

Client 1234
Sample ClientAddress
City, ST 99999
Phone: (555) 555-5555
Fax: (555) 555-5555Patient Name: **Patient, Sample**
Patient DOB / Sex: **01/01/1954 / F**
Specimen Type: **Tissue**
Body Site: **Left Breast**
Specimen ID: **X99-99**
MRN: **9999999**
Reason for Referral: **Breast Cancer**Ordering Physician(s): **Sample Doctor, MD**
Treating Physician(s): **Sample Doctor, MD**
Accession / CaseNo: **9999999 / XXX99-999999**
Collection Date: **06/01/2020**
Received Date: **10/16/2020 04:01:00 PM EDT**
Report Date: **10/22/2020 04:08:22 PM EDT****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.E542K

Clinical Significance:

Somatic mutations of Phosphatidylinositol-4,5-Bisphosphate 3-Kinase Catalytic Subunit Alpha (PIK3CA) are associated with longer progression-free survival in patients with metastatic hormone receptor-positive and HER2-negative breast cancer when treated with Piqray® (alpelisib) and fulvestrant vs. fulvestrant alone (11.0 months vs 5.7 months) [1-2]. Approximately 40% of patients with advanced hormone receptor-positive breast cancer harbor a PIK3CA mutation [3].

NOTE: Due to tumor heterogeneity and sampling, tumor specimens containing mostly non-malignant tissue and stroma may have mutation levels below the limit of detection for this assay. Poor DNA quality resulting from improper fixation and storage of archival paraffin 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 11 mutations in the Phosphatidylinositol-4,5-Bisphosphate 3-Kinase Catalytic Subunit Alpha (PIK3CA) gene (Exon7: p.C420R, Exon 9: p.E542K, p.E545A, p.E545D [c.1635G > T only], p.E545G, p.E545K, p.Q546E, and p.Q546R, 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 be eligible for treatment with PIQRAY (alpelisib).

References:

References:

1. Andre F, Ciruelos EM, Rubovszky G et al. Alpelisib + fulvestrant for HR+, HER2- advanced breast cancer: Results of the Phase III SOLAR-1 trial. Presented at the European Society for Medical Oncology (ESMO) 2018 Congress (Abstract LBA3_PR) on October 20, 2018.
2. Sabine V, Crozier C, Brookes C, et al. Mutational analysis of PI3K/AKT signaling pathway in tamoxifen exemestane adjuvant multinational pathology study. Journal of Clinical Oncology. 2014;32:2951-2958.

Electronic Signature**Sample Doctor, MD, Pathologist**

The Technical Component Processing and Analysis of this test was completed at Genoptix Rutherford, 2110 Rutherford Road, Carlsbad, CA / 92008 / 800-755-0802 / CLIA # 05D1018666. The Professional Component of this test was completed at NeoGenomics Florida, 12701 Commonwealth Drive, Suite 5, Fort Myers, FL / 33913 / 866-776-5907 / CLIA # 10D0998082. / Medical Director(s): Sample Director. 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® (alpelisib) 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 any of 11 mutations in the PIK3CA gene in certain 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

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www.piqray-info.com