Roche Ventana MMR RxDx gets expanded approval

Aug. 15, 2022—Roche announced that the FDA has approved a label expansion for the Ventana MMR RxDx panel, an immunohistochemistry companion diagnostic test to aid in identifying patients whose solid tumors are deficient in DNA mismatch repair (dMMR) and who may be eligible for Keytruda (pembrolizumab). The panel also aids in identifying patients with endometrial cancer whose tumors are proficient in DNA mismatch repair (pMMR) and who may be eligible for a combination of Keytruda and the tyrosine kinase inhibitor Lenvima (lenvatinib).

The panel is intended for the assessment of expression of MMR proteins in formalin-fixed, paraffin-embedded tumor tissue stained with the OptiView DAB IHC detection kit and ancillary reagents in the panel for Ventana anti-MLH1 (M1), Ventana anti-MSH2 (G219-1129), and Ventana anti-MSH6 (SP93) and the OptiView DAB IHC detection kit with the OptiView amplification kit and ancillary reagents for Ventana anti-PMS2 (A16-4) on a BenchMark Ultra instrument.

This label expansion follows the FDA approval of the Ventana MMR RxDx panel in April of last year as the first IHC predictive test to identify patients with endometrial carcinoma who are eligible for treatment with the anti-PD1 immunotherapy Jemperli (dostarlimab-gxly).