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USE OF A SIMPLE, RAPID TEST (BIOKIT-HSV-2) TO CONFIRM SCREENING HSV-2 ANTIBODY RESULTS BY HERPESELECT -HSV-2 ELISA (“FOCUS”)

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Objectives: To evaluate an accessible, cost-effective alternative to western blot (WB) to confirm HSV-2 screening antibody results by HerpeSelect HSV-2 ELISA.

Methods: 1,297 sera from Seattle men who have sex with men (N=673) or lower risk sera submitted to a diagnostic laboratory for HSV testing (N=624) were tested by Focus-HSV-2 (Focus Diagnostics, Cypress CA) and WB. Of 1235 evaluable sera, 442 (35.8%) were positive by Focus and 793 (64.2%) were negative. All 442 positive sera and 340 of 442 negative sera (total N=782) were then tested by biokit-HSV-2 ("biokit"; Biokit USA, Lexington MA). Test results were compared with WB. Then, ability of the biokit-HSV-2 test to confirm positive Focus results (index values >1.1) was assessed.

Results: Sensitivity, specificity, positive and negative predictive values were: 99.7, 79.8, 80.5, and 99.7 for Focus and 94.7, 92.9, 91.8, and 95.4 for biokit. Concordance was 87.8 (Focus-biokit); 88.8 (Focus-WB) and 93.7 biokit-WB). Discordant results were rare in Focus negative sera: 11 (3%) by biokit and 1 (<1%) by WB. Of 442 positive Focus results, 357 (80.8%) confirmed by biokit; 356 (80.5%) by WB. Of 105 Focus positive results that did not confirm, 68 (65%) were negative by both biokit and WB and most (89/105; 84.8%) were low positive (index value >1.1; <3.5).

Use of biokit on Focus positive sera increased the specificity from 79.8 to 94.5 with sensitivity of 99.7; PPV 94.7; and NPV 99.7. Results that did not give a clear indicator of HSV-2 infection status increased from 21/1297 (1.6%) to 106/1297 (8.2%) with the confirmatory step.

Conclusions: The biokit-HSV-2 test, when used as a confirmatory test, can markedly increase the specificity of HSV-2 antibody screening results by Focus HerpeSelect.