Warde Medical Laboratory

LABORATORY REPORT

Example Client, XYZ123
1234 Warde Road
Ann Arbor MI 48108

EXAMPLE, REPORT W
WX0000003827 M 07/08/1978 45 Y

Referral Testing

Collected: 10/02/2023 10:43 Received: 10/02/2023 10:43

Test Name	Result	Flag	Ref-Ranges	Units	Site
ER/PR HER-2/NEU IHC Reflx FISH	See Below				WMQC

Test	Result	Flag	Ref Range
ER/PR, PARAFFIN BLOCK IMMUNOHISTOCHEMICAL ASSAY:			
Paraffin Block Number	S12-3456 A6		
Primary Tumor Site	LEFT BREAST BX W/ MARGINS		
Quest Internal Number	2023-1234		
RESULTS:			
ESTROGEN RECEPTOR	90		%
ER Staining Intensity	STRONG		
ER Interpretation	POSITIVE		
PROGESTERONE RECEPTOR	80		%
PR Staining Intensity	STRONG		
PR Interpretation	POSITIVE		

This specimen was examined by a pathologist and showed sufficient tumor cells for testing. Positive 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 paraffin embedded tissue sections by immunohistochemistry (HRP-linked polymer system) using monoclonal antibodies to the estrogen receptor (Leica Microsystems, clone 6F11) and the progesterone receptor (Leica Microsystems, clone 16). Interpretation was based on CAP/ASCO guidelines, which defines ER and PgR protein expression as follows:

1. RECEPTOR POSITIVE: at least 1% of tumor cell nuclei are immunoreactive or show positive nuclear staining of any intensity.
2. RECEPTOR NEGATIVE: less than 1% of tumor cell nuclei are immunoreactive or show staining of any intensity.
3. UNINTERPRETABLE: conditions prevent interpretation such as controls display unexpected result,

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preanalytic/analytic conditions do not comply with guidelines, negative result in the absence of stained intrinsic epithelial element, and artifacts involve most of the test sample.

The ER and PgR were scored for invasive component only if invasive tumor or mixed invasive tumor and DCIS are present. If no invasive tumor is present, the DCIS may be scored for ER/PgR, see comment.

Reference:
Hammond ME, et al. American Society of Clinical Oncology/College of American Pathologists Guideline Recommendations for Immunohistochemical Testing of Estrogen and Progesterone Receptors in Breast Cancer. Arch Pathol Lab Med 2010;134:e48-72.
Results interpreted and reviewed by Lynne Lin-Chang, M.D.

ER/PR: External controls are adequate.

ER/PR Internal control tissue (i.e. benign mammary glands, endometrium, myometrium, etc.) is present and exhibits positive immunoreactivity.

HER2 (HercepTest-[R]), IHC
IMMUNOHISTOCHEMICAL ASSAY:

Sample fixed in Formalin?	YES
Fixed between 6-48 hours?	9 HRS, 52 MINS
Routine Tissue Processing?	YES
Paraffin Block Number	S12-3456 A6
Primary Tumor Site	LEFT BREAST BX W/ MARGINS
Quest Internal Number	2023-1234

RESULTS:

Staining Intensity	1+
HER2 Overexpression	NEGATIVE

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

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caution and submit another specimen for retesting if possible.

This test was performed on paraffin embedded tissue sections by immunohistochemistry using the FDA approved Dako HercepTest(TM) kit. Interpretation was based on CAP/ASCO guidelines, which defines a HER2 protein expression by immunohistochemistry as follows:

1. POSITIVE/IHC 3+: circumferential membrane staining that is complete, intense, observed in a homogeneous and contiguous population and within >10% of the invasive tumors and readily appreciated using a low power objective.
2. EQUIVOCAL/IHC 2+: circumferential membrane staining that is incomplete and/or weak/moderate and within >10% of the invasive tumor cells or complete and circumferential membrane staining that is intense and within < or = to 10% of the invasive tumor cells.
3. NEGATIVE/IHC 1+/0: incomplete membrane staining that is faint/barely perceptible and within >10% of the invasive tumor cells /no staining observed or membrane staining that is incomplete and is faint/barely perceptible and within < or = to 10% of the invasive tumor cells.
4. INDETERMINATE: technical issues prevent IHC from being reported as positive, negative, or equivocal.

If an EQUIVOCAL result is obtained, a reflex HER2 FISH test will be ordered per CAP/ASCO recommendation.

Reference:
Wofff AC, et al. Recommendations for Human Epidermal Growth Factor Receptor 2 testing in Breast Cancer: American Society of Clinical Oncology/College of American Pathologists Clinical Practice Guideline Update. Arch Pathol Lab Med. 2013 Oct 7 Epub.
Results interpreted and reviewed by M.D.

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

FLUORESCENCE IN SITU HYBRID.
HER-2/neu, FISH TNP
TNP-Reflex testing not required.

TNP- WE CURRENTLY REFLEX HER2 IHC TESTING TO FISH ONLY

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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(s) performed at
Quest Diagnostics Nichols Institute
33608 Ortega Highway
San Juan Capistrano, CA 92675-2042
Laboratory Director: J M Nakamoto MD, PhD

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

Reported Date: 2023.10.02 10:43