ProbeTec lysis buffer. US and UPT urine specimens were processed according to the manufacturer's recommended procedure with the BD ProbeTec ET assay (Becton Dickinson).
Results Out of 134 males from the detention center and the STD clinic, 115 were negative and 19 positive for either CT or NG in both US and UPT collection devices. Five patients were positive for both CT and GC. The CT prevalence was 8.2 %. The NG prevalence was 10.44%.
Conclusions Good results agreement was found between the Copan UriSwab and the BD urine collection devices for the detection of CT and GC with the BD ProbeTec ET assay. The UriSwab is easy to transport and process in the laboratory for the detection of CT, GC and other STI infectious agents with molecular assays and can also be used for culturing all urogenital bacteria. The UriSwab can facilitate self-collection for STI screening.

P3-S1.32 A VALIDATION STUDY OF THE GEN-PROBE APTIMA COMBO2 (AC2) ASSAY FOR DETECTING *CHLAMYDIA TRACHOMATIS* AND *NEISSERIA GONORRHOEAE* IN DRY SWABS

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Background Vaginal swabs are an optimal specimen for detection of *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (GC). The Gen-Probe Aptima system (Aptima) requires use of a sample transport media, whereas the Becton Dickinson ProbeTec ET System (Probetec) can utilise dry swabs. The use of dry swabs allows for collection of STD test samples at non-clinical testing venues.
Methods Swabs were collected from 180 sexually active women aged 15–25 years, who had asymptomatic BV and two or more risk factors for STDs. The participants received home vaginal swab self-collection kits for BV and STD testing. Participants mailed the kits directly to the lab. Probetec swabs were tested within 14 days of collection. A dry transport swab was placed into an Aptima vaginal swab collection tube, generally within 14 days of collection and stored at −80°C. Aptima swabs were thawed and tested in batches. Specimens with discordant results in the two nucleic acid amplification test systems were retested with both systems.
Results There were 58 women (32%) positive for GC and 62 (34%) positive for CT. The level of agreement between the Aptima and Probetec systems was higher for CT (176/180, 98%) than for GC (171/180, 95%). Of the 13 samples with discordant results, five were resolved with repeat testing. All eight remaining samples had discordant GC results: seven were Probetec positive, Aptima negative and one was Probetec negative, Aptima positive.
Conclusions Vaginal swabs tested in the Aptima system were equivalent to Probetec in detecting CT but were less sensitive for the detection of GC. Dry swabs cannot be recommended for detection of GC from vaginal swabs using the Aptima system.

P3-S1.33 EVALUATION OF THE ROCHE COBAS 4800 FOR THE DETECTION OF *CHLAMYDIA TRACHOMATIS* AND *NEISSERIA GONORRHOEAE* USING MINIMALLY INVASIVE SAMPLES IN WOMEN

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Background The Roche cobas 4800 (cobas) is a new diagnostic assay that utilises an automated workstation to isolate nucleic acids from clinical specimens and a real time instrument for the detection of *C trachomatis* (CT) and *N gonorrhoeae* (NG). The objective of this study was to compare the performance characteristics of the cobas to the BD Viper (Viper) and GenProbe Aptima Combo 2 (AC2) assays for the detection of CT and NG using a patient infected standard (PIS).
Methods Specimens were obtained from women attending STD, family planning, or OB/GYN clinics from 12 geographically distinct locations. Urine and vaginal swabs were obtained from each participant as were endocervical (data not shown) and liquid based cytology samples (data not shown). Women were randomised to either self-obtained (SOV) or clinician-obtained (COV) vaginal swab collection. Four sites performed testing by AC2, cobas, and Viper for urine and by cobas for vaginal swabs. A patient was considered infected if at least two of the assays with different molecular targets gave positive results from cervical or urine samples.
Results Overall CT sensitivity ranged from 91.9% to 93.9% and specificity ranged from 99.7% to 99.8% for all sample types. Overall GC sensitivity ranged from 97.0% to 100% and specificity from 99.9% to 100% see Abstract P3-S1.33 table 1.
Conclusions The cobas assay has excellent sensitivity and specificity when compared to PIS. There was no difference in performance between the SOV and COV specimens or between the vaginal and urine specimens. Self-obtained vaginal swabs provide opportunities for increased efficiency within the clinical settings. The assay is easy to perform, automated, and can be completed in <4 h.

