



Test Catalog

Diagnostic. Prognostic. Predictive. Predisposition.





HER2 Colorectal

Alternative Name

HER2 neu

Methodology

FISH

Test Description

Probes: HER2 (17q11.2-q12) | Centromere 17 (Cen 17)

Disease(s): Colorectal cancer

Clinical Significance

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 provides HER2 amplification status to aid in determining anti-HER2 targeted therapies for patients with colorectal cancer. Scoring is performed based on clinical guideline and clinical trial recommendations for colorectal cancer.

Specimen Requirements

- **Pathology Report:** For global HER2 FISH cases we require a copy of the HER2 IHC pathology report (if it is not available to us in NeoLINK™). Client Services will call your office or lab for missing IHC reports.
- **Bone Marrow Aspirate:** N/A
- **Peripheral Blood:** N/A
- **Fresh, Unfixed Tissue:** N/A
- **Fluids:** N/A
- **Paraffin Block:** H&E slide (required) plus paraffin block. Circle H&E for tech-only.
- **Cut Slides:** H&E slide (required) plus 2 unstained slides cut at 4 microns. Circle H&E for tech only.

Storage & Transportation

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

CPT Code(s)*

88374x1 automated. Codes may differ if manual analysis is performed.

New York Approved

Yes

Level of Service

Global, Technical

Turnaround Time

3-5 Days

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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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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