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NEW TEST

Comprehensive Solid Tumor Fusion Panel

Order Code: FCOMP

Fee Code: NA124, NA037 (CPT 81456, 88381-TC, G0452-26, 88381-26)

Effective January 3, 2024, the MLabs Molecular Diagnostics Laboratory began offering a Comprehensive Solid Tumor Fusion Panel. This assay is designed to detect nearly all described gene fusions in solid tumors using anchored multiplex PCR (Archer) and next-generation sequencing (NGS). This approach enables gene fusions to be detected for the targeted genes, regardless of the fusion partner.

Test Usage: Rearrangements resulting in gene fusions are seminal somatic alterations in many solid tumor neoplasms that are often strongly associated with tumor pathogenesis, histopathology, clinical behavior, and response to therapy. In many cases, these gene fusions are disease-defining and essential or supportive for diagnosis, according to diagnostic guidelines including the World Health Organization (WHO) Classification of Tumors; particularly for bone and soft tissue tumors, neuro-oncology tumors, and head and neck tumors. Gene fusions in solid tumors are also important for guiding clinical management, including targeted therapies for specific gene fusions, as well therapeutic determinations based on the diagnosis and prognosis informed by the presence or absence of gene fusions. This assay employs anchored multiplex PCR and next-generation sequencing (NGS) to detect gene fusions involving specific exons within one of the 146 different genes interrogated by this assay (see below).

ACVR2A	AKT1	AKT2	AKT3	ALK
AR	ARAF	ARHGAP26	ARHGAP6	AXL
BCOR	BRAF	BRD3	BRD4	CAMTA1
CCNB3	CCND1	CDX1	CIC	CRTC1
CSF1	CSF1R	DNAJB1	DNMT3B	EGF
EGFR	EPC1	ERBB2	ERBB4	ERG

ESR1	ESRRA	ETV1	ETV4	ETV5
ETV6	EWSR1	FGF1	FGFR1	FGFR2
FGFR3	FGR	FOS	FOSB	FOXO1
FOXO4	FOXR2	FUS	GLI1	GRB7
GRM1	HMGA2	IGF1R	INSR	INSR
JAK2	JAK3	JAZF1	KAT6B	KIT
MAML2	MAP2K1	MAP3K3	MAP3K8	MAST1
MAST2	MBTD1	MDM2	MDM2	MEAF6
MERTK	MET	MGEA5	MITF	MKL2
MN1	MSMB	MUSK	MYB	MYBL1
MYC	NCOA1	NCOA2	NCOA3	NFATC2
NFE2L2	NFIB	NOTCH1	NOTCH2	NPM3
NR4A3	NRG1	NTRK1	NTRK2	NTRK3
NUMBL	NUTM1	PAX3	PAX8	PDGFB
PDGFD	PDGFRA	PDGFRB	PHF1	PHF21A
PHKB	PIK3CA	PKN1	PLAG1	PPARG
PRDM10	PRKACA	PRKACB	PRKCA	PRKCB
PRKCD	PRKD1	PRKD2	PRKD3	RAD51B
RAF1	RELA	RET	ROS1	RSPO2
RSPO3	SRF	SS18	SS18L1	STAT6
TAF15	TAF15	TCF12	TEK	TERT
TFE3	TFEB	TFG	THADA	TMPRSS2
USP6	VEGFD	VGLL2	WWTR1	YAP1
YWHAE				

Test Limitations: This assay will not detect molecular alterations other than gene fusions and will only detect fusions involving at least one targeted gene region within the defined gene fusion target list, with a fusion partner in the designed 5' or 3' direction (see below). The panel is designed to detect gene fusions in solid tumors – gene fusions recurrent in hematolymphoid neoplasms are not targeted by this panel.

A negative result does not rule out the presence of a gene fusion not covered by this assay or that is present below the limit of detection of this assay. Because gene fusions are expressed at variable levels, a limit of detection for all gene fusions cannot be determined. The limit of detection for the gene fusions evaluated during validation is 20% fusion-bearing cells. Increased expression of genes not involved in the fusion, e.g., resulting from gene amplification, may also affect the limit of detection.

Rare alterations such as polymorphisms, mutations or fusion breakpoints within or outside of gene-specific primer binding sites may lead to false-negative results. In addition, this assay will only detect gene fusions from rearrangements that result in expressed fusion transcripts (productive rearrangements). This may lead to discrepancies between the results of this testing and gene rearrangement studies in which RNA expression is not evaluated e.g., FISH. This assay may detect one or more transcript(s) resulting from alternate splicing and may lead to a report reflecting an alternate transcript if the longest fusion transcript is not covered by this assay.

Test results should be interpreted in the context of clinical findings, tumor sampling, histopathology, and other laboratory data. If results obtained do not match other clinical or laboratory findings, please contact the laboratory for possible interpretation. Misinterpretation of results may occur if the information provided is inaccurate or incomplete.

Collection Instructions: For formalin-fixed, paraffin-embedded tissue, a block containing an area with a high percentage of neoplastic cells (for micro-/macro-dissection) is preferred. Unstained, UNBAKED slides (5-8, 10-micron slides; 10-15 if few neoplastic cells are present) with associated H&E stained slide are also acceptable. Decalcified tissue or other fixatives will be accepted, and the assay attempted, however these may result in failed testing due to degraded nucleic acid. Both blocks and slides should be stored at room temperature. A Diff-Quik or Papanicolaou stained aspirate smear (preferable containing a high percentage and overall amount of neoplastic cells) is also acceptable following digital imaging. Store at room temperature.

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