EV0913

ePoster Viewing

Molecular virology

Evaluation of anogenital lesion swabs with the cobas® HSV 1 and 2 test for detection of HSV DNA compared with an alternate molecular method

S. Taylor[1], K. Fife[2], E. Hook- III[3], R. Patel[4], K. Ding[5], J. Duncan[5], O. Liesenfeld[5], J. Osiecki[6], M. Lewinski[5]

[1]*Louisiana State University School of Medicine, New Orleans- LA, USA*

[2]*Indiana University School of Medicine, Indianapolis- IN, USA*

[3]*University of Alabama at Birmingham, Birmingham- AB, USA*

[4]*Royal South Hants Hospital, Southampton- England, United Kingdom*

[5]*Roche Molecular Systems, Pleasanton- CA, USA*

[6]*Roche Molecular Systems, Pleasanton CA, USA*

Objectives: Genital herpes is a common sexually transmitted disease caused by Herpes simplex viruses type 1 (HSV-1) or type 2 (HSV-2). The diagnosis of genital herpes can be established by testing anogenital lesion specimens from symptomatic patients by culture or molecular methods. Nucleic acid amplification tests have proven to be rapid and sensitive tools for the direct detection of HSV-1 and HSV-2 DNA in clinical specimens. The objective of this study was to evaluate the newly developed **cobas®** HSV 1 and HSV 2 Test using clinician-collected swab specimens from external anogenital lesions as part of a large multicenter clinical trial.

Methods: Patients suspected of HSV infection were selected for participation. Specimens were collected at 8 geographically diverse sites using 2 swabs per study subject. The first swab was used for the BD ProbeTec™ HSV 1 & 2 Assays (Sparks, Maryland, USA), and the second with the cobas® HSV 1 and 2 Test. All testing was performed at 3 sites according to manufacturer's instructions. For the **cobas**® HSV 1 and HSV 2 Test, anogenital swab specimens collected in MSwab transport (Copan, Brescia, Italy) were uncapped and loaded directly on the automated **cobas®** 4800 system for processing, PCR setup, amplification and detection. The overall percent agreement (OPA), positive percent agreement (PPV) and negative percent agreement (NPV) were calculated by comparing **cobas**® HSV 1 and HSV 2 Test results with BD ProbeTec™ Herpes Simplex viruses (HSV 1 & 2) Q^x Amplified DNA Assays. Discrepant analysis was performed by Sanger sequencing on discordant samples.

Results: There were 407 evaluable results from 203 female and 204 male subjects with 232 HSV positive subjects; 73 HSV-1 positive (44 female, 29 male) and 159 HSV-2 positive (79 female, 80 male) subjects. The OPA, the PPA and NPA of the **cobas**® HSV 1 and HSV 2 Test compared to the BD ProbeTec HSV 1 & 2 Assays for HSV-1 was was 98.0% (399/407) 98.6% (73/74) and 97.9% (326/333), respectively, and for HSV-2 was 96.1% (391/407), 99.4% (159/160) and 93.9% (232/247), respectively. Of the 7 discordant HSV-1 false positive samples, 4 tested positive by Sanger sequencing; 2 did not yield nucleic acid for sequencing and 1 remains to be tested. Of the 15 discordant HSV-2 false positive samples, 6 tested positive by Sanger sequencing, 5 samples did not yield nucleic acid for sequencing, and 4 remain to be tested.

Conclusion: The **cobas**® HSV 1 and 2 Test, performed on the automated **cobas**® 4800 system, displayed excellent performance compared to an alternate molecular method when evaluating 407 clinician-collected anogenital swab specimens from symptomatic patients.