TECHNICAL NOTICE
THE MEDICAL FOUNDATION

Test Name: MET Gene Amplification by FISH **Effective Date: 5/1/2018**

TMF No:
36279

Performance Lab Name:
Flow Cytometry / Molecular Pathology

Test Mnemonic:
MET FISH

CPT Code:
88374

Test Includes:
Tissue based FISH tests include technical and professional components which are billed either as global charges or as separate TC and PC charges depending upon the place of service.

Also See:

36269 Non-Small Cell Lung Carcinoma Mutation Analysis Panel (BRAF, EFGR, and KRAS) with ALK, RET, ROS1 and MET by FISH if Indicated

36035 No-Small Cell Lung Carcinoma Panel by FISH (ALK, RET, ROS1, MET)

Patient Prep:
NOTICE: Genetic tests are often subject to limited coverage and/or prior-authorization requirements. Consult the patient's medical insurance provider before ordering this test.

Spec Collect:
Tumor tissue.

Spec Process:
Formalin fix and paraffin embedded tissue block containing viable tumor. Neutral buffered formalin is the preferred fixative and tissue should be sectioned and fixed as soon as possible after surgery for best tissue preservation. In selecting the paraffin blocks, submit the largest area of tumor available that shows the least degeneration or necrosis. Preservation of nuclear detail can help assess quality of fixation. Tissue block should show at least 20 percent nucleated tumor cells. Single small biopsy or cytology cell block may be acceptable depending on the amount of tumor tissue present.

Spec Store Transport:
Room temperature. Also acceptable: Refrigerated. Avoid excessive heat (greater than 55°C). Ship in cooled container during summer months.

Spec Stability:
Room temperature: Indefinitely

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Joyce Simpson, M.D. • *Medical Director*

Refrigerated: Indefinitely
Frozen: Unacceptable

Spec Reject:
Insufficient well preserved tumor cells in submitted tissue block. Specimens processed in alternative fixatives (alcohol, Prefer®) or heavy metal fixatives (B-4 or B-5). Decalcified specimens.

Spec Remarks:
Include surgical pathology report. Tissue block will be returned after testing.

Use and Clinical Significance:
Patients with MET gene amplification is detected in 2-4% of previously untreated NSCLC patients and has been associated with poor prognosis. This test is useful for a patient with NSCLC, who have progressed on chemotherapy and may benefit from MET targeted therapy (e.g. MET inhibitor crizotinib or cabozantinib) as next-line therapy. However MET amplification is often acquired as a resistance mutation following EGFR tyrosine kinase inhibitor therapy

Methodology:
Analysis for MET gene amplification was performed using Fluorescence in Situ Hybridization (FISH) with the probes targeting the MET (7q31.2) gene and the chromosome 7 centromere (CEP7). Cells were evaluated from regions of tumor on sections from a paraffin-embedded tissue block identified on histopathologic review of a matching H&E stained section. A MET/CEP7 ratio of 2.0 or greater or an average number of MET signal per cell of 5.0 or greater indicates amplification of the MET gene locus.

This test was developed using an analyte specific reagent. Its performance characteristics were determined by the South Bend Medical Foundation Laboratory. This test has not been cleared or approved by the U.S. Food and Drug Administration; however, FDA clearance or approval is not currently required for clinical use. The results are not intended to be used as the sole means for clinical diagnosis or patient management decisions. The Medical Foundation is certified under CLIA as qualified to perform high complexity clinical laboratory testing.

Day Run:
Once per week

Time Reported:
7-10 days

Test Type:
GENETIC

Please direct comments or questions regarding this notice to Albert Huho, M.D. (ahuho@sbmf.org), Qing Li, Ph.D. (qli@sbmf.org), Kevin Maggert (kmaggert@sbmf.org) or South Bend Medical Foundation (574) 234-4176 or (800) 544-0925.