

Introduction Rapid Point-Of-Care Tests (POCTs) for *Chlamydia trachomatis* (CT) may reduce onward transmission and reproductive sexual health (RSH) sequelae by reducing turnaround times between diagnosis and treatment. The io single module system (Atlas Genetics Ltd) runs clinical samples through a microfluidic CT cartridge, delivering results in 30 min. We evaluated its performance in four RSH clinics.

Methods 757 females aged >16 provided additional-to-routine self-collected vulvovaginal swab (VVS). Samples were tested fresh on io within 7 days of collection or were frozen at -80°C for later testing. The io CT-assay performance was compared against clinic BD Viper™ Nucleic Acid Amplification Test (NAAT), with discrepant results resolved on the Artus CT/NG assay. The gold standard for discrepant results required agreement from 2/3 tests. Factors associated with CT infection were analysed using logistic regression.

Results Insufficient volume (n=3), missing clinic NAAT data (n=21), and 'invalid' (n=24), where io failed to give a result on two successive runs, meant final analyses were conducted on 709 women (94.3%). CT prevalence was 7.2% (51/709). Sensitivity, specificity, positive (PPV) and negative (NPV) predictive values were respectively: 96.1% (95% Confidence Interval (CI): 86.5–99.5), 97.7% (95% CI: 96.3–98.7), 76.6% (95% CI: 64.3–86.2) and 99.7% (95% CI: 98.9–100). There was no significant difference in performance between fresh and frozen samples, or between symptomatic and asymptomatic patients. Risk factors associated with CT infection were sexual contact CT only.

Conclusion The io CT-assay is the only 30 min, fully automated, high-performing NAAT currently CE-marked for CT diagnosis in women, making it a highly promising diagnostic, to enable specific treatment, initiation of partner notification and appropriately intensive health promotion at the point of care.

010.3 PROSPECTIVE CLINICAL EVALUATION OF THE APTIMA MYCOPLASMA GENITALIUM ASSAY (CE-IVD) IN VARIOUS SPECIMENS FROM SYMPTOMATIC AND ASYMPTOMATIC PATIENTS IN FRANCE

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Introduction The aim of the study was to evaluate the clinical performances of the Aptima *Mycoplasma genitalium* CE-IVD assay (AMG, Hologic) for the detection of *M. genitalium* in clinical male and female samples in comparison with the in-house real-time PCR (qPCR) assay routinely used in our laboratory. The Aptima assay uses target capture, transcription-mediated amplification (TMA), and hybridization protection to detect the *M. genitalium* 16S rRNA.

Methods A total of 1431 clinical specimens obtained from 1235 patients were prospectively enrolled from February to June 2016 at the Bacteriology Department of Bordeaux University Hospital (France). For the AMG assay, various specimens collected in the appropriate APTIMA medium were processed according to the manufacturer's instructions on the Panther system (Hologic). DNA extracts were obtained using the MagNA Pure 96 DNA and viral NA small Volume Kit on the MagNA Pure 96™ instrument (Roche Diagnostics). The

in-house *M. genitalium* qPCR assay targeting the MgPa adhesin gene was performed on the cobas z480 analyzer (Roche Diagnostics). Additional RUO *M. genitalium* TMA assays, MGAlt1 and MGAlt2, and the CE-marked SpeedX Resistance-Plus™ MG assay were performed on the blinded discordant specimens to determine a definitive *M. genitalium* infection status. All the confirmed *M. genitalium*-positive specimens were tested for macrolide resistance using three comparative assays: the in-house FRET qPCR assay, the SpeedX Resistance-Plus™ MG assay and the nested reverse-transcription PCR sequencing assay.

Results The comparison of the AMG assay with the in-house qPCR result showed a moderate correlation, with a kappa value of 0.69. The TMA assay had a very good clinical sensitivity (100%) and specificity (99.33%) for *M. genitalium* detection across all specimen types tested. Its sensitivity was significantly higher than that of the in-house qPCR, 100% versus 61.33%. The prevalence of *M. genitalium* infection was 5.90% (72/1220 patients) and the prevalence of macrolide resistance-associated mutation was 5.47% (4/73).

Conclusion The Aptima *Mycoplasma genitalium* assay performed on the fully automated Panther system is a very sensitive and specific method for detection of *M. genitalium* in clinical specimens. On the Panther platform this assay can be easily combined with the assay for chlamydia and gonorrhoea detection from the same sample.

010.4 CONCORDANCE BETWEEN RANDOM CATCH URINE AND MID-VAGINAL MICROBIOTA

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Introduction The vaginal microbiota is thought to play a protective role against STIs. While urine has long been used for detection of genital STIs, there have been few studies evaluating the use of urine samples in vaginal microbiome studies. We hypothesise that urine samples could serve as a surrogate for vaginal swab collection. We sought to compare mid-vaginal swabs and random catch urine samples.

Methods Mid-vaginal swabs and random catch urine samples were collected in one sitting from 75 reproductive-age women. Microbiota composition was characterised by sequencing the V3-V4 regions of the 16S rRNA gene on the Illumina platform. Vaginal microbiota were targeted for classification using PECAN, a rapid and accurate taxonomic classifier designed for the vaginal environment. Hierarchical clustering was used to assign community state type (CST) to each sample. CST-I, -II, -III, and -V are dominated by *L. crispatus*, *L. gasseri*, *L. iners* and *L. jensenii*, respectively, while CSTs IV-A and IV-B represent low-Lactobacillus states with an array of strict and facultative anaerobes. Kappa statistics and Jensen-Shannon distances were used to evaluate the concordance of urine and vaginal samples.