P3-S1.34 EVALUATION OF THE ROCHE COBAS 4800 FOR THE DETECTION OF *CHLAMYDIA TRACHOMATIS* AND *NEISSERIA GONORRHOEAE* USING ENDOCERVICAL SPECIMENS

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Background The Roche cobas 4800 (cobas) is a new diagnostic assay that utilises an automated workstation to isolate nucleic acids from clinical specimens and a real time instrument for the detection of *C trachomatis* (CT) and *N gonorrhoeae* (NG). The objective of this study was to compare the performance characteristics of the cobas to the BD Viper (Viper) and GenProbe Aptima Combo 2 (AC2) assays for the detection of CT and NG using a patient infected standard (PIS).
Methods Specimens were obtained from women attending STD, family planning, or OB/GYN clinics from 12 geographically distinct

Abstract P3-S1.33 Table 1 Sample Type Vag

Sample Type	n	CT Sensitivity [95% CI]	CT Specificity [95% CI]	n	NG Sensitivity [95% CI]	NG Specificity [95% CI]
Urine	4271	**92.3%** (251/272) [88.5 to 94.9]	**99.7%** (3989/3999) [99.5 to 99.9]	4274	**98.5%** (64/65) [91.8 to 99.7]	**99.9%** (4206/4209) [99.8 to 100]
SOV	2083	**93.9%** (123/131) [88.4 to 96.9]	**99.7%** (1946/1952) [99.3 to 99.9]	2083	**97.0%** (32/33) [84.7 to 99.5]	**100%** (2049/2050) [99.7 to 100]
COV	2165	**91.9%** (125/136) [86.1 to 95.4]	**99.8%** (2024/20 290) [99.4 to 99.9]	2164	**100%** (33/33) [89.6 to 100.0]	**100%** (2130/2131) [99.7 to 100.0]

Abstract P3-S1.34 Table 1 Sample Type Cx

Sample type	n	CT sensitivity [95% CI]	CT specificity [95% CI]	n	NG sensitivity [95% CI]	NG specificity [95% CI]
ES	4253	**91.6%** (240/262) [87.6 to 94.4]	**99.8%** (3984/3991) [99.6 to 99.9]	4252	**95.6%** (65/68) [87.8 to 98.5]	**100%** (4182/4184) [99.8 to 100]
LBC Prequot	4238	**92.8%** (246/265) [89.1 to 95.4]	**99.6%** (3958/3973) [99.4 to 99.8]	4239	**97.1%** (67/69) [90.0 to 99.2]	**99.9%** (4167/4170) [99.8 to 100]
LBC Postquot	4202	**89.7%** (235/262) [85.4 to 92.8]	**99.7%** (3930/3940) [99.5 to 99.9]	4203	**95.7%** (66/69) [88.0 to 98.5]	**100%** (4132/4134) [99.8 to 100.0]

locations. Endocervical swabs (ES) and samples in ThinPrep liquid based cytology medium (LBC) were obtained from each participant as were urine samples (data not shown) and vaginal swabs (data not shown). LBC were sampled prior to cytology (prequot) for cobas and AC2 and after cytology (postquot) for cobas only. A patient was considered infected if at least 2 of the assays with different molecular targets gave positive results from the ES or urine samples.

Results Overall CT sensitivity ranged from 89.7 to 92.8% and specificity ranged from 99.6 to 99.8% for all sample types. Overall GC sensitivity ranged from 95.6 to 97.1% and specificity from 99.9 to 100% see Abstract P3-S1.34 table 1.

Conclusions The cobas assay has excellent sensitivity and specificity when compared to PIS. Equivalent performance was observed for the ES and LBC samples, providing clinicians with flexibility to tailor endocervical sample acquisition to their particular setting. There was no statistical difference between the pre- and post-quot LBC samples allowing specimen handling to be suited to the needs of the microbiology and cytology laboratories. The assay is easy to perform, automated, and can be completed in <4 h.

