FDA clears Promega OncoMate MSI Dx system

July 29, 2021—Promega's OncoMate MSI Dx analysis system has been cleared by the FDA as an IVD medical device to determine microsatellite instability status in colorectal cancer tumors.

OncoMate MSI is a fluorescent, multiplex PCR-based fragment-sizing test. The system targets five mononucleotide repeat markers (BAT-25, BAT-26, NR-21, NR-24, and MONO-27) that were selected for high sensitivity and specificity to alterations in repeat lengths in samples containing mismatch repair defects. Turnaround time is as few as 10 hours.