BECAUSE TIME MATTERS

IDYLLA™ GENEFUSION ASSAY

BIOCARTIS

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 3 minutes hands-on time (HOT)
Assay turnaround time (TAT) of approx. 180 minutes

Directly from 1-3 FFPE slices

MINIMUM SPECIMEN REQUIREMENTS

- If ≥20 mm^2 tissue area: 1 x 5 µm FFPE tissue section
- If <20 mm^2 tissue area: 3 x 5 µm FFPE tissue sections
- ≥ 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 SHOWING EXCELLENT PERFORMANCE

The Idylla™ GeneFusion Assay reveals strong analytical and clinical potential compared to conventional methods such as IHC, FISH and NGS.[1-3]

ALK, ROS1, RET AND METEX14

Study 1: Memorial Sloan Kettering Cancer Center, New York, NY, US[1]

ALK	ROS1	RET	METex14
sensitivity 97%	sensitivity 92%	sensitivity 100%	sensitivity 100%
specifity 100%	specifity 100%	specifity 100%	specifity 100%
142 samples	142 samples	142 samples	142 samples
29 ALK +	24 ROS1+	31 RET+	20 METex14+

SOC: MSK-IMPACT (hybrid capture-based DNA NGS) and MSK-Fusion (anchored multiplex PCR-based RNA NGS)

Study 2: Mayo Clinic, Rochester, MN, US[2]

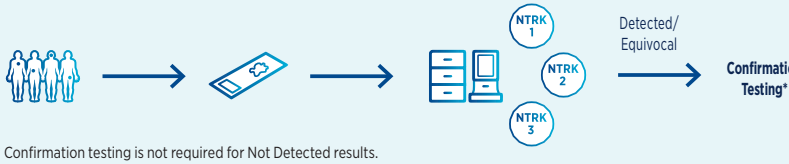
ALK	ROS1	RET	METex14
sensitivity 100%	sensitivity 100%	sensitivity 100%	sensitivity 100%
specifity 98%	specifity 100%	specifity 100%	specifity 100%
64 samples	64 samples	64 samples	64 samples
12 ALK +	10 ROS1+	12 RET+	10 METex14+

SOC: Five NGS panels currently used at Mayo Clinic

NTRK

NTRK gene fusions are found across several adult and pediatric tumor types (0.3% across all tumor types).[4] **Immunohistochemistry (IHC)** is currently the most commonly used screening method. However, it is essential to note that its **sensitivity may be limited** when it comes to detecting gene fusions involving NTRK3.[5]

NTRK pan-cancer testing algorithm designed to detect virtually all NTRK fusions, including the often overlooked NTRK3 by IHC:



* Confirmation testing is not required for Not Detected results.

(1) Chu et al., Clinical Utility and Performance of an Ultrarapid Multiplex RNA-Based Assay for Detection of ALK, ROS1, RET, and NTRK1/2/3 Rearrangements and MET Exon 14 Skipping Alterations, J Mol Diag, 2022
(2) Buglioni et al., Clinical Utility Validation of an Automated Ultrarapid Gene Fusion Assay for NSCLC, JTO Clinical and Res Reports, 2022
(3) Gilson et al., Validation of the Idylla GeneFusion assay to detect fusions and MET exon-skipping in non-small cell lung cancers, Scientific Reports, 2023
(4) Epidemiology of NTRK gene fusions (esmo.org)
(5) Solomon et al., NTRK fusion detection across multiple assays and 33,997 cases: diagnostic implications and pitfalls, Modern Pathology, 2020

GENE FUSION FACTS

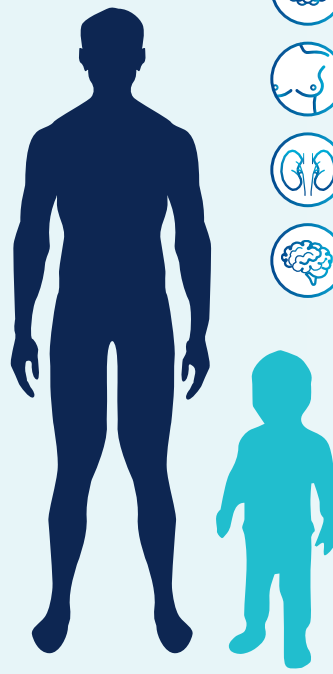
Gene fusions represent an important class of somatic alterations in cancer. Due to their inherent expression in tumor tissue alone they have become important biomarkers for cancer research, prognosis, and targeted therapies.[1,2]

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.

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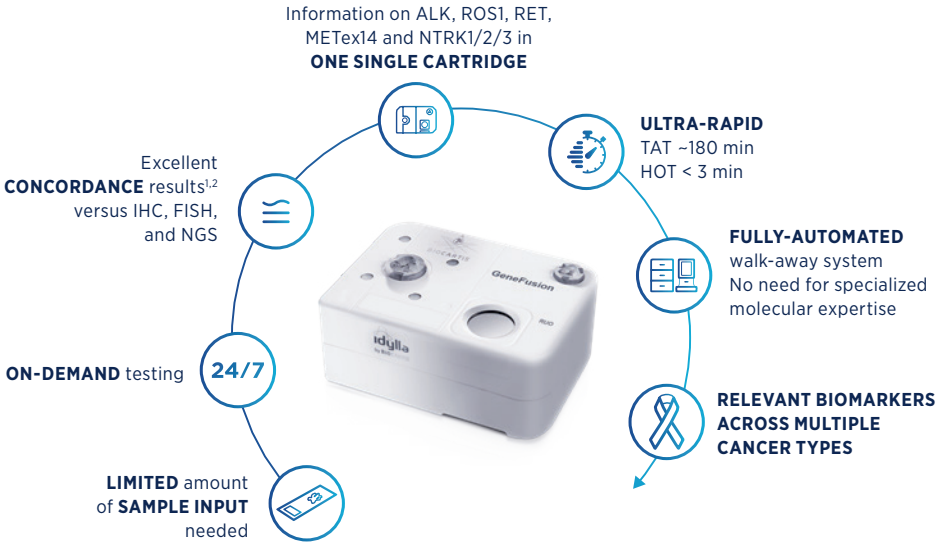

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