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

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.

References:
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

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.

www.piqray-info.com

© 2020 NeoGenomics Laboratories, Inc. All rights reserved. NeoGenomics Laboratories and the associated logo are trademarks of NeoGenomics Laboratories, Inc.