

Nucleic Acid Amplification Tests (NAATs) for *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (GC) have become routine. These methods are validated for use with urogenital samples and have a faster turn-around-time for results with automation. Testing of non-validated samples is common which raises concerns about assay performance. In Australia, the 2005 Public Health Laboratory Network (PHLN) guideline recommends repeat testing of all initial positive GC NAAT results with a suitable alternate NAAT assay. In this study, results from > 70,000 patient samples from 2 laboratories were reviewed in accordance with the PHLN recommendations. The laboratories used the APTIMA Combo 2 (AC2) and APTIMA *Neisseria gonorrhoeae* (AGC) assays with the PANTHER instrument.

72,253 AC2 results were available for analysis which included 1,174 (1.68%) initially AC2 reactive (positive or equivocal) samples which also had results for the AGC assay used as the confirmatory assay. For the reactive samples, the agreement between the AC2 and AGC assays occurred in 97.19% of samples; 1135 were positive in both assays and 6 were equivocal in both assays. Sample types tested included those with manufacturer's validation claims; urine, ThinPrep, vaginal, endocervical and urethral swabs and non-validated samples including throat, rectal, eye and joint fluids. Samples from throat swabs showed the highest numbers of discordant results followed by rectal swab samples. The percentage agreement of results obtained from all sample types was excellent, with an overall PPV of > 99%.

Without confirmatory testing, false positive results would have been reported for 13 samples representing 0.02% of all samples tested. This study demonstrates that the initial AC2 results can be accepted with high confidence.

#### P2.002 EVALUATION OF A REAL-TIME PCR-BASED TEST FOR BACTERIAL VAGINOSIS

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**Background** Bacterial vaginosis (BV) is the most common cause of vaginal discharge in women. Since BV is associated with significant morbidity, accurate tools for diagnosing the disease are important. The Amsel criteria (AC) and Nugent score (NS) are currently used for BV diagnosis. Recently, a number of PCR-based tests providing objective, sensitive and specific BV detection have been described. This study aimed to evaluate a newly developed BV test based on quantitative detection of *Gardnerella vaginalis*, *Atopobium vaginae*, *Lactobacillus* spp. and total Bacteria using multiplex PCR.

**Methods** PCR criteria were elaborated based on the relative counts of the targeted bacteria to classify vaginal microflora as BV, no BV or intermediate. Vaginal samples for the test evaluation were obtained from 274 patients addressing a gynaecologist for routine examination. All participants were of reproductive age, not pregnant and not menstruating at the time of enrollment. BV was diagnosed using the AC and NS.

**Results** According to the NS results, 66 patients were BV positive, 156 were BV negative, and 52 were classified as intermediate. All patients positive by the NS were positive by the AC, and all patients negative by the NS were negative by the AC. Among 66 BV positive samples, 62 demonstrated PCR results corresponding to BV, and 4 samples were BV negative by PCR (94% sensitivity). Of the 156 negative samples, 151 were interpreted as BV negative using PCR criteria, and 5 samples - as BV positive (97% specificity).

**Conclusion** A multiplex real-time PCR test for BV was developed showing 94% sensitivity and 97% specificity.

#### P2.003 FEASIBILITY AND ACCEPTABILITY OF SELF-COLLECTED VAGINAL SWABS FOR DIAGNOSIS OF BACTERIAL VAGINOSIS AMONG PREGNANT WOMEN IN A COMMUNITY SETTING IN RURAL MYSORE, INDIA

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**Background** Bacterial vaginosis (BV) is a common cause of adverse birth outcomes. Its association with other obstetric and gynecologic complications and HIV are increasingly recognised. This study examined the acceptability and feasibility of using self-collected vaginal swabs (SVS) for screening of BV in a community setting among rural pregnant women in Mysore Taluk, India.

**Methods** A community based cross-sectional study was carried out between June 2007 and December 2010. Mobile medical clinics offered antenatal care and HIV testing in all 144 rural villages in Mysore Taluk. Women were also screened for BV using SVS and asked about their experience with the collecting process. Gram-stain evaluation of vaginal samples using Nugent score (NS) was conducted by two trained laboratory personnel.

**Results** Among the 1675 women attending the mobile medical clinics from the 144 villages, 1541 (92%) were included in the analyses. 1639 agreed to provide vaginal swabs (97.8% response rate). The quality of the swabs was satisfactory in 1545 of the cases. There were 134 non-interpretable slides owing to poor quality. The median age of women was 20 years (range 14 to 40 years). Majority (98.7%) reported themselves as Hindus and 1634 (97.5%) were housewives. The prevalence of BV was 9.9% with a NS of 7–10 and 14.9% of women had intermediate flora on Nugent score of 4–6. While 212 women (12.9%) reported collecting the vaginal swab as being 'very easy', 1402 (85%) found it 'easy' and 22 (1.3%) reported it as 'difficult'. Only 12 women were unable to collect the swab for various reasons.

**Conclusion** These study results support the use of self-collected vaginal swabs for diagnosing BV. Self-collected swabs to detect BV were well accepted by most of rural pregnant women in this region, and the quality of the swabs seemed to be satisfactory.

#### P2.004 DOES BACTERIAL VAGINOSIS HAVE AN ASSOCIATION WITH SIL?

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**Background** Literature documents incomplete and conflicting evidence between bacterial vaginosis and its association with cervical intraepithelial neoplasia in cervicovaginal smears (CS).

**Aim** To investigate if there is an association between bacterial vaginosis (BV) and squamous intraepithelial lesion (SIL) in CS.

**Methods** A retrospective analysis of 6902 cervicovaginal cases accrued during January 2006 -December 2009 from an opportunistic screening programme was done. The cases diagnosed as unsatisfactory (n = 239), glandular cell abnormalities (n = 9) and carcinoma (n = 12) were excluded. Thus the study was based on 6642 cases. These were reviewed to identify SIL and BV. The correlation with histology was done wherever available. A diagnosis of BV was rendered if 10 clue cells per low power field and at least 5 fields showing cocco-bacteria were detected on Pap stained smears. Statistical evaluation was carried by applying Z test to determine if BV has an association to SIL in CS.

**Results** Of the 6642 cases analysed, BV was present in 13% cases and absent in 87% cases. SIL was reported in 7% BV present group and 2% in the BV absent group (P < 0.001). The difference between