Background The laboratory diagnosis of syphilis is a crucial point in the diagnostic evaluation of the syphilis. The aim of this study was to evaluate the diagnostic performance of the new commercial immunoblotting "recomLine Treponema" (Mikrogen Diagnostik, Germany) assay which includes two new recombinant antigens (Tp257 (Gpd) and Tp483) in addition to the four (Tp47, TmpA, Tp17, Tp15) shown in a previous version.

Methods The presence of specific antibody response to *T. pallidum* was evaluated by comparing the immunoblotting test, that detects both IgG and IgM antibodies, with the "Syphilis TP" (Architect system, Germany) immunoassay, that detects the total *T. pallidum* specific antibody and routinely used in our Hospital for serological screening. The serum samples included in this study were obtained from 112 patients with suspect or clinical evidence of syphilis infection.

Results Of the 112 samples analysed for specific *T. pallidum* antibody by "Syphilis TP" assay, 90 samples were detected positive, 8 negative, 10 borderline and 4 samples showed an not interpretable result.

Of the 112 samples analysed for specific IgG and IgM antibodies by "recomLine Treponema" assay, 97 (86.6%) specimens resulted positive (100% were IgG positive and 16.49% were also IgM positive), 7 (6.25%) negative and 8 (7.14%) borderline (6 for the IgG and 2 for the IgM).

Conclusion The comparison between the two test showed that the "recomLine Treponema" assay identified more positive samples, less negative and borderline samples and not interpretable results.

This preliminary results underline that the "recomLine Treponema" (Mikrogen Diagnostik, Germany) test is clinically valid not only because it can be used as confirmatory test but also because it allows to discriminate between IgG and IgM antibodies.

Future objectives of this study will be to validate the "recomLine Treponema" test on other groups of subjects and compare it with other serological tests.

**P2.066** COMPARING THE PERFORMANCE CHARACTERISTICS OF CSF-TRUST AND CSF-VDRL FOR SYPHILIS: A CROSS-SECTIONAL STUDY


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Background In the past decade, China has observed an annual increasing rate of syphilis over 14% and the cases of neurosyphilis were increased accordingly. The WHO standard method for screening neurosyphilis is examination of CSF fluid and a mandatory test to determine the performance characteristics of CSF-TRUST as compared to CSF-VDRL for laboratory diagnosis of neurosyphilis.

Methods CSF and serum samples were collected from 824 individual STD clinic patients who have syphilis and are suspected to progress to neurosyphilis in a 9-month period. CSF-VDRL and CSF-TRUST were performed in parallel on the same day when collected. TPPA tests were also performed on the CSF and the serum samples, and Biochemical analysis of the CSF samples was also performed.

Results The overall agreement between CSF-TRUST and CSF-VDRL was 97.3%. The reactive ratios of the CSF samples were 22.1% by CSF-TRUST and 24.8% by CSF-VDRL, respectively. All CSF-TRUST reactive cases were reactive in the CSF-VDRL. Twenty-two samples with CSF-TRUST negative were tested CSF-VDRL reactive with low titers (1:1 to 1:4). Over 97% of the double reactive CSF samples (CSF-VDRL and CSF-TRUST) had an identical titer or a titer within a 2-fold difference. The agreement of CSF-TPPA and CSF-VDRL was 71.9%. Similarly the agreement of CSF-TPPA and CSF-TRUST was 69.2%.

Conclusions CSF-TRUST reagent kit is commercially available in China with SFDA certificate. It seems that CSF-TRUST and CSF-VDRL are congruence in most cases, but CSF-TRUST is less sensitive than CSF-VDRL. Nevertheless, our results suggested that CSF-TRUST may be used as an alternative for laboratory diagnosis of neurosyphilis in clinical settings with CSF-VDRL unavailable.

