**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 Medtrix 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 – 9,983). Across studies, prevalence of HIV ranged from <1% to 78% (median, 25.3%), and of \textit{Treponema pallidum} (TP) from <1% to 40.2% (median, 8.2%). RT sensitivity for HIV against EIA 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.

**Introduction** Syphilis is a globally occurring sexually transmitted disease caused by \textit{Treponema pallidum}, a non-cultured \textit{viro} bacterium. Molecular typing of \textit{Treponema pallidum} strains isolated from patients are useful for investigating the molecular epidemiologic patterns, diversity of strains and antimicrobial resistance patterns. To date, there was no data on the circulating or prevalent subtype in Brazil. In this study we aimed to determine \textit{T. pallidum} strain diversity and analyse for the mutation associated with macrolide resistance from patients with primary syphilis attended at CSEGPs.

**Methods** We analysed 24 samples of primary lesion collected from patients attended at CSEGPs between 2013 and 2015. DNA was extracted with DNeasy kit (Qiagen). Standard PCR targeting \textit{tpp47} and \textit{polA} genes was used for screening. Molecular typing was performed by CDC established methods, by determination of the 60 bp repeats within the \textit{arp} gene, and RFLP analysis of \textit{tpr} subfamily II genes (E, G and J). Completed by sequence analysis of a variable region of the \textit{tp0548} gene. The 23S rDNA was identified by DNA sequencing of PCR product.

**Results** \textit{T. pallidum} DNA was detected in samples from 15 patients. Among 12 specimens typed, subtype found were 14d/g (6), 14d/d (5) and 12b/d (1). From 10 samples analysed for 23 rDNA mutation, all showed A2058-G, no mutation was detected at A2059. One case presented a different subtype in re-infection. The first was 14d/g and the second was 14d/d.

**Conclusion** \textit{T. pallidum} detected in the samples of patients with primary syphilis are of subtypes 14d/g, 14d/d and 12b/d. The macrolide resistance mutation A2058-G was detected in...
all samples analysed. *T. pallidum* subtyping discriminated re-infection.

**P1.45 EVALUATION OF SEKURE RPR REAGENT ON THE SK500 CLINICAL CHEMISTRY SYSTEM**

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**Introduction** An automated and accurate laboratory assay would be of considerable utility to the diagnosis of syphilis and treatment follow-up. We compared the Sekure RPR (Rapid Plasma Reagin) test performed on the SK500 Clinical Chemistry System to RPR card test results.

**Methods** Serum samples were collected in the context of a 2 year observational cohort study of syphilis infected patients and controls. Syphilis was diagnosed using non-treponemal and treponemal testing. Sera collected at the time of diagnosis (M0) and at 3, 6, 9 and 12 months post-treatment were tested by a Macro-Vue RPR card test (RPR-C) (Becton Dickinson) and a Sekure RPR test (RPR-S) (Sekisui Diagnostics). RPR-S results are expressed in RPR units (R.U.), whereby 1 R.U. equals a 1-fold change in RPR-C titre. The agreement, linearity and reportable ranges were determined using RPR-C results as the gold standard. Linear regression was used to assess correlations from before and after implementation of an extra dilution step for samples with a strong suspicion of prozone effect.

**Results** In total, 451 samples from 150 participants were tested, including 120 new syphilis cases and 30 controls. All 30 controls tested negative. Initially there was a weak correlation between RPR-C and RPR-S values ($r=0.15$). Further analyses identified 72 RPR-S samples with a strong suspicion of prozone effect. We therefore included an extra dilution step (10x) and retested 60/72 samples; values within the expected range were obtained for 58 of them. After implementing the extra dilution step the correlation was moderate ($r=0.61$), increasing further to $r=0.91$ for samples with RPR-C titres $\geq 128$. Of the 92 samples that tested RPR-C positive and RPR-S negative, 8 were from M0 (RPR-C: 1–4), which would have led to missed diagnoses.

**Conclusion** A reasonable correlation was found between the tested methods for mid-range RPR-C results (titre $\leq 128$). However, prozone may occur in samples with high antibody concentrations. More investigation is required to elucidate the false negative RPR-S results.

**P1.46 COMPARISON OF TWO ENZYME IMMUNOASSAYS FOR THE DETECTION OF IGG AND IGM ANTI-TREPONEMA PALLIDUM ANTIBODIES**

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**Introduction** We aimed to compare two commercial enzyme immunoassays (EIA) for the detection of IgG and IgM anti-*T. pallidum* (Tp) antibodies.

**Methods** Serum samples were collected in the context of a larger study looking at diagnostic biomarkers for syphilis.

Patients with syphilis diagnosed by a treponemal and a nontreponemal assay, were followed for up to two years after treatment. Specimens collected at visit of diagnosis (B), and after three (M3) and six months (M6) of treatment were tested by EIAs detecting anti-Tp IgG and IgM from the manufacturers Euroimmun (EU) and Mikrogen (MI).

**Results** We tested 338 samples collected from 119 new syphilis cases (23 primary (P), 49 secondary (S), 31 early latent (EL), 16 late latent (LL) and 30 uninfected controls. A total of 40 participants contributed to 1 sample, 29 to 2 samples and 80 to 3 samples. The controls contributed only to the samples collected at B. Overall 147, 86 and 105 samples were obtained at B, M3 and M6, respectively. The IgM assays were in agreement for 78.1% of samples; it varied according to the syphilis stage: P: 82.1%; S: 72.5%; EL: 80.8%; LL: 72.1% and decreased from B to M3: B: 84.4%; M3: 73.3%; M6: 73.3%. More samples tested positive with the MI (149) versus the EU (100) (p<0.001). EU tested all control samples IgM negative, MI reported 1 positive and 1 borderline. The agreement of both IgG assays was 97.4%; it increased with the stage of infection: P: 91.1%; S: 97.7%; EL: 100%; LL: 100%; and over time: B: 95.2%; M3: 98.8%; M6: 99.0%. More samples tested positive with the EU (305) versus the MI (300) assay. EU reported all control samples IgG negative, MI detected 1 borderline sample.

**Conclusion** A good but not perfect agreement was observed for the EIAs detecting IgM. The agreement was highest in primary syphilis and lowest in late latent cases, and decreased over time of treatment. The MI IgM assay reported significantly more positive samples. Overall, we found a good agreement for the EIAs detecting IgG. Albeit that it was somewhat lower for primary syphilis and at baseline.