anderson
Diagnostics & Labs

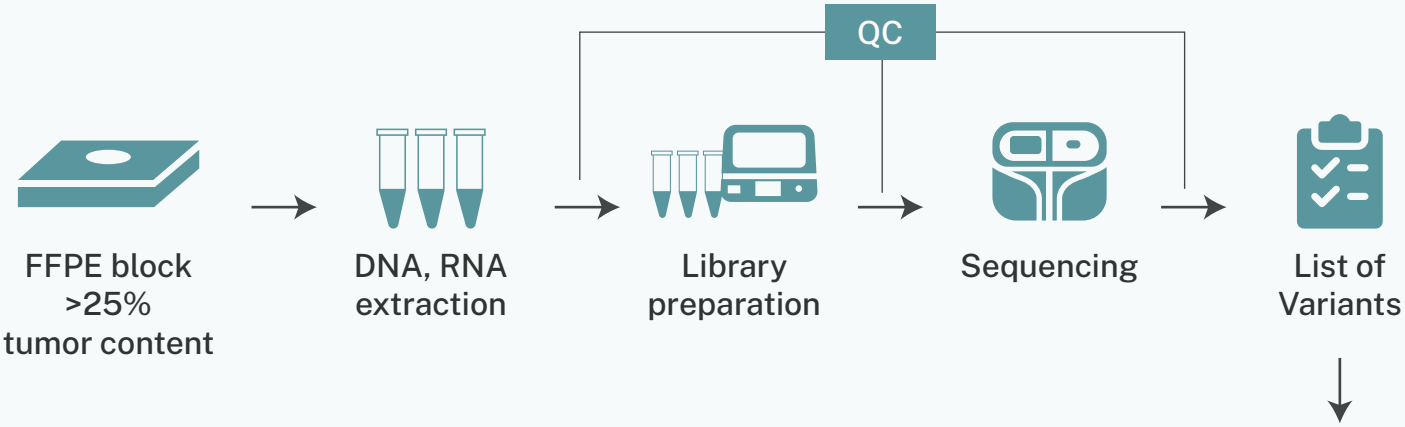
Oncomine Focus Assay

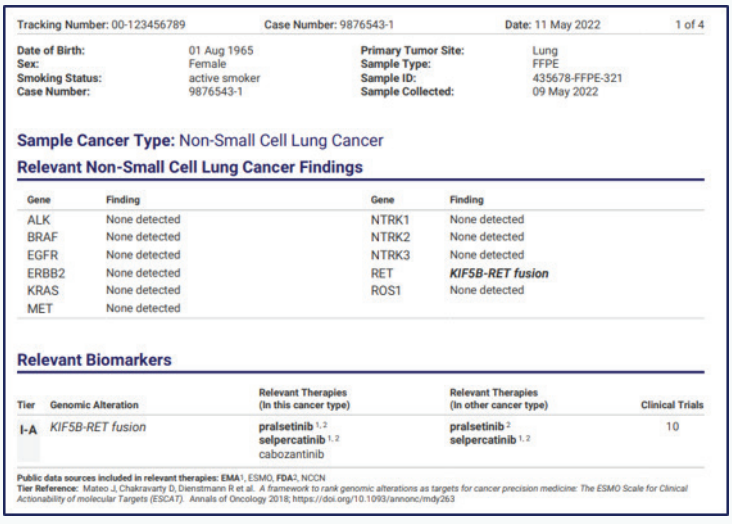
Single Panel for Testing 18 Types of Solid Tumors

Oncomine focus

- Hot spot screening of relevant, druggable mutations, copy number changes and fusions for various Cancers
- Analysing of 1000 variants across 52 genes for --cancers
- ACMG/AMP guidelines-based reporting with drugs and target information
- NGS based assay eliminate need of multiple technology FISH, IHC, Realtime
- High Sensitivity and Specificity
- Identifies druggable targets in various cancers and unknown primary

Workflow





Tracking Number: 00-123456789 Case Number: 9876543-1 Date: 11 May 2022 1 of 4

Date of Birth:	01 Aug 1965	Primary Tumor Site:	Lung
Sex:	Female	Sample Type:	FFPE
Smoking Status:	active smoker	Sample ID:	435678-FFPE-321
Case Number:	9876543-1	Sample Collected:	09 May 2022

