimens for subsequent detection of STD pathogens in MSM using a TaqMan-based real-time multiplex PCR.

Methods Two rectal swabs were obtained by the physician from each participant in a study to determine carriage of STD pathogens among MSM. One of the swabs was placed into a tube containing 1 ml of Genelock transport medium and while the other swab was firmly pressed onto an FTA Card with three side to side motions held at approximately 60° angle each time. Genomic DNA was eluted from three discs (3 mm diameter) punched out of each card after storage at room temperature for up to 6 months and tested by a real-time multiplex PCR assay which simultaneously detects *lymphogranuloma venereum* (LGV), non- LGV, *Chlamydia trachomatis* (CT), and *Neisseria gonorrhoeae* (GC), and human DNA control. For comparison, an aliquot of sample from genelock tube was extracted using the Qiagen DNA mini kit and tested with same real-time multiplex PCR assay.

Results Using purified DNA obtained from the Genelock specimens, the real-time multiplex PCR assay detected nine GC and 17 non-LGV CT; while 7 GC and 15 non-LGV CT were detected in DNA samples eluted from the FTA Cards and used directly for PCR. There were three GC and non-LGV co-infections and no LGV was detected using both specimen collection methods. A substantial number of specimens were found to be PCR inhibitory either collected in Genelock (18.3%) or on FTA Cards (15.4%).

Conclusions The FTA Elute Micro Card allows stable storage and convenient transport of rectal swab specimens at room temperature. DNA can be eluted from the card with simple processes instead of numerous purification procedures for downstream real-time PCR amplification and aetiology detection. This preliminary evaluation shows the potential use of FTA Card for rectal specimen collection and PCR testing, and may also provide a cost-saving alternative to expensive international shipping of specimens on dry ice from remote study sites.

P3-S1.16 COMPARISON OF THE ABBOTT M2000 REALTIME CT ASSAY FOR *CHLAMYDIA TRACHOMATIS* MONITORING IN TANZANIA COMPARED TO THE ROCHE AMPLICOR CT ASSAY

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Background The Abbott m2000 RealTime CT assay was evaluated as a new option for the detection of *Chlamydia trachomatis* in specimens obtained from Tanzania, and its performance was compared to the performance of the Roche Amplicor CT Assay.

Methods Duplicate swab specimens were collected from villages throughout Tanzania. 304 duplicate samples were shipped to the Johns Hopkins STD laboratory at 2–8°C for the detection of *C trachomatis*. All swab specimens were shipped in a dry state, expressed in 1 ml of sterile molecular grade DEPC water upon arrival, and analysed using the Roche Amplicor CT assay. Prior to Roche Amplicor amplification and detection, DNA extraction was performed using the Roche Magna Pure LC robot. The duplicate swab specimens were shipped to Indiana University for Abbott m2000 RealTime CT assay analysis. The bacterial load was measured by the DC value of the m2000 RealTime CT.

Results Of 304 specimens, 44 (14.5%) were positive for CT via Roche Amplicor CT assay, and 53 (17.4%) were positive for CT via Abbott m2000 RealTime CT assay. The relative quantitation for the m2000 assay ranged from DC 0.62 to DC 22.16. If the Roche PCR assay was considered to be the reference standard, the Abbott m2000 RealTime CT assay sensitivity was 44/44 (100%), specificity was 251/260 (96.53%), positive predictive value was 251/251(100%), and negative predictive value was 44/53 (83.01%). The κ score was 0.890. Discordant specimens, which were determined to be negative by Roche Amplicor and positive by Abbott m2000 RealTime, were tested by Gen-Probe TMA. Of nine discordant tests, two were positive, five were negative, and two were of insufficient volume for retesting. After discordant testing, there appeared to be five samples that were graded to be false positives by m2000. The Abbott m2000 RealTime CT assay sensitivity remained 100%, while specificity increased to 256/258 (99.2%). The negative predictive value increased to 46/48 (95.83%). The κ score was 0.9748 after discordant results were further analysed.

Conclusions Abbott m2000 RealTime CT assay demonstrates excellent sensitivity and specificity compared to the Roche Amplicor CT Assay for the detection of *C trachomatis*. It may be advantageous to be able to measure the relative concentration for CT in some epidemiologic studies.

P3-S1.17 SYNDROMIC MANAGEMENT OF CERVICITIS AND VAGINAL DISCHARGE AT A STI CLINIC IN JAMAICA: LOW CURE RATES FOR CHLAMYDIAL INFECTION AND TRICHOMONIASIS

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Background Management of cervicitis and abnormal vaginal discharge in Jamaica is based on the syndromic approach recommended by the

WHO. To evaluate current algorithms for treatment of gonorrhoea, chlamydial infection and trichomoniasis, we conducted laboratory testing with vaginal specimens from women presenting with cervicitis or vaginitis syndromes at a sexually transmitted infections clinic in Kingston and at follow-up to assess cure rates for these infections.

Methods From August, 2010 through January, 2011, vaginal swab specimens were obtained from 258 women >18 years old during a routine clinical examination prior to syndromic treatment according to local guidelines. Treatment for gonorrhoea, chlamydial infection and trichomoniasis was prescribed for women with cervicitis. Treatment for trichomoniasis, bacterial vaginosis and candidiasis was prescribed for women with abnormal vaginal discharge. Women returned the next week for follow-up assessment and specimen collection. Specimens were tested for *Neisseria gonorrhoeae* (NG) and *Chlamydia trachomatis* (CT) using APTIMA Combo2 and for *Trichomonas vaginalis* (TV) using APTIMA analyte-specific reagents. All baseline specimens were tested. Follow-up specimens from women with a positive baseline test or who remained symptomatic were also tested. Patients with a positive follow-up test were contacted and instructed to return to the clinic for additional treatment. Cure was defined as a positive baseline test and a negative follow-up test.

