Warde Medical Laboratory

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: 09/21/2023 13:36 Received: 09/21/2023 13:36

Test Name	Result	Flag	Ref-Ranges	Units	Site

Lung Cancer (NSCLC), ROS1 (6q22) Rearrangement, FISH

Lung Ca (NSCLC), ROS1, FISH	See Below	QCRL

Order ID:

Specimen Type: Paraffin Embedded Tissue

Clinical Indication: FISH STUDY FOR ONCOLOGY

RESULT:
POSITIVE FISH RESULT FOR ROS1 TARGETED THERAPY

Block ID:

Specimen site: LUNG

INTERPRETATION:
FISH analysis, using the probe described below showed an abnormal pattern of hybridization consistent with a ROS1 rearrangement in 92% of the interphase cells. Overexpression of the ROS1 kinase, through rearrangement (involving CD74, SLC34A2, FIG and others) has been implicated in the development of non-small cell lung carcinoma (NSCLC).

Please expect the results of any other concurrent study in a separate report.

RECOMMENDATIONS:
Correlation with other clinical and laboratory findings is recommended. This assay is intended to be used on formalin-fixed paraffin-embedded tissue samples from patients with NSCLC to aid in the identification of those who may be responsive to treatment with Xalkori? (crizotinib). Reference: J Clin Oncol. 2012 March 10; 30(8): 863-870.

NOMENCLATURE:
nuc ish(3'ROS1x3-6,5'ROS1x3-5)(3'ROS1 sep 5'ROS1x0-2)[46/50]

ASSAY INFORMATION:
Method: FISH
Cells Counted: 50

Fluorescence in-situ hybridization (FISH) was performed using the Dako SureFISH break-apart probe specific for the ROS1 gene region located at 6q22. Pathologist marked H and E slide was referenced for scoring the FISH slides.

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Cutoff value for ROS1 rearrangement is 9% of interphase cells in paraffin-embedded specimens.

This test was developed and its analytical performance characteristics have been determined by Quest Diagnostics Nichols Institute, San Juan Capistrano, CA. It has not been cleared or approved by the U.S. Food and Drug Administration. This assay has been validated pursuant to the CLIA regulations and is used for clinical purposes.

Guang Li, PhD, FACMG (800) NICHOLS-4307

Electronic Signature:

Test Performed at:
Quest Diagnostics Nichols Institute
33608 Ortega Highway
San Juan Capistrano, CA 92675-2042 I Maramica MD, PhD, MBA

Clinical Indication:	NA	QCRL
Specimen Type/Source	NA	QCRL
Prior Therapy/Transplant	NA	QCRL

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

Reported Date: 2023.09.28 13:30 NSCLF

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

F321000003
WX0000003826
Printed D&T: 09/28/23 13:30

Ordered By: KAJAL SITWALA, MD, PhD
WX00000000002353

Kajal V. Sitwala, MD, PhD - Medical Director
Form: MM RL1