Sample Cancer Type: Non-Small Cell Lung Cancer

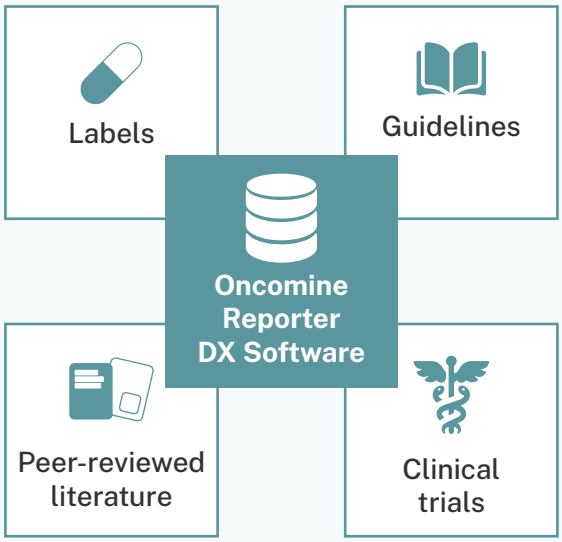
Relevant Non-Small Cell Lung Cancer Findings

Gene	Finding	Gene	Finding
ALK	None detected	NTRK1	None detected
BRAF	None detected	NTRK2	None detected
EGFR	None detected	NTRK3	None detected
ERBB2	None detected	RET	*KIF5B-RET fusion*
KRAS	None detected	ROS1	None detected
MET	None detected		

Relevant Biomarkers

Tier	Genomic Alteration	Relevant Therapies (In this cancer type)	Relevant Therapies (In other cancer type)	Clinical Trials
I-A	*KIF5B-RET fusion*	**pralsetinib** [1,2] **selpercatinib** [1,2] cabozantinib	**pralsetinib** [2] **selpercatinib** [1,2]	10

Public data sources included in relevant therapies: EMA[1], ESMO, FDA[2], NCCN
Tier Reference: Mateo J, Chakravarty D, Dienstmann R et al. *A framework to rank genomic alterations as targets for cancer precision medicine: The ESMO Scale for Clinical Actionability of molecular Targets (ESCAT).* Annals of Oncology 2018; https://doi.org/10.1093/annonc/mdy263



Actionable Report

Oncomine Knowledge base Reporter

List of genes

SNV's; Indels	*AKT1, ALK, AR, BRAF, CDK4, CTNNB1, DDR2, EGFR, ERBB2, ERBB3, ERBB4, ESR1, FGFR2, FGFR3, GNA11, GNAQ, HRAS, IDH1, IDH2, JAK1, JAK2, JAK3, KIT, KRAS, MAP2K1, MAP2K2, MET, MTOR, NRAS, PDGFRA, PIK3CA, RAF1, RET, ROS1, SMO*
CNV's	*AKT1, ALK, AR, BRAF, CCND1, CDK4, CDK6, EGFR, ERBB2, FGFR1, FGFR2, FGFR3, FGFR4, KIT, KRAS, MET, MYC, MYCN, PDGFRA, PIK3CA*
Fusions	*ABL1, AKT3, ALK, AXL, BRAF, EGFR, ERBB2, ERG, ETV1, ETV4, ETV5, FGFR1, FGFR2, FGFR3, MET, NTRK1, NTRK2, NTRK3, PDGFRA, PPARG, RAF1, RET, ROS1*

