

## 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.

### 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

<b>ROS1 fusions (13)</b>	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
		SDC4 exon 4; ROS1 exon 34
	SLC34A2-ROS1	SLC34A2 exon 4; ROS1 exon 32
		SLC34A2 exon 4; ROS1 exon 34
		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	
<b>RET fusions (7)</b>	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
<b>MET Exon 14 skipping</b>	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 $\geq$ 20 mm <sup>2</sup> 3 x 5 µm FFPE tissue sections if tissue area < 20 mm <sup>2</sup>
Neoplastic cells	$\geq$ 10%, if less macro-dissection is required

## Total turnaround time

Time	Approx. 180 minutes
------	---------------------

## Catalog number

Idylla™ GeneFusion Assay	A0121/6
--------------------------	---------



The Idylla™ GeneFusion Assay contains SuperScript™ III Reverse Transcriptase and is provided subject to a license under patents or patent applications owned by or licensed to Life Technologies Corporation, which license is limited to the human diagnostic field and research field and specifically excludes applications in forensics (including human identity testing). The SuperScript™ III trademark is owned by Life Technologies Corporation.

Patents US 7,700,339, 8,168,383, 8,481,279, 8,486,645, 8,232,060, 8,288,102, 8,377,642, 9,988,688, 9,523,130, 9,096,855, 10,526,661, 9,364,477, 9,539,254, 10,551,383 and pending US applications and all their respective foreign equivalents are under license from Cell Signaling Technology, Inc.

Idylla™ GeneFusion Assay is available for Research Use Only (RUO), not for use in diagnostic procedures. Idylla™ platform is CE-marked IVD in Europe. Idylla™ is available for sale in EU, USA and some other countries. Please check availability with the local Biocartis representative.

Biocartis and Idylla are registered trademarks in Europe, the United States and other countries. The Biocartis and Idylla trademarks and logos are used trademarks owned by Biocartis. © Biocartis, March 2021.