

ALK/ROS1/RET Gene Fusion Detection Kit

(Real-Time PCR assay)

GENE MUTATION IN LUNG CANCER

Gene fusion refers to a new hybrid gene formed by connecting parts or all of two different genes' sequences. The encoded fusion protein produced by this gene fusion can mediate the occurrence and development of tumors. In non-small cell lung cancer (NSCLC), gene fusions, as an important class of molecular mutations, serve as ideal targets for targeted therapy. Therefore, precise detection of gene fusions in NSCLC is crucial for selecting patients who can benefit from corresponding targeted treatments.

Gene fusion-positive NSCLC patients account for 8% to 12% of all NSCLC patients. Currently, various tyrosine kinase inhibitors (TKIs) targeting different gene fusions have been approved for clinical treatment. Late-stage NSCLC patients with gene fusion-positive can significantly benefit from corresponding targeted therapies. Additionally, multiple studies have shown that receptor tyrosine kinase fusions are one of the mechanisms for acquired resistance in NSCLC patients receiving specific targeted drug treatments. As a result, the NCCN guidelines for lung cancer diagnosis and treatment list anaplastic lymphoma kinase (ALK), c-ros oncogene 1 (ROS1), and rearranged during transfection (RET) as genes that must be tested.

MAJOR FUSION GENES AND APPROVED DRUGS IN NON-SMALL CELL LUNG CANCER

Genes	Mutation Frequency	Approved Drugs (FDA, NMPA)
ALK	5%-8%	Alectinib, Crizotinib, Ensartinib (NMPA only), Ceritinib, Brigatinib, lorlatinib
ROS1	2%-3%	Enrectinib, Crizotinib
RET	1%-4%	Pralsetinib, Selpercatinib

DETECTED GENES

Reaction Tube	Exon of Fusion Genes	Reaction Tube	Exon of Fusion Genes
1	EML4 exon6;ALK exon20	4	EML4 exon14; ins123 ALK exon20
	EML4 exon6 ins33; ALK exon20		EML4 exon6:ALK exon19
	EML4 exon6;ins18 ALK exon20	5	SLC34A2 exon4:ROS1 Exon32
	EML4 exon13;ALK exon20		SLC34A2 exon13 del2046; ROS1 Exon32
	EML4 exon13; ins69 ALK exon20		CD74 exon6;ROS1 Exon32
	EML4 exon18;ALK exon 20		SDC4 exon2;ROS1 Exon32
	EML4 exon20;ALK exon20		SDC4 exon4; ROS1 Exon32
EML4 exon20;ins18 ALK exon20	SLC34A2 exon4;ROS1 Exon34		
2	EML4 exon2;ALK exon20	6	SLC34A2 exon13 del2046; ROS1 Exon34
	EML4 exon2;ins117 ALK exon20		CD74 exon6;ROS1 Exon34
	EML4 exon15;ALK exon20		SDC4 exon2;ROS1 Exon34
	EML4 exon17; ins68 ALK exon20		SDC4 exon4;ROS1 Exon34
3	EML4 exon14; del12 ALK exon20	7	EZR exon10;ROS1 Exon34
	EML4 exon14 ins11; del49 ALK exon20		TPM3 exon8;ROS1 Exon35
	EML4 exon17 ins23: del46 ALK exon20		GOPC exon8;ROS1 Exon35
	EML4 exon17 ins6; del46 ALK exon20		LRIG3 exon16;ROS1 Exon35
	EML4 exon15 del60; del71 ALK exon20		CCDC6 exon5;ROS1 Exon35
			CLTC exon31;ROS1 Exon35

Reaction Tube	Exon of Fusion Genes	Reaction Tube	Exon of Fusion Genes
8	GOPC exon4;ROS1 Exon36	9	KIF13A exon18;RET Exon12
	LIMAI exon10;ROS1 Exon36		CUX1 exon10;RET Exon12
9	KIF5B exon15;RET Exon12	10	KIF5B exon16;RET Exon12
	KIF5B exon22; RET Exon12		CCDC6 exon1;RET Exon12
	KIF5B exon23;RET Exon12		TRIM33(RFG7) exon14; RET Exon12
	KIF5B exon18;RET Exon12		RUFY2 exon9;RET Exon12
	NCOA4(RFG)exon 6; RET Exon12	11	KIF5B exon24; RET Exon8
	TRIM33(RFG7)exon11; RET Exon12		KIF5B exon24; RET Exon11
	KIAA1468 exon10;RET Exon12	12	KIF5B exon15; RET partial Exon11

PRODUCT INFORMATION

Product Name	Technology	Pack Size	Sample Type
ALK/ROS1/RET Gene Fusion Detection Kit	Real-Time PCR assay	6 Tests/Kit	Tumor tissue Peripheral blood Pleural effusion

DETECTION SIGNIFICANCE

Before first-line treatment of inoperable stage III and IV NSCLC patients, common gene detection of lung cancer should be performed, and treatment is recommended to be guided based on molecular classification.

FEATURES & ADVANTAGES

Stable and Reliable: Detection with closed tubes , avoid contamination

High Sensitivity: Detects fusion mutations as low as 100 copies in RNA samples.

Comprehensive Coverage: Covers the most common fusion forms of ALK, ROS1 and RET.

Fast Results: It takes 1 working day for the hospital/laboratory to complete the detection process.

DETECTION PROCESS



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