What role does PIK3CA mutation play in breast cancer?
Mutations in the PIK3CA gene can act as cancer drivers and are found in ~40% of hormone receptor-positive (HR+) breast cancer cases. They are the most common mutations in HR+ breast cancer and have been associated with a poor prognosis.

Why should I test for PIK3CA mutation in my HR+/HER2- breast cancer cases?
Until now, there has been no targeted therapy available for patients with advanced or metastatic HR+/HER2- breast cancer. PIQRAY® (alpelisib) is now available as the first targeted therapy approved for advanced or metastatic HR+/HER2- breast cancer patients who have progressed after endocrine therapy and whose tumors have a PIK3CA mutation. Only patients with a PIK3CA mutation are eligible for biomarker-driven therapy with PIQRAY.

Is there a companion diagnostic test for PIQRAY?
Yes, the FDA-approved companion diagnostic test is QIAGEN’s therascreen® PIK3CA RGQ PCR. NeoGenomics, a premier cancer diagnostic company, is providing this test with the name PIK3CA CDx Mutation Analysis in an exclusive Companion Diagnostic Testing Program.

What is the Companion Diagnostic Testing Program?
The Companion Diagnostic Testing Program is offered only through NeoGenomics and is designed to ensure access to testing for patients eligible for PIQRAY. Enrolled patients receive coverage for one test result. Repeat or monitoring tests are not accepted in this program. The Companion Diagnostic Testing Program is sponsored by Novartis Pharmaceuticals Corporation.

How do I order the test and access the Companion Diagnostic Testing Program?
The ordering health care provider must complete and sign the PIK3CA Mutation CDx Test Request Form and submit it to NeoGenomics, or complete the information and attestation in NeoGenomics’ or Genoptix’s online ordering system. Completion of this form is required, and submission also enrolls the patient in the Companion Diagnostic Testing Program.

If additional tests are ordered on the same specimen, please also complete a standard, printed NeoGenomics or Genoptix test requisition or create a new accession in online ordering.
What are the specimen requirements?
NeoGenomics offers PIK3CA testing on formalin-fixed paraffin-embedded (FFPE) tumor resection or biopsy samples. Breast tumor tissue (either primary or metastatic) is required; non-breast tumors are not accepted for this test. The paraffin block is preferred. Alternatively, send 1 H&E slide plus 6-12 unstained slides for core needle biopsy (or 5-10 slides for resection) cut at 5 microns. Please use positively-charged slides and 10% NBF fixative. Do not use zinc fixatives.

We are working on development of liquid biopsy plasma testing and expect it to be available mid-2020.

Who should get tested, and when?
The test is intended to identify a PIK3CA mutation in HR+/HER2- male or post-menopausal female breast cancer patients with advanced or metastatic disease that progressed on or after endocrine therapy. Testing is appropriate when patients present with metastases.

Which HR/HER2 biomarker profiles qualify?
Participation in the Companion Diagnostic Testing Program is available to patients whose tumors are IHC positive for either or both estrogen receptor (ER) and progesterone receptor (PgR or PR) AND negative for HER2 by IHC, ISH, or FISH.

What are technical details of the test?
PIK3CA CDx Mutation Analysis runs on the QIAGEN RotorGene Q MDx platform using the therascreen® PIK3CA RGQ PCR Kit. This is a real-time qualitative PCR assay for the detection of 11 mutations in the PIK3CA gene using genomic DNA extracted from FFPE breast tumor tissue. Mutations detected are in exon 7 (C420R), exon 9 (E542K, E545A, E545D [c.1635G>T only], E545G, E545K, Q546E, Q546R), and exon 20 (H1047L, H1047R, H1047Y).

When can I expect the results?
Results are typically ready in 7 days and will be sent to the ordering physician’s office or laboratory by their preferred method of delivery.

What if I get a bill?
If you should receive a bill, please contact the NeoGenomics Billing Department at 866-776-5907, option 2.

Who should I contact if I have a question?
If you have questions about our testing process, please contact NeoGenomics Client Services at 800-755-1605 or client.services@neogenomics.com.

Further information about PIQRAY and PIK3CA is available at www.us.piqray.com and www.PIK3CA.com.

References
1. therascreen® PIK3CA RGQ PCR [package insert]. Hilden, Germany: QIAGEN.