Tempus gets FDA premarket approval for xT CDx

May 1, 2023—Tempus announced that the FDA has approved the company's premarket approval application for its companion diagnostic test, xT CDx, to identify patients who may benefit from treatment with the targeted therapies listed in the product's indications for use. It is a qualitative next-generation sequencing–based in vitro diagnostic device for use in the detection of single nucleotide variants, multi-nucleotide variants, and insertion and deletion alterations in 648 genes and includes the evaluation of microsatellite instability. It uses DNA isolated from formalin-fixed, paraffin-embedded tumor tissue specimens and matched normal blood or saliva specimens from patients previously diagnosed with cancer who have solid malignant neoplasms. It also includes companion diagnostic claims for patients with colorectal cancer.