

Client 1234
Sample Client

Address
City, ST 99999
Phone: (555) 555-5555
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Patient Name: **Patient, Sample**
Patient DOB / Sex: **01/01/1955 / F**
Specimen Type: **Paraffin Tissue**
Body Site: **Rt 5th rib**
Specimen ID: **XX-99**
MRN: **9999999**

Ordering Physician(s): **Sample Doctor, M.D.**
Treating Physician(s): **Sample Doctor, M.D.**
Accession / CaseNo: **9999999 / XXX99-999999**
Collection Date: **12/18/2020**
Received Date: **06/11/2021 04:44:00 PM EDT**
Report Date: **06/14/2021 04:43:56 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:

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 therascreen 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 therascreen PIK3CA companion diagnostic is FDA-approved to aid in identifying breast cancer patients who may eligible for treatment with PIQRAY® (alpelisib). NOTE: Detection of the exon 9 p.Q546R mutation is reported for non-New York patients under the designation of laboratory developed test (LDT) and not under the designation of FDA-approved in vitro companion diagnostic assay. The p.Q546R mutation is not analyzed for New York patients.

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

Reviewed by: **Sample Doctor, M.D., Ph.D., Pathologist**

The Technical Component Processing, Analysis and Professional Component of this test was completed at NeoGenomics Rutherford, 2110 Rutherford Road, Carlsbad, CA / 92008 / 800-755-0802 / CLIA #05D1018666 / Medical Director(s): Derek D. Lyle, 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.