

P1410

Poster Session V

Molecular and non-molecular diagnostics of viruses

PERFORMANCE CHARACTERISTICS OF AN AUTOMATED ASSAY ON THE COBAS® 4800 SYSTEM TO DETECT HERPES SIMPLEX VIRUS WITH THE COBAS® HSV 1 & 2 TEST

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Objectives: 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 of the newly developed **cobas**® HSV 1 and 2 Test by evaluating previously tested samples diluted in Mswab media.

Methods: Clinical lesion swab specimens previously collected in universal transport medium (200uL) were added directly to MSwab Media for evaluation with the **cobas**® HSV 1 and 2 Test. Specimens were previously tested using a panel of laboratory developed TaqMan® (LDT) assays to detect sexually transmitted infections. Specimens were extracted using the DSP Virus/Pathogen kit on the QIASymphony SP robot (Qiagen Inc. Valencia, CA). LDT assays to detect HSV-1 and HSV-2 used primers and probes described previously (van Doornum *et al*, 2003. J Clin Micro 41:576-580) and Platinum® Quantitative PCR SuperMix-UDG reagents (Invitrogen / Life Technologies, Calsbad, CA). LDT assays were run on LC480 real-time PCR instruments (Roche Applied Science) in a CPA-UK Accredited laboratory.

Results: Evaluation of 173 samples by the **cobas**® HSV 1 and 2 Test and the LDT assay resulted in a positive percent agreement and negative percent agreement for HSV 1 of 97.4% of 95.6% , and for HSV 2 of 95.5% and 100% respectively.

Conclusion: The **cobas**® HSV 1 and 2 Test, run on the fully automated **cobas**® 4800 system, demonstrated excellent performance for detecting HSV 1 and 2 from previously evaluated clinical specimens diluted in MSwab medium when compared to our laboratory developed TaqMan® PCR tests. The automated **cobas**® 4800 system offers advantages for routine testing of specimens in a busy clinical laboratory.