



Test Catalog

Diagnostic. Prognostic. Predictive. Predisposition.





HER2 Colorectal

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 colorectal carcinoma. Staining is performed according to the package insert. Scoring is performed based on clinical guideline and clinical trial recommendations for colorectal cancer.

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. Hainsworth JD, Meric-Bernstam F, Swanton C, et al. Targeted Therapy for Advanced Solid Tumors on the Basis of Molecular Profiles: Results From MyPathway, an Open-Label, Phase IIa Multiple Basket Study [published correction appears in J Clin Oncol. 2019 Feb 1;37(4):360]. J Clin Oncol. 2018;36(6):536-542. doi:10.1200/JCO.2017.75.3780

2. Sartore-Bianchi A, Trusolino L, Martino C, et al. Dual-targeted therapy with trastuzumab and lapatinib in treatment-refractory, KRAS codon 12/13 wild-type, HER2-positive metastatic colorectal cancer (HERACLES): a proof-of-concept, multicentre, open-label, phase 2 trial [published correction appears in Lancet Oncol. 2016 Oct;17 (10):e420]. Lancet Oncol. 2016;17(6):738-746. doi:10.1016/S1470-2045(16)00150-9
3. Valtorta E, Martino C, Sartore-Bianchi A, et al. Assessment of a HER2 scoring system for colorectal cancer: results from a validation study. Mod Pathol. 2015;28(11):1481-1491. doi:10.1038/modpathol.2015.98

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