

Laboratory News

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CHANGES TO HER-2/NEU ONCOPROTEIN BY IMMUNOHISTOCHEMISTRY

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Effective Jan 4, 2016, HER2 testing by Immunohistochemistry (IHC) will be changed from the Dako Hercep Test Kit to the Leica Oracle Kit. An update in instrumentation was the driving force behind the change. Though both systems are FDA approved for breast cancer testing, the Leica Oracle test is a fully automated procedure performed on the Bond Max instrument.

This procedural change will include converting from a rabbit polyclonal antibody to a mouse monoclonal antibody (clone CB11). Results will continue to be semi-quantitative and interpreted using the same American Society of Clinical Oncologists/College of American Pathologists scoring criteria. Laboratory testing will be performed twice per week.

Along with IHC testing, Marshfield Labs will continue to offer fluorescence in-situ hybridization (FISH) testing for HER2. Both IHC and FISH are FDA-approved testing methods for HER2.

Please refer to <u>Marshfield Labs' Test Reference Manual</u> for additional information on HER2 by either IHC or FISH.

QUESTIONS

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BEYOND numbers

TEST INFORMATION Test Name: HER-2/NEU Oncoprotein, Immunohistochemistry Test Code: HER2NEU Key Words: Histology, HER2/Neu, Surgical Pathology, Immunohistochemistry, C-erbB2, HER2, Gastric, Breast, Esophageal Specimen Type: Paraffin embedded, 10% formalin fixed, breast, gastric, or esophageal tissues Performing Lab: Marshfield CPT Coding: 88360