which culture sensitivity is substantially lower. Reassuringly we had no confirmed cases of ceftriaxone-resistant GC; yet it remains imperative to culture all patients prior to treatment to identify emerging resistant strains.

## P2.036 DETECTION OF HERPES SIMPLEX VIRUSES 1 AND 2 FROM CLINICAL SAMPLES WITH A FULLY-AUTOMATED PCR TEST ON THE COBAS® 4800 SYSTEM

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**Background** Identification of genital herpes can have important implications for clinical management of HIV infected patients, immunosuppressed individuals, pregnant women, and individuals with HSV seronegative partners. This study was performed to establish preliminary performance characteristics for the newly developed cobas® HSV-1/2 Test by evaluating analytical sensitivity and specificity, specimen stability, and clinical performance compared with the BD ProbeTec™ HSV-1/2 Test.

**Methods** Analytical sensitivity was determined using viral culture spiked into a contrived background matrix at predetermined concentrations. Nine levels of viral target were evaluated using the prototype cobas® HSV-1/2 Test. These viral culture panels were also used to assess analytical sensitivity compared to the BD ProbeTec™ HSV-1/2 Test. Preliminary exclusivity of the cobas® HSV-1/2 Test was evaluated with other herpes family viruses (n = 7) and a collection of microorganisms that might be found in lesion swab specimens (n = 31). We also evaluated clinical lesion swab specimens (collected in UVT media for the BD Test and MSwab Media for the cobas® Test). Transport and storage stability of anogenital lesion swab samples collected in MSwab media was assessed by testing specimens stored at RT, 2–8C and –20C.

**Results** The cobas® HSV-1/2 test displayed excellent analytical sensitivity of 150 vp/mL (HSV 1) and 100 vp/mL (HSV-2). When compared to the BD ProbeTec™ HSV-1/2 Test, superior sensitivity was observed for both HSV-1 and HSV-2 with the cobas® HSV-1/2 Test. Exclusivity studies showed no cross reactivity. The cobas® HSV-1/2 Test showed excellent performance with lesion swab specimens, observing a sensitivity and specificity of 100% and 100% for HSV-1 and 100% and 94% for HSV-2, respectively. Preliminary specimen stability studies for routine laboratory workflow indicate favourable performance.

**Conclusion** The cobas® HSV-1/2 test, run on the fully automated cobas® 4800 system, exhibited excellent preliminary performance characteristics, suitable for identifying low concentration HSV-1 and HSV-2 from anogenital lesions.

## P2.037 MULTICENTER EVALUATION OF THREE NOVEL 4TH GENERATION HIV AG/AB COMBO ASSAYS: ABBOTT ARCHITECT, ROCHE HIV COMBI AND SIEMENS ADVIA CENTAUR

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**Background** Currently, 24 out of 39 laboratories in Quebec use the AxSYM HIV Ag/Ab Combo for HIV screening. This kit will be discontinued December 2013 and three novel 4th generation screening HIV assays (Architect, Roche Elecsys HIV Combi and ADVIA CENTAUR), approved by Health Canada, represent the alternative to AxSYM.

**Objective and Methods:** To investigate the performance of these 3 novel screening HIV Combo assays, in 6 clinical sites from Quebec. A total of 150 samples from patients with documented acute infection, a panel of 25 Seracare HIV-1 specimens, 3 quality control specimens (HIV-1.2 Ab POS, p24Ag POS, HIV-1.2 NEG), and 5577 sera from routine diagnostic patients were tested.

**Results** Sensitivity assessment- The 3 novel combos demonstrated comparable 100% sensitivity. Confirmed positive samples on the Architect and Roche Elecsys presented much greater S/CO values than AxSYM.

Specificity assessment- Each novel combo was compared separately to the AxSYM. Discordant results were confirmed using supplemental confirmatory assays.

The specificity of Architect was evaluated using 1099 specimens: 1095/1099 were non reactive, 3/1099 were reactive and 1/1099 was discordant. For Roche Combo, 3282 specimens were tested: 3222/3282 were non reactive, 41/3282 were reactive, and 19/3282 were discordant. The Advia Centaur was evaluated using 1196 specimens, 1177/1196 were non reactive, 12/1196 were reactive and 7 were discordant.

