FDA clears digital PCR test for monitoring CML therapy

Feb. 19, 2019—Bio-Rad Laboratories announced that its QXDx AutoDG ddPCR System, which uses the company's droplet digital PCR technology, and the QXDx BCR-ABL %IS Kit received FDA clearance. The system and kit, when used together, can monitor molecular response to treatment in patients with chronic myeloid leukemia.

"Bio-Rad is proud to announce our first FDA-cleared liquid biopsy test in oncology," Annette Tumolo, Bio-Rad executive vice president and president, Life Science Group, said in a press release. "The QXDx AutoDG ddPCR System and QXDx BCR-ABL %IS Kit represent the first-ever digital PCR solution that can monitor and directly quantitate the molecular response of patients with chronic myeloid leukemia under tyrosine kinase inhibitor therapy."

Using the QXDx BCR-ABL %IS Kit, clinicians can monitor residual disease in patients with CML, even at low levels. The QXDx AutoDG ddPCR System is designed to be flexible, allowing users to run either FDA-cleared in vitro diagnostic tests or laboratory-developed tests on the platform.