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Pathvysion™ (HER2/NEU) by FISH

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| Test Ordering Code: | 2071 |
| CPT Codes: | 88368 x 2 |
| Specimen: | Four to six slides of 4-5 micron thick sections of formalin fixed, paraffin embedded breast tissue blocks transported at 20-25* C. Please include one hematoxylin and eosin stained slide and the pathology report or the tissue selection for assay should be performed by a pathologist. |
| Turnaround Time: | 5 - 7 business days |
| Clinical Significance: | Knowing a patients HER2 gene amplification status is essential to understanding how to treat breast cancer and to predicting a patient's survival. Abnormally high quantities of the HER2 gene have been associated with rapid tumor cell growth, resistance to therapy and shorter disease-free periods and overall survival. Certain breast cancer treatments are more appropriate when the HER2 gene is amplified. Therefore, the detection and quantification of HER2 status represents a critical point for the doctor to decide how to approach a patient's therapy choices. |
| Indications for Testing: | Invasive Breast Cancer |
| Methodology: | Fluorescent in situ Hybridization (FISH). The determination of the presence of amplification for the HER-2/ neu oncogene is based on the counting of fluorescent signals for HER-2/ neu and CEP 17 contained within the interphase nuclei of invasive carcinoma cells. Manufacturer's guidelines for nonamplified and amplified cells are based on enumeration of 20 interphase nuclei from tumor cells per target reported as the ratio of average HER-2/ neu copy number to that of CEP*17. This test has been approved by the U.S. Food and Drug Administration (FDA) for patients with metastatic breast cancer who could benefit from Herceptin therapy. |
| Reporting of Results: | NOT AMPLIFIED: Her-2/neu: CEP 17 < 2.0 AMPLIFIED: Her-2/neu: CEP 17 >= 2.0 |
| References: | Information for Patients: http://www.pathvysion.com/Patients_6.asp Information for Physicians: http://www.pathvysion.com/HealthcareProfessionals_7.asp Ariga R, Zarif A, Korasick J, Reddy V, Siziopikou, Gattuso P. Correlation of her-2/neu gene amplification with other prognostic and predictive factors in female breast carcinoma. Breast J 2005 11(4) 278-80 Pauletti G, Godolphin W, Press MF, Salmon DJ. Detection and quantitation of HER-2/neu gene amplification in human breast cancer archival material using fluorescence in situ hybridization. Oncogene 1996 13(1):63-72 Press MF, Bernestein L, Thomas PA, Meisner LF, Zhou JY, Ma Y, Hung G. Robinson RA, Harris C, El_Naggar, Salamon DJ, Phillips RN, Ross JS, Wolman SR Flom KJ. HER-2/neu gene amplification characterized by fluorescence in situ hybridization: poor prognosis in node-negative breast carcinomas. J Clin Oncol 1997 15(8): 2894-904 |