

Client: Example Client ABC123
123 Test Drive
Salt Lake City, UT 84108
UNITED STATES

Physician: Doctor, Example

Patient: Patient, Example

DOB: 9/27/1963
Gender: Male
Patient Identifiers: 01234567890ABCD, 012345
Visit Number (FIN): 01234567890ABCD
Collection Date: 00/00/0000 00:00

MET Gene Amplification by FISH

ARUP test code 3001313

MET FISH Result **Amplified**
Controls were run and performed as expected.
This result has been reviewed and approved by Parisa Adelhardt, M.D.

MET/CEP7 FISH Ratio 2.3

Average MET Signal Number per Cell 3.78.0

Average CEP7 Signal Number per Cell 3.23.5

Total Cell Count 40

Scoring Method Manual

MET FISH Reference Number ABC 123

MET FISH Source Tissue

H=High, L=Low, *=Abnormal, C=Critical

INTERPRETIVE INFORMATION: MET Gene Amplification, FISH

Fluorescence in situ hybridization (FISH) analysis for MET gene amplification was performed on a section from a paraffin-embedded tissue block using differentially labeled fluorescent probes targeting the MET gene and the chromosome 7 centromere (CEP 7) (Agilent Technologies). Cells were evaluated from regions of tumor identified on histopathologic review of a matching hematoxylin- and eosin-stained section. Controls performed appropriately.

Based on the preclinical validation of this assay, MET gene amplification is defined as either a MET/CEP7 ratio of 2.0 or greater or an average MET gene copy number per cell of 6.0 or greater. Based on the assay performance during test validation, the test is expected to detect MET amplification status in 100 percent of patients. Assay range and limit of detection were generated using normal and known positive cases respectively.

MET gene amplification is observed in a variety of tumor types, including non-small cell lung carcinoma. High-level MET amplification (MET/CEP7 ratio greater than 5. See Ou et al. 2011) is considered an emerging biomarker for therapy with crizotinib in non-small cell lung carcinoma by the National Comprehensive Cancer Network (see NCCN Clinical Practice Guidelines in Oncology for Non-Small Cell Lung Carcinoma).

MET amplification may also be acquired as a therapy resistance alteration, eg, following anti-EGFR tyrosine kinase inhibition.

Reference:

Ou SH, Kwak EL, Siwak-Tapp C, et al. Activity of crizotinib (PF02341066), a dual mesenchymal-epithelial transition (MET) and anaplastic lymphoma kinase (ALK) inhibitor, in a non-small cell lung cancer patient with de novo MET amplification. J Thorac Oncol. 2011;6:942-6.

This test was developed and its performance characteristics determined by ARUP Laboratories. It has not been cleared or approved by the US Food and Drug Administration. This test was performed in a CLIA certified laboratory and is intended for clinical purposes.

H=High, L=Low, *=Abnormal, C=Critical

VERIFIED/REPORTED DATES

Procedure	Accession	Collected	Received	Verified/Reported
MET FISH Result	23-271-119601	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
MET/CEP7 FISH Ratio	23-271-119601	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
Average MET Signal Number per Cell	23-271-119601	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
Average CEP7 Signal Number per Cell	23-271-119601	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
Total Cell Count	23-271-119601	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
Scoring Method	23-271-119601	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
MET FISH Reference Number	23-271-119601	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
MET FISH Source	23-271-119601	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00

END OF CHART

H=High, L=Low, *=Abnormal, C=Critical

Unless otherwise indicated, testing performed at:

ARUP LABORATORIES | 800-522-2787 | aruplab.com
500 Chipeta Way, Salt Lake City, UT 84108-1221
Jonathan R. Genzen, MD, PhD, Laboratory Director

Patient: Patient, Example
ARUP Accession: 23-271-119601
Patient Identifiers: 01234567890ABCD, 012345
Visit Number (FIN): 01234567890ABCD
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