**P2.067** SYPHILIS TESTING IN THE PUBLIC HEALTH SETTING IN NORTH RHINE-WESTPHALIA, 2011–2012


1 A Lucht, S Kuttnier-May, D Münstermann, H J Hagedorn. Labor Krone GbR, Bad Salzuflen, Germany; Landeszentrum Gesundheit NRW, Münster, Germany

Background According to the Robert-Koch-Institut (RKI) syphilis incidence is increasing in Germany especially among men who have sex with men (MSM). North Rhine-Westphalia (NRW) is the federal state with the highest number of syphilis infections. By order of the Ministry of Health the Landeszentrum Gesundheit (lZg.nrw) organises and supports anonymous syphilis testing by local public health authorities (LPHA). Aim of this study was to assess how many syphilis cases could be detected and if hard-to-reach risk groups use the possibility of syphilis testing in this public health setting.

Methods 46 out of 53 LPHA in NRW offered their clients after counselling a syphilis screening test (chemiluminescent microparticle immunoassay, CMIA, Abbott) performed in the German syphilis laboratory (Labor Krone, Bad Salzuflen). Reactive tests were confirmed by treponema pallidum particle agglutination assay (TPPA) and fluorescent treponemal antibody absorption test (FTA-abs)-IgG and further tested by 19s-IgM-FTA-abs and rapid plasma reagin assay (RPR).

Results In 2011–2012, 7961 clients were tested. There were 54.8% men, 44.4% women, mean age was 32.8 years, 35.8% were MSM, 28.4% female sex workers (FSW), 705 reactive tests could be confirmed by further analysis. 17.2% positive results were classified as active infections, 7.5% as suspected latent infections, and 75.3% as known, already treated treponemal infections. In 2011, the LPHA detected 79 out of 986 notifiable syphilis infections in NRW with higher proportions of MSM (67.1%) and women (22.7%), most of them FSW, in comparison to 52.7% MSM and 9.1% women in NRW reported to RKI.

Discussion Approximately 87% of the LPHA in NRW offered syphilis testing. A relevant number of active and latent syphilis was detected among LPHA clients and it could be shown that the LPHA were able to detect syphilis especially in high risk groups such as MSM and FSW which might have otherwise not been tested.

**P2.068** STUDY ON THE PERFORMANCE OF THE DETERMINE® SYPHILIS RAPID TEST


1 H J Hagedorn, A Kraminer-Hagedorn, S Kuttnier-May, H Nitschke, A Lucht, D Münstermann, H Brockmeyer. Labor Krone GbR, Bad Salzuflen, Germany; Spirolab GmbH, Bad Salzuflen, Germany; Landeszentrum Gesundheit Nordrhein-Westfalen, Muenster, Germany; Gesundheitsamt, Koeln, Germany; Klinik für Dermatologie und Venerologie der Ruhruniversität, Deutsche STI Gesellschaft, Bochum, Germany

Background The usefulness of syphilis rapid tests in STI counselling services is under discussion in Germany. For this reason, we evaluated the performance of the Determine® Syphilis rapid test (TP-RT) in comparison to standard serological syphilis tests.

Materials and Methods The TP-RT was carried out in 2,205 serum or plasma samples from the German syphilis consilatory laboratory (Labor Krone GbR, Bad Salzuflen) representing a broad spectrum of relevant samples from public health institutions, STI and HIV ambulances, hospitals and others, including samples from 532 MSM, 417 female sex workers and 260 pregnant women. The
Conclusions
The prevalence of biologic false-positive (BFP) non-treponemal tests ranges from 4–15% among HIV-infected persons. Abnormalities in B cell function are hypothesized to increase the probability of BFP in this population. Our aim was to determine the impact of combination antiretroviral therapy (cART) and degree of immunosuppression on BFP Rapid Plasma Reagin (RPR) tests among HIV-infected persons.

