



Test Catalog

Diagnostic. Prognostic. Predictive. Predisposition.





PIK3CA Mutation CDx - Tissue

Alternative Name

Formerly named PIK3CA CDx Mutation Analysis by PCR

Methodology

Molecular

Test Description

PIK3CA Mutation CDx – Tissue is an FDA-approved qualitative companion diagnostic assay performed on DNA extracted from FFPE breast tissue to detect 10 mutations in exons 7, 9, and 20 of the PIK3CA gene. [Completion of the PIK3CA Mutation CDx Test Request Form with provider's signature is required for this CDx test.](#)

Clinical Significance

This test is intended to identify PIK3CA mutations in patients with advanced hormone receptor-positive, HER2-negative (HR+/HER2-) breast cancer who may be candidates for therapy with the PI3Kalpha-specific inhibitor PIQRAY® (alpelisib). In results from the phase III SOLAR-1 study, patients with PIK3CA mutations and prior endocrine therapy had significantly improved progression-free survival when treated with alpelisib and fulvestrant compared to fulvestrant alone (11.0 vs. 5.7 months). Patients without a PIK3CA mutation did not obtain the survival benefit of alpelisib found in the mutation-positive group.

Approximately 70% of breast cancer cases are HR+/HER2-, and approximately 40% of these carry a PIK3CA mutation.

Specimen Requirements

- **FFPE tissue:** Breast tumor tissue (either primary or metastatic) is required; non-breast tumors are not accepted for this test. 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. Decalcified specimens are not accepted.

Storage & Transportation

Use cold pack for transport, making sure cold pack is not in direct contact with specimen.

CPT Code(s)*

Inquire for Testing Program details.

New York Approved

Yes

Level of Service

Global

Turnaround Time

7 days

References

1. theascreen® PIK3CA RGQ PCR [package insert]. Hilden, Germany: QIAGEN; document ID coming soon
2. Andre F, Ciruelos E, Rubovszky G, et al. Alpelisib for PIK3CA-mutated, hormone receptor-positive advanced breast cancer. *N Engl J Med.* 2019;380(20):1929-1940.
3. Sabine V, Crozier C, Brookes C, et al. Mutational analysis of PI3K/AKT signaling pathway in tamoxifen exemestane adjuvant multinational pathology study. *J Clin Oncol.* 2014;32:2951-2958.

*The CPT codes provided with our test descriptions are based on AMA guidelines and are for informational purposes only. Correct CPT coding is the sole responsibility of the billing party.

Please direct any questions regarding coding to the payor being billed.

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Committed to research as the means to improve patient care, we provide Pharma Services for pharmaceutical companies, in vitro diagnostic manufacturers, and academic scientist-clinicians. We promote joint publications with our client physicians. NeoGenomics welcomes your inquiries for collaborations. Please contact us for more information.

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