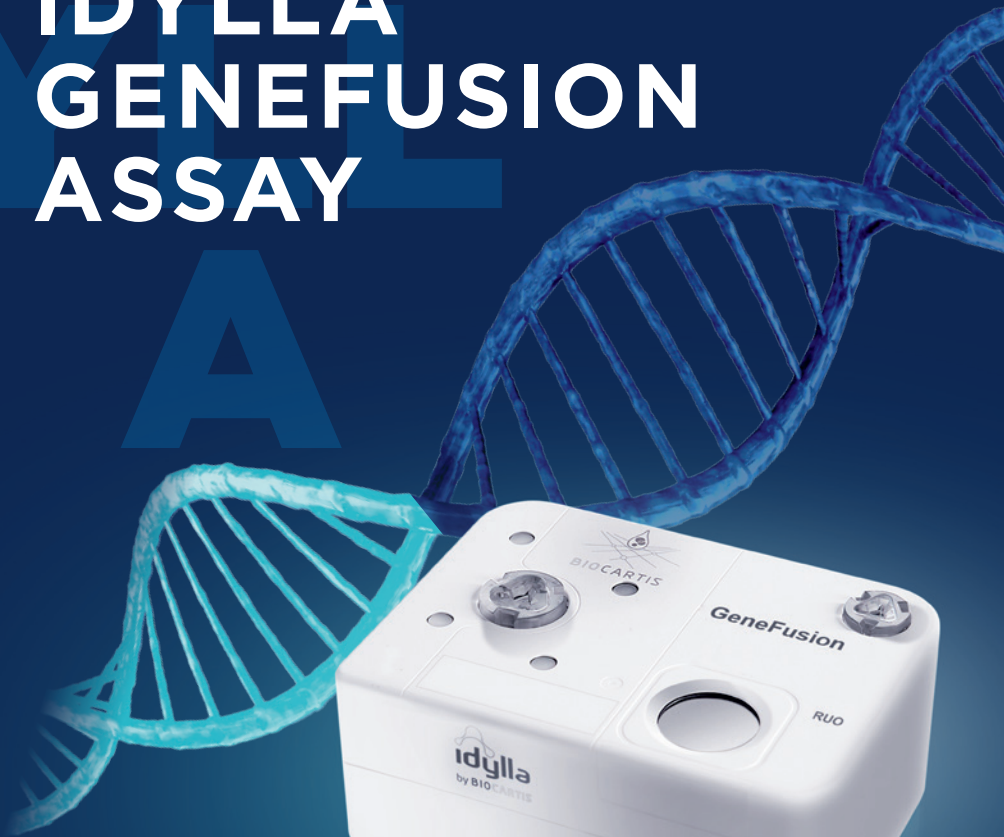


BECAUSE  
TIME MATTERS

# IDYLLA™ GENEFUSION ASSAY



Idylla™ GeneFusion Assay is for Research Use Only,  
not for use in diagnostic procedures.

# INTRODUCING IDYLLA™ GENEFUSION ASSAY FOR SPEED AND SIMPLICITY



Detection of ALK, ROS1, RET & MET Exon 14 skipping plus NTRK1/2/3 fusion screening in one cartridge



Fully automated molecular testing platform  
On-demand testing



Less than 2 minutes hands-on time (HOT)  
Assay turnaround time (TAT) of approx. 180 minutes



Directly from 1-3 FFPE slices



## MINIMUM SPECIMEN REQUIREMENTS

- If  $\geq 20$  mm<sup>2</sup> tissue area: 1 x 5  $\mu$ m FFPE tissue section
- If  $< 20$  mm<sup>2</sup> tissue area: 3 x 5  $\mu$ m FFPE tissue sections
- $\geq 10\%$  neoplastic cell content



# IDYLLA™ GENEFUSION ASSAY DETECTION OF KNOWN AND NOVEL FUSIONS

A unique combination of 2 detection technologies:



Highly sensitive detection of the most relevant gene fusions directly from RNA transcripts by real-time PCR (RT-qPCR).



Expression imbalance detecting gene fusions irrespective of fusion partner based on the 3' kinase overexpression caused by the partner gene.

Detection Method	ALK	ROS1	RET	MET ex14	NTRK 1	NTRK 2	NTRK 3
Specific fusion detection	●	●	●	●	-	-	-
Expression imbalance	●	●	●	-	●	●	●

## THE RIGHT SOLUTION FOR ANY LAB

### FAST, EASY AND OBJECTIVE

The Idylla™ GeneFusion Assay consolidates traditional testing workflows into one streamlined, fully-automated process providing reliable, objective information on ALK, ROS1, RET, METex14 skipping and NTRK1/2/3 in about 180 minutes.

### ONLY LIMITED AMOUNT OF SAMPLE NEEDED

The Idylla™ GeneFusion Assay provides simultaneous detection of strategic biomarkers on-demand from a limited amount of sample thereby saving valuable tissue specimens.

### FIRST LINE ACTIONABLE INFORMATION

The Idylla™ GeneFusion Assay provides a rapid actionable solution which can be seamlessly integrated into virtually any laboratory workflow complementing comprehensive NGS.

