

MayoComplete Lung Cancer-Targeted Gene Panel with Rearrangement, Tumor

Patient ID SA00174996	Patient Name TESTINGRNV, NORMAL	Birth Date 1955-03-01	Sex M	Age 70
Order Number SA00174996	Client Order Number SA00174996	Ordering Physician CLIENT, CLIENT	Report Notes	
Account Information C7028846 DLMP Rochester		Collected 28 Mar 2025 00:00		

MayoComplete Lung Cancer Panel

Result

MCR

Provided diagnosis: squamous cell carcinoma involving lymph node

Microsatellite Instability (MSI) status: Stable (MSS)

No reportable sequence variants or rearrangements were detected within the analyzed regions of the tested genes listed in the method description.

Interpretation

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Current data suggests that the efficacy of targeted therapies in patients with non-small cell lung cancer is limited to tumors with rearrangements or mutations in certain genes [PMID 23562183, PMID 27151654, PMID 27080216,

PMID 27283860, PMID 25971939, PMID 25971938, PMID

24162815]. Thus, the absence of a targetable mutation or rearrangement within this tumor suggests that therapies may have limited value for this patient. However, for patients with advanced, recurrent, or metastatic non-small cell lung cancer without targetable genomic aberrations, immune checkpoint blockade may be considered in proper clinical settings [fda.gov/drugs].

MSI: Stable (MSS)

NO evidence of microsatellite instability was detected suggesting the presence of normal DNA mismatch repair function within the tumor. Current data suggest that advanced stage solid tumors with intact mismatch repair (MSS) are less likely to be responsive to treatment with immunotherapies such as anti-PD-1 therapies [PMID 28596308, PMID 29355075].

Additional Information

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CLINICAL TRIALS

Possible clinical trials of benefit for this patient can be found at the following sites:

1) ClinicalTrials.gov:

www.clinicaltrials.gov/ct2/search/advanced

2) Mayo Clinic: www.mayo.edu/research/clinical-trials/ 3) National Cancer Institute: www.cancer.gov/clinicaltrials/search

Specimen

MCR

Tissue, Tumor

Tissue ID

MCR

12345

Method

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Microscopic examination is performed by a pathologist to identify areas of tumor for enrichment by macrodissection.

Next generation sequencing is performed to test for the presence of microsatellite instability and a mutation within all coding regions and exon/intron boundaries of the following 12 targeted genes: ALK, BRAF, EGFR, ERBB2, HRAS, KRAS, MDM2, MET, NRAS, RET, ROS1, and STK11.

A qualitative PCR-based assay is performed to detect rearrangements (fusions) within the ALK, ROS1 and RET genes, MET exon 14 skipping, and expression imbalance for ALK, ROS1, RET, NTRK1, NTRK2 and NTRK3 genes.

Variant nomenclature is based on build GRCh37 (hg19). For details about gene transcripts (RefSeq accession numbers), specific targeted regions of each gene, and additional information on this test, see www.mayocliniclabs.com (Test ID MCLNG).

Disclaimer

1 MCR

This test cannot differentiate between somatic and germline

Performing Site Legend

Code	Laboratory	Address	Lab Director	CLIA Certificate
MCR	Mayo Clinic Laboratories - Rochester Main Campus	200 First Street SW, Rochester, MN 55905	Nikola Baumann Ph.D.	24D0404292

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alterations. Additional testing may be necessary to clarify the significance of results if there is a potential hereditary risk.

DNA variants of uncertain significance may be identified.

A negative result does not rule out the presence of a variant that may be present but below the limits of detection of this assay. The analytical sensitivity of this assay for sequence reportable alterations is 5% mutant allele frequency with a minimum coverage of 500X in a sample with at least 20% tumor content.

Point mutations and small insertion/deletion mutations will be detected in the ALK, BRAF, EGFR, ERBB2, HRAS, KRAS, MDM1, MET, NRAS, RET, ROS1, and STK11 genes only. This test may detect single exon deletions but does not detect multi-exon deletions, duplications, larger-scale genomic copy number variants, copy neutral loss of heterozygosity (LOH), or epigenetic modifications such as promoter methylation. DELINS of 1,000 bp or less are detectable with at least 50 or more supporting reads. This test does not detect point mutations, insertion/deletion mutations, large single or multi-exon deletions or duplications, or genomic copy number variants for the NTRK1, NTRK2, and NTRK3 genes.

Gene fusions (rearrangements) and expression imbalance involving the ALK, ROS1, RET, NTRK1, NTRK2, and NTRK3 genes only will be detected.

Variant allele frequency (VAF) is the percentage of sequencing reads supporting a specific variant divided by the total

sequencing reads at that position. In somatic testing, VAF should be interpreted in the context of several factors including, but not limited to: tumor purity/heterogeneity/copy number status (ploidy, gains/losses, loss of heterozygosity) and sequencing artifact/misalignment [PMID: 27144058, PMID: 29769535].

Rare polymorphisms may be present that could lead to false-negative or false-positive results.

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

Test results should be interpreted in the context of clinical, tumor sampling, histopathological, and other laboratory data. If results obtained do not match other clinical or laboratory findings, contact the laboratory for discussion. Misinterpretation of results may occur if the information provided is inaccurate and/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 PCR failure.

Released By

Ying-Chun Lo, M.D., Ph.D.

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Received: 29 Mar 2025 15:24

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Laboratory Notes

- 1 This test was developed and its performance characteristics determined by Mayo Clinic in a manner consistent with CLIA requirements. This test has not been cleared or approved by the U.S. Food and Drug Administration.

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