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P2.062 OPTIMIZATIONS AND QUALITY ASSURANCE OF THE LABORATORY DIAGNOSIS AND TREATMENT OF SEXUALLY TRANSMITTED INFECTIONS IN BELARUS

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[1]**O Pankratov**, [1]I Shimanskaya, [2]A Lukyanau, [3]M Unemo, [4]M Domeika, Eastern European Network for Sexual Reproductive Health. *[1]Belarusian Medical Academy of Postgraduate Education, Minsk, Belarus; [2]Belarusian State Medical University, Minsk, Belarus; [3]3WHO Collaborating Centre for Gonorrhoea and other STIs, Örebro, Sweden; [4]Department of Control and Prevention of Communicable Diseases, Uppsala County Council, Uppsala, Sweden*

Background In 2007–2008, a questionnaire-based study evaluated the quality of the 316 State laboratory services that were engaged in diagnosis of STIs in Belarus. This comprehensive survey clearly demonstrated that many of the tests and testing algorithms used in the laboratory diagnosis were inappropriate and not in accordance with international evidence-based recommendations.
Methods STI specialists from Belarus actively participated in the development of Eastern European consensus guidelines for the diagnosis of several STIs; an international collaborative work by the Eastern European Network for Sexual and Reproductive Health (EE SRH).
Results The international evidence-based guidelines developed by the EE SRH have subsequently been adapted to national conditions and legalised by the Ministry of Health of Belarus as the national standard for laboratory diagnosis of STIs. Briefly, antibody testing for diagnosis of genital *Chlamydia trachomatis* and *Trichomonas vaginalis* infections has been abandoned. Internationally validated nucleic acid amplification tests (NAATs) have been strongly promoted and also introduced for diagnosis of several STIs. Diagnosis of *Mycoplasma genitalium* using NAATs was initiated and routine screening and/or testing for *Ureaplasma urealyticum, Mycoplasma hominis, Gardnerella vaginalis* and *Mobiluncus spp.* was excluded from the recommendations supported by the State. Laboratory specialists from the 11 laboratories of the dermatovenereological dispensaries were trained in diagnostics using NAATs and laboratories supplied by the necessary equipment and reagents for NAAT diagnostics. The cultivation of *Neisseria gonorrhoeae* has been optimised and gonococcal antimicrobial resistance surveillance has been established. Finally, evidence-based national STI clinical protocols, including treatment recommendations, have been elaborated and legalised by the Ministry of Health of Belarus.
Conclusion The international EE SRH collaborative project has significantly improved the quality of the STI diagnostics and treatment in Belarus. A new EE SRH project is planned for Belarus, aiming to monitor and evaluate the implementation of the current developments.

P2.063 VALIDATION OF COPAN ENAT, A MOLECULAR TRANSPORT MEDIUM, FOR THE COLLECTION AND PRESERVATION OF URINE SPECIMENS FOR THE DETECTION OF STI INFECTIONS WITH THE SEEGENE ANYPLEX II STI-7 V1.1 ASSAY

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S Razeti. *Arrow Diagnostics Srl, Genoa, Italy*

Backgrounds Urine is used for screening STI infections with molecular assays. Copan developed the eNat, a molecular medium that preserves and stabilises nucleic acid (NC), for collection, and storage of clinical specimens for microbial detection by real-time PCR. Seegene uses dry container (DC) for urine collection for detection of urogenital pathogens with the Anyplex II STI-7 (STI7).

Study objective was to validate the eNat for nucleic acid preservation in urines for STDs detection with the STI7 assays.

Methods In this study, 80 urines, collected in DC from patients attending a Milan STD clinic. Urines were tested as per current method and after adding urine to 1ml eNat. To find the urine volume with same sensitivity as urine in DC, 1, 2, and 3ml urine in 1 ml eNAT were tested. After vortexing the eNAT samples, NC was extracted from 350ul with the Automated Purification Systems (NIMBUS IVD) and eluted in 100ul buffer. Purified NCs were tested with the with the Seegene STI7 assay.
Results In the 80 urine samples tested, 43 negative and 37 positive were detected with DC, while 1 ml, 2 ml and 3 ml urine in eNAT detected 45.40.40 negative or partial negative (1, 2, 3) and 35.40.40 positive (1, 2, 3) respectively. More co-infections were detected with eNAT 3 ml. Loss of sensitivity with 1 ml eNAT and inhibition with DC versus 3 ml in eNAT was detected in 7 samples.
Conclusions Good agreement was found between Copan eNat-3 ml urine and urine in DC for the detection of 7 STI with the Seegene assay. Copan eNAT, is available in leak proof tube, easy to transport-store urines, prevents bacterial overgrowth, stabilises NC at RT and is compatible with the STI7 assay.

