BECAUSE
TIME MATTERS

IDYLLA™ GENEFUSION PANEL

BIOCARTIS

IDYLLA™ GENEFUSION PANEL RAPID TESTING FOR FAST TREATMENT DECISIONS

Detection of ALK, ROS1 & RET fusions and MET exon 14 skipping in one cartridge

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

Limited sample input
Directly from 1-3 FFPE slices

Fully automated molecular walk-away system
On-demand testing

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 PANEL
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 detects gene fusions, irrespective of the fusion partner, based on the 3' kinase overexpression caused by that partner gene. Expression imbalance results are indicative for the presence of a fusion and should be confirmed with another technology.

Detection Method	ALK	ROS1	RET	MET ex14
Specific fusion detection	●	●	●	●
Expression imbalance	●	●	●	-

THE RIGHT SOLUTION FOR ANY LAB

FAST, EASY AND OBJECTIVE

The Idylla™ GeneFusion Panel consolidates traditional testing workflows into one streamlined, fully automated process providing reliable, objective information on ALK, ROS1 & RET fusions and METex14 skipping in about 180 minutes.

ONLY LIMITED AMOUNT OF SAMPLE NEEDED

The Idylla™ GeneFusion Panel provides simultaneous detection of internationally recommended biomarkers from a limited amount of sample thereby saving valuable tissue specimens.

FIRST LINE ACTIONABLE INFORMATION

The Idylla™ GeneFusion Panel is a rapid actionable solution which can be seamlessly integrated into virtually any laboratory workflow.

IDYLLA™ GENEFUSION PANEL SHOWS EXCELLENT PERFORMANCE

The Idylla™ GeneFusion Panel demonstrated high concordance results in a clinical comparison study where ALK was compared with IHC and ROS1, RET and METex14 skipping were compared with NGS.

FUSION SPECIFIC RESULTS ONLY

	ALK	ROS1	RET	MET ex14
PPA	89.5% (34/38)	80.0% (12/15*)	92.9% (13/14)	90.6% (48/53**)
NPA	99.2% (118/119)	100.0% (187/187)	100.0% (188/188)	100.0% (149/149)
Overall concordance	**96.8% (152/157)**	**98.5% (199/202)**	**99.5% (201/202)**	**97.5% (197/202)**

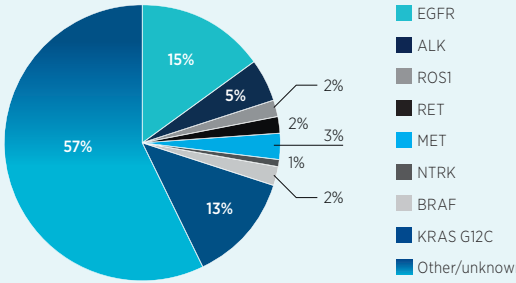
*Of the 3 discordant ROS1 positive samples, the Oncomine™ Focus Assay indicated that there was a low read count for 2 of the 3 samples. All 3 discordant samples tested negative for ROS1 with IHC.
**Of the 5 discordant METex14 positive samples, the Oncomine™ Focus Assay indicated that there was a low read count for 4 of the 5 samples.

INCLUDING CONFIRMED[1] EXPRESSION IMBALANCE

	ALK	ROS1	RET
PPA	100.0% (38/38)	80.0% (12/15)	100.0% (14/14)
NPA	99.2% (118/119)	100.0% (187/187)	100.0% (188/188)
Overall concordance	**99.4% (156/157)**	**98.5% (199/202)**	**100.0% (202/202)**

(1) Confirmed = samples that are expression imbalance positive using the Idylla™ GeneFusion Panel and that were confirmed with the reference method. Expression imbalance results are indicative for the presence of a fusion and should be confirmed with another technology.

GENE FUSION FACTS



Actionable biomarkers in NSCLC according to international guidelines

Although lung cancer remains the leading cause of cancer deaths worldwide, the survival rate has increased over the past few years due to the rapidly evolving treatment landscape for Non-Small Cell Lung Cancer (NSCLC).

