FDA approves Qiagen PIK3CA CDx

June 3, 2019—Qiagen announced the launch of its Therascreen PIK3CA RGQ PCR Kit after it received U.S. regulatory approval as a companion diagnostic to aid in identifying breast cancer patients eligible for treatment with alpelisib (Piqray, Novartis), which was co-approved by the FDA.

The Therascreen PIK3CA Kit is the first companion diagnostic assay to obtain premarket approval from the FDA for use in any cancer indication for detection of activating mutations in the PIK3CA gene, the company said, and the first FDA-approved assay for guiding treatment decisions using plasma specimens as a liquid biopsy. The assay detects 11 PIK3CA mutations, which are estimated to be present in approximately 40 percent of hormone receptor–positive advanced or metastatic breast cancer patients.

“We are making the Therascreen PIK3CA Kit available immediately following this FDA approval through leading laboratories in the U.S. as a result of Qiagen’s Day-One Lab Readiness program for precision medicine,” Thierry Bernard, senior VP and head of Qiagen’s molecular diagnostics business area, said in a release. “We are convinced that our new Therascreen PIK3CA Kit, which expands our market-leading Therascreen portfolio of companion diagnostics, and the approval of Piqray together provide a valuable treatment option for those searching for new ways to combat advanced breast cancer.”

The real-time qualitative PCR kit is processed on the company’s Rotor-Gene Q MDx.