Qiagen launches Therascreen PITX2 test in Europe

Feb. 14, 2018—Qiagen announced the European launch of its novel Therascreen PITX2 RGQ PCR Kit, a clinically validated DNA methylation assay that helps predict the response of certain high-risk breast cancer patients to anthracycline-based chemotherapy. The CE-IVD marked assay is Qiagen's first epigenetic test in breast cancer.

"We are very pleased to introduce this important test for personalized health care used to assess the best treatment approach for high-risk breast cancer patients. This reliable, clinically validated assay determines the PITX2 DNA methylation ratio to differentiate between patients who are more likely—or less likely—to show beneficial response to anthracyclines," Thierry Bernard, senior VP of the molecular diagnostics business area, Qiagen, said in a statement. "The simple workflow of the Therascreen PITX2 assay provides automated processing from sample to insight in less than 48 hours. The test can easily be adopted by customers already running other Therascreen assays on our widely used QIAsymphony automation platform."

The Therascreen PITX2 RGQ PCR Kit determines the percent methylation ratio (PMR) in promoter 2 of the pituitary homeobox transcription factor 2 (PITX2) gene as a novel biomarker. The clinical performance of the Therascreen PITX2 assay was evaluated in a retrospective clinical study in lymph node-positive, estrogen receptor-positive, and HER2-negative high-risk breast cancer patients treated with anthracycline-based chemotherapy. Patients with low PMRs demonstrated increased disease-free survival, applying a 10-year follow-up as the primary study endpoint.

The assay is processed on the company's Rotor-Gene Q MDx real-time cycler with automated analysis and calculation of the PITX2 PMR using Rotor-Gene AssayManager software.

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