

Drug indication based on marker status for NSCLC

Marker	FDA approved drug	Response association
EGFR, KRAS, MET	Erlotinib, Gefitinib, Afatinib	<ul style="list-style-type: none"> Most of the alterations in the EGFR gene indicate response to all three drugs, while some mutations indicate resistance to them. Alterations in the MET or KRAS gene may indicate limited response to all three drugs.
EGFR	Osimertinib	EGFR T790M mutation indicates possible response to Osimertinib.
ALK, ROS1, MET	Crizotinib	<ul style="list-style-type: none"> ALK or ROS1 rearrangements indicate response to Crizotinib. MET alterations may indicate response to Crizotinib.
ALK	Cartisib, Alectinib	ALK rearrangement indicates response to both the drugs.
BRAF	Vemurafenib, Dabrafenib	BRAF mutations indicate possible response to both the drugs.
EGFR, MET, PIK3CA	Traztuzumab	Alterations in EGFR, MET or PIK3CA genes are associated with limited response to Traztuzumab.

References

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CARE IN CURE

Empowering Personalized Treatment for Non-Small Cell Lung Cancer (NSCLC) with Personalized Diagnostics.



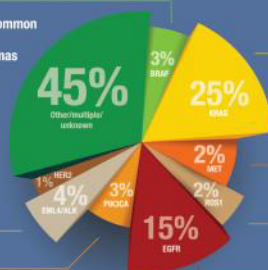
Name of Test	BRAF Mutation Analysis
Clinical Utility	<ul style="list-style-type: none"> BRAF mutation is found in a variety of cancers. Patients exhibiting these mutations benefit from BRAF inhibitors. This assay analyzes Exon 15 to detect the V600 mutation.
Test Code	N113
Technology	PCR, Sequencing
Sample requirements	Formalin Fixed Paraffin Embedded (FFPE) block must contain minimum 10% tumor cells.
Pre-Test Requirement	Copy of the Histopathology report, Brief clinical history.
TAT	Sample by Tue at 11am; Report on Mon.
Accreditations	NABL/CAP certified

Highlights

- Test clinically actionable genomic alterations and biomarkers based on therapeutic significance
- Status of the markers are used to identify response to FDA approved therapies
- Comprehensive testing method using sequencing and FISH platforms
- In compliance with the ACMG and NCCN guidelines

Name of Test	KRAS mutation, codon 12 & 13 fragment analysis
Clinical Utility	<ul style="list-style-type: none"> 97% of K-RAS mutations in NSCLC involve codons 12 or 13. This assay detects G12C, G12S, G 12 R, G12D, G12V, G12A, G13R, G13C/G13D alterations.
Test Code	N067
Technology	PCR, Fragment Analysis, Sequencing by SNaPshot assay.
Sample requirements	Formalin Fixed Paraffin Embedded (FFPE) block must contain minimum 10% tumor cells.
Pre-Test Requirement	Copy of the Histopathology report, Brief clinical history.
TAT	Sample by Tue at 11am; Report on Mon.
Accreditations	NABL/CAP certified

Incidence of common alterations in Adenocarcinomas



Name of Test	ALK-1 Breakpart Rearrangement
Clinical Utility	<ul style="list-style-type: none"> Approximately 3-5% of Non-Small Cell Lung Carcinomas (NSCLC) have a rearrangement of the ALK gene, resulting in fusion between ALK and another gene, ALK activation, impaired apoptosis and abnormal cell proliferation. FISH technique is the gold standard for detecting ALK-1 gene rearrangements.
Test Code	XX031
Technology	Fluorescence In-situ Hybridization (FISH)
Sample requirements	Formalin Fixed Paraffin Embedded (FFPE) block
Pre-Test Requirement	Copy of the Histopathology report, Brief clinical history.
TAT	Sample Daily by 4pm; Report in 7 Days.
Accreditations	NABL/CAP certified

Name of Test	MET (7q31) Amplification
Clinical Utility	<ul style="list-style-type: none"> Over-expression of MET has been observed in variety of neoplasms of kidney, lung, head & neck, ovary, breast, thyroid, brain, stomach, pancreas and colon. This amplification has been associated with an unfavorable prognosis in Non-Small Cell Lung Cancer (NSCLC) and resistance to EGFR inhibitors.
Test Code	XX050
Technology	Fluorescence In-situ Hybridization (FISH)
Sample requirements	Formalin Fixed Paraffin Embedded (FFPE) block
Pre-Test Requirement	Copy of the Histopathology report, Brief clinical history.
TAT	Sample Daily by 4pm; Report in 7 Days.

Name of Test	PIK3CA Mutation Analysis
Clinical Utility	<ul style="list-style-type: none"> Mutations in the PIK3CA gene have been identified in carcinomas arising from colon, breast, ovary, liver, stomach and lung as well as in glioblastomas. Identification of the mutation helps in risk stratification and classification. This assay analyzes Exon 9 and exon 20 to detect all the clinically relevant mutations.
Test Code	N114
Technology	PCR, Sequencing
Sample requirements	Formalin Fixed Paraffin Embedded (FFPE) block
Pre-Test Requirement	Copy of the Histopathology report, Brief clinical history.
TAT	Sample by Tue at 11am; Report on Mon.
Accreditations	NABL/CAP certified

Name of Test	EGFR Mutational Analysis
Clinical Utility	<ul style="list-style-type: none"> Patients positive for EGFR mutations benefit from Tyrosine Kinase inhibitors (Gefitinib). This assay detects insertions/deletions in codons 19 and 20. It also detects the most common mutations in codons 18, 19, 20 and 21.
Test Code	N072
Technology	PCR, Fragment Analysis, Sequencing
Sample requirements	Formalin Fixed Paraffin Embedded (FFPE) block must contain minimum 10% tumor cells.
Pre-Test Requirement	Copy of the Histopathology report indicating site of biopsy, Brief clinical history.
TAT	Sample by Tue at 11am; Report on Mon.
Accreditations	NABL/CAP certified

Name of Test	ROS1 (6q22) Rearrangement
Clinical Utility	<ul style="list-style-type: none"> ROS1 has seven chromosomes described so far in Non-Small Cell Lung Carcinoma (NSCLC). FISH detection assay encompasses all described and as yet undescribed rearrangements covering the whole spectrum unlike molecular assays.
Test Code	XX049
Technology	Fluorescence In-situ Hybridization (FISH)
Sample requirements	Formalin Fixed Paraffin Embedded (FFPE) block
Pre-Test Requirement	Copy of the Histopathology report, Brief clinical history.
TAT	Sample Daily by 4pm; Report in 7 Days.
Accreditations	NABL/CAP certified

Also available:
 Lung Cancer Mutation panel (ALK and EGFR) 278P
 ALK & ROS1 278P
 Cancer 50 gene panel 808P