Results Baseline prevalence of infection with NG was 11.7%, CT was 20.7%, TV was 25.6%. At least one of these STIs was detected by laboratory testing in 40.7% of women. Co-infections were common. Women with TV were more likely to have NG or CT than women without TV (OR: 2.6, 95% CI 1.4 to 4.8). STI testing at follow-up indicated cure rates of 77.3% for NG, 43.5% for CT and 47.1% for TV infections. CT incidence at follow-up was 5.9%; no incident NG or TV infections were detected.

Conclusions With syndromic management, just over half of the STIs in women that were detected by laboratory testing at baseline were cured at follow-up. Reinfection, incorrect or inadequate treatment, failure to comply with treatment instructions or treatment failure could potentially explain prevalent STIs that were detected at follow-up. The low cure rates for chlamydial infection and trichomoniasis are cause for concern.

P3-S1.18 SIDE EFFECTS OF DOXYCYCLINE IN ADOLESCENTS TREATED FOR PELVIC INFLAMMATORY DISEASE

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Background Our purpose was to assess adverse reactions to doxycycline in adolescents under treatment for PID.

Methods At the Harris County (Houston), Texas, USA Juvenile Detention Center from May 2008 through January 2010, we evaluated adolescents in whom we diagnosed PID. We used the diagnostic criteria and outpatient antibiotic regimen for PID recommended by the CDC. We gave 250 mg ceftriaxone intramuscularly once, and, if they were not pregnant, vomiting, or ill enough to also require metronidazole, we prescribed doxycline, 100 mg twice a day for 14 days. The doxycycline was given before, during, or after breakfast, and approximately 2 h after supper. With the medicine, patients were routinely given a packet of two crackers. We re-assessed these patients at 48—72 h and again at least at 7 and 14 days. At each follow-up, we discussed side effects of doxycycline.

Results We evaluated 141 consecutive patients in whom we made the diagnosis of mild to moderate PID: 55% were black, 31% Hispanic, and 15% white. The mean age (SD) was 15.4 (1.2) years. Of the 141 patients, 86 (61%) had no problems when the doxycline was given with two crackers. Forty-five (32%) required more substantial food to avoid nausea and/or vomiting: the medication was given immediately after breakfast or with a sandwich after supper. Those who had side effects in the morning had usually skipped breakfast. Ten (7%) complained of significant gastrointestinal side effects that were not relieved by the simultaneous ingestion of food, and we gave a dose of promethezine 1 h before the doxycycline.

Conclusion 39% of our patients required more than a small amount of food (two crackers) to avoid gastrointestinal side effects from doxycline. Our results suggest that clinicians should advise adolescents to take this antibiotic after eating a greater amount of food if a small snack does not prevent this problem. Because some patients (7%) did not tolerate doxycline even after they ate a meal or a sandwich, we also recommend early contact with patients who have PID to assess the need to change medications or to add an anti-emetic.

P3-S1.19 EVALUATION OF THE COBAS® 4800 CT/NG TEST USING CLINICIAN AND SELF-COLLECTED VAGINAL SWABS, CERVICAL SPECIMENS IN PRESERVCYT SOLUTION, AND PHARYNGEAL THROAT WASH SPECIMENS

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Objective To evaluate the limit of detection (LOD), inclusivity, exclusivity, and interfering substances of the cobas® 4800 CT/NG Test using vaginal, PreservCyt, and pharyngeal specimens.

Methods *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (NG) cultures were diluted into pools of negative patient specimens at six concentrations to determine the LOD (lowest concentration giving a ≥95% hit rate). A panel of 15 serovars of CT, plus the Swedish variant (nvCT), and 45 strains of NG was diluted into each sample matrix to determine inclusivity. To ensure specificity, a panel of 184 non-CT and non-NG organisms that may be found in the oral or urogenital region was tested at Ġ≥10^5 CFU or copies/ml. The organisms were diluted into CT/NG positive and negative samples. Ten CT/NG positive and negative samples were spiked with blood (up to 5%), leukocytes (up to 10^7 cells/ml), cervical mucus, and saliva at concentrations up to 10% to check for interference. Ten (for pharyngeal) and 18 (for urogenital) over-the-counter products were also tested.

Results LODs were as follows: Vaginal CT 10 IFU/ml, NG 100 CFU/ml; PreservCyt CT 0.6 IFU/ml, NG 3.5 CFU/ml, Pharyngeal CT 0.5 IFU/ml, NG 2.25 CFU/ml. All 15 serovars of CT, plus the Swedish variant (nvCT), and 45 strains of NG were detected at, or near the LOD. No cross reactivity was noted with 184 non-CT and non-NG organisms in any specimen type. Vaginal but not PreservCyt samples showed interference from leukocytes at >10^6 cells/ml. This interference was noted as clot detections and samples were not processed. Pharyngeal samples showed false negative results in the presence of blood at >0.25%, and saliva at >2.5%. No interference was noted with any over-the-counter products in any specimen type.

Conclusions Vaginal, PreservCyt, and pharyngeal specimens are suitable sample types for the cobas® 4800 CT/NG Test.

P3-S1.20 AETIOLOGY OF URETHRAL DISCHARGE SYNDROME AND ITS ASSOCIATION WITH SEXUAL PRACTICES AMONG MALES ATTENDING STI CLINICS IN INDIA

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Background Studies to validate the aetiology of urethral discharge (UD) syndrome are limited in India. The objectives of the study