P3-S1.35 SYSTEMIC AND MUCOSAL IGG AND IGA ANTIBODY RESPONSES IN GENITAL *CHLAMYDIA TRACHOMATIS* INFECTION

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Background *Chlamydia trachomatis* (CT) is the most common sexually transmitted infection in the UK. Screening and treatment programmes do not appear to have reduced the population levels of Chlamydia. Ideally a vaccine stimulating both humoural and T-cell responses against CT should be developed. We therefore wished to further study the humoural immune response to chlamydial infection both systemically and mucosally in the female genital tract in natural infection.

Methods Cervical secretions (obtained with Weck-Cel spears, Medtronic) and serum from twenty-six women diagnosed chlamydia-positive were assessed for Chlamydia-specific IgA and IgG responses (Anilab systems, Finland) at baseline and at 4 months follow-up. Samples from thirty chlamydia-negative women were used as controls. The Mann–Whitney non-parametric test was used to compare groups.

Results There was a significant difference between CT+ve and CT−ve IgG in serum samples (IgG median absorbance values p=0.006, median CT-ve samples 0, +ve samples 0.255) and IgA serum values (p=0.005, CT+ve median 0.491, CT−ve 0.119). There was no significant difference between cervical IgG and IgA levels between CT+ve and CT−ve women (IgG median absorbance values, CT+ve samples 0.012, 0 CT−ve; IgA CT−ve 0.202, CT+ve, 0.032), although there was a trend towards raised cervical IgG in CT +ve samples (p=0.08). There was no significant difference between antibody levels at baseline and 4 months for the 10 CT+ve women who have returned so far.

Discussion Our data suggests that the local and systemic antibody responses to genital chlamydial infection are highly variable. No CT +ve samples studied display positive absorbance levels in all four tested parameters. However, serum IgG and IgA responses are significantly raised in CT+ve individuals, and these values remain high at 4 months follow-up. This is in contrast to local responses which are not significantly different between CT+ve and CT−ve individuals, although there is a trend towards raised cervical IgG in CT+ve samples. The results of this study so far indicate that local immune responses, in comparison to systemic responses, are not well-defined. This may have implications both for chlamydial vaccine development, and mucosal assessment of candidate vaccines.

P3-S1.36 ASSESSING THE DIAGNOSIS AND TREATMENT OF URETHRITIS AMONG MEN ATTENDING AN URBAN STD CLINIC

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Background Urethritis is inflammation of the urethra, the main symptoms of which are dysuria and discharge, and two of the most common causes of which are *Chlamydia trachomatis* and *Neisseria gonorrhoeae*. The objectives of this study were to: (1) Determine the prevalence of atypical urethritis among participants, (2) Assess the sensitivity and specificity of using gram stain to diagnose gonorrhoea, and (3) Evaluate the effect of diagnostic test used on the time to treatment.

Methods A random sample of 600 eighteen to 60-year-old men who visited the SE STD Clinic from January 2008 to December 2009 and had a gram stain and nucleic acid amplification test (NAAT) performed were studied. Atypical urethritis was defined as having evidence of inflammation on gram stain but no evidence of gonorrhoea (ie, NGU) and a NAAT negative for both bacteria. The sensitivity and specificity of gram stain were calculated using NAAT as the gold standard. An analysis of variance was used to assess the relationship between time to treatment and diagnostic test—F statistics and corresponding p values were calculated. All statistical analyses were performed using SAS software V. 9 (SAS Institute Inc.) and WinPepi (Abramson, J.H. Epidemiologic Perspective and Innovations).

Results Of the 600 cases, 493 (82.3%) were Black, 253 (42.2%) had clinical urethritis, and 204 (47.0%) had a previous STD history. The mean age was 30.6 years (SD=10.3). One hundred and five cases of gonorrhoea, 110 cases of chlamydia, and three co-infections were diagnosed (Abstract P3-S1.36 table 1). None of the men diagnosed with gonorrhoea via gram stain were co-infected with chlamydia. The prevalence of atypical urethritis among this study population was 31.2%. The sensitivity of gram stain was 84.3%, the specificity was 100%, the positive predictive value (PPV) was 100%, and the negative predictive value (NPV) was 96.7%. The mean time to treatment was 2.52 days (SD=2.17). Analysis of variance revealed that gram stain (F=41.50, p<0.0001) and NAAT (F=19.18, p<0.0001) had significantly different effects on time to treatment.