confirmed HIV-positive. Specificity was high (> 99.8%) for both tests. Four early infections could only be detected by CMIA and confirmed by RT-PCR whereas RA and immunoblot analysis were still negative.

Discussion Approximately half of the LPHA in NRW offered their clients the RA. Clients deciding for RA were slightly different according to age, gender, risk behaviour and HIV status. It could not be shown so far that by offering RAs the LPHA attracted special risk groups which might otherwise not have been tested for HIV. It needs to be considered that some early HIV infections could be detected by CMIA but not by RA.

P2.059 EVALUATION OF A 2ND GENERATION REAL TIME PCR SYSTEM FOR DIAGNOSIS OF *CHLAMYDIA TRACHOMATIS*: IMPACT ON LABORATORY WORKFLOW

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Background The aim of this study was to evaluate the performance and the impact on laboratory workflow of Cepheid Xpert CT, a new generation of Real Time PCR test that provides results in 90 min, with only 2 min of hands on time in comparison with traditional molecular method used (Alert q-PCR ELItech, Nanogen).

Methods 101 selected women (< 25 and; 15% > 25 years old with risk factors) have been enrolled for this evaluation**.** Performances and laboratory workflow were compared: Xpert CT was run on GeneXpert System and Alert q-PCR on ABI 7300 (Life Technologies). Residual samples (500 uL UTM endocervical swabs) previously tested with Alert q-PCR have been used for the Xpert CT assay.

Results On a total of 101 samples, 98 were concordant and 3 were discordant: 2 were positive with Xpert CT and negative for Alert q-PCR and 1 was positive with Alert q-PCR and negative with Xpert CT. It was appreciated the value of Sample Adequacy Control (SAC) in Xpert CT, that presented low Ct value (below 20) in case of severe infection. *Laboratory Workflow*: GeneXpert® steps n = 23 for extraction, amplification and detection (the whole RT-PCR process happened inside the cartridge), TAT 90 min. Alert q-PCR for a run of 24 samples: extraction steps n = 253, amplification and detection steps n = 286, hands on time 70 min, extraction 55 min, amplification and detection 2h, TAT 4 h.

Conclusions GX simplified the laboratory workflow ensuring standardisation, accuracy and reliability of analytical data. The value of SAC supports the quality of sampling to avoid false negative results due to insufficient cells detected. Need evaluation for discrepancy results.

P2.060 MULTIPLEX REAL-TIME PCR FOR THE SIMULTANEOUS DETECTION OF 7 SEXUALLY TRANSMITTED PATHOGENS REVEALS A HIGH RATE OF MULTIPLE INFECTIONS

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Background Sexually transmitted infections are caused by a relatively well defined group of pathogens. Their individual detection using cultural and molecular techniques is time-consuming and costly. Multiplex real-time PCR is a rapid and more cost-effective alternative and allows the detection of multiple infections.

Methods We have validated the Anyplex II™ STI-7, a semiquantitative, highly multiplexed real-time PCR kit (Seegene), using a selection of specimens positive by routine methods (culture, PCR, cytology) for at least one of the 7 different targets. Specimens were assumed to be negative for those parameters not previously tested. DNA was isolated using the easyMAG® (bioMérieux) followed by melting curve analysis-based PCR on a CFX96™ thermocycler (Bio-Rad) and automatic data interpretation with the Seegene Viewer software. Discrepant results were resolved with independent molecular tests.

Results Resolved results showed 100% sensitivity and specificity for *Chlamydia trachomatis* (17 positive/73 negative specimens), *Neisseria gonorrhoeae* (13/71), *Trichomonas vaginalis* (6/84), *Mycoplasma genitalium* (18/72) and *Mycoplasma hominis* (30/60). For *Ureaplasma* species (57/30) 100% sensitivity and 93.3% specificity were observed. The STI-7 test (the only test capable of separating the two major species) revealed that among the 57 *Ureaplasma*-positive specimens 7 (12.3%) were positive for *U. urealyticum*, 39 (68.4%) for *U. parvum* and 11 (19.3%) for both species. Often, 2 or more targets were detected, e.g. of the 17 *C. trachomatis*-positive specimens 8 were positive for 1 and 7 for 2 additional organisms. Ureaplasmas were the most prevalent species being present in about 2/3 of the specimens.

Conclusion We conclude that the STI-7 multiplex PCR is a rapid and reliable test for the simultaneous detection of the most important sexually transmitted pathogens providing an efficient means for a more thorough evaluation of the clinical significance of the various organisms.

P2.061 ACCURACY OF SYNDROMIC DIAGNOSIS (SD) FOR VAGINAL DYSCHARGE AND CERVICITIS IN WOMEN OF REPRODUCTIVE AGE IN BOGOTA, COLOMBIA

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Objective Determine the diagnostic accuracy of the symptoms and signs used in the syndromic diagnosis of low genital tract infections (LGTIs) in symptomatic women.

Materials and Methods: A diagnostic validity study of sexually active women (14–49 years old) consulting with symptoms of LGTI at three outpatient facilities in Bogota, Colombia were recruited in 2010. Exclusion criteria: hysterectomy, pregnancy or antibiotics in the 7 previous days. Symptoms and signs and syndromic diagnosis were evaluated by a physician for two syndromes: Vaginal discharge caused by Bacterial vaginosis (BV) Candida albicans (CA) and Trichomonas vaginalis (TV) and Cervicitis caused by N. gonorrhoeae (NG), and C trachomatis (CT). Those were compared against PCR for CT and NG; Nugent's criteria for BV; wet smear for TV and blood agar culture for CA. Sensitivity, specificity, LR (+), LR (-) for each syndrome and its symptoms and signs were calculated

Results 1372 subjects were evaluated. The prevalence of NG and CT was 1.3% (18/1372) and 9.1% (125/1372); for BV, TV and CA infection was 39.9% (548/1372), 0.8% (11/1372) and 11.1% (152/1372). Sensitivity and Specificity are for syndromic approach for cervicitis 13.3%(CI 95 8.2–20) and 90.9% (CI95 89.1–92.4) respectively. Vaginal discharge is the sign with the most sensitivity for cervicitis and BV, TV and CA infections: 93% and 78%, respectively. In cervicitis, the most specific sign is mucopurulent cervical discharge (91.8%) and for BV, TV and CA infections is erythema valvular (68%).

Conclusions SD for vaginal discharge syndrome has a high sensitivity and a low specificity resulting in a high rate of unnecessary antibiotic treatment (64.9%). SD for cervicitis, has a low sensitivity and high specificity resulting in a high % of false negatives and lack of needed antibiotic treatment in 86.7%. SD alone is an ineffective strategy for LGTIs.

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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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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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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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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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