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Background HSV infections during pregnancy are generally asymptomatic and associated with high rate of neonatal morbidity and death. Differential serologic diagnosis of HSV infections in pregnancy is important for the correct assessment of the infection status. The aim of this study was to evaluate the performance of Roche Elecsys® assays for the type specific determination of HSV-1 and HSV-2 IgG antibodies.

Methods A total of 800 samples obtained from sexually active adults (n = 300), pregnant women (n = 400) and herpes infection suspected patients(n = 100) were analysed using Roche Elecsys® HSV-1 and HSV-2 assays and commercially available Focus Diagnostics HerpeSelect, Radim HERPES S.V and Diasorin LIAISON type specific ELISA assays.

A commercially available Western Blot assay was used for the resolution of the discrepant results.

For further confirmation of the type specific detection performance of the Elecsys® HSV-1 and HSV-2 assays 310 potentially cross reactive samples for HSV-2 and 123 samples for HSV-1 were analysed.

Results The Elecsys® HSV-1 IgG assay showed a relative sensitivity of 95.6 to 100%. The relative specificity was between 97.6 and 100%. The Elecsys® HSV-2 IgG assay showed a relative sensitivity of 92.6 to 100%. The relative specificity was between 98.7 and 100%. These assays exhibits excellent differentiation between HSV-1 and HSV-2 infections with no cross reactivity to other herpes viruses like CMV, VZV or EBV.

Conclusion The results obtained with the type specific Roche Elecsys® HSV-1 and HSV-2 assays indicate that these assays are useful, specific and sensitive for the differential determination of HSV-1 and HSV-2 IgG antibodies in serum or plasma samples. The advantage of the Roche Elecsys® assays compared to ELISA based assays, is that these assays are rapid and can be performed in a fully automated process.

P5.072 THE PERFORMANCE OF TWO IGG ELISA METHODS TO DETECT HSV-2 INFECTIONS AMONG SOUTH-AFRICAN WOMEN WHO ARE AT HIGHER RISK OF BECOMING HIV INFECTED

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Background Specimens collected in Pretoria for the FEM-PrEP study, a phase III trial on pre-exposure prophylaxis for HIV prevention among African women, were tested for Herpes Simplex Virus type II (HSV-2). We present here the performance of the Focus HerpeSelect and Kalon HSV-2 gG2 ELISA.

Methods The HSV-2 infection was determined in 701 women at baseline with two IgG ELISAs: Kalon HSV-2 gG2 ELISA (Kalon Biologicals Ltd.) and HerpeSelect HSV IgG ELISA (Focus Technologies). Participants were considered true positive for HSV-2 when specimens were reactive in both assays. In order to determine incident HSV-2 infections during the study, specimens collected at final visit (i.e. after 52 weeks/at product interruption visit) of participants being HSV-2 seronegative at baseline were tested using the same assays.

Results At baseline, 287 and 315 positive results were found using the Kalon- and Focus assay, respectively. All Kalon positives were also positive in the Focus assay and considered to be true infections (initial prevalence: 40.9%). Of the 28 specimens positive with the Focus only, 10 of them became true positive at final visit. We therefore assume that the Kalon missed 10 infections and, the Focus detected falsely 18 positives at baseline, resulting in a final HSV-2 prevalence of 42.4% at baseline. At final visit, an additional 33 new infections were found. At baseline we obtained a sensitivity of 100% (95% CI: 98.8–100) and 96.6% (95% CI: 93.9–98.4) and a specificity of 95.5% (95% CI: 93.1–97.3) and 100% (95% CI: 99.1–100) for Focus and Kalon respectively.

Conclusion Although our study confirms the assay performance findings of previous studies in Sub-Saharan countries, we found less pronounced differences in terms of sensitivity and specificity of both assays using the cut-off as prescribed by the manufacturers. The prevalence of HSV-2 found in our study corresponds to previously reported results.

P5.073 COMPARISON OF COBAS® 4800 HPV ASSAY TO DIGENE HYBRID CAPTURE 2, ROCHE LINEAR ARRAY, AND AMPLICOR IN THE DETECTION OF HIGH-RISK HUMAN PAPILLOMAVIRUS GENOTYPES IN WOMEN WITH PREVIOUS ABNORMAL PAP SMEARS

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Introduction Cobas® 4800 HPV assay has been evaluated as a screening and triage application recently. The aim of this study was to evaluate the performance of the Cobas® 4800 HPV assay for the detection and identification of high-risk (HR) HPV genotypes after treatment of high grade lesion by comparison with the Hybrid Capture 2® (HC2), Amplicor (Amp), and Linear Array (LA) HPV tests.

Methods Four hundred and six PreservCyt® specimens from women undergoing management for a high-grade Pap abnormality were evaluated and results compared with the HC2, Amp, and LA HPV test results, in addition to histological diagnosis of a contemporaneously collected biopsy.

Results The sensitivity in detection of underlying high-grade histological diagnosis by Cobas® 4800 HPV was 90.6%, for HC2 86.1%, whilst for Amp and LA 92.9% and 91.8% respectively. Restricting detection of Cobas® 4800 HPV to only types 16 and 18 resulted in sensitivity of 60.0%. Detection of HR genotypes by Cobas® 4800 HPV showed a concordance of 86.9%, 96.1%, and 96.3% when compared to HC2, Amp and LA respectively. Detection of HPV 16 and 18 by Cobas® 4800 HPV showed a concordance of 97.3% and 99% respectively when compared to LA.

Conclusion The performance of Cobas® 4800 HPV was equivalent to the Amp and LA HPV tests for HR HPV detection. Cobas® 4800 HPV identified more underlying histologically-confirmed high-grade lesions than the HC2 HPV test, with the added advantage of identifying HPV 16 and 18 genotypes present.

P5.074 IMMUNE ACTIVATION AFTER STIMULATION WITH CRYPTOCOCCUS NEOFORMANS ANTIGENS PRE AND POST ART INITIATION IN HIV-1 POSITIVE UGANDANS

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Background Cryptococcus meningitis immune reconstitution inflammatory syndrome (CM-IRIS) is a medical condition that complicates recovery from immunodeficiency as a result of anti retroviral therapy (ART) in patients living with Human Immunodeficiency Virus type 1 (HIV-1) in the sub Sahara Africa region.