Testicular Carcinoma 17

BRAF, CTNB1, FGFR3, HRAS, KIT, KRAS, NRAS

Thyroid Cancer 18

AKT, BRAF,CTNB1, HRAS, IDH1, KRAS, NRAS, NTRK1, RET

Soft Tissue Sarcoma 16

CCND1, CDK4, ERG, FGR1, HRAS, KRAS, NRAS, PIK3CA

Skin Basal Cell Carcinoma 15

CTNB1, HRAS, KRAS, NRAS, PIK3CA

Prostate Cancer 14

AR, BRAF, ERG, ETV1, ETV4, ETV5, FGFR1, HRAS, IDH1, KRAS, MYC, RAF1

Pancreatic Cancer 13

CDK6, CTNB1, FGFR1, KRAS, MYC

Ovarian Cancer 12

BRAF, CCND1, CTNB1, FGFR1, KIT, KRAS , MYCN, PIK3CA

Melanoma Cancer 11

BRAF, CCND1, CDK4, GNA11, GNAQ, IDH1, KRAS, MAPK21, MYC, NRAS

Liver Cancer 10

BRAF, CCND1, CTNB1, IDH1, IDH2, KRAS, MYC, NRAS

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01 Bladder Cancer

AKT1, CCND1, EGFR, FGFR1, FGFR3, HRAS, KRAS, MUCM PIK3CA

02 Breast Cancer

AKT1, CCND1, ERBB2, FGFR1, MYC, NTRK3, PIK3CA

03 Colon Cancer

KRAS, NRAS, HRAS, BRAF, PIK3CA, AKT1

04 Endometrial Cancer

AKT1, CCND1, CTNB1, ERBB2, ESR1, FGFR1, FGFR2, KRAS, MYC, NRAS, PIK3CA

05 Esophageal Cancer

CCND1, CDK6, CTNB1, EGFR2, FGFR1, FGFR2, KRAS, MAP2K1, MYC, PIK3CA

06 Gastric Cancer

AR, BRAF, CCND1, CDK4, CDK6, EGFR, ERBB2, ERBB3, FGFR3, KRAS, MET MYC, PIK3CA

07 GIST Cancer

BRAF, CCND1, KIT, PDGFRA, PIK3CA

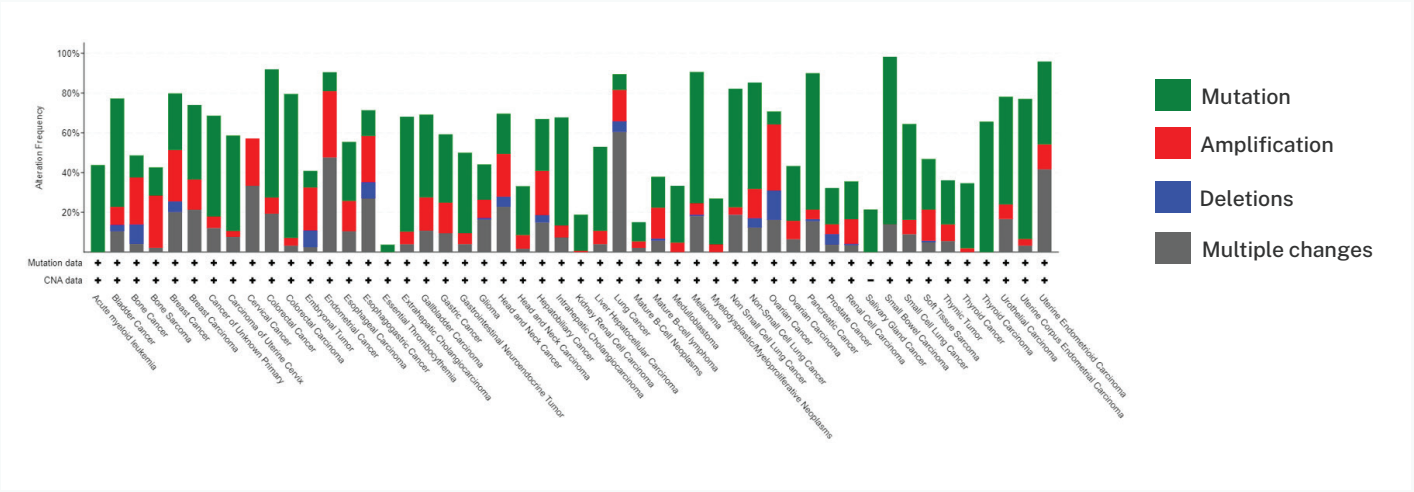
