significant difference in oligotype populations was observed between URE and SYM (PERMANOVA test p=0.0072, F2.182), but not between SYM and ASP (PERMANOVA test [JW2] p=0.1797, F1.601).

Conclusion SYM and ASP oligotype populations were dominated by Lactobacillus and Streptococcus species. Microbiota observed in FVU samples of symptomatic patients with microscopy confirmed urethritis (URE) were distinct to those with symptoms but no urethritis on microscopy (SYM).

**P1.39 EVALUATION OF A CHEMILUMINESCENCE ASSAY FOR THE DETECTION OF TREPONEMA PALLIDUM ANTIBODIES FOR THE SEROLOGICAL DIAGNOSIS OF SYPHILIS**

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**Introduction** Syphilis is a sexually transmitted disease caused by *Treponeuma pallidum*, which produces 5.6 million new cases worldwide in 2012 and results in significant morbidity and mortality. Despite the availability of diagnostic tests and affordable treatment, the disease remains a global health problem. Detection of non treponemal and treponemal antibodies is the most reliable method for laboratory diagnosis of syphilis. Recently a chemiluminescence microparticle immunoassay (CMIA) has been introduced for the detection of treponemal antibodies and evaluation of its performance against reference methods is needed.

**Methods** Sera samples were tested with three syphilis serology tests: Venereal Disease Research Laboratory (VDRL) for non treponemal antibodies, fluorescein treponemal antibody absorption (FTA-ABS) test and CMIA. The sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV) and agreement (Cohen’s kappa coefficient) of CMIA was calculated against FTA-ABS (reference group) for the diagnosis of syphilis.

**Results** Sera samples from 80 patients with suspected syphilis were included in this study. According to serology results: 29 syphilis non reactive sera (VDRL, FTA-ABS and CMIA non reactive), 8 VDRL reactive but FTA-ABS and CMIA non reactive sera and 43 syphilis reactive sera including 10 samples with non reactive VDRL test but FTA-ABS and CMIA reactive (past or treated syphilis) and 33 samples with all reactive tests (ongoing syphilis). General agreement between FTA-ABS and CMIA was 91.2% with kappa coefficient 0.82. CMIA clinical sensitivity was 97.7%, clinical specificity was 83.8%, PPV was 87.5% and NPV 96.9%.

**Conclusion** CMIA has the advantages of automation and avoids the subjectivity of FTA-ABS test. According to our results, CMIA has a good agreement with FTA-ABS but has low specificity. Limitations of this test for the diagnosis of syphilis should be taken into account since confirmatory test like FTA-ABS must still be done along with VDRL test and viewed in the context of clinical presentation.
Abstracts

Methods We searched the medical literature for studies evaluating performance of dual syphilis/HIV RTs against laboratory-based reference tests for syphilis and HIV, and compared performance across studies. For the syphilis component of the RTs, we compared results using laboratory-based treponemal tests (TPPA or TPHA) as the reference and (when available) TPPA+/RPR+ as the reference, considering RPR titers > 1:4 to represent active syphilis (vs. previously treated infections).

Results We found 19 studies evaluating dual syphilis/HIV RT performance, of which 7 (37%) were field evaluations studying at least one of three diagnostics: SD Bioline HIV/Syphilis Duo Test (n = 4); Chembio Dual Path Platform HIV-Syphilis Assay (n = 2); or Medtrina Multiplo Rapid TP/HIV Antibody Test (n = 1). All used HIV EIA and TPPA or TPHA tests as reference standards; 6 also reported RPR titers. Study populations were pregnant women (n = 3), female sex workers (n = 1), high-risk men (n = 2) and STD clients (n = 1), representing a total of 13,915 persons (median study size, 415 participants; range 175 – 9983). Across studies, prevalence of HIV ranged from < 1% to 78% (median, 25.3%), and of T. pallidum (TP) from < 1% to 40.2% (median, 8.2%). RT sensitivity for HIV against AEA ranged from 93.8% to 100% (median, 99.1%), and specificity from 97% to 100% (median, 99.4%). RT sensitivity for TP against TPPA or TPHA ranged from 52.7% to 96.5% (median, 81%), and specificity from 89% to 100% (median, 98.8%), with better performance in study populations with higher TPPA/RPR+ prevalence. Using TPPA+/RPR+ > 1:4 as the standard, RT sensitivity ranged from 88.5% to 100% (median, 94.3%).

Conclusion In the few published field evaluations of dual syphilis/HIV RTs, performance of the HIV component was high for all tests studied. Sensitivity of the syphilis component against TPPA was poorer, but was more accurate using probable active syphilis infection as the standard.

A NEW MAGNETIC PARTICLE-BASED AGGLUTINATION ASSAY FOR ANTI-CARDIOLIPIN ANTIBODY DETECTION IN SYPHILIS

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Introduction A magnetic particle based assay was developed for the detection of non- treponemal anti-cardiolipin antibodies in sera of suspected syphilis cases. The presence of this group of antibodies in combination with a reactive treponemal test indicates active syphilis. In this study, we aimed to overcome technical difficulties with attaching cardiolipin to solid support. The newly developed assay potentially offers advantages of better result interpretation, accuracy, and minimum equipment need compared to traditional non- treponemal tests in diagnosing syphilis.

Methods To develop the non- treponemal magnetic agglutination assay (NT-MAA), cardiolipin antigen was modified first through a chemical oxidation process. The oxidised antigen was later covalently linked to magnetic particles. To test the beads, serum samples were mixed with cardiolipin-magnetic particle complex, and incubated in round bottom well microplates. The test was interpreted as reactive when agglutination was observed. Non-reactive sample demonstrated a “button” in the centre of a microwell. The NT-MAA was evaluated using a panel of previously characterised human sera (n = 80) and results were compared to rapid plasma reagin (RPR, ASI) and Treponema pallidum particle agglutination tests (TP-PA, Fujirebio). A true positive sample was defined as being reactive for both RPR and TP-PA, while a true negative as both RPR and TP-PA non-reactive.

Results Out of 80 sera tested, 48 were found true positive and 32 true negative with the reference tests. In comparison, the NT-MAA, demonstrated a sensitivity and specificity of 100% and 96.8%, respectively.

Conclusion Magnetic particle-based assays offer high flexibility because they work with different assay formats. This exploratory study, describes technical advances for development of non- treponemal test (NT-MAA), and also demonstrated an encouraging performance with the studied samples. Additional evaluation with syphilis samples from defined clinical stages of syphilis will help further validate test performance.