

Conclusion Low baseline CD4 T-cell count, haemoglobin, aspartate transaminase and sCD14 levels are predictive of suboptimal CD4 T-cell recovery in this cohort of HIV-1 subtype C infected patients. These markers are potentially useful in identifying patients who need frequent clinical monitoring to minimise unfavourable outcomes associated with poor CD4 T-cell recovery.

015.2 COMPARISON OF THE ROCHE COBAS 4800 CTNG TEST WITH MICROBIAL CULTURE FOR DETECTING NEISSERIA GONORRHOEA IN GENITAL AND NON-GENITAL SPECIMENS IN NEW ZEALAND

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Background In New Zealand it has been usual practise to detect *Neisseria gonorrhoeae* (NG) by culturing endocervical and urethral specimens obtained by pelvic examination. However there is a significant false negative rate. The use of newer nucleic acid amplification tests (NAATS) increases the detection of NG and allows testing of non-invasively collected samples. A large retrospective audit was performed on 18,913 microbial culture and cobas 4800 NG PCR results with the aim to determine if urogenital and non-genital specimens could be screened without the need for supplementary testing of positive results.

Methods Results from culture and PCR were compared; discrepancies were resolved by clinical correlation and/or an in-house assay targeting the *opa* gene and the *porA* pseudogene.

Results NG PCR diagnosed 33% more urogenital and 25% more rectal infections than culture; and testing of non-invasive specimens by PCR resulted in 37% more patients being screened for infection. Female urine is not suitable as a sole screening specimen by this assay as sensitivity was only 86.7%. There were insufficient pharyngeal or eye swabs available for the study to rule out the need for supplementary testing by additional DNA targets.

This study also showed an association between 'failed' cobas 4800 results and NG positive culture results, likely caused by mucopurulent discharge. Treating specimens with 1.4% Dithiothreitol enabled resolution of 89% of these specimens, of which 18% were positive for CT and/or NG.

In our population, 8% of NG positives were *porA* negative, and 22% were *opa* negative. Confirmatory testing of a pharyngeal specimen identified a cross-reacting commensal *Neisseria* which gave a false positive cobas 4800 NG result.

Conclusion The cobas 4800 NG test is acceptable for urogenital and rectal specimens without supplementary testing in our low prevalence (< 1%) population, however other non-genital sites require confirmation.

015.3 EVALUATION OF AN IMMUNOCHROMATOGRAPHIC POINT-OF-CARE TEST FOR THE SIMULTANEOUS DETECTION OF NONTREPONEMAL AND TREPONEMAL ANTIBODIES IN PATIENTS WITH SYPHILIS

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Background We described the evaluation of the DPP Syphilis Screen and Confirm Assay, a point-of-care test (POC) for the simultaneous detection of nontreponemal and treponemal antibodies for the serological diagnosis of patients with syphilis.

Methods A total of 248 samples from patients with active syphilis (173), past syphilis (15) and from individuals considered as no infected by *Treponema pallidum* (60) were studied with the DPP

Syphilis Screen and Confirm, Rapid Plasma Reagin (RPR), and fluorescent treponemal antibody absorption (FTA-Abs) tests. In addition patients with active syphilis cases (36) primary, (39) secondary, and (98) latent, were evaluated. The DPP Syphilis Screen and Confirm device consists of a plastic cassette with a recombinant *T. pallidum* and a synthetic nontreponemal test line antigens and a procedural control line.

Results The sensitivity of the DPP Syphilis Screen and Confirm, nontreponemal and treponemal tests was 97.6% and 96.8% while the specificity was 94.7% and 93.1% respectively, when compared to the predicates RPR and FTA-abs tests. The treponemal and nontreponemal clinical sensitivity of primaries was 100% (36/36), for both and for secondary syphilis was also 100% (39/39), for both test and predicates. For patients with latent syphilis the sensitivity was 97.96% (96/98) for the treponemal test and 98.98% (97/98) for the nontreponemal test while for the predicates FTA-ABS and RPR was 100% (98/98) and 98.98% (97/98), respectively. With patients without syphilis the specificity of the DPP Syphilis Screen and Confirm test was 91.66% (55/60) for the treponemal line and 96.66% (58/60) for the nontreponemal line.

Conclusion These results indicates that the DPP Syphilis Screen and Confirm POC test could be a useful tool for the serological diagnosis of syphilis, including resource-poor settings where there is a need to provide counselling and treatment on site and thus prevent the further spread of the disease.

015.4 FIELD PERFORMANCE OF THE ALERE DETERMINE HIV COMBO ASSAY IN A LARGE AUSTRALIAN MULTI-CENTRE STUDY IN A SEXUAL HEALTH CLINIC SETTING

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Background Rapid HIV testing has been available to gay and other men who have sex with men (MSM) overseas for many years. Alere's Determine HIV Combo 'fourth generation' rapid test containing antibody and antigen components is now available in Australia, but field performance data for this assay are limited.

Methods From September 2011, MSM attending four Sydney public sexual health clinics were offered rapid HIV testing using the Determine HIV Combo and also had sexually transmissible infection screening and conventional HIV serology. Rapid test sensitivity, specificity, and positive and negative predictive values (PPV, NPV) were calculated by comparing results to reference tests (Abbott Architect HIV Ag/Ab Combo, Biorad Genscreen HIV antigen and HIV Western blot).

Results In 15 months, 1716 men had 2043 rapid tests performed with four invalid rapid tests (0.2%) excluded from analysis. Of 34 men confirmed as HIV-positive by national HIV case definitions, 29 had reactive rapid tests (sensitivity = 85.3%, 95% CI: 68.2–94.5). With 29 true reactive rapid tests from a total of 44 reactive tests, PPV overall was 65.9% (50.0–79.1). Of five men with false non-reactive tests, four were seroconvertors. Rapid tests were non-reactive in 1990 out of 2005 cases where laboratory HIV testing was negative; hence, overall specificity was 99.3% (95% CI: 98.7–99.6) and NPV was 99.8% (99.4–99.9). Of 15 men with false reactive rapid tests, four had