Methods
We conducted a retrospective study of 711 HIV-infected patients enrolled in the Johns Hopkins HIV Clinical Cohort. BFP RPR was defined as a reactive RPR and a non-reactive FTA-ABS. We conducted two analyses: (1) A cross-sectional analysis in which patients with BFP tests were compared to two control groups: HIV-infected patients (i) with syphilis and (ii) without syphilis. (2) A longitudinal analysis to determine the factors associated with BFP RPR tests, independent of CD4 T-cell response. This was done using equations for the analyses.

Results
96 participants (15.5%) had BFP tests and 273 (48.1%) had syphilis. Twenty-two of 96 (23%) had persistent BFP tests. cART use was associated with decreased odds of BFP tests compared to persons with syphilis [adjusted odds ratio (aOR) 0.31, 95% CI: 0.15–0.63] and without syphilis [aOR 0.42 (0.22–0.81)]. cART use was also associated with decreased odds of BFP persistence over time [OR 0.07 (0.01–0.53)]. Neither CD4 count nor HIV RNA was associated with BFP test results. Lower RPR titers, injection drug use and Hepatitis B were associated with increased odds of BFP.

Conclusions
The use of cART appears to significantly decrease the odds of BFP RPR tests, independent of CD4 T-cell response. This may be the result of cART’s effects on B-cell functions.

Abstract P2.070 Table 1

<table>
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<th>TTPA reactive</th>
<th>LIA reactive</th>
<th>Unconfirmed</th>
<th>Confirmed</th>
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<tr>
<td>All titters</td>
<td>345</td>
<td>326/345</td>
<td>9/19</td>
<td>10 (2.9%)</td>
</tr>
<tr>
<td>RPR 1:1</td>
<td>112</td>
<td>99/112</td>
<td>5/13</td>
<td>8 (7.1%)</td>
</tr>
<tr>
<td>RPR 1:2</td>
<td>104</td>
<td>100/104</td>
<td>2/4</td>
<td>2 (1.9%)</td>
</tr>
<tr>
<td>RPR 1:4</td>
<td>74</td>
<td>73/74</td>
<td>1/1</td>
<td>0</td>
</tr>
<tr>
<td>RPR 1:8</td>
<td>55</td>
<td>54/55</td>
<td>1/1</td>
<td>0</td>
</tr>
</tbody>
</table>

Conclusions
In our setting, only patients with serum RPR titers ranging from 1:1 to 1:2 would have been misclassified as syphilis cases had a confirmatory test not been conducted. A safe and cost-effective approach, for EIA/CLIA reactive and RPR reactive samples management in a reverse sequence algorithm may be to submit only samples with low RPR titers (≤ 1:2) instead of all EIA/CLIA and RPR reactive samples for confirmation.

Abstract P2.071

<table>
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</table>

Conclusions
To quantify detection of syphilis with the DETERMINE® Syphilis test versus single or combined treponemal/cardiologic tests in a Primary Care setting.

Methods
The 107 positive DETERMINE® syphilis results obtained in 1898 samples were compared to combined RPR/VDRL and FTA results. True positives were defined as either serological confirmation by either cardiolipin and/or specific treponemal positive results at diagnosis or at 1 week follow-up, or signs and symptoms classically compatible with syphilis which resolved completely and rapidly on administration of single dose benzathine penicillin G. All positive cases showed a sustained positive

Poster presentations

P2.069

FACTORS ASSOCIATED WITH BIOLOGIC FALSE POSITIVE RAPID PLASMA REAGIN (RPR) SEROLOGIES IN HIV-1-INFECTED PERSONS


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Objectives
The prevalence of biologic false-positive (BFP) nontreponemal tests ranges from 4–15% among HIV-infected persons. Abnormalities in B cell function are hypothesized to increase the probability of BFP in this population. Our aim was to determine the impact of combination antiretroviral therapy (cART) and degree of immunosuppression on BFP Rapid Plasma Reagin (RPR) tests among HIV-infected persons.

