Non-Small Cell Lung Cancer Molecular Markers

Lung cancer is the leading cause of cancer-related mortality in the U.S. and generally responds poorly to traditional chemotherapy agents. Over 80% of lung cancer cases are classified as non-small cell lung cancer (NSCLC). Individuals with advanced or metastatic disease should undergo biomarker testing to identify oncogenic driver mutations for which effective drugs (targeted therapy) may be available and PD-L1 expression testing to assess if immune checkpoint inhibitor therapy is an option.

TYPICAL TESTING STRATEGY

Minimum initial biomarkers recommended as a standard of care include EGFR and BRAF mutational status, ALK and ROS1 rearrangement status, and PD-L1 expression by IHC. Broad molecular profiling (including NTRK genes rearrangement status) is strongly encouraged to identify other driver mutations for which effective therapy might be available.

DISEASE OVERVIEW

Treatment Issues
Biomarker testing is a standard of care in patients with advanced or metastatic NSCLC as results determine the best first-line therapy. For more detailed information on the therapy selection process, please refer to current National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology.

TEST INTERPRETATION

Results
- Positive (e.g., presence of gene mutation, gene rearrangement, gene amplification, PD-L1 expression): predicts response to targeted therapy with tyrosine kinase inhibitor (TKI) and/or immune checkpoint inhibitor therapy
- Negative: may predict lack of benefit from targeted therapy with TKI and/or immune checkpoint inhibitor therapy

For more detailed information, please refer to the individual test background information provided with the test result.

Limitations
- Results must be interpreted in the context of clinical findings and morphological and other relevant data.
- Results may be compromised if the recommended tissue-fixation procedures have not been followed.
- Each methodology has its own known limitations. For more detailed information, please refer to the individual test background information provided with the test result.

REFERENCES


RELATED INFORMATION

Non-Small Cell Lung Cancer - Non-Small Cell Lung Cancer Molecular Markers
PD-L1 Testing
PD-L1 Testing Algorithm
RELATED TESTS

Lung Cancer Panel with KRAS 2008895
Method: Polymerase Chain Reaction/Pyrosequencing/Immunohistochemistry

ALK (D5F3) by Immunohistochemistry with Reflex to ALK Gene Rearrangements by FISH 2011431
Method: Immunohistochemistry/Fluorescence in situ Hybridization

ALK (D5F3) with Interpretation by Immunohistochemistry 2007324
Method: Immunohistochemistry

ALK Gene Rearrangements by FISH, Lung 3001302
Method: Fluorescence in situ Hybridization

BRAF V600E Mutation Detection in Circulating Cell-Free DNA by Digital Droplet PCR 2013921
Method: Polymerase Chain Reaction

EGFR Mutation Detection by Pyrosequencing 2002440
Method: Polymerase Chain Reaction/Pyrosequencing

KRAS Mutation Detection 0040248
Method: Polymerase Chain Reaction/Pyrosequencing

MET Gene Amplification by FISH 3001313
Method: Fluorescence in situ Hybridization

PD-L1 28-8 pharmDx by Immunohistochemistry with Interpretation, nivolumab (OPDIVO) 2013684
Method: Immunohistochemistry

RET Gene Rearrangements by FISH 3001312
Method: Fluorescence in situ Hybridization

ROS1 with Interpretation by Immunohistochemistry with Reflex to FISH if Equivocal or Positive 2008414
Method: Immunohistochemistry

ROS1 by FISH 3001308
Method: Fluorescence in situ Hybridization

Solid Tumor Mutation Panel by Next Generation Sequencing 2007991
Method: Massively Parallel Sequencing