08 Head & Neck Cancer

CCND1, CDK6, EGFR, ERBB2, FGFR1, FGFR3, HRAS, KRAS, MET, NRAS, PIK3CA

09 Lung Cancer

EGFR, BRAF, MET, RET, ERBB2, KRAS, ALK, RET, ROS, NTRK

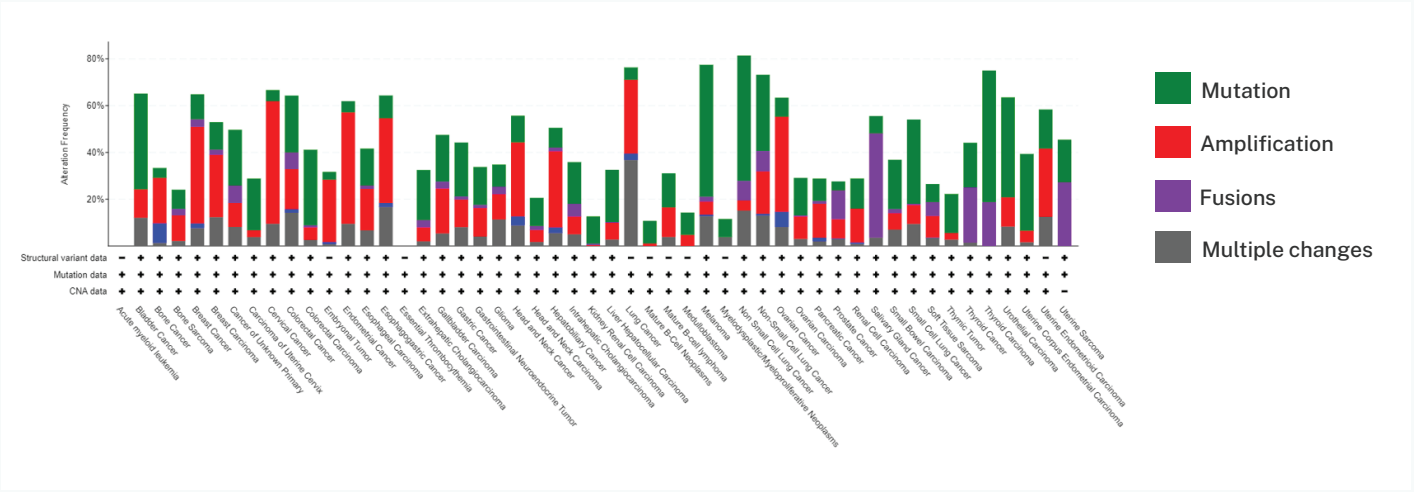
SNV and CNV profile of oncomine focus genes in Pan-cancer data



All types of solid tumors showing the presence of mutation and copy number variation, in the genes present in oncomine focus assay. Hence, this assay best suited to identify druggable mutation, driver mutation or CNV changes and prognostic bio-markers.

Analyzed using: **cbioportal.org.**

Oncomine Fusion assay genes profile in Pan-cancer data



Multiple tumors such as Bone sarcoma, breast cancer, CRC, cholangiocarcinoma, gastric cancer, Head and neck cancer, melanoma, lung cancer, prostate cancer, salivary gland carcinoma, thyroid cancer, uterine sarcoma are showing fusion drivers in >2% of the cases, that can be detected by Oncomine focus assay.

Analyzed using: **cbioportal.org.**

Evidence based variant classification by Oncomine Reporter

Tier I (Therapeutic, Diagnostic, Prognostic)

Variants of strong clinical significance

Level A

FDA Approved

Professional Guidelines

Level B

Well powered studies

Tier II (Therapeutic, Diagnostic, Prognostic)

