Adaptive gets expanded FDA clearance for ClonoSEQ assay

Aug. 20, 2020—Adaptive Biotechnologies received FDA clearance for its ClonoSEQ assay to detect and monitor minimal residual disease in blood or bone marrow from patients with chronic lymphocytic leukemia. The assay is an in vitro diagnostic that uses multiplex polymerase chain reaction and next-generation sequencing to identify and quantify rearranged IgH (VDJ), IgH (DJ), IgK, and IgL receptor gene sequences, as well as translocated BCL1/IgH (J) and BCL2/IgH (J) sequences in DNA extracted from bone marrow from patients with B-cell acute lymphoblastic leukemia or multiple myeloma and blood or bone marrow from patients with chronic lymphocytic leukemia.

The company has launched a service for ClonoSEQ patients to obtain blood draws at any of LabCorp's patient service centers in the United States or by a qualified professional in the patient's home through Adaptive's collaboration with Phlebotek Solutions, a nationwide provider of mobile phlebotomy services.

"The FDA clearance of ClonoSEQ in CLL represents a significant advancement for patients with CLL," Lance Baldo, chief medical officer of Adaptive Biotechnologies, said in a press statement. "We believe this first-time clearance for ClonoSEQ in blood will be advantageous for both providers and patients. Given the risks that COVID-19 poses for cancer patients, we are proud to be collaborating with two best-in-class service providers to offer ClonoSEQ patients flexible and safe options for blood sample collection outside of a hospital or clinic."