Methods
We conducted a retrospective study of 711 HIV-infected patients enrolled in the Johns Hopkins HIV Clinical Cohort. BFP RPR was defined as a reactive RPR and a non-reactive FTA-ABS. We conducted two analyses: (1) A cross-sectional analysis in which patients with BFP tests were compared to two control groups: HIV-infected patients (i) with syphilis and (ii) without syphilis. (2) A longitudinal analysis to determine the factors associated with BFP persistence over time. A persistent BFP test was defined as a BFP test at all visits in patients who had more than one visit with a documented RPR test. We used logistic regression and Generalized Estimating Equations for the analyses.

Results
96 participants (15.5%) had BFP tests and 273 (48.1%) had syphilis. Twenty-two of 96 (23%) had persistent BFP tests. cART use was associated with decreased odds of BFP tests compared to persons with syphilis [adjusted odds ratio (aOR) 0.31, 95% CI: 0.15–0.63] and without syphilis [aOR 0.42 (0.22–0.81)]. cART use was also associated with decreased odds of BFP persistence over time [OR 0.07 (0.01–0.53)]. Neither CD4 count nor HIV RNA was associated with BFP test results. Lower RPR titers, injection drug use and Hepatitis B were associated with increased odds of BFP.

Conclusions
The use of cART appears to significantly decrease the odds of BFP RPR tests, independent of CD4 T-cell response. This may be the result of cART’s effects on B-cell functions.

P2.070

NO MISCLASSIFICATION OF SYphilIS CASES USING A REVERSE SEQUENCE ALGORITHM IN REACTIVE ENZYME IMMUNOASSAY AND REACTIVE RPR SAMPLES WHEN RPR TITER ABOVE 1:2


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Background
Recent recommendations propose that serum samples reactive by both syphilis enzyme immunoassay (EIA) or chemoluminescent immunoassay (CLIA) and RPR may not need treponemal confirmatory testing. There is uncertainty regarding the confirmation rate of EIA/CLIA reactive and low titer RPR samples.

Methods
Reactive samples for EIA/CLIA and low titer RPR from five Quebec diagnostic laboratories between December 14th 2011 and December 3rd 2012 were prospectively tested with TPPA and, if negative or inconclusive, with a line immunoassay (LIA). Syphilis infection confirmation was defined by a reactive TPPA or LIA.

Results
Samples reactive for EIA/CLIA and RPR with titers ranging from 1:1 to 1:8 were submitted for confirmatory testing (N = 345). Of these, 335 (97.1%) were confirmed and 2.9% (95% CI 1.4–5.3%) were misclassified as syphilis cases. When stratifying by RPR titer, unconfirmed samples (misclassified cases) were found only in samples with RPR titer of 1:1 and 1:2. Samples with titers above 1:2 were classified as true syphilis cases. Proportion of confirmed cases increased with RPR titer (p = 0.01).

Conclusions
In our setting, only patients with serum RPR titers ranging from 1:1 to 1:2 would have been misclassified as syphilis cases had a confirmatory test not been conducted. A safe and cost-effective approach, for EIA/CLIA reactive and RPR reactive samples management in a reverse sequence algorithm may be to submit only samples with low RPR titers (≤ 1:2) instead of all EIA/CLIA and RPR reactive samples for confirmation.

P2.071

SUPERIOR DETECTION OF SYphilIS WITH THE RAPID TEST DETERMINE® COMPARED TO COMBINED CARDIOLIPIN AND TREPONEMAL SPECIFIC TESTS


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Objectives
To quantify detection of syphilis with the DETERMINE® Syphilis test versus single or combined treponemal/cardiologic tests in a Primary Care setting.

Methods
The 107 positive DETERMINE® syphilis results obtained in 1898 samples were compared to combined RPR/VDRL and FTA results. True positives were defined as either serological confirmation by either cardiolipin and/or specific treponemal positive results at diagnosis or at 1 week follow-up, or signs and symptoms classically compatible with syphilis which resolved completely and rapidly on administration of single dose benzathine penicillin G. All positive cases showed a sustained positive