Variants of potential clinical significance

Level C

FDA Approved

In different tumor, small published studies

Level D

Preclinical trials

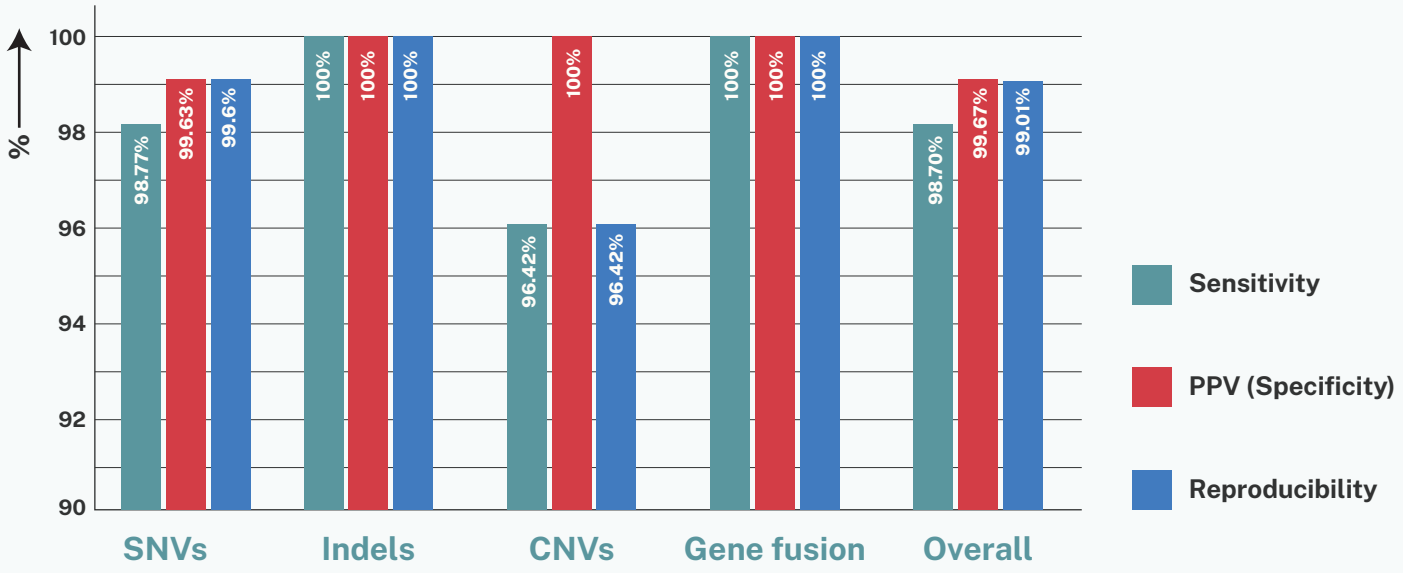
Tier III (Variants of unknown clinical significance)

Not observed at a significant allele frequency in the general or specific subpopulation databases, or pan-cancer or tumor-specific variant databases

Tier IV

Benign or likely benign variants

Assay sensitivity and specificity



- Can identify mutation with 5% variant allele frequency (5% mutant DNA, among 95% normal DNA).
- LOD for RNA fusion is 255 copies of RNA.
- RNA fusions and CNV changes detected by NGS has equal sensitivity to FISH. Hence multiple testing is not required.

List of druggable targets

List of FDA approved drugs covered		
Biomarker	**Drugs**	**Disease**
BRAF V600E; BRAF V600K	Vemurafenib, Cobimetinib, Dabrafenib, Trametinib, Atezolizumab, Encorafenib	Melanoma, NSCLC, CRC
ALK Fusion, EML4-ALK	Crizotinib, Ceritinib, Alectinib, Brigatinib, Lorlatinib	NSCLC
c-KIT	Imatinib, Sunitinib, Regorafenib, Ripertinib	GIST
EGFR	Cetuximab, Mobocertinib, Afatinib, Gefitinib, Amivantamb, Osimertinib, Erlotinib	Lung cancer
EGFR	Panitumumab, Dacomitinib	CRC
ERBB2	Fam-trastuzumab Deruxtecan-nxki	NSCLC
ERBB2/HER2 amplification	Trastuzumab, Pertuzumab, Ado-trastuzumab Emtansine	Breast cancer, Gastric cancer
FGFR2-Fusions	Pemigatinib, Infigratinib	Cholangiocarcinoma
FGFR3 mutation/Fusion	Erdafitinib	Urothelial Cancer
KRAS	Cetuximab, Panitumumab, Sotorasib	CRC, NSCLC
NRAS	Panitumumab	CRC
MET, exon skipping	Capmatinib	NSCLC
NTRK1, NTRK2, NTRK3-fusions	Larotrectinib, Entrectinib	Pan solid tumors
PIK3CA	Olaparib, Alpelisib	Breast cancer, Pan solid tumors
RET-Fusions	Pralsetinib, Selpercatinib	NSCLC
RET-Fusions/mutation	Selpercatinib	Thyroid cancer
Ros1-fusions	Entrectinib, Crizotinib	NSCLC

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