Results A 77% concordance and a 0.70 kappa value were observed for CST assignments, indicating substantial agreement in microbiota structure and composition between vaginal and urine samples within a woman. Out of 17 discordant pairs, 10 pairs had one sample assigned to CST-IV and the other to

CST-III. These two CSTs are known to be associated with rapidly fluctuating dysbiotic states. When comparing the population structure of all urine and vaginal samples, no statistical differences were observed (PERMANOVA: $F_{1,148}=1.0815$, $p=0.31$).

Conclusion Vaginal and random catch urine samples from the same participant showed substantial agreement on bacterial composition. Random catch urine samples could present another sampling option to assess the vaginal and urogenital microbiota.

010.5 TESTING OF BD MAX™ VAGINAL PANEL RESIDUAL SPECIMENS USING THE BD MAX™ CT/GC/TV ASSAY

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Introduction Vaginitis is a common problem in women's health globally. Sexually Transmitted Infections (STI) are also highly prevalent and often have symptoms similar to vaginitis. *Trichomonas vaginalis* (TV) is a causative agent of vaginitis that is exclusively sexually transmitted and thus falls into both of these diagnostic categories. To better understand co-infection rates for STI and vaginitis, we used the BD MAX- CT/GC/TV (MCGT) assay for detection of *Chlamydia trachomatis* (CT), *Neisseria gonorrhoeae* (GC) and TV on samples previously tested with BD MAX- Vaginal Panel (MVP).

Methods Women who reported vaginitis symptoms were enrolled in a study that evaluated the performance of MVP. A subset of the vaginal swabs collected and frozen was tested using MCGT. The presence of CT, GC or TV was assessed in women with Bacterial Vaginosis (BV) only, *Candida spp.* only (Ca), BV+Ca, or negative for vaginitis as determined by the MVP. This last category included women with all negative results as well as women with TV only, since for this analysis TV was classified as an STI.

Results Self-collected samples gave reportable results for 528 women to date. 210 (39.8%), 62 (11.7%), 95 (18.0%) and 161 (30.5%) were diagnosed with BV, Ca, BV+Ca or no vaginitis, respectively. TV, CT and GC were present in samples from 62 (11.7%), 32 (6.1%) and 8 (1.5%), respectively. STI positivity rates among those with BV, Ca, BV+Ca and vaginitis negative women were 23.3, 9.7, 25.3% and 8.7%. Of the 62 TV results obtained with MCGT, 61 were detected with MVP, with an overall agreement of 99.8% (527/528).

Conclusion STI rates were high among women seeking care for vaginitis and co-infection was common. While treatment for vaginitis may include appropriate management for TV, CT and GC management requires appropriate diagnostics in order to prescribe the appropriate treatment. Testing of the same vaginal specimen on the BD MAX instrument for both vaginitis and STI diagnostics is an efficient solution which maximises the number of results available to effectively guide patient management.

010.6 CLEARANCE OF MYCOPLASMA GENITALIUM AND TRICHOMONAS VAGINALIS AMONG ADOLESCENTS AND YOUNG ADULTS WITH PELVIC INFLAMMATORY DISEASE: RESULTS FROM THE TECH-N STUDY

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Introduction While the broad-spectrum antibiotics recommended for treatment of pelvic inflammatory disease (PID) effectively treats *Neisseria gonorrhoeae* (GC) and *Chlamydia trachomatis* (CT), coverage may be inadequate for *Mycoplasma genitalium* (MG) and *Trichomonas vaginalis* (TV). Untreated MG and TV may result in vaginal dysbiosis, increasing the risk for recurrent STIs and HIV. The objective of this study is to evaluate longitudinal MG and TV outcomes compared with GC/CT outcomes over the 90 day following treatment.

Methods 259 Female AYA aged 13–25 years with mild-moderate PID enrolled in a randomised trial of a technology enhanced community health nursing study designed to prevent STIs after PID. Participants completed audio computer-assisted self-interviews and provided vaginal specimens at baseline, 30 days and 90 days and were notified and referred for treatment for positive results. Generalised estimating equations were used to measure changes in the prevalence of MG and TV compared with GC/CT over time.

Results At baseline, 29% were positive for CT or GC at baseline (25% CT and 8% GC), 19% for MG, and 16% for TV. Ninety-four percent of the effective sample was retained at 90 days and 44% reported completing all medication doses. At 30 days, 17 (8%) of women were positive for CT or GC, while 36 (17%) were MG positive, and 22 (10%) were positive for TV. At 90 days, 13 (6%) were positive for CT or GC, 39 (18%) for MG, and 30 (14%) for TV. GC/CT infection was declining on average over time (odds ratio 0.48, 95% CI 0.36 to 0.63 per additional month). MG was not significantly changing over time (odds ratio 0.94, 95% CI 0.84 to 1.05), at a different rate than GC/CT ($p<0.001$). TV was also consistent over time (odds ratio 0.92, 95% CI 0.78 to 1.09), also at a different rate than GC/CT ($p<0.001$).

Conclusion Youth treated with the recommended syndromic management protocols clear infection with GC/CT, but often have recurrent, persistent, and/or new MG/TV infections during the 90 day post-PID follow-up period.

Oral Presentation Session 11 STI Diagnosis and Clinical Observations

011.1 DECLINE IN GENITAL SHEDDING IN THE YEAR AFTER FIRST CLINICAL EPISODE GENITAL HERPES SIMPLEX VIRUS TYPE 1

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