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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 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.