P2.064 COMPARISON OF URINE COLLECTED IN DRY CONTAINER TO URINE COLLECTED, TRANSPORTED AND PRESERVED IN THE COPAN URISWAB FOR THE DETECTION OF STDS WITH THE SEEPLEX STD6 ACE ASSAY

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A Archenti. *ASL Milano - Prevention Laboratory, Milan, Italy*

Backgrounds Molecular urine devices are not compatible for all molecular assays and are not good bacteria culture. Copan produces the UriSwab (US), a LBM device used with the WASP automation. It's a leak-proof screw-cap tube with 3 treated sponges on a plastic stick to absorb and retain urine during transport and prevent bacterial overgrowth. UriSwab can be used for urine self-collection for STD screening by culture and molecular assays. Urine collected in dry container (DC) were compared to US for detection of *Trichomonas vaginalis* (TV), *Mycoplasma hominis* (MH), *Mycoplasma genitalium* (MG), *Chlamydia trachomatis* (CT), *Neisseria gonorrhoeae* (NG) and *Ureaplasma urealyticum* (UU).
Methods Duplicate urines were collected to-date from 153 patients attending a Milan STD clinic. One urine was collected in DC and another in US. For the DC, 5 ml urine was placed in a tube, and both, DC tube and US were centrifuged at 3000 g/20 min. After discarding the supernatant, the cell pellets were eluted in PBS and nucleic acid was extracted with the QIAamp DNA Mini kit (Qiagen). 3 ul purified sample was tested with the Seeplex® STD6 ACE assay (Seegene Inc).
Results In the 153 urine, DC and US had 90 negative and 52 positive concordant (91.25%) and 9 discordant (9.75%) results; positive included 10 CT, 11 MH, 8 UU, 5 NG and 3 MG. In the discordant, DC had 3 positive missed by US while US had 4 positive missed by DC. No inhibition or TV was detected, the study is-ongoing.
Conclusions Good agreement was found between the Copan US and the DC for storing urines for STIs with the Seeplex® STD6 ACE. The US is leak-proof, easy-to-transport, store urines for STIs with molecular assays, prevents overgrowth, stabilises bacteria for culture and facilitates self-collection for STI screening.

P2.065 PRELIMINARY EVALUATION OF A COMMERCIALLY AVAILABLE IMMUNOBLOTTING METHOD WITH *TREPONEMA PALLIDUM* RECOMBINANT ANTIGENS FOR SEROLOGICAL DIAGNOSIS OF SYPHILIS

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A Pierro, L Bragaglia, A Moroni, M Landini, V Sambri. *Unit of Clinical Microbiology, St. Orsola-Malpighi University Hospital, Bologna, Italy*

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 "*recom*Line Treponema" (Mikrogen Diagnostik, Germany) assay which includes two new recombinant antigens (Tp257 (Gpd) and Tp453) 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 "*recom*Line Treponema" assay, 97 (86.61%) 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 "*recom*Line Treponema" assay identified more positive sample, less negative and borderline samples and not interpretable results.

This preliminary results underline that the "*recom*Line 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 "*recom*Line 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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[1]**W Gu**, [1]Y Yang, [1]L Wu, [1]S Yang, [2]L Ng. *[1]Shanghai Skin Disease Hospital, Shanghai, China; [2]National Microbiology Laboratory, Public Health Agency of Canada, Winnipeg, MB, Canada*

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 VDRL laboratory procedure. The situation is even more challenging in China as there are no commercial VDRL reagents approved by the SFDA for CSF-VDRL examination. In this study we aimed 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 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

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[1]**A Lucht**, [2]S Kuttner-May, [1]D Münstermann, [1]H J Hagedorn. *[1]Labor Krone GbR, Bad Salzuflen, Germany; [2]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 (chemiluminiscent microparticle immunoassay, CMIA, Abbott) performed in the German syphilis consiliary 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

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[1]**H J Hagedorn**, [2]A Kraminer-Hagedorn, [3]S Kuttner-May, [4]H Nitschke, [1]A Lucht, [1]D Münstermann, [5]N H Brockmeyer. *[1]Labor Krone GbR, Bad Salzuflen, Germany; [2]Spirolab GmbH, Bad Salzuflen, Germany; [3]Landeszentrum Gesundheit Nordrhein-Westfalen, Muenster, Germany; [4]Gesundheitsamt, Koeln, Germany; [5]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 2,203 serum or plasma samples from the German syphilis consiliary 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