

See how you can
guide the path
her cancer takes



Idylla™ EGFR Mutation Assay

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EGFR

Lung cancer is the most common cancer worldwide, contributing for 13% of all cancer types¹. 85% of lung cancers are non-small cell lung cancers (NSCLC), of which histologically adenocarcinoma is the most prevalent². The prevalence of EGFR mutations in NSCLC is 10-15% of Western and up to 50% of Asian patients³. The most common EGFR mutations are the L858R mutation in exon 21 and deletions at exon 19⁴.

Idylla™, Biocartis' fully automated, real-time PCR based system, offers fast and easy access to high quality biomarker data.

The Idylla™ EGFR Mutation Assay allows detection of EGFR mutations directly from formalin-fixed paraffin-embedded (FFPE) tissue sections in approx. 2.5 hours with less than 2 minutes hands-on time.

The Idylla™ EGFR Mutation Assay is capable of detecting 53 relevant mutations in exons 18, 19, 20 and 21; at an average sensitivity of 1-5% based on research data.

The game-changing real-time PCR based technology uses a unique combination of PlexPrime™ and PlexZyme™, which allows very high sensitivity and specificity combined with high multiplexing capability.*

“Idylla is a cost-effective solution ensuring accurate and fast detection of all relevant mutations”

Prof. Giancarlo Troncione,
Department of Public Health, Anatomic Pathology Unit,
University of Napoli Federico II School of Medicine,
Napoli, Italy

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About Idylla™ EGFR Mutation Assay

Idylla™, Biocartis' fully automated, real-time PCR-based system combines:



OUTSTANDING EASE OF USE

- Fully automated sample processing
- Directly from FFPE tissue samples
- No manual deparaffinization required
- All reagents integrated within the cartridge
- Contamination-controlled design



ACCURACY

- High specificity and high average sensitivity of 1-5% based on research data
- Detection of 53 relevant mutations in one cartridge



SPEED

- Less than 2 minutes hands-on-time
- Total turnaround time approx. 2.5 hours



CONNECTIVITY

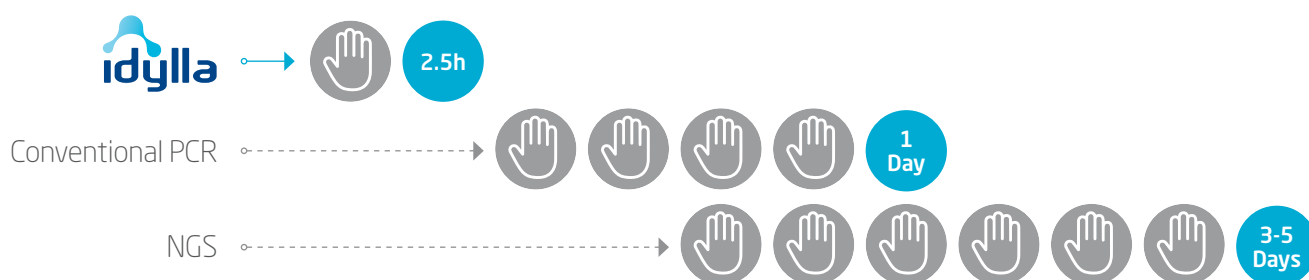
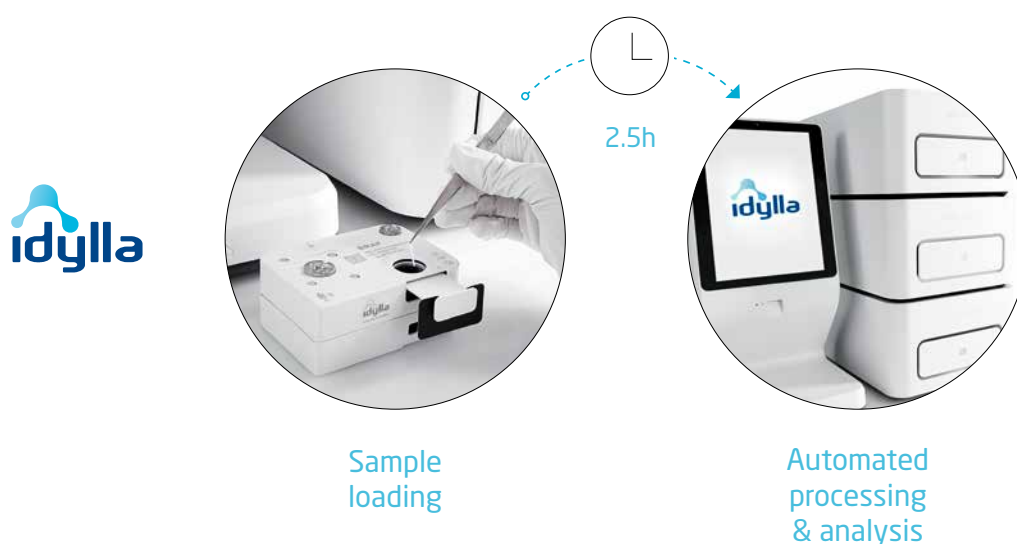
- Remote assistance, monitoring and upgrading



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Comparative workflows

The Idylla™ system in combination with the Idylla™ EGFR Mutation Assay differs from other technologies in its outstanding ease-of-use and short turnaround time.





