FDA authorizes first NGS test for detecting HIV-1 DRMs

Nov. 8, 2019—Vela Diagnostics received FDA authorization to market its in vitro diagnostic test for the detection of HIV-1 genomic drug resistance mutations in patients taking or about to start antiviral therapy. The assay uses the plasma of patients infected with HIV-1 to detect HIV-1 group M drug resistance mutations in the protease, reverse transcriptase, and integrase regions of the pol gene. It is the first HIV drug resistance assay that uses NGS technology that the FDA has authorized for marketing in the United States.

“The granting of the de novo designation of our NGS assay by the U.S. FDA is a major milestone in HIV diagnostics. Vela strives to bring relevant products to clinicians to help patients around the world. With the Sentosa SQ HIV-1 Genotyping Assay, laboratories will now have a sample-to-report solution to aid in monitoring and treating HIV-1 infection,” Sam Dajani, Vela’s acting CEO and chairman of the board, said in a company press release.

The assay is validated on the Sentosa NGS workflow and has a hands-on time of less than two hours and a turnaround time of two days.