# IDYLLA™ GENEFUSION ASSAY SHOWS EXCELLENT PRELIMINARY PERFORMANCE<sup>1</sup>

## IDYLLA™ VERSUS IHC AND FISH

Idylla™ vs IHC	ALK	ROS1	Idylla™ vs FISH	RET
PPA	93% (69/74)	100% (13/13)	PPA	100% (9/9)
NPA	98% (138/141)	100% (113/113)	NPA	100% (25/25)
<b>Overall concordance</b>	<b>96%</b>	<b>100%</b>		<b>100%</b>

## REDUCE INCONCLUSIVE RESULTS

The Idylla™ GeneFusion Assay was able to generate accurate results in 29/32 inconclusive IHC and FISH results.

## IDYLLA™ VERSUS NEXT GENERATION SEQUENCING

Idylla™ vs NGS	ALK	ROS1	RET	MET ex14
PPA	92% (65/71)	97% (36/37)	98% (43/44)	90% (61/67)
NPA	96% (143/149)	99% (187/189)	100% (202/202)	100% (143/143)
<b>Overall concordance</b>	<b>95%</b>	<b>99%</b>	<b>99%</b>	<b>97%</b>

**NTRK**  
1/2/3

## GET MORE INFORMATION FROM YOUR SAMPLE

Detect NTRK fusions with the Idylla™ GeneFusion Assay using expression imbalance. The Idylla™ GeneFusion Assay was able to detect 25/34 NTRK fusions in different cancer types. NTRK specificity was 100% across tested samples with no false positives identified.

(1) The concordance study was performed on NSCLC and thyroid cancer samples with prototype cartridges but re-analyzed with final Idylla™ GeneFusion Assay (RUO) decision tree.

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PPA: Positive Percent Agreement - NPA: Negative Percent Agreement

# GENE FUSION FACTS

Gene fusions represent an important class of somatic alterations in cancer. Due to their inherent expression in tumor tissue alone they have become important biomarkers for cancer research, prognosis, and targeted therapies.<sup>1,2</sup>

Discovery and further understanding of fusion genes across multiple cancer types may provide more effective therapies in the future for cancer patients.

Over the last 20 years, many gene fusions have been discovered in hematological cancers, solid tumors, and sarcomas.

## ADULT



SALIVARY GLAND CANCER



THYROID CANCER



HEPATIC CANCER



LUNG CANCER



GI CANCER



CNS CANCER



SARCOMA



MELANOMA

## PEDIATRIC



SARCOMA



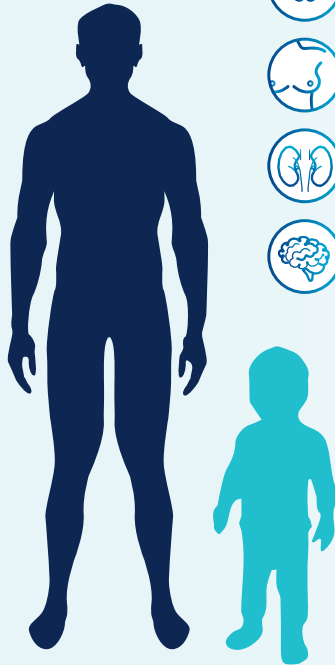
SECRETORY BREAST CANCER



RENAL CANCER



CNS CANCER

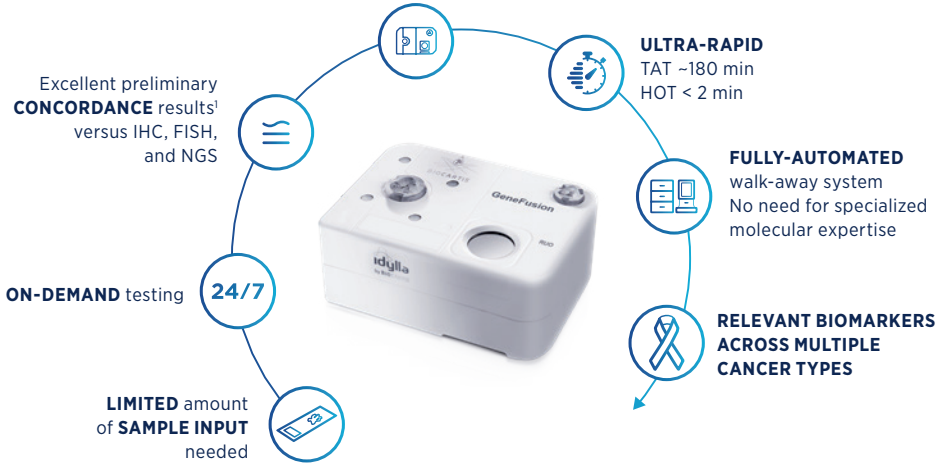


(1) Stransky et al. The landscape of kinase fusions in cancer. Nat Commun. 5, 4846, 2014.

(2) Mertens et al. The emerging complexity of gene fusions in cancer. Nat Rev Cancer 15, 371-381, 2015.

# IDYLLA™ GENEFUSION ASSAY FOR SPEED AND SIMPLICITY BECAUSE TIME MATTERS

Information on ALK, ROS1, RET, METex14 and NTRK1/2/3 in **ONE SINGLE CARTRIDGE**

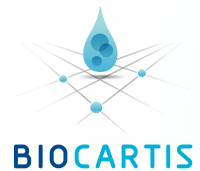


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(1) The concordance study was performed with prototype cartridges but re-analyzed with final Idylla™ GeneFusion Assay (RUO) decision tree. The Idylla™ GeneFusion Assay contains SuperScript™ III Reverse Transcriptase and is provided subject to a license 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™ platform is CE-marked IVD in Europe. Idylla™ GeneFusion Assay is for Research Use Only (RUO), not for use in diagnostic procedures. 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.