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 ViperTM Nucleic Acid Amplification Test (NAAT), with discrepant results resolved on the Artus CT/NG assay. The gold standard for discrepants 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.

O10.3 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 96TM 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-PlusTM 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-PlusTM 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.

O10.4 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. jensenni*, 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