

Overview

Useful For

Providing prognostic information and guiding treatment primarily for patients with lung, gastric, and renal tumors as well as other tumor types

Reflex Tests

| Test Id | Reporting Name | Available Separately | Always Performed |
|---------|--------------------|----------------------|------------------|
| _PBCT | Probe, +2 | No, (Bill Only) | No |
| _PADD | Probe, +1 | No, (Bill Only) | No |
| _PB02 | Probe, +2 | No, (Bill Only) | No |
| _PB03 | Probe, +3 | No, (Bill Only) | No |
| _IL25 | Interphases, <25 | No, (Bill Only) | No |
| _I099 | Interphases, 25-99 | No, (Bill Only) | No |
| _I300 | Interphases, >=100 | No, (Bill Only) | No |

Testing Algorithm

This test does not include a pathology consult. If a pathology consultation is requested, PATHC / Pathology Consultation should be ordered and the appropriate FISH test will be ordered and performed at an additional charge.

This test includes a charge for application of the first probe set (2 FISH probes) and professional interpretation of results.

Additional charges will be incurred for all reflex probes performed. Analysis charges will be incurred based on the number of cells analyzed per probe set. If no cells are available for analysis, no analysis charges will be incurred.

Method Name

Fluorescence In Situ Hybridization (FISH)

NY State Available

Yes

Specimen

Specimen Type

Tissue

Necessary Information

- A pathology report is required in order for testing to be performed.** Acceptable pathology reports include working drafts, preliminary pathology or surgical pathology reports.
- A reason for testing must be provided.** If this information is not provided, an appropriate indication for testing may

be entered by Mayo Clinic Laboratories.

Specimen Required

Submit only 1 of the following specimens:

Specimen Type: Tissue

Preferred: Tissue block

Collection Instructions: Submit a formalin-fixed, paraffin-embedded (FFPE) tumor tissue block. Blocks prepared with alternative fixation methods may be acceptable; provide fixation method used.

Acceptable: Slides

Collection Instructions: Four consecutive, unstained, 5 micron-thick sections placed on positively charged slides, and 1 hematoxylin and eosin-stained slide.

Forms

[If not ordering electronically, complete, print, and send an Oncology Test Request](#) (T729) with the specimen.

Specimen Minimum Volume

Two consecutive, unstained, 5-micron-thick sections placed on positively charged slides, and 1 hematoxylin and eosin-stained slide.

Reject Due To

All specimens will be evaluated at Mayo Clinic Laboratories for test suitability.

Specimen Stability Information

| Specimen Type | Temperature | Time | Special Container |
|---------------|---------------------|------|-------------------|
| Tissue | Ambient (preferred) | | |
| | Refrigerated | | |

Clinical & Interpretive**Clinical Information**

MET is a proto-oncogene and its overexpression is associated with disease progression. Recent studies have shown *MET* amplification to be a major mechanism of acquired resistance to epidermal growth factor receptor tyrosine kinase domain inhibitor (EGFR-TKI). *MET* amplification has been reported in approximately 5% of patients not treated with EGFR-TKI and up to 20% of patients with acquired resistance to gefitinib or erlotinib.

Reference Values

An interpretive report will be provided.

Interpretation

A positive result is detected when the *MET*:D7Z1 ratio is > or =2.0.

The *MET* locus is reported as amplified when the *MET*:D7Z1 ratio of 2.0 or greater.

Patients with 5 or more copies of *MET* have a poor prognosis.

The absence of an abnormal clone does not rule out the presence of a neoplastic disorder.

Cautions

This test is not approved by the US Food and Drug Administration and is best used as an adjunct to existing clinical and pathologic information.

Fixatives other than formalin (eg, Prefer, Bouin) may not be successful for FISH assays, however nonformalin-fixed samples will not be rejected.

Paraffin-embedded tissues that have been decalcified are generally unsuccessful for FISH analysis. The pathologist reviewing the hematoxylin and eosin-stained slide may find it necessary to cancel testing.

Supportive Data

The probe set was independently validated in a blinded study on 29 paraffin-embedded tissue samples from patients with various tumors. A series of normal control samples were used to generate the normal cutoffs. The probe performed as intended and abnormalities including aneusomy, duplication and deletion of *MET* were identified, and may be observed in addition to *MET* amplification in tumor samples.

