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MAYO CLINIC LABORATORIES

Test Definition: MCRSP

MayoComplete Targeted RNA Sequencing Panel, Next-Generation Sequencing, Tumor

Overview

Useful For

Primarily for identifying gene fusions that help in the diagnosis of solid tumors

Secondarily, for identifying gene fusions that have therapeutic or prognostic significance

Genetics Test Information

This test uses next-generation sequencing to evaluate 1445 genes for the presence of somatic gene fusions, known abnormal transcript variants in the *MET* and *EGFR* genes, and *BCOR* exon 15 internal tandem duplications. See Targeted Fusion Genes for MayoComplete Targeted RNAseq Panel for details regarding the targeted gene regions evaluated by this test.

This test is performed to evaluate for somatic gene fusions within solid tumor samples. It **does not assess** for germline alterations.

Additional Tests

Test Id	Reporting Name	Available Separately	Always Performed
SLIRV	Slide Review in MG	No, (Bill Only)	Yes

Testing Algorithm

When this test is ordered, slide review will always be performed at an additional charge.

Special Instructions

- Tissue Requirements for Solid Tumor Next-Generation Sequencing
- Targeted Fusion Genes for MayoComplete Targeted RNAseq Panel

Highlights

This test evaluates formalin-fixed, paraffin-embedded tumor or cytology slides, for gene fusions, to assist in the diagnosis and management of patients with solid tumors.

This test also detects *BCOR* internal tandem duplications of exon 15, and splice variants for the *EGFR* and *MET* genes.

Method Name

Sequence Capture and Targeted Next-Generation Sequencing (NGS)

NY State Available

Yes

Specimen

Specimen Type

Varies

Ordering Guidance

Multiple oncology (cancer) gene panels are available. For more information see Hematology, Oncology, and Hereditary Test Selection Guide.

Necessary Information

A pathology report (final or preliminary), at minimum containing the following information, **must accompany specimen for testing to be performed**:

1. Patient name
2. Block number-must be on all blocks, slides, and paperwork (can be handwritten on the paperwork)
3. Tissue collection date
4. Source of the tissue
5. Diagnosis, potential diagnosis, or differential diagnoses

Specimen Required

This assay requires at least 10% tumor nuclei.

-Preferred amount of tumor area with sufficient percent tumor nuclei: tissue 144 mm(2)

-Minimum amount of tumor area: tissue 36 mm(2)

-These amounts are cumulative over up to 10 unstained slides and must have adequate percent tumor nuclei.

-Tissue fixation: 10% neutral buffered formalin, not decalcified

-For specimen preparation guidance, see Tissue Requirements for Solid Tumor Next-Generation Sequencing. In this document, the sizes are given as 4 mm x 4 mm x 10 slides as preferred: approximate/equivalent to 144 mm(2) and the minimum as 3 mm x 1 mm x 10 slides: approximate/equivalent to 36 mm(2).

Preferred: Submit 3, if available, or 2 of the following specimens.
Acceptable: Submit **at least one** of the following specimens.

Specimen Type: Tissue block
Collection Instructions: Submit a formalin-fixed, paraffin-embedded tissue block with acceptable amount of tumor tissue.

Specimen Type: Tissue slides
Slides: 1 Hematoxylin and eosin-stained and 10 unstained
Collection Instructions:
Submit the followings slides:
1 Slide stained with hematoxylin and eosin
AND
10 Unstained, nonbaked slides with 5-micron thick sections of the tumor tissue.
Note: The total amount of required tumor nuclei can be obtained by scraping up to 10 slides from the same block.
Additional Information:

1. Hematoxylin and eosin-stained and unstained slides will not be returned.
2. Broken or cracked unstained slides will be rejected. Stained slides that were broken and repaired (ie, double

mounted) at the client site will not be rejected, as, in most cases, they can still be reviewed under the microscope. However, due to the double mounting, digital scanning cannot be performed.

Specimen Type: Cytology slides (direct smears or ThinPrep)
Slides: 1 to 3 Slides
Collection Instructions: Submit 1 to 3 slides stained and coverslipped with a total of 5000 nucleated cells (preferred) or at least 3000 nucleated cells (minimum).
Note: Glass coverslips are preferred; plastic coverslips are acceptable but will result in longer turnaround times.
Additional Information:
1. Cytology slides will not be returned. An image of the slides will be stored per regulatory requirements.
2. Stained slides that were broken and repaired (ie, double mounted) at the client site will not be rejected, as, in most cases, they can still be reviewed under the microscope. However, due to the double mounting, digital scanning cannot be performed.

Forms
If not ordering electronically, complete, print, and send a Oncology Test Request (T729) with the specimen.

Specimen Minimum Volume
See Specimen Required

Reject Due To

Broken or cracked unstained slides	Reject
Broken or cracked stained slides that cannot be repaired	Reject

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Varies	Ambient (preferred)		
	Refrigerated		

Clinical & Interpretive

Clinical Information
Molecular analysis of biomarkers is increasingly being utilized in oncology practices to support and guide diagnosis, prognosis, and therapeutic management of patients.

This next-generation sequencing assay interrogates 1445 genes for the presence of gene fusions that can result from chromosomal translocations, interstitial deletions, and inversions, that have clinical implications for diagnosis, prognosis and therapy in solid tumors.

