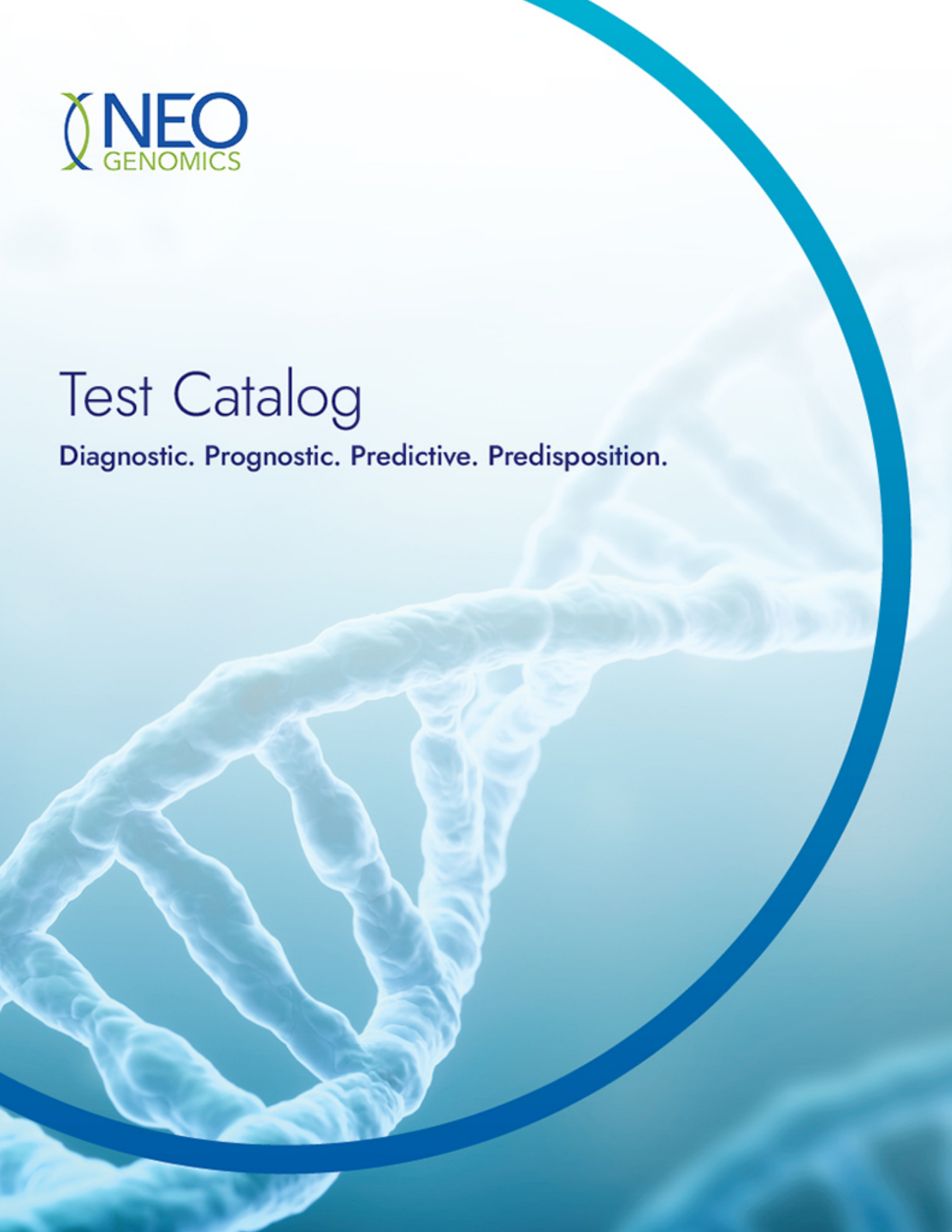
NEO GENOMICS

Test Catalog

Diagnostic. Prognostic. Predictive. Predisposition.



HER2 Breast

Alternative Name
HER2, HER-2/neu, PATHWAY HER2 (4B5), anti-Her2

Methodology
Immunohistochemistry (IHC)

Test Description
This test uses the Ventana PATHWAY anti-HER-2/neu antibody (clone 4B5) for the semi-quantitative detection of HER-2 antigen in sections of FFPE normal and neoplastic tissue. The test is FDA-approved with the indication as an aid in the assessment of breast cancer patients for whom Herceptin treatment is considered. Staining is performed according to the package insert. Scoring for breast cases is performed according to ASCO/CAP 2023 guidelines.

HER2 is an oncogene that is over-expressed in a variety of cancers including some breast carcinomas. The expected breast cancer overexpression rate varies based on the grade and type of cancer. Known artifacts, such as edge artifact, tissue retraction and tissue crush may give the false impression of overexpression. Care should be taken to avoid assessing these areas, especially in needle core biopsies that generally harbor all of these artifacts.

Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type
  or
- One (1) unbaked, unstained slide for H&E staining (required) and two to three (2-3) positively charged unstained slides (all cut at 4-5 microns) for each test/antibody ordered
- Block and slide identifiers should be clearly written and match exactly with the specimen ID and specimen labeling as noted on the requisition.

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

CPT Code(s)*
88360x1; 88361x1

New York Approved
Yes

Level of Service
Stain Only, Global

Turnaround Time
Global: 48 hours, Image Analysis (tech-only): 48 hours, Tech-Only (stain only): 24 hours

*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.

© 2024 NeoGenomics Laboratories, Inc. All Rights Reserved. All other trademarks are the property of their respective owners.

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
© 2024 NeoGenomics Laboratories, Inc. All Rights Reserved.
All other trademarks are the property of their respective owners
Rev. 120424