Amongst the 66 specimens that were reactive with novel and AxSYM combos, 52 (79%) were confirmed positive. All discordant results were confirmed negative. The 5494 specimens that were negative with both kits (novel and AxSYM) demonstrated lower S/CO values on Architect and Roche than on AxSym.

**Abstract P2.037 Table 1**

| | Architect | Roche | Advia Centaur |
|---|---|---|---|
| Sensitivity (%) | 100 | 100 | 100 |
| Specificity (%) | 99.90 | 99.53 | 99.75 |
| Concordance with AxSYM (%) | 99.90 | 99.42 | 99.41 |

**Conclusions** The 3 novel HIV Ag/Ab Combo demonstrated good performance (sensitivity, specificity and concordance) with better segregation of positive and negative samples than AxSYM. All 3 kits represent a good alternative to the AxSYM.

## P2.038 HEPATITIS C VIRUS (HCV) ACUTE INFECTION IN HIV-INFECTED MSM DUE TO SEXUAL TRANSMISSION: DESCRIPTION OF SIX CASES

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**Background** The transmission of HCV happens mostly across percutaneous exposure to blood. The role of the sexual transmission has not been well defined. In the last years HCVcases due to sexual transmission in HIV-infected MSM have been described. METHODS: Descriptive study of HIV-infected patients seen in our clinic, who showed HCV antibodies simultaneously with HCV-RNA-positive test and that previously had a negative test for antibody, without reporting injection drug use. Period of study: August 2011 to February 2013. RESULTS: We have diagnosed six cases. Age: 40.2 ± 6.22; length of HIV infection: 9.83 ± 6.17 yr. All the patients reported unsafe sex in the six previous months and all were on ART with HIV viral load ≤ 50 copies/ml. HBV-coinfection:1/6 (16.6%); Anti-HBs Ab ≤ 10 UI: 2/6 (33.3%). Previous sexual transmitted infections (STI): 5/6 (83.3%). Baseline CD4 count: 686.2 ± 198.3 cells/μL. Median ASAT: 200.6 ± 163 IU/L; median ALAT: 491.8 ± 334.4 IU/l. Median HCV-RNA at presentation: 2.133.293 ± 1.703.605 IU/mL.

HCV genotype: G4 3/5 (60%), G1 2/5 (40%) (result of 1 patient, pending). Polymorphism of IL28B not favourable in 4/6: rs12979860 CT and rs8099917 TG (2 patients pending genetic analysis). Fibroscan® at diagnosis: F2 3/6 (50%), F0 (1), F1 (1), F3 (1). No patient showed jaundice as a clinical presentation. During the evolution nobody presented decline ≥ 2 log of HCV-PCR at 1st month of the diagnosis, neither on the 3rdmonth spontaneous viral clearance. A patient has received treatment withpegIFN+ribavirine six months after the diagnosis, with rapid virological response (negative HCV-PCR at 4 wk).

**Conclusion** This report suggests that hepatitis C is an emergent STI in MSM population HIV-infected. The evolution towards chronicity is common. It should also be considered in case of sudden increase of transaminases, even without symptoms and therefore should be a part of the annual serology screening.

## P2.039 LATE PRESENTATION TO CARE REMAINS A PROBLEM IN CROATIAN NATIONWIDE COHORT

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**Background** Late presentation to care of HIV-positive individuals and late introduction of antiretroviral therapy can lead to occurance of opportunistic diseases and higher morbidity and mortality of patients. Croatia is a country with a low-level HIV epidemic. Even after interventions undertaken during the Croatian Global Fund Project in 2004–2006 late presentation to care remains a problem.

**Methods** The aim of this study was to determine the percentage of late presenters among newly-diagnosed HIV-positive individuals who entered clinical care from January of 2007 till December of 2011. Late presenters were defined as patients with < 350 CD4 T-cells per $\mu$l. CD4 T-cell count was measured by flow cytometry (Beckman Coulter Flow Count reagent).

**Results** The number of patients diagnosed with HIV did not grow dramatically over the years (52 newly-diagnosed HIV-individuals entered clinical care in 2007, and 77 in 2010). The percentage of late presenters however, did grow over the years, from 46.2% in 2007 to 64% in 2011. Still, the number of patients presented to care with less than 200 CD4 T-cells/$\mu$l was the lowest in 2011 (30 patients out of 48, 62.5%), and highest in 2007 (19 out of 24 patients, 79.2%).

