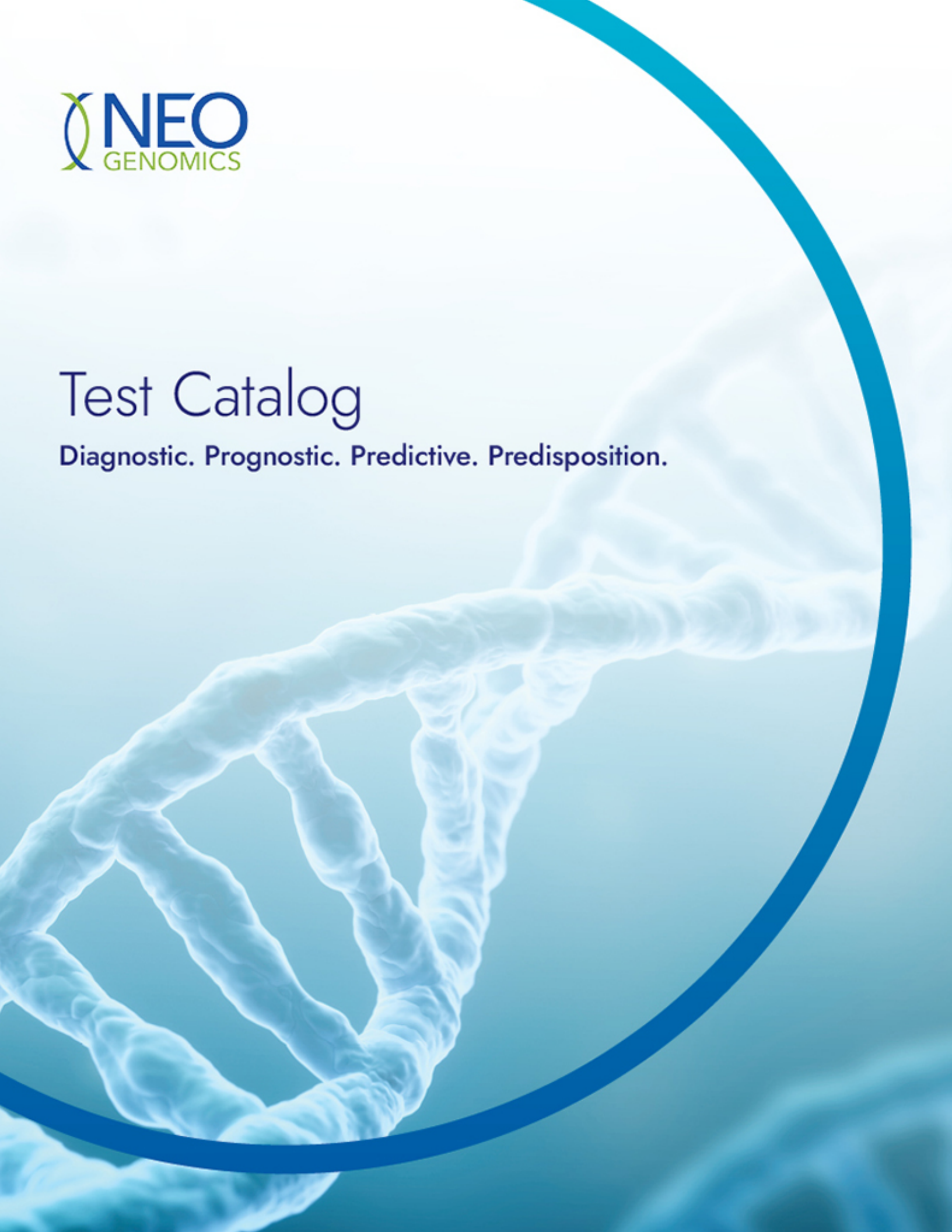
NEO GENOMICS

Test Catalog

Diagnostic. Prognostic. Predictive. Predisposition.



HER2 (Other)

Alternative Name
HER2 (human epidermal growth factor receptor 2), HER-2/neu

Methodology
Immunohistochemistry (IHC)

Test Description
HER2, a member of the epidermal growth factor receptor family, is a transmembrane protein with tyrosine kinase activity. Gene amplification and protein overexpression of HER2 have been found in a variety of tumors. 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 tissues. Staining is performed according to the package insert. Scoring is performed using the following:

- **HER2 (Other) with Breast scoring** uses the 2018 CAP/ASCO guidelines for breast cancer for HER2 evaluation. Breast scoring is recommended indications such as endometrium cancer, salivary duct carcinoma, serous carcinoma, ovarian cancer, and other clinical indications without consensus guidelines.
- **HER2 (Other) with Gastric scoring** uses the 2016 CAP/ASCP/ASCO consensus guidelines for gastric/gastroesophageal adenocarcinoma for HER2 evaluation.

Specimen Requirements
- A formalin-fixed, paraffin-embedded (FFPE) tissue block is preferred specimen type
  or
- One (1) unbaked, unstained slide cut at 4-5 microns for H&E staining (required) and two to three (2-3) positively charged unstained slides cut at 3-4 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

New York Approved
Yes

Level of Service
Global, Stain Only

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

References

1. Bartley AN, Washington MK, Ventura CB, et al. HER2 Testing and Clinical Decision Making in Gastroesophageal Adenocarcinoma: Guideline From the College of American Pathologists, American Society for Clinical Pathology, and American Society of Clinical Oncology. Arch Pathol Lab Med. 2016;140(12):1345-1363. doi:10.5858/arpa.2016-0331-CP
2. Cancer Protocol Templates- Biomarker Reporting. College of American Pathologists. https://www.cap.org/protocols-and-guidelines/cancer-reporting-tools/cancer-protocol-templates. Accessed November 24, 2020.
3. Wolff AC, Hammond MEH, Allison KH, et al. Human Epidermal Growth Factor Receptor 2 Testing in Breast Cancer: American Society of Clinical Oncology/College of American Pathologists Clinical Practice Guideline Focused Update. Arch Pathol Lab Med. 2018;142(11):1364-1382. doi:10.5858/arpa.2018-0902-SA

*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.

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Rev. 032824