

types were calculated by comparing results to the patient infected status (PIS) algorithm of wet mount and TV culture.

Results Results from 838 participants were available for evaluation. The overall prevalence of TV in this population was 120/838 (14.3%). Using the self-collected vaginal swab as the reference comparator, there was excellent agreement between vaginal swabs, neat and UPT urine, and endocervical swabs (kappa 0.93–0.95). Of these specimen types, endocervical had the lowest yield but still had excellent agreement with vaginal specimens.

Conclusions Vaginal, urine, and endocervical samples showed excellent agreement for diagnosis of TV and are all acceptable specimens for use with the BD Viper™ System in extracted mode. The development of NAATS testing for TV, especially with the potential use of self-collected vaginal swab and urine specimens should greatly facilitate screening for this common STI.

P2.075 EVALUATION OF FEMALE URINE AND VAGINAL SWABS USING THE BD PROBETEC™ TRICHOMONAS VAGINALIS Qx AMPLIFIED DNA ASSAY ON THE BD VIPER™ SYSTEM IN EXTRACTED MODE AND A CLEARED NAAT TV ASSAY AS COMPARED TO PIS

doi:10.1136/sextrans-2013-051184.0340

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Background *Trichomonas vaginalis* (TV) is a sexually transmitted organism associated with vaginitis, cervicitis, urethritis, low birth weight, preterm delivery, pelvic inflammatory disease and HIV transmission and acquisition. Nucleic acid amplification testing improves the sensitivity for detection of pathogens. The performance of the BD ProbeTec™ TV Qx (TVQ) Amplified DNA Assay and the Gen-Probe Aptima TV assay were compared to patient infected status (PIS) established by the InPouch TV culture and wet mount for the detection of trichomonas in women.

Methods Participants with symptoms of trichomonas or presenting for routine visit were enrolled from seven geographically diverse centres. First void urine, a patient collected vaginal swab, and three clinician-collected vaginal swabs were obtained from each participant. Urine was aliquoted into BD neat and UPT tubes as well as an Aptima UTT tube. The first two clinician-collected vaginal swabs were randomised for wet mount and InPouch TV culture. The third was used for the Aptima TV assay.

Results There were a total of 1034 compliant participants with evaluable PIS. Specimen and instrument level exclusions resulted in 830 compliant vaginal result sets and 733 neat, UPT and UTT urine result sets for evaluation. For vaginal specimens, the sensitivity (specificity) of the TVQ Assay and the Aptima TV Assay compared to PIS were 98.3% (99%) and 100% (98.3%), respectively. For BD neat and UPT urine specimens, the sensitivity (specificity) of the TVQ Assay compared to PIS were 95.5% (98.7%) and 94.6% (98.6%). For the Aptima UTT urine specimen, the sensitivity and specificity of the Aptima TV Assay compared to PIS were 97.3% and 98.7%.

Conclusion The BD ProbeTec™ *Trichomonas vaginalis* Qx Amplified DNA Assay on the BD Viper™ System in extracted mode demonstrated excellent performance characteristics that were comparable to the only commercially available nucleic acid amplification assay for the detection of *Trichomonas vaginalis*.

P2.076 DEVELOPMENT OF A MOLECULAR BEACON-MEDIATED DIAGNOSTIC PROBE ASSAYS FOR THE DETECTION OF TRICHOMONAS VAGINALIS IN DRY SWABS SPECIMENS OF SYMPTOMATIC WOMEN

doi:10.1136/sextrans-2013-051184.0341

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Introduction *Trichomonas vaginalis* (TV) is a protozoan parasite that infects the genitourinary tract of 250 million individuals annually, leading to trichomoniasis. The infection is associated with preterm delivery, low foetus birth weight and increased susceptibility to other STDs as well as increased HIV acquisition. Infection with *Trichomonas* is globally underestimated because of ineffective screening protocols and under equipped pathological laboratories especially in developing countries. As a consequence, trichomoniasis is associated with poor reproductive health, with numerous clinical sequelae and complications. In developing countries like India, due to forbidden cost of commercial kits, syndromic management is preferred. Hence, a cost effective and quick diagnostic assay is urgently required. The present study is an attempt to develop an inexpensive, specific and sensitive quantitative assay for *Trichomonas vaginalis*.

Methods Specimens were retrieved consecutively from patients with vaginal complaints. In-house primers and molecular TV beacon (Tv-B) were designed to detect the presence of unique regions in the genome of *Trichomonas* in clinical isolates. The sensitivity and specificity of the inhouse primers were evaluated against published primers and the method was validated against qPCR based commercial kit using DNA isolated from 802 dry clinical swabs.

Results In-house designed PCR based assay for detection of trichomonas was highly sensitive as could detect as low as 10fg of genomic DNA (3–5 pathogens). Using molecular beacon, Tv-B, 83 women (10.3%) tested positive for trichomonas out of 802 women (age 15 yrs –55 yrs). The assay was extremely specific and sensitive (99.25% and 94.64% respectively). The PPV was found to be 94% and NPV was 99%. The assay could be used for quantification of load of infection.

Conclusion The results demonstrated that in house developed test for TV is highly specific, sensitive, pocket and user friendly.

P2.077 USE OF THE OSOM® TRICHOMONAS RAPID TEST IN AN EMERGENCY ROOM SETTING

doi:10.1136/sextrans-2013-051184.0342

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Background The availability of sensitive point-of-care tests for *Trichomonas vaginalis* (TV) in emergency rooms (ER) is important to facilitate immediate diagnosis and treatment. We evaluated the use of the OSOM® *Trichomonas* Rapid Test, an FDA-approved immunochromatographic capillary flow assay, among female patients in an ER located in the southeastern United States.

Methods The University of North Carolina Hospitals located in Chapel Hill, North Carolina, US replaced wet mount microscopy (WM) for vaginal TV detection with the OSOM® *Trichomonas* Rapid Test (Genzyme Corporation, US) in October 2011. We analysed 10 months of data for women evaluated in the ER with the rapid test, and compared the positivity rate with a similar 10-month period determined by WM. We assessed characteristics of women identified with trichomoniasis using the rapid test, and the proportion who received appropriate therapy.