FDA expands approval for Ventana PD-L1 (SP263) assay

March 13, 2023—Roche announced that the FDA has approved the Ventana PD-L1 (SP263) assay as a companion diagnostic to identify patients with non-small cell lung cancer who are eligible for treatment with Libtayo, a PD-1 inhibitor therapy developed by Regeneron. Libtayo (cemiplimab-rwlc) was approved in February 2021 for the first-line treatment of patients with advanced NSCLC whose tumors have a tumor proportion score of greater than or equal to 50 percent, as determined by an FDA-approved test.

Ventana PD-L1 (SP263) assay testing is performed on Roche's BenchMark Ultra instrument and is visualized using the OptiView DAB IHC detection kit.