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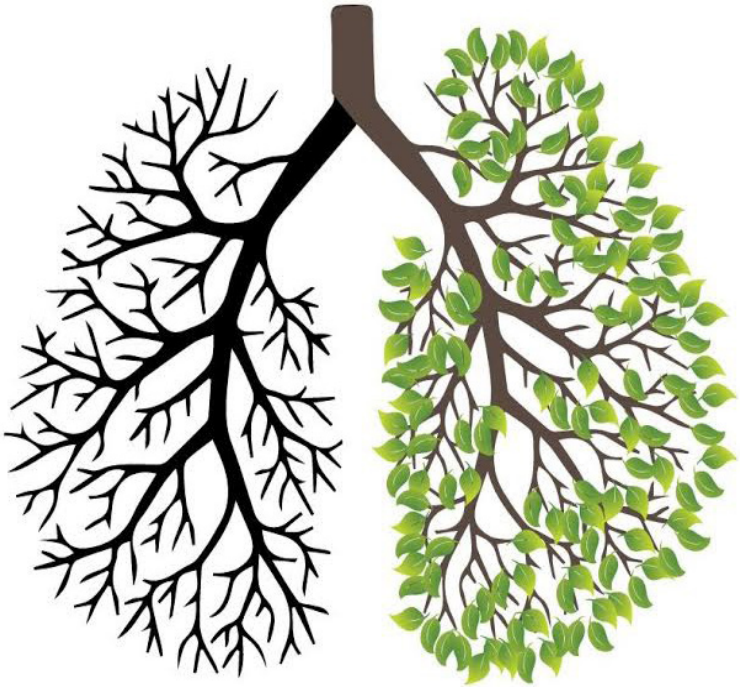
Clinical Testing for

Lungs & Colon Cancer



India's Leading Super Specialised Laboratory Network

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EGFR Mutation Analysis by ARMS PCR

- Identifies patients with those specific mutations in the TK domain of the EGFR gene (exons 18-21).
- Stratifying patients for TKI therapies targeting epidermal growth factor receptor (EGFR).

ALK gene rearrangement by FISH

- ALK gene rearrangements are present in about 5% of NSCLC and the new FDA-approved Vysis ALK Break Apart FISH Probe Kit detects a specific rearrangement in the ALK gene.
- Identifies patients eligible for treatment with FDA approved Crizotinib (XALKORI).

ALK- D5F3 by Immunohistochemistry

- Valuable tool for the pre-screening of patients with ALK gene rearrangement in NSCLC.
- Allows use of archival tissues & retain tissue morphology during analysis .

ROS1 gene rearrangement by FISH

- ROS1 rearrangements lead to constitutively active fusion proteins and are detected in 1% to 2% of NSCLC cases.
- Aids in identifying patients eligible for treatment with tyrosine kinase inhibitor, crizotinib and presence of rearrangement is associated with sensitivity to Crizotinib.

PD-L1 by Immunohistochemistry

- Programmed Death Ligand 1 plays a critical role in Immunotherapy.
- Assessment of PDL1 helps to identify patients of NSCLC who will benefit from immunotherapy drugs.
- Offered as IHC 22C3 pharmDx clone Dako & on Ventana platform.

MET gene rearrangement by FISH

- MET is a Receptor Tyrosine Kinase and is one of the most frequently dysregulated pathways in human cancer for both solid tumors and hematological malignancies.
- Predicts prognosis of lung cancer and MET amplification is associated with resistance to gefitinib or erlotinib in patients with NSCLC.

KRAS Mutation

- This test detects mutations in Exon 2 (codon 12/13) and Exon 3 (codon 61).
- Presence of these mutations is a strong predictor of resistance to anti-EGFR therapy with Tyrosine Kinase inhibitors such as Cetuximab and Panitumumab.

Extended KRAS

- This test detects Exon 4 (codon 146) mutation along with mutations in Exon 2 (codon 12/13) and Exon 3 (codon 61).

- Mutations in exon 4 are detected in approximately 1-4% of colorectal cancers and thus it also provides a rationale for broader KRAS testing beyond the most common hotspot alleles in exons 2 and 3.
- Presence of these mutations is a strong predictor of resistance to anti-EGFR therapy with Tyrosine Kinase inhibitors such as Cetuximab and Panitumumab.

