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Bio-Rad releases first FDA-cleared Digital PCR assay for CML treatment

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Using the QXDx BCR-ABL %IS Kit, clinicians can accurately and reproducibly monitor residual disease in patients with CML.

Bio-Rad Laboratories, Inc., a global leader of life science research and clinical diagnostic products, has announced that its QXDx AutoDG ddPCR System, which uses Bio-Rad's Droplet Digital PCR technology, and the QXDx BCR-ABL %IS Kit are the industry's first digital PCR products to receive U.S. Food and Drug Administration (FDA) clearance. Used together, Bio-Rad's system and kit can precisely and reproducibly monitor molecular response to treatment in patients with chronic myeloid leukemia (CML).

"Bio-Rad is proud to announce our first FDA-cleared liquid biopsy test in oncology," said Annette Tumolo, Bio-Rad EVP and President, Life Science Group. "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."

CML is a cancer of white blood cells that is characterized by a fusion of the BCR and ABL genes. Tyrosine kinase inhibitor (TKI) therapy has transformed CML into a manageable chronic disease for many patients. The current standard for monitoring treatment response in patients with CML is using reverse transcription quantitative PCR (RT-qPCR), but this method can produce variable results, particularly when measuring low levels of the disease. Using the QXDx BCR-ABL %IS Kit, clinicians can accurately and reproducibly monitor residual disease in patients with CML, even at low levels, offering physicians better insight into the management of this disease.

The QXDx AutoDG ddPCR System is designed to be flexible, allowing users to run either FDA-cleared in vitro diagnostic tests or lab developed tests on the platform.