

**Results** We confirm the initially reported specificity and further narrow down its confidence interval (specificity 99.5%, 95% CI 99.4–99.6%), and show that this high specificity is valid across diverse patient categories. Here we demonstrate that differences in positive predictive values between patient categories reflect the prevalence of syphilis in these categories, and are not due to differences in specificity. In addition, in a sensitivity analysis we show that these conclusions are robust for several assumptions.

**Conclusion** Our analysis shows that the high specificity found in the initial study, stands up after implementation in a population with a low syphilis prevalence (0.9%). Using a selected serum sample collection is therefore a valid manner in the evaluation of syphilis serological diagnostic assays. Confirmatory syphilis testing remains mandatory in low prevalence populations, even when the screening test has a very high specificity.

**P5.090 EVALUATION OF A DOUBLE RAPID TEST FOR SYPHILIS AND HIV: SD BIOLINE HIV/SYPHILIS DUO**

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**Background** Although syphilis and HIV are primarily transmitted through sexual intercourse, they can also be transmitted from mother to child during pregnancy or at delivery. Testing pregnant women for syphilis and HIV is an important public health measure to prevent vertical transmission. Several countries have included screening of pregnant women using rapid HIV testing, and recently also rapid syphilis testing. Screening pregnant women for both diseases with one test is not only desirable but could also be very convenient. We present the results of the laboratory-based evaluation of a new test: the SD Bioline HIV/Syphilis Duo.

**Methods** We used archived serum specimens characterised as positive or negative for HIV and/or Syphilis. The gold standard positive for HIV was EIA (Vironostika® HIV Uni-Form II Ag/Ab, bioMérieux) with confirmation using Western blot. The reference standard positive for syphilis was the Rapid Plasma Reagin test (RPR, bioMérieux) with confirmation using the *Treponema pallidum* Particle Agglutination (TPPA) assay (Fujirebio, Japan). Reference standard negatives were EIA negative and RPR negative for HIV and syphilis respectively. For Syphilis we used a total of 665 samples, including 198 positives, and for HIV we used 662 samples including 91 positives. There were 42 samples positive for both HIV and syphilis. The samples were tested with the SD Bioline HIV/Syphilis Duo by a laboratory technician blinded to the gold standard results.

**Results** For Syphilis we observed a sensitivity of 100% (198/198) and a specificity of 99.57% (465/467). The two RPR negative/Bioline positive samples were negative for TPPA. For HIV, both the sensitivity and specificity were 100% (91/91 and 571/571 respectively).

**Conclusions** The SD Bioline HIV/Syphilis Duo test has a good performance in archived sera. Its high sensitivity suggests that this dual test would be of use in screening programmes for syphilis and HIV.

**P5.091 HEAD-HEAD COMPARISON OF REACTIVITY AND SIGNAL STRENGTH VALUE FOR REACTIVITY AMONG SEVEN TREPONEMAL ASSAYS: A PRELIMINARY REPORT**

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**Background** Automated immunoassays (AI) for detection of *T. pallidum* antibodies are increasingly used for syphilis screening in the United States. These assays demonstrate fast performance, reduced labour requirements, and high throughput with walk-away capability. Limited data are available about the relative seroreactivity among commercial treponemal assays, especially in low risk populations. Additionally, it is unknown to what extent the AI signal strength values, used to assess reactivity, are associated with non-AI treponemal reactivity. We compared concordance of seroreactivity among 7 treponemal tests and assessed AI signal strength values associated with reactivity.

**Methods** Previously identified reactive and nonreactive sera (n = 566) were obtained from Kaiser Northern and Southern California regional laboratories. All sera were tested with AIs: BioPlex 2200 Syphilis IgM/IgG (BioRad), treponemal LIAISON (DiaSorin), Advia-Centaur syphilis (Siemens), and non-AIs (INNOLIA syphilis score (INNOGENETICS), TrepSure (Phoenix Biotech), Treponemal Pallidum Particle Agglutination (TP-PA) (Fujirebio), and Fluorescent Treponemal Antibody-Absorption (FTA-ABS) (Zeus Scientific) tests. Reactivity was interpreted according to manufacturers' instructions.