Since these new therapies are becoming increasingly biomarker-driven, an urgent and growing need for **biomarker testing has emerged.**

Molecular testing therefore plays a key role in the diagnostic work-up for NSCLC patients to guide therapy choices and improve outcomes.

Chromosomal translocations that **generate fusion genes** are a major cause of NSCLC, and their **accurate & fast diagnosis is critical for effective treatment.**

Consequently, international treatment guidelines (ESMO, NCCN) recommend testing for ALK, ROS1, RET, METex14 skipping & NTRK re-arrangements in every patient diagnosed with NSCLC.

GUIDELINES

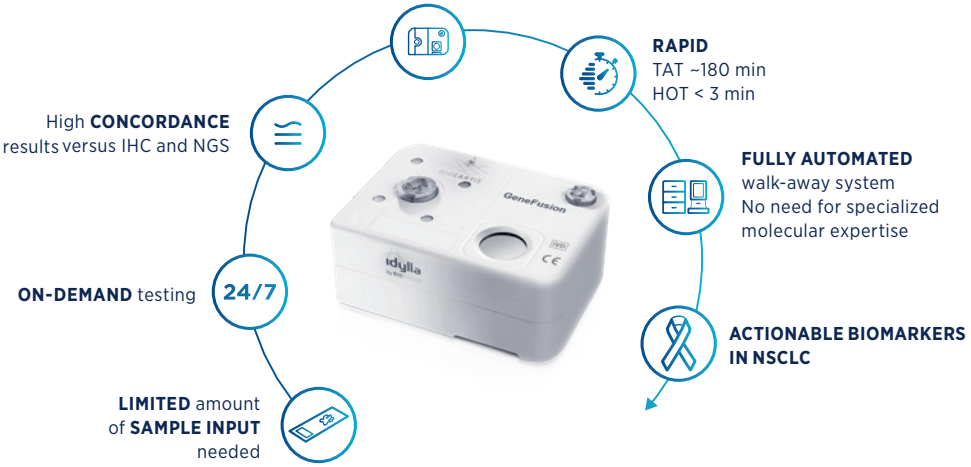
ESMO	ALK, ROS1, NTRK
NCCN	ALK, ROS1, RET, METex14 skipping, NTRK
CAP/IASLC/AMP	TAT of 10 working days between samples receipt and reporting of molecular test results

Turnaround time (TAT) is today an important barrier to molecular testing.
It has been demonstrated that 10 to 20% of advanced lung cancer patients don't receive the appropriate targeted therapy because they are clinically unable to wait for the molecular biomarker results.[1] Timely recognition of these alterations, particularly in symptomatic patients or in those with an extensive disease burden, is thus critical in the clinic.[2]

(1) Finall et al. Integration of rapid PCR testing as an adjunct to NGS in diagnostic pathology services within the UK: evidence from a case series of non-squamous, non-small cell lung cancer (NSCLC) patients with follow-up. J Clin Pathol. 2022 Jan (2) 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 Diagn. 2022 Apr

IDYLLA™ GENEFUSION PANEL RAPID TESTING FOR FAST TREATMENT DECISIONS

Information on ALK, ROS1 & RET fusions
and METex14 skipping in
ONE SINGLE CARTRIDGE



Catalog number: A0120/6

Biocartis NV
Generaal de Wittelaan 11B
2800 Mechelen - Belgium
+32 15 632 888

Follow us on

www.biocartis.com
customerservice@biocartis.com

BIOCARTIS

The Idylla™ GeneFusion Panel 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 and Idylla™ GeneFusion Panel are available as an IVD in Europe and many other countries outside the US. Please check availability with a local Biocartis representative. Biocartis and Idylla are registered trademarks in Europe, the US and many other countries. The Biocartis and Idylla trademarks and logos are used trademarks owned by Biocartis. © Biocartis NV, February 2023.

OUS.FL052.EN.R1.03/2023