

Client 1234
Sample ClientAddress
City, ST 99999
Phone: (555) 555-5555
Fax: (555) 555-5555Patient Name: **Patient, Sample**
Patient DOB / Sex: **01/01/1964 / F**
Specimen Type: **Paraffin Tissue**
Body Site: **Bone Thoracic vertebra**
Specimen ID: **XX99-99**
MRN: **9999999**Ordering Physician(s): **Sample Doctor, MD**
Accession / CaseNo: **9999999 / XXX99-999999**
Collection Date: **04/22/2022**
Received Date: **09/26/2022 05:40:00 PM EDT**
Report Date: **10/03/2022 04:07:21 PM EST****Interpretation:**

PCR analysis demonstrates the PRESENCE of sensitizing mutation(s) in the PIK3CA gene, which predicts an increased likelihood of response to the PIK3CA inhibitor PIQRAY® (alpelisib).

Results:

Test	Result
PIK3CA Mutation CDx - Tissue	Positive
Mutation(s) Detected	p.H1047R

Clinical Significance:

Approximately 40% of patients with advanced hormone receptor-positive breast cancer harbor a somatic mutation in the Phosphatidylinositol-4,5-Bisphosphate 3-Kinase Catalytic Subunit Alpha (PIK3CA) gene, which is usually associated with poor prognosis.[1-2] However, patients with metastatic hormone receptor-positive and HER2-negative breast cancer treated with PIQRAY® (alpelisib) plus fulvestrant demonstrate longer progression-free survival than when given fulvestrant alone (11.0 months vs 5.7 months).[3]

NOTE: Due to tumor heterogeneity and sampling, specimens with low tumor content may have mutation levels below the limit of detection for this assay. Poor DNA quality resulting from improper fixation and/or storage of archival samples may cause assay failure.

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Methodology:

Following pathologist identification of tumor-rich areas based on hematoxylin and eosin (H&E) staining, DNA is extracted from microdissected formalin-fixed paraffin-embedded (FFPE) tissue sections using the QIAamp® DSP DNA FFPE tissue kit. The theascreen PIK3CA assay is a real time qualitative PCR assay for the detection of 10 mutations in the Phosphatidylinositol-4,5-Bisphosphate 3-Kinase Catalytic Subunit Alpha (PIK3CA) gene (exon 7: p.C420R, exon 9: p.E542K, p.E545A, p.E545D [c.1635G>T only], p.E545G, p.E545K and p.Q546E, and exon 20: p.H1047L, p.H1047R and p.H1047Y). The theascreen PIK3CA companion diagnostic is FDA-approved to aid in identifying breast cancer patients who may eligible for treatment with PIQRAY® (alpelisib).

References:

1. Cancer Genome Atlas Network. Comprehensive molecular portraits of human breast tumors. Nature. 2012 Oct 4;490(7418):61-70.
2. Sobhani N, Roviello G, Corona SP, et al. The prognostic value of PI3K mutational status in breast cancer: a meta-analysis. J Cell Biochem. 2018;119(6):4287-4292.
3. Andre F, Ciruelos EM, Rubovszky G; SOLAR-1 Study Group. Alpelisib for PIK3CA-Mutated, Hormone Receptor-Positive Advanced Breast Cancer. N Engl J Med. 2019 May 16;380(20):1929-1940.

Electronic Signature**Sample Doctor, M.D., Ph.D., Pathologist**

The Technical Component Processing, Analysis and Professional Component of this test was completed at NeoGenomics California, 31 Columbia, Aliso Viejo, CA / 92656 / 866-776-5907 / CLIA #05D1021650 / Medical Director(s): Vladislav Chizhevsky, M.D.

The performance characteristics of this test have been determined by NeoGenomics Laboratories. This laboratory is CLIA certified to perform high complexity clinical testing.

Images that may be included within this report are representative of the patient but not all testing in its entirety and should not be used to render a result.

The CPT codes provided with our test descriptions are based on MoIDX and 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 payer being billed.

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Result Letter for Patients

Test Performed:**PIK3CA Mutation Companion Diagnostic – Tissue****Your Result:****POSITIVE for PIK3CA mutation**

A sample of your cancer tissue was tested for mutations in the PIK3CA gene. This test is used to help determine if PIQRAY® (apelsib) might be right for you.



What does a positive result mean?

A positive result means that a mutation, or a genetic change, was identified in the PIK3CA gene. Having a PIK3CA mutation in the cancer tissue means an FDA-approved therapy called PIQRAY may be right for you. This test result is one of the factors you and your care providers will use to make a decision about PIQRAY therapy (www.piqray-info.com).



About PIK3CA

PIK3CA mutations are linked to cancer growth and how aggressive the cancer type is. Everyone, with or without cancer, has PIK3CA genes in every cell. When a PIK3CA mutation occurs in a tumor cell, it can drive the cancer's growth by interfering with how often a cell divides, how long it lives, and how it matures. PIK3CA mutations are the most common mutations in hormone receptor-positive, HER2-negative metastatic breast cancer, and they occur in about 4 out of 10 cases.



About the PIK3CA Mutation CDx—Tissue test

This test is approved by the FDA to detect certain mutations in the PIK3CA gene in some breast cancer patients. It is a companion diagnostic (CDx) test for the drug PIQRAY. Testing may be done on the original (primary) breast tumor or on tissue from a body site to which it spread (metastasis).

This test does not measure risk of cancer that runs in families; no conclusions about inherited cancer risk should be drawn from a positive or negative result. Please talk to your care provider if you have questions about genetic testing for hereditary cancer risk.



Next steps

Please discuss options for your treatment with your physician and medical care team.

Electronic Signature

Sample Doctor, M.D., Ph.D., Pathologist

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www.piqray-info.com