**Results** Seroreactivity ranged from 40.5 – 43.9% for AIs, and 33.0–42.2% for non-AIs. In all 7 tests, 30% (167/566) were reactive, and positive agreement among assays was 82.3%. The overall seroreactivity among AIs was 38.9% (220/566) and positive agreement was 92.6%. Minimum signal strength values of 11.72 (Centaur, range: 1.1–45), 4.4 (BioPlex, range: 1.1–8) and 9.4 (Liaison, range: 1.1–70) correlated 100% with TPPA reactivity. The proportion of AI-seroreactive specimens that were also TP-PA reactive were: 86.5% (198/229) for BioPlex, 85.2% (202/237) for ADVIA-Centaur, and 81.6% (200/245) for LIAISON.

**Conclusion** Although there is some variation in seroreactivity among the 7 tests, there is good correlation. A large proportion of AI tests with a minimal signal-to-cutoff ratio were associated with a positive TP-PA, suggesting that a second treponemal test may not be necessary to confirm AI-reactive, RPR-nonreactive sera.

**P5.092 EVALUATION OF A LABORATORY DEVELOPED TEST FOR THE DETECTION OF TRICHOMONAS VAGINALIS USING A MODIFICATION OF THE ABBOTT M2000 REALTIME SYSTEM**

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**Background** Assays for the detection of *Trichomonas vaginalis* (TV) are available on certain commercial platforms. The objective of this study was to assess the performance characteristics of a new laboratory developed test (LDT) for the detection of TV from urine, and swab samples, when tested on the Abbott m2000 platform; a platform widely used for the detection of *C. trachomatis* (CT) and *N. gonorrhoeae* (NG).

**Methods** Residual swab samples that had been previously eluted into CT transport medium and urine were placed into Abbott transport tubes. Testing for CT/NG was performed on the m2000 platform per package insert; the remaining residual extracted DNA was used for TV testing on the m2000 platform. TV specific primers, probe, and thermal cycling conditions were optimised in our laboratory. Residual DNA from each sample was manually transferred to an amplification plate containing master mix. Real-time PCR was performed on the m2000 platform in open mode with the TV LDT results being compared to an LDT for TV that has been validated and used in our laboratory for more than a decade. Assay agreement was assessed using Kappa statistics.

**Results** A total of 49 urine specimens, 50 vaginal and 33 endocervical swabs were evaluated. Positive percent agreement was 92.0 for urine, and 100%, for both of the swab specimen types compared to the routine assay. Negative percent agreement between the two assays was 100% for all three specimen types. Kappa scores between the two assays were 0.918, 1.000, and 1.000 for urine, vaginal, and endocervical swabs, respectively.

**Conclusions** The TV LDT assay, performed on the Abbott *m*2000 platform, has excellent agreement with a molecular assay for TV being used in our laboratory. Advantages to using the *m*2000 for TV testing include automation and the use of residual DNA from the CT/NG assay for TV detection.

**P5.093 EVALUATION OF A NEW AMPLIFIED DNA ASSAY ON THE BECTON DICKINSON VIPER SYSTEM IN EXTRACTED MODE FOR THE DETECTION OF *TRICHOMONAS VAGINALIS* FROM VAGINAL SPECIMENS**

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**Background** The BD ProbeTec™ *Trichomonas vaginalis* (TV) Qx amplified DNA Assay (TVQ) is a new test for qualitative detection of TV DNA that can be performed on the automated BD Viper System. The objective of this study was to compare the performance of this new assay to a patient infected status (PIS) and to an FDA approved molecular assay using vaginal swabs.

**Methods** Vaginal swabs were obtained from women attending STD or family planning clinics at 7 sites. A patient collected vaginal swab was tested by TVQ; APTIMA TV (ATV) testing was performed using a clinician obtained vaginal swab according to the package insert. Additional clinician obtained vaginal swabs were used for wet mount and culture. A patient was considered infected if either the wet mount or culture was positive for TV and not infected if both tests were negative. Agreement between the TVQ and ATV assays was assessed using Kappa statistics.

**Results** Data were available for TVQ evaluation from 838 women, 116 of whom were defined as infected with TV. Despite being in the definition of the PIS, wet mount still had a sensitivity of only 68.7% which was statistically lower than the other assays ( $p < 0.001$ ). TVQ sensitivity and specificity estimated based on the PIS were 94.2% and 99.7%, respectively. TVQ performed similarly to the ATV assay ( $\kappa = 0.938$ ).

