Molecular Genetics
PIK3CA Mutation CDx - Tissue

866.776.5907, option 3

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:
<table>
<thead>
<tr>
<th>Test</th>
<th>Result</th>
<th>Mutation(s) Detected</th>
</tr>
</thead>
<tbody>
<tr>
<td>PIK3CA Mutation CDx - Tissue</td>
<td>Positive</td>
<td>p.E542K</td>
</tr>
<tr>
<td>Mutation(s) Detected</td>
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</tbody>
</table>

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.

Methodology:

References:

Electronic Signature
Sample Doctor, M.D., Pathologist
The Technical Component Processing, Analysis and Professional Component of this test was completed at Genoptix 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 test has not been approved by the FDA. The FDA has determined such clearance or approval is not necessary. 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 MolDX 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.