Clinical Reference

1. Cappuzzo F, Marchetti A, Skokan M, et al: Increased *MET* gene copy number negatively affects survival of surgically resected non-small-cell lung cancer patients. *J Clin Oncol* 2009;27(10):1667-1674
2. Go H, Jeon YK, Park HJ, et al: High *MET* gene copy number leads to shorter survival in patients with non-small cell lung cancer. *J Thorac Oncol* 2010;5(3):305-313
3. Okuda K, Sasaki H, Yukiue H, et al: *MET* gene copy number predicts the prognosis for completely resected non-small cell lung cancer. *Cancer Sci* 2008;99(11):2280-2285
4. Karamouzis MV, Konstantinopoulos PA, Papavassiliou AG: Targeting *MET* as a strategy to overcome crosstalk-related resistance to EGFR inhibitors. *Lancet Oncol* 2009;10:709-717
5. Engelman JA, Zejnullahu K, Mistudomi T, et al: *MET* amplification leads to gefitinib resistance in lung cancer by activating ERBB3 signaling. *Science* 2007;316:1039-1043

Performance**Method Description**

The test is performed using a commercially available probe set for *MET* and the centromere region of chromosome 7 (D7Z1). Paraffin-embedded tissues are cut at 5 microns and mounted on positively charged glass slides. The selection of tissue and the identification of target areas on the hematoxylin and eosin (H and E)-stained slide are performed by a pathologist. Using the H and E-stained slide as a reference, target areas are etched with a diamond-tipped etcher on the back of the unstained slide to be assayed. The probes are hybridized to the appropriate target areas and 2 technologists each analyze 30 interphase nuclei (60 total) with the results expressed as a ratio of *MET*:D7Z1 signals.(Unpublished Mayo method)

PDF Report

No

Day(s) Performed

Monday through Friday

Report Available

7 to 10 days

Specimen Retention Time

Slides and H&E used for analysis are retained by the laboratory in accordance to CAP and NYS requirements. Client provided paraffin blocks and extra unstained slides (if provided) will be returned after testing is complete.

Performing Laboratory Location

Rochester

Fees & Codes**Fees**

- Authorized users can sign in to [Test Prices](#) for detailed fee information.
- Clients without access to Test Prices can contact [Customer Service](#) 24 hours a day, seven days a week.
- Prospective clients should contact their account representative. For assistance, contact [Customer Service](#).

Test Classification

This test was developed using an analyte specific reagent. Its performance characteristics were determined by Mayo Clinic in a manner consistent with CLIA requirements. This test has not been cleared or approved by the US Food and Drug Administration.

CPT Code Information

88271x2, 88291-DNA probe, each (first probe set), Interpretation and report

88271x2-DNA probe, each; each additional probe set (if appropriate)

88271x1-DNA probe, each; coverage for sets containing 3 probes (if appropriate)

88271x2-DNA probe, each; coverage for sets containing 4 probes (if appropriate)

88271x3-DNA probe, each; coverage for sets containing 5 probes (if appropriate)

88274 w/modifier 52-Interphase in situ hybridization, <25 cells, each probe set (if appropriate)

88274-Interphase in situ hybridization, 25 to 99 cells, each probe set (if appropriate)

LOINC® Information

| Test ID | Test Order Name | Order LOINC® Value |
|---------|----------------------|--------------------|
| METF | MET (7q31), FISH, Ts | 90926-7 |

| Result ID | Test Result Name | Result LOINC® Value |
|-----------|------------------|---------------------|
| 55203 | Result Summary | 50397-9 |
| 55204 | Interpretation | 69965-2 |
| 55206 | Result | 62356-1 |

| | | |
|-------|------------------------|---------|
| CG938 | Reason for Referral | 42349-1 |
| 55207 | Specimen | 31208-2 |
| 55208 | Source | 31208-2 |
| 55209 | Tissue ID | 80398-1 |
| 55210 | Method | 85069-3 |
| 55211 | Additional Information | 48767-8 |
| 55212 | Disclaimer | 62364-5 |
| 55224 | Released By | 18771-6 |