**Conclusions** The TVQ assay performed significantly better than wet mount and had comparable sensitivity and specificity to an FDA approved molecular assay for the detection of TV. This study provides additional evidence of the poor performance of wet mount for TV. The use of patient collected vaginal swabs for the detection of TV DNA provides clinicians with the opportunity to increase efficiency within the clinic while obtaining improved results over wet mount.

**P5.094 EVALUATION OF GENTAMICIN SUSCEPTIBILITY OF *NEISSERIA GONORRHOEA* ISOLATES IN ARGENTINA**

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**Introduction** The effective treatment of infection by *Neisseria gonorrhoeae* (Ng) is critical for the individual patient management and essential in the control of gonorrhoea. The emergence of decreased susceptibility to third generation cephalosporins and its association with treatment failure in many regions of the world can quickly make them unsuitable as first-line therapy. Thus it becomes necessary to consider alternatives for future therapeutics. The aminoglycoside gentamicin, was chosen as an alternative treatment after the emergence of penicillinase-producers strains in Africa. This responds to its low cost, also due to the fact that it can be administered in a single dose of 240 mg and because studies showed cure rates of > 95%. Despite some treatment failure reports, gentamicin has proven successful in the treatment of gonococcal urethritis for many years. In Argentina, no susceptibility data are available.

**Materials and Methods:** Retrospective study of a total of 355 Ng isolates derived to our laboratory for susceptibility studies in 2011 from 13 provinces. MIC to gentamicin was determined by agar dilution method according to CLSI. We used Ng ATCC 49226 as control for dilutions of antibiotics, using the interpretation criteria reported in bibliography.

**Results** Gentamicin susceptibility showed that 99.7% of Argentine isolates were in a narrow range of MIC (4–8 µg/ml) with 74.6% showing an MIC of 8 µg/ml. The MIC range was 4–16 µg/ml, MIC 50 and MIC 90 agreed 8 µg/ml. A 74.6% (265/355) isolates included in this study showed resistance to one or more of the following antibiotics: penicillin (36.3%), tetracycline (43.9%) and ciprofloxacin (48.4%).

**Conclusions** The Argentine gonococcal population susceptibility to gentamicin is similar to that reported by other regions of the world. *In vitro* studies of regular assessment would be needed to ensure the effectiveness of gentamicin as alternative drug for the treatment of gonorrhoea.

**P5.095 CEFIXIME TREATMENT FAILURE IN INFECTIONS WITH CEFIXIME SUSCEPTIBLE *N. GONORRHOEA* STRAINS**

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**Background** In the last years the Gram-negative bacterium *Neisseria gonorrhoeae*, already known to be resistant to penicillins, tetracyclines, macrolides and fluoroquinolones has raised attention by developing resistance and consequently treatment failures in some cases to the recommended first line treatment: extended-spectrum cephalosporins (ceftriaxone and cefixime). Therefore bacterial culture, the gold standard for definite diagnosis should be performed for antibiotic susceptibility testing, beside the widely used nucleic acid amplification testing (NAAT). However we could observe discrepancies between cefixime susceptible *N. gonorrhoeae* cultures and clinical treatment failures for some years.

**Methods** In this retrospective study, 2006–2012, clinical outcome data of patients with acute gonococcal urethritis/cervicitis, oral cefixime treatment (400mg, one dose) and cefixime susceptible *N. gonorrhoeae* culture were collected at the STD outpatient clinic of the Department of Dermatology and Venereology, Medical University of Graz, Austria. The diagnosis was made by microscopy (Gram or methylene blue staining), culture including antimicrobial susceptibility testing and in situ hybridization (GenProbe Pace II) of urethral/cervical swab specimens. Control urethral/cervical swaps were performed within one to two weeks.

**Results** Out of total 218 patients with gonorrhoea, 120 patients fulfilled the inclusion criteria. 14 of 120 (11.7%) showed a treatment failure after oral cefixime despite a positive susceptibility testing. Most treatment failures were observed in 2011 (3/11; 21.4%) and 2012 (4/17; 19%). Rates for 2007, 2008 and 2009 were 2/12; 14.3%, 3/16; 15.8% and 2/11; 15.4%. In 2006 and 2010, no treatment failure in cefixime susceptible *N. gonorrhoeae* infections was seen.