NRAS Mutation

- This test detects mutations in Exon 2 (codon 12/13) and Exon 3 (codon 61).
- Mutations in the NRAS gene are associated with resistance to anti-epidermal growth factor receptor (EGFR) therapies in colorectal cancer patients without KRAS mutations.

Extended NRAS

- This test detects Exon 4 (codon 146) mutation along with mutations in Exon 2 (codon 12/13) and Exon 3 (codon 61).
- Presence of these mutations is a strong predictor of resistance to anti-EGFR therapy with Tyrosine Kinase inhibitors such as Cetuximab and Panitumumab.

BRAF V600E Mutation Analysis

- This assay detects all known/novel mutations in exon 15 of BRAF gene including mutations present at residue V600.
- BRAF V600E mutations are associated with increased sensitivity to BRAF inhibitor, Vemurafenib.

Microsatellite instability (MSI)

- Clinical test to detect patients having hereditary non polyposis colorectal cancer (HNPCC)/Lynch syndrome.
- MSI tumors have a more favorable prognosis and are less prone to lymph node and systemic metastasis.

UGT1A1 Genotyping Analysis

- FDA recommended clinical test to detect UGT1A1 (TA) polymorphism for the assessment of risk of irinotecan toxicity.
- Assists in selection of initial irinotecan dosage.

Final Diagnosis Panel

- Performing comprehensive set of markers to establish exact diagnosis.
- IHC markers decided by the team of oncopathologists.
- Initial market to assess lineage- PAN CK/ Vitamin/ Chromogranin/ S100/CD45, subsequent targeted approach leading to the final diagnosis.

Test Information

Test Code	Test Name	Technique	Specimen	TAT / Reported on
SMO10088	EGFR Mutation Analysis By ARMS PCR	ARMS PCR	FFPE tissue block	7th working day
SFI10010	ALK by FISH	FISH	FFPE tissue block	5th working day
SIH10107	ALK D5F3 by IHC	Immunohistochemistry	Formalin Fixed Paraffin Embedded (FFPE) tissue block/Representative Tissue placed in Formalin sent at room temperature by courier. Polylysine coated slides are also acceptable (12-15 for FDP; For other panels depending upon the number of markers requested) with an additional H&E slide is required. Slides to be transported in proper slide mailers (plastic) with proper labelling.	4th- 5th Working day
SFI10021	ROS1 gene Rearrangement	FISH	FFPE tissue block	5th working day
SIH10131	PDL1 by IHC	Immunohistochemistry	Formalin FXD Tissue	7th working day
SFI10022	MET gene Amplification by FISH	FISH	FFPE tissue block	5th working day hrs
SMO10128	KRAS Mutation Analysis (exons 2,3,4)	PCR & Sequencing	FFPE tissue block	10th working day
SMO10129	NRAS Mutation Analysis (exons 2,3,4)	PCR & Sequencing	FFPE tissue block	10th working day
SMO10130	Extended RAS Testing (exons 2,3,4 of KRAS & NRAS)	PCR & Sequencing	FFPE tissue block	9th working day
SMO10131	Extended RAS Reflex Panel (exons 2,3,4 of KRAS & NRAS)	PCR & Sequencing	FFPE tissue block	14th working day
SP10025	BRAF V600E Mutation	See Individual Assays	FFPE tissue block	10th working day
SMO10069	Gilbert Syndrome Genotyping (UGT1A1)	PCR & Sequencing	3-4ml Whole blood in EDTA (Lavender top) vacutainer	10th working day
SIH10097	MSI by Immunohistochemistry (IHC Marker)	Immunohistochemistry	Formalin Fixed Paraffin Embedded (FFPE) tissue block/Representative Tissue placed in Formalin sent at room temperature by courier. Polylysine coated slides are also acceptable (12-15 for FDP; For other panels depending upon the number of markers requested) with an additional H&E slide is required. Slides to be transported in proper slide mailers (plastic) with proper labelling.	4th -5th Working day
SP10100	Final Diagnosis Panel BY IHC	Immunohistochemistry		5th Working Day