Highly standardized

The Idylla™ EGFR Mutation Assay, performed on the Biocartis Idylla™ System, is a molecular assay for the qualitative detection of exon 18 (G719A/S/C), exon 21 (L858R, L861Q), exon 20 (T790M, S768I) mutations, exon 19 deletions and exon 20 insertions in the *EGFR* oncogene.

The Idylla™ EGFR Mutation Assay, from sample-to-result, starts with formalin-fixed, paraffin-embedded (FFPE) human tissue from non-small cell lung cancers to liberate DNA for subsequent real-time PCR amplification and detection.

1. N. Navani, PhD, et al. Lung cancer diagnosis and staging with endobronchial ultrasound-guided transbronchial needle aspiration compared with conventional approaches: an open-label, pragmatic, randomized controlled trial. *Lancet Respir Med* (2015)
2. American Cancer Society. *Global Cancer Facts & Figures 2nd Edition*
3. W. A. Cooper et al. Molecular biology of lung cancer. *J Thorac Dis* (2013)
4. NCCN Guidelines Version 4.2016 Non-Small Cell Lung Cancer

Allele detection	Exon 18	c.2156G>C (G719A)
		c.2155G>A (G719S)
		c.2155G>T (G719C)
		c.2154_2155delinsTT (G719C)
	Exon 19	c.2239_2248delinsC (del9)
		c.2239_2247del (del9)
		c.2238_2248delinsGC (del9)
		c.2240_2248del (del9)
		c.2239_2251delinsC (del12)
		c.2240_2251del (del12)
		c.2235_2249del (del15)
		c.2236_2250del (del15)
		c.2239_2253del (del15)
		c.2237_2251del (del15)
		c.2235_2252delinsAAT (del15)
		c.2240_2254del (del15)
		c.2238_2252del (del15)
		c.2237_2252delinsT (del15)
		c.2234_2248del (del15)
		c.2236_2253delinsCTA (del15)
		c.2237_2253delinsTA (del15)
		c.2237_2253delinsTC (del15)
		c.2235_2251delinsAG (del15)
		c.2236_2253delinsCAA (del15)
		c.2238_2252del (del15)
		c.2230_2249delinsGTCAA (del15)
		c.2240_2257del (del18)
		c.2237_2255delinsT (del18)
		c.2239_2258delinsCA (del18)
		c.2237_2254del (del18)
		c.2238_2255del (del18)
		c.2239_2256del (del18)
		c.2236_2253del (del18)
		c.2237_2257delinsTCT (del18)
		c.2236_2255delinsAT (del18)
		c.2236_2256delinsATC (del18)
		c.2237_2256delinsTT (del18)
		c.2237_2256delinsTC (del18)
		c.2235_2255delinsGGT (del18)
		c.2238_2258del (del21)
		c.2236_2256del (del21)
		c.2253_2276del (del24)
	Exon 20	c.2369C>T (T790M)
		c.2303G>T (S768I)
		c.2308_2309insGCCAGCGTG (insASV9)
		c.2308_2311insCCAGCGTGAT (insASV11)
		c.2311_2312insGCGTGGACA (insSVD)
		c.2310_2311insGGT (insG)
		c.2319_2320insCAC (insH)
	Exon 21	c.2573T>G (L858R)
		c.2573_2574delinsGT (L858R)
		c.2573_2574delinsGA (L858R)
		c.2582T>A (L861Q)
		EGFR Total (acting as Sample Processing Control)
Sample type		1 × 5 μm FFPE tissue section ≥10% tumor cells (if < 10%: macro-dissection is needed)
Total turnaround time		approx. 2.5 hours



Order information

Idylla™ EGFR Mutation Assay RUO	6 cartridges/box	Catalog# A0061/6
Idylla™ Instrument CE-IVD	1 unit	Catalog# P0010
Idylla™ Console CE-IVD	1 unit	Catalog# P1010

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NOTICE TO PURCHASER

*This Idylla™ EGFR Mutation Assay contains PlexZyme™ and PlexPrime™ technology covered by patents granted and pending in certain jurisdictions, which are supplied under license of SpeedX Pty Ltd.

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