

TECHNICAL SHEET IDYLLA™ GeneFusion ASSAY

The Idylla™ GeneFusion Assay is an assay for the **qualitative detection** of defined **gene fusions** for **ALK, ROS1, RET**, as well as **MET Exon 14 skipping** and **expression imbalance** for **ALK, ROS1, RET** and **NTRK1/2/3**. The Idylla™ GeneFusion Assay has been optimized for the use of formalin-fixed, paraffin-embedded (FFPE) tumor tissue sections. The Idylla™ GeneFusion Assay uses the Biocartis Idylla™ Platform and covers the entire process from **sample-to-result**, including fully integrated sample preparation, liberation of nucleic acids, reverse transcription of mRNA, real-time PCR amplification and detection, data analysis, and result reporting as applicable.

The Idylla™ GeneFusion Assay covers a panel of defined gene fusion variants for ALK, ROS1 and RET based on their occurrence in NSCLC, although detection of these gene fusion variants can be applied pan-cancer.

FEATURES

Fusion specific detection		
ALK fusions (17)	EML4-ALK	EML4 exon 2; ALK exon 20
		EML4 exon 6a; ALK exon 20
		EML4 exon 6b; ALK exon 20
		EML4 exon 13; ALK exon 20
		EML4 exon 15; ALK exon 20
		EML4 exon 17; ALK exon 20
		EML4 exon 18; ALK exon 20
		EML4 exon 20; ALK exon 20
	KIF5B-ALK	KIF5B exon 15; ALK exon 20
		KIF5B exon 17; ALK exon 20
		KIF5B exon 24; ALK exon 20
	HIP1-ALK	HIP1 exon 28; ALK exon 20
		HIP1 exon 30; ALK exon 20
	KLC1-ALK	KLC1 exon 9; ALK exon 20
	TPR-ALK	TPR exon 15; ALK exon 20
	TFG-ALK	TFG exon 4; ALK exon 20
		TFG exon 6; ALK exon 20

Fusion specific detection - continued		
ROS1 fusions (13)	CD74-ROS1	CD74 exon 6; ROS1 exon 32
		CD74 exon 6; ROS1 exon 34
	SDC4-ROS1	SDC4 exon 2; ROS1 exon 32
		SDC4 exon 4; ROS1 exon 32
	SLC34A2-ROS1	SDC4 exon 4; ROS1 exon 34
		SLC34A2 exon 4; ROS1 exon 32
		SLC34A2 exon 13; ROS1 exon 32
	EZR-ROS1	EZR exon 10; ROS1 exon 34
	TPM3-ROS1	TPM3 exon 8; ROS1 exon 35
	GOPC-ROS1	GOPC exon 4; ROS1 exon 36
GOPC exon 8; ROS1 exon 35		
LRIG3-ROS1	LRIG3 exon 16; ROS1 exon 35	
RET fusions (7)	KIF5B-RET	KIF5B exon 15; RET exon 11
		KIF5B exon 15; RET exon 12
		KIF5B exon 16; RET exon 12
		KIF5B exon 22; RET exon 12
		KIF5B exon 23; RET exon 12
	KIF5B exon 24; RET exon 11	
CCDC6-RET	CCDC6 exon 1; RET exon 12	
MET Exon 14 skipping	MET Exon 14 skipping transcript detection at the exon 13-exon 15 junction	

Expression imbalance detection

- ALK Expression imbalance
- ROS1 Expression imbalance
- RET Expression imbalance
- NRTK1 Expression imbalance
- NRTK2 Expression imbalance
- NRTK3 Expression imbalance

Measures if expression imbalance is present between the 5' PCR and 3' PCR of the kinase gene. Expression imbalance shows kinase domain expression, and is indicative for the presence of a fusion.

Internal GeneFusion controls

RNA Housekeeping gene 1	ERCC3
RNA Housekeeping gene 2	TMUB2
RNA MET Wild-type	Detection of the wild-type MET isoform mRNA containing the MET Exon 14 sequence
DNA control	KIF11

Minimum specimen requirements

Sample type	1 x 5 µm FFPE tissue section if tissue area ≥ 20 mm ² 3 x 5 µm FFPE tissue sections if tissue area < 20 mm ²
Neoplastic cells	$\geq 10\%$, if less macro-dissection is required

Total turnaround time

Time	Approx. 180 minutes
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Catalog number

Idylla™ GeneFusion Assay	A0121/6
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