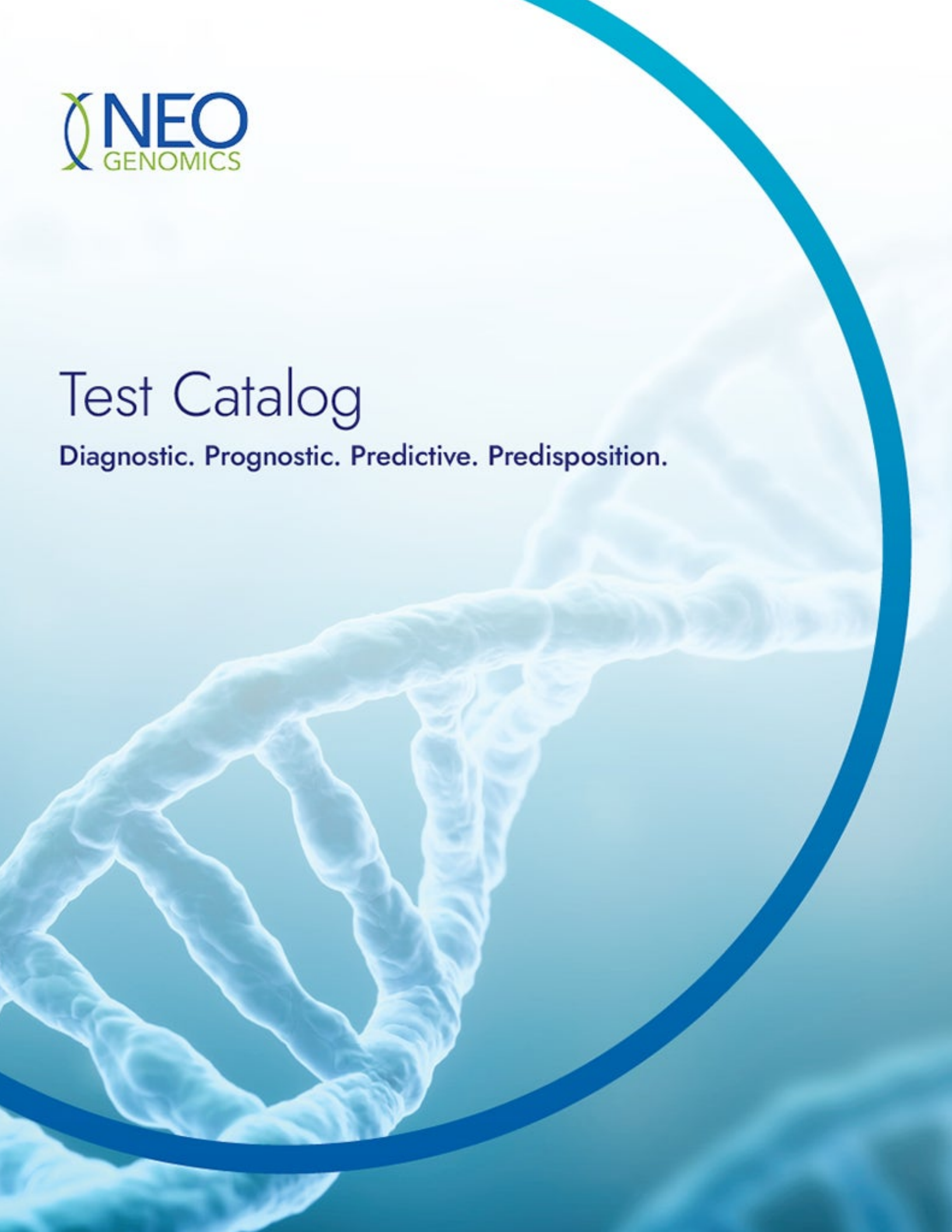
NEO GENOMICS

Test Catalog

Diagnostic. Prognostic. Predictive. Predisposition.



PIK3CA Mutation CDx - Plasma

Alternative Name
PIK3CA CDx Liquid Biopsy

Methodology
Molecular

Test Description
PIK3CA Mutation CDx - Plasma is an FDA-approved qualitative companion diagnostic assay performed on cell-free circulating tumor DNA extracted from the peripheral blood plasma of certain breast cancer patients to detect 10 mutations in exons 7, 9, and 20 of the PIK3CA gene. Plasma testing is appropriate when no primary or metastatic breast tumor tissue is available, or the only available tissue is decalcified and therefore unsuitable for molecular testing. Tissue is the recommended specimen type in all other cases.

Please see FAQs and more about options to test plasma in conjunction with tissue here.

Clinical Significance
This test is intended to identify PIK3CA mutations in patients with advanced hormone receptor-positive, HER2-negative (HR+/HER2-) breast cancer who may be candidates for therapy with the PI3K alpha-specific inhibitor PIQRAY® (alpelisib).

Specimen Requirements
- **Peripheral blood:** Please contact Client Services at 866-776-5907, option 3, to review special collection and handling requirements and to receive the test request form and shipping supplies.

Storage & Transportation
Please contact Client Services.

CPT Code(s)*
Please contact Client Services.

New York Approved
Yes

Level of Service
Global

Turnaround Time
7 days

References

1. therascreen® PIK3CA RGQ PCR [package insert]. Hilden, Germany: QIAGEN.
2. Andre F, Ciruelos E, Rubovszky G, et al. Alpelisib for PIK3CA-mutated, hormone receptor-positive advanced breast cancer. *N Engl J Med.* 2019;380(20):1929-1940.
3. Sabine V, Crozier C, Brookes C, et al. Mutational analysis of PI3K/AKT signaling pathway in tamoxifen exemestane adjuvant multinational pathology study. *J Clin Oncol.* 2014;32:2951-2958.

*The CPT codes provided with our test descriptions are based on 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 payor being billed.

NeoGenomics Laboratories is a specialized oncology reference laboratory providing the latest technologies, testing partnership opportunities, and interactive education to the oncology and pathology communities. We offer the complete spectrum of diagnostic services in molecular testing, FISH, cytogenetics, flow cytometry, and immunohistochemistry through our nation-wide network of CAP-accredited, CLIA-certified laboratories.

Committed to research as the means to improve patient care, we provide Pharma Services for pharmaceutical companies, in vitro diagnostic manufacturers, and academic scientist-clinicians. We promote joint publications with our client physicians. NeoGenomics welcomes your inquiries for collaborations. Please contact us for more information.

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Rev. 012823