Genital swab claim cleared for HSV test, 11/15

Quest Diagnostics announced that its Focus Diagnostics products business has received 510(k) clearance to add the genital swab claim to its Simplexa HSV 1 and 2 Direct molecular test on the 3M Integrated Cycler. The new labeling clearance follows the agency's de novo clearance and CLIA moderate-complexity categorization of the Simplexa HSV 1 and 2 Direct in March 2014. The FDA cleared the test at that time for use with cerebrospinal fluid from patients suspected of HSV central nervous system infection, including encephalitis.

***Focus Diagnostics**, 562-240-6500*