



LABORATORY REPORT

Example Client, XYZ123
1234 Warde Road
Ann Arbor MI 48108

EXAMPLE, REPORT W
WX0000003826 F 12/05/1988 34 Y

Referral Testing

Collected: 09/26/2023 14:07 Received: 09/26/2023 14:07

Table with 6 columns: Test Name, Result, Flag, Ref-Ranges, Units, Site. Row 1: HER-2, IHC with Reflex to HER-2, FISH. Row 2: Primary Tumor Site, NA, QCRL. Row 3: Sample Fixed in Formalin?, NA, QCRL. Row 4: Fixed between 6-72 hours?, NA, QCRL. Row 5: Paraffin Block Number: ABC-123-456, QCRL. Row 6: Quest Internal Number: 98765, QCRL. Row 7: Staining Intensity: 1+, QCRL. Row 8: HER2 Overexpression: NEGATIVE, QCRL.

This specimen was examined by a pathologist and showed sufficient invasive tumor cells for testing. High, low, and negative protein expression controls worked as expected.

CAP/ASCO recommends sample cold ischemia time of less than one hour with fixation in 10% neutral-buffered formalin for no less than 6 hours and no more than 72 hours, and routine processing. If the cold ischemia time, fixative, fixation time, and processing did not meet standard assay conditions, please interpret with caution and submit another specimen for retesting if possible.

This test was performed on formalin-fixed, paraffin-embedded tissue sections using the FDA approved HER-2 Pathway (4B5) rabbit monoclonal antibody to HER2/neu and Ventana BenchMark XT/ULTRA platform. The specimen was examined by a pathologist and showed sufficient viable tumor cells for testing. Positive and negative protein expression controls worked as expected. HER-2 Pathway (4B5) staining result is interpreted based on CAP/ASCO guidelines (Arch Pathol Lab Med. 2018;142:1364-1382), which defines a HER2 protein expression by immunohistochemistry as follows: POSITIVE/IHC 3+: Circumferential membrane staining that is complete, intense, and in >10% of tumor cells. EQUIVOCAL/IHC 2+: Weak to moderate complete membrane staining observed in >10% of tumor cells. NEGATIVE/IHC 1+: Incomplete membrane staining that is faint/barely perceptible and in >10% of tumor cells. NEGATIVE/IHC 0: No staining is observed or membrane staining that is incomplete and is faint/barely perceptible and in less than or equal to 10% of tumor cells.

This result was reviewed and interpreted by Kiva Iverson, M.D.

Percentage of invasive cells with incomplete membrane staining that is faint/barely perceptible: >10%

Cold ischemia time: <1 HOUR
Test Performed at:
Quest Diagnostics Nichols Institute
33608 Ortega Highway

LAB: L - LOW, H - HIGH, AB - ABNORMAL, C - CRITICAL, . - NOT TESTED



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Test not performed. Reflex testing not required since established criteria was not met. TNP- WE CURRENTLY REFLEX HER2 IHC TESTING TO FISH ONLY FOR SPECIMENS WITH 2+ RESULTS. IHC RESULTS OF 0, 1+ OR 3+ WILL NOT BE TESTED BY THE FISH METHOD UNTIL OTHERWISE REQUESTED. PLEASE REFER TO THE RESULT OBTAINED BY IHC. Test Performed at: Quest Diagnostics Nichols Institute 33608 Ortega Highway San Juan Capistrano, CA 92675-2042 I Maramica MD, PhD, MBA

Performing Site: QCRL: QUEST DIAGNOSTICS REFERENCE LAB CAPISTRANO 33608 Ortega Highway San Juan Capistrano CA 92675

Reported Date: 2023.09.26 14:09 HER2

LAB: L - LOW, H - HIGH, AB - ABNORMAL, C - CRITICAL, . - NOT TESTED