**Conclusion** The percentage of late presenters in Croatia is still quite high, even though there are fewer patients with less than 200 CD4 T-cells/$\mu$l. A national strategy for earlier entrance to care should be developed.

## P2.040 MULTIPLEXED FLUORESCENCE IMMUNOASSAY SYSTEM FOR RAPID SEROLOGIC TESTING AT THE POINT-OF-CARE

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**Background** MBio Diagnostics is developing a multiplexed immunoassay platform capable of simultaneous detection of serologic disease markers from a single drop of blood. Here we demonstrate the system in the context of HIV and AIDS-related co-infection testing. Multianalyte testing at the time of HIV diagnosis is essential for individualised management of HIV infection. The MBio System is designed to address the unmet need for timely and cost-effective co-infection testing.

**Methods** The MBio multiplexed immunoassay system is based on single-use disposable cartridges and an inexpensive reader. A simple, 10 minute assay protocol was developed for delivering HIV-1 antibody (Ab) reactivity results on whole blood, plasma, or serum samples. A total of 87 whole blood samples were run with the 10 minute assay. 50 HIV-1 Ab negative samples were used to establish cutoffs. 37 HIV-1 Ab positive samples were used to assess system sensitivity. A set of 5 commercially available HIV-1 seroconversion panels were also used to assess the system. System demonstration in the context of syphilis and hepatitis C virus (HCV) testing was also performed on a subset of clinical specimens.

**Results** Ab reactivity results using the 10 minute assay protocol showed 100% concordance with known HIV serostatus for the 87 whole blood samples tested. Data for the seroconversion panels showed that MBio System performance meets or exceeds package insert data for FDA-approved HIV Ab rapid diagnostic tests. Simultaneous detection of syphilis (*T. pallidum*) and HCV Ab reactivity has been demonstrated.

**Conclusions** The dataset presented here demonstrates a simple, 10 minute assay protocol on the MBio multiplexed immunoassay system. Multianalyte testing from unprocessed whole blood at the POC should enable improved therapeutic decision making, particularly in limited resource settings.

## P2.041 INTRODUCING A NEW TYPE OF HIV RAPID TESTING BASED ON ORAL FLUID AT NON-GOVERNMENTAL ORGANISATIONS OF KYRGYZ REPUBLIC

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**Background** In Kyrgyz Republic HIV mainly spreads among the high risk behaviour population groups (mainly injection drug users - IDUs). Approximately 450,000 people are being tested for HIV in Kyrgyzstan per annum and less than 1% of them are IDUs, when testing of IDUs results in more than 60% of all new infections. Thus, access to testing remains the main challenge and priority for the national response to HIV.

**Methods** The UNDP in Kyrgyzstan, jointly with the Republican AIDS centre have started a roll out of HIV rapid testing based on oral fluid. For this pilot, there've been assessed and selected 12 non-governmental organisations (NGOs), who work with IDUs, sex workers and men who have sex with men. A pool of non-medical testing counsellors was certified after trainings on rapid testing, based on CDC/WHO training modules. OraQuick Advanced HIV 1–2 rapid test was selected for the roll out of the pilot.

**Results** Within the first three months of the pilot, 1,335 clients of the mentioned above NGOs, were tested for HIV by using oral fluid rapid tests. Some 6% of tested, had preliminary positive results of rapid test and were referred to nearest AIDS centres for further HIV confirmatory tests (ELIZA, Western Blot). There were only 2 cases of false positive results of rapid tests, which is less than 0.15% of all rapid tests results.

**Conclusions** Kyrgyz Republic is the first country in the Central Asian region, who introduced this new type of HIV rapid testing at community based organisations. First few months of the pilot have shown that non-medical professionals can provide this type of services to their clients, after the proper training. Now, people from the high risk behaviour population groups, especially those that had never been tested for HIV, are being tested at NGOs with rapid tests.

## P2.042 AN AUDIT OF HIV TESTING RATES IN PATIENTS ADMITTED WITH PNEUMONIA PRE- AND POST- IMPLEMENTATION OF OPT-OUT HIV TESTING FOR ACUTE MEDICAL ADMISSIONS

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**Background** UK National Guidelines for HIV Testing recommend that an HIV test should be considered in all general medical