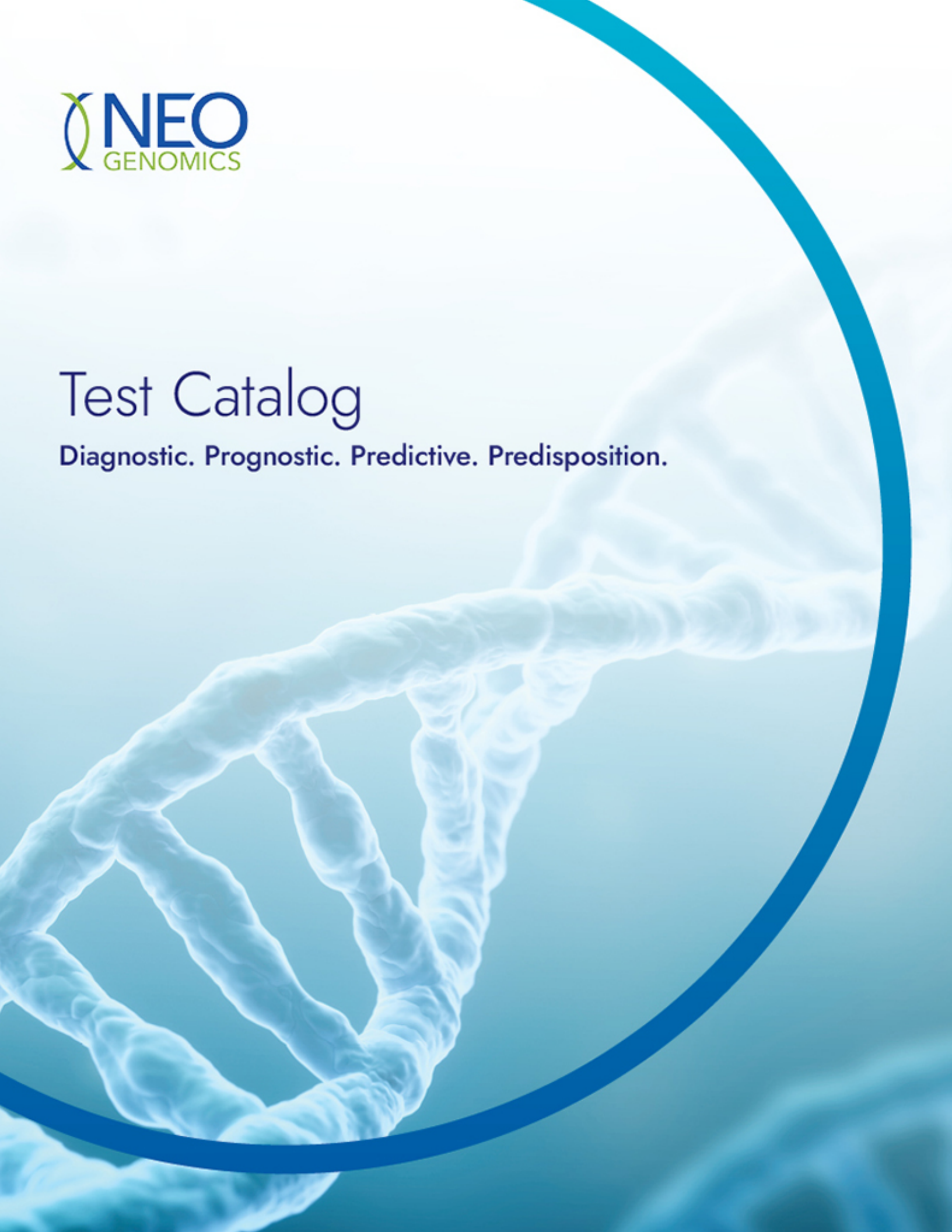
NEO GENOMICS

Test Catalog

Diagnostic. Prognostic. Predictive. Predisposition.



NeoTYPE® Cholangiocarcinoma Profile

Alternative Name
Cholangiocarcinoma Profile

Methodology
FISH

Immunohistochemistry (IHC)

Molecular

Test Description
The NeoTYPE Cholangiocarcinoma Profile analyzes 19 biomarkers through a combination of next-generation sequencing (NGS), FISH, and IHC as listed below. Test orders include summary interpretation of all results to help guide treatment decisions. A microsatellite instability (MSI) NGS result of “indeterminate” will create a reflex to MSI by PCR as long as the tumor percentage is ?40% and paired normal tissue is available.

- NGS (15 genes + 2 biomarkers): APC, ARID1A, BAP1, BRAF, EGFR, ERBB2, HRAS, IDH1, IDH2, KRAS, MET (c-MET), NRAS, PBRM1, SMAD4, TP53, plus Microsatellite instability (MSI) and Tumor Mutation Burden (TMB).
- FISH (1 biomarker): FGFR2
- IHC (1 biomarker): PD-L1 LDT

Clinical Significance
The NeoTYPE Cholangiocarcinoma Profile is intended to detect genetic aberrations reported in cholangiocarcinoma to aid in diagnosis and prognosis of the disease.

Cholangiocarcinoma (CCA) is an uncommon biliary tract cancer that typically presents at an advanced disease stage and is characterized by an aggressive disease course and poor clinical outcome. The most commonly mutated genes include KRAS, BRAF, BAP1, and SMAD4, associated with cell signaling pathways (MAPK signaling), cell cycle control and chromatin dynamics. Many potential therapies have been identified, including lapatinib (ERBB2), cetuximab and panitumumab (EGFR). Other potential targets include IDH1/2 and PD-L1.jab

Specimen Requirements
- **FFPE tissue:** Paraffin block preferred. Please use 10% buffered formalin fixative. Do not use zinc fixatives.

Storage & Transportation
Use cold pack for transport, making sure cold pack is not in direct contact with specimen.

CPT Code(s)*
81445, 88360, 88374x1 or 88377x1

New York Approved

Yes

Level of Service

Global

Turnaround Time

14 Days

References

1. Jain, A. et al. Cholangiocarcinoma With FGFR Genetic Aberrations: A Unique Clinical Phenotype. *JCO Precision Oncology* 2018:2, 1-12.
2. Zhou, M., Zhu, Y., Hou, R., Mou, X., & Tan, J. (2019). Identification of candidate genes for the diagnosis and treatment of cholangiocarcinoma using a bioinformatics approach. *Oncology Letters*, 18, 5459-5467. https://doi.org/10.3892/ol.2019.10904
3. Labib, P.L., Goodchild, G. & Pereira, S.P. Molecular Pathogenesis of Cholangiocarcinoma. *BMC Cancer* 19, 185 (2019). https://doi.org/10.1186/s12885-019-5391-0

*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.

*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.

9490 NeoGenomics Way
Fort Myers, FL 33912
Phone: 239.768.0600/ Fax: 239.690.4237
neogenomics.com

Rev. 051724