EntroGen gets PMA for CRCdx RAS mutation detection kit

Nov. 21, 2023—The FDA has granted premarket approval for EntroGen's CRCdx RAS mutation detection kit as a companion diagnostic for Vectibix (panitumumab). The qualitative real-time PCR-based test is intended for the detection of 35 variants of KRAS and NRAS exon 2, 3, and 4 somatic mutations in genomic DNA extracted from formalin-fixed, paraffin-embedded colorectal cancer tissue samples.

"We expect CRCdx to improve access to RAS testing at small and midsize laboratories by simplifying the testing procedure while improving the turnaround time and lowering the diagnostic costs," Matthew Minkovsky, CEO of EntroGen, said in a press release.

The test can be completed in approximately two hours from isolation of DNA to test result.