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Abstract (poster session)

A fully-automated polymerase chain reaction (PCR) test for detection of herpes simplex viruses 1 and 2 on the cobas® 4800 system

K. Ding*, S. Igdari, M. Magarajan, R. Mababangloob, D. Kosarikov (Pleasanton, US)

Objectives: To establish preliminary performance characteristics for the newly developed cobas® HSV-1/2 Test by evaluating analytical sensitivity and specificity, specimen stability, and 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 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 room temperature, 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 with 7 other herpes family viruses or 38 organisms evaluated. 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 favorable performance. Conclusion: The cobas® HSV-1/2 test, run on the fully automated cobas 4800 system, exhibited excellent performance characteristics and was found to be suitable for identifying low concentration HSV-1 and HSV-2 from anogenital lesions.