Reference Values

An interpretive report will be provided.

Interpretation

The interpretation of molecular biomarker analysis includes an overview of the results and the associated diagnostic, prognostic, and therapeutic implications.

Cautions

This assay is not validated for the detection of single nucleotide variations, deletions-insertions, copy number alterations, or gene expression.

Fusions of uncertain significance may be identified.

The sensitivity of this assay for gene fusions depends on several variables including decreased sensitivity with decreased tumor percentage, and decreased sensitivity with decreased level of expression of a variant. A negative result does not rule out the presence of a gene fusion, splice variant, or *BCOR* exon 15 internal tandem duplication that may be present but below the limits of detection of this assay. The analytical sensitivity of this assay is a minimum coverage of 5 unique variant molecules in a sample with at least 10% tumor content.

This assay can detect in-frame and out-of-frame fusions involving 1445 genes. Sensitivity for detecting out-of-frame fusions, such as exon-intron, intron-intron or fusion transcripts that contain sequence alterations (including insertions or deletions), may be lower due to bioinformatics detection limitations. This assay may only detect fusions involving at least 1 gene in the defined gene fusion target list of interest. This assay may not detect fusions involving deep intron or intergenic regions and will not detect chromosomal rearrangements that do not create a fusion transcript (ie, enhancer repositioning). Variants not expressed, or expressed at very low level, are not detected by this assay.

Rare variants, or alterations derived from the production of a gene fusion, may be present that could lead to false-negative or false-positive results.

The presence or absence of a fusion may not be predictive of response to therapy in all patients.

Test results should be interpreted in the context of clinical findings, tumor sampling, and other laboratory data. If results obtained do not match other clinical or laboratory findings, contact the laboratory for an updated interpretation. Misinterpretation of results may occur if the information provided is inaccurate or incomplete.

Reliable results are dependent on adequate specimen collection and processing. This test has been validated on cytology slides and formalin-fixed, paraffin-embedded tissues; other types of fixatives are discouraged. Improper treatment of tissues, such as decalcification, may cause polymerase chain reaction failure.

RNA is particularly labile and degrades quickly. Rapid preservation of the tumor sample after collection reduces the

likelihood of degradation. Still, there can be biological factors, such as tumor necrosis, which interfere with obtaining a high-quality RNA specimen despite rapid preservation.

Broken or cracked unstained slides are not compatible with the instrumentation used in our performing laboratories and will be rejected. Additional material may be requested.

Attempts will be made to repair broken or cracked stained slides; however, if they are unable to be repaired (ie, shattered in transit), they will be rejected and discarded due to safety concerns.

Supportive Data

Performance Characteristics:
Validation studies demonstrated that concordance between this test, and the reference method, for detection of gene fusions, *BCOR* in-tandem duplications, and splice variants within *MET* and *EGFR* is 96.6% (256/265). No gene fusions were detected in 14 normal tissues, and no gene fusions were detected in the negative control sample (100% specificity). The sensitivity of this assay for detecting *CIC*::*DUX4* fusions is lower (approximately 70%-80%), based on preclinical testing; tumors that are fusion negative but suspected to be *CIC*-rearranged may require orthogonal methods including immunohistochemistry, fluorescence in situ hybridization, real-time polymerase chain reaction, gene expression profiling, and/or methylation profiling.

To ensure that this assay detects fusions based on the established sensitivity, this test will be performed on cases that are estimated by a pathologist to have at least 10% tumor cells.

Clinical Reference

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12. Mehra R, Tomlins SA, Yu J, et al. Characterization of TMPRSS2-ETS gene aberrations in androgen-independent metastatic prostate cancer. Cancer Res. 2008;68(10):3584-3590
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Performance

Method Description
RNA-based next-generation sequencing is performed to test for the presence of rearrangements involving 1445 genes, selected splice variants in *MET* and *EGFR* genes, and internal tandem duplications within exon 15 of the *BCOR* gene. See Targeted Fusion Genes for MayoComplete Targeted RNAseq Panel for details regarding the targeted gene regions evaluated by this test genes.(Unpublished Mayo method)

A pathology review and macro dissection to enrich for tumor cells are performed prior to slide scraping.

PDF Report
No

Day(s) Performed
Monday through Friday

Report Available
12 to 20 days

Specimen Retention Time
Tissue blocks: Unused portions of blocks will be returned; Tissue slides: Hematoxylin and eosin-stained and unstained slides will not be returned. Unused slides are stored for at least 5 years; Extracted RNA: 3 months

Performing Laboratory Location
Mayo Clinic Laboratories - Rochester Main Campus

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 and its performance characteristics determined by Mayo Clinic in a manner consistent with CLIA requirements. It has not been cleared or approved by the US Food and Drug Administration.

CPT Code Information

81456

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
MCRSP	MayoComplete Targeted RNAseq Panel	95123-6

Result ID	Test Result Name	Result LOINC® Value
623361	Result	82939-0
623362	Interpretation	69047-9
623363	Additional Information	48767-8
623364	Specimen	31208-2
623365	Tissue ID	80398-1
623366	Method	85069-3
623367	Disclaimer	62364-5
623368	Released By	18771-6