

## FDA expands approval for Ventana PD-L1 assay

May 2023—Roche announced FDA approval of the Ventana PD-L1 (SP263) assay as a companion diagnostic to identify patients with locally advanced and metastatic non-small cell lung cancer eligible for treatment with Libtayo (cemiplimab-rwlc), a PD-1 inhibitor therapy developed by Regeneron. Libtayo's approval is based on results of the phase three EMPOWER-Lung 1 study. The OptiView DAB IHC detection kit is used for staining on a BenchMark Ultra instrument.

[Roche](#), 317-521-2000