

## Qiagen to enhance precision medicine in breast cancer

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**It is the first FDA approved assay for guiding treatment decisions in breast cancer using plasma specimens as a liquid biopsy.**



QIAGEN has launched the **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 **PIQRAY (alpelisib)**, a newly approved therapy developed and marketed by Novartis.

The **therascreen PIK3CA Kit** is the first companion diagnostic assay to obtain premarket approval from the U.S. Food and Drug Administration (FDA) for use in any cancer indication for detection of activating mutations in the **PIK3CA** gene. It is also the first FDA approved assay for guiding treatment decisions in breast cancer using plasma specimens as a liquid biopsy.

The assay detects 11 **PIK3CA** mutations, which are estimated to be present in approximately 40 per cent of hormone receptor-positive (HR+) advanced or metastatic breast cancer patients. QIAGEN's **therascreen PIK3CA Kit** was co-developed in collaboration with Novartis and co-approved with **PIQRAY (alpelisib)** by the FDA.