

Lung Cancer Panel - Next Generation Sequencing and Reflex Testing

Indication: Mutations in the genomic regions listed below are associated with either sensitivity or resistance to targeted therapy.

Testing method: Amplicon-based targeted next generation sequencing assay is used for detection of hot spot mutations in genes associated with lung cancer. Additional genes will be evaluated when requested.

Diagnostic sensitivity: This assay is designed to detect known single nucleotide variants and small indels within defined regions. Nucleotide insertions and deletions more than 25bp or outside of the defined regions may not be detected. Gene rearrangements are not detected; a reflex test needs to be requested.

Technical sensitivity: This assay may not detect certain mutations if the proportion of tumor cells in the sample studied is less than 20%.

Laboratory Notes

Clinical Panel

Gene	Exon / Amino Acid (AA) Coverage
EGFR	Exons 3, 7, 18-21 (AA 108-142, 287-297, 598-627, 708-728, 729-761, 762-817, 857-875)
EGFR	Exon 20 (T790M)
KRAS	Exons 2-3 (AA 1-22, 38-63)
NRAS	Exons 2-3 (AA 1-19, 38-62)
BRAF	Exons 11, 15 (AA 439-472, 581-606) including p.V600E variant
MET	Exons 2, 14, 16, 19 (AA 168-205, 375-400, 990-1010, 1093-1114, 1229-1266)
ERBB2	Exons 19-21 (AA 754-769, 772-818, 839-883)

Turnaround Time: 5-7 business days

Sample Requirements: The presence of adequate tumor in the material submitted for analysis should be confirmed by a surgical pathologist. A section from archival paraffin material or frozen surgical biopsies should be confirmed to contain > 50% tumor by a surgical pathologist. If the submitted material for analysis contains < 50% of tumor, areas of predominant tumor will be microdissected to enrich for neoplastic cells.

- Formalin-fixed, paraffin-embedded tissue
- 5-6 tissue sections (please include H&E slide and a copy of pathology report)
- Cytology slides
- Fresh frozen tissue (ship frozen)

CPT Codes: 81445, **G0452**. 88381 may apply.

REFLEX TESTS

If EGFR negative, **reflex to ALK** (FISH), if ALK negative, **reflex to ROS1** (FISH) (88377x2)

Fusion Testing (NGS) (81445)

ALK, ROS1, RET, MET (including exon 14 skipping), NTRK1, NTRK2, NTRK3

PD-L1 22C3 (IHC) (88360)

PD-L1 28-2 (IHC) (88360)