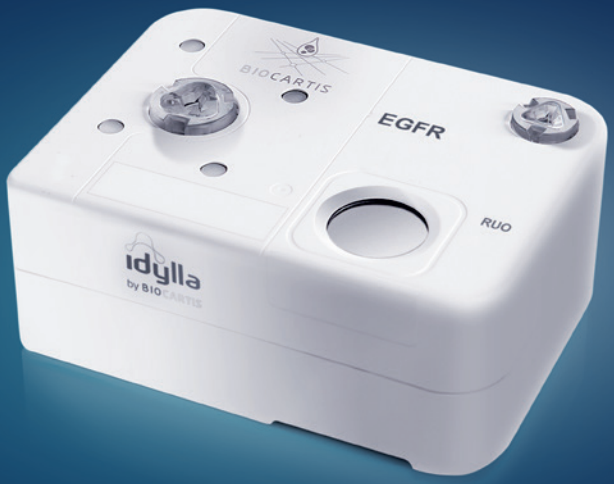
BECAUSE
TIME
MATTERS

IDYLLA™ EGFR MUTATION ASSAY



BIOCARTIS

Idylla™ EGFR Mutation Assay is for research use only. Not for use in diagnostic procedures.

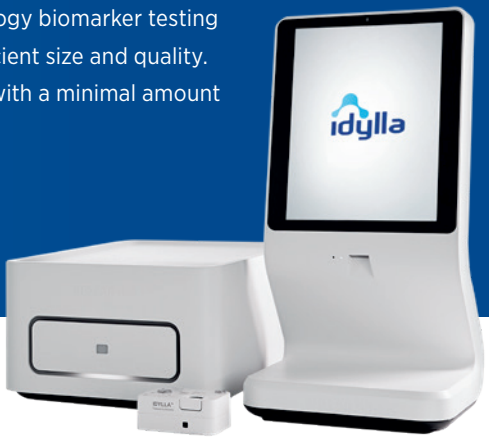
THE IDYLLA™ EGFR MUTATION ASSAY FAST & RELIABLE INFORMATION ON EGFR MUTATION STATUS

- Comprehensive assay covering 51 mutations in EGFR exons 18, 19, 20 and 21
- Directly from 1 FFPE tissue section
- 150 minutes assay turn around time
- Highly sensitive & standardized platform
- < 2 minutes hands-on time
- Fully automated solution - suitable for any lab

IDYLLA™ EGFR MUTATION ASSAY TISSUE SPECIMEN REQUIREMENTS

One of the biggest challenges in oncology biomarker testing is the ability to obtain samples of sufficient size and quality. The Idylla™ assay is designed to work with a minimal amount of sample:

- 1 x 5 µm FFPE tissue section
- Neoplastic cell content ≥ 10%
  - If < 10%, macrodissection needed



IDYLLA™ EGFR MUTATION ASSAY EXCELLENT PERFORMANCE

The Idylla™ EGFR Mutation Assay shows high concordance to reference methods across a variety of different sample types

STUDY	# SAMPLES	REFERENCE METHOD	SAMPLE TYPE	CONCORDANCE
Brohawn et al. 2018[1]	23	PCR	FFPE tissue	100%
De Luca et al. 2018[2]	43	Ion Torrent NGS	DNA	100%
De Montpréville et al. 2017[3]	93	Sentosa NGS	FFPE tissue, fresh frozen tissue, cytological samples	100%
Arcila et al. 2018[4]	62	NGS	FFPE tissue, DNA, cytological samples (cell pellets, smears), touch preps, NGS libraries	100%
Al-Turkmani et al. 2018[5]	8	Ion Torrent NGS	Fresh touch preps	100%
Al-Turkmani et al. 2018[6]	34	Ion Torrent NGS	FFPE tissue	100%

The Idylla™ EGFR Mutation Assay can significantly reduce the time until the biomarker test result becomes available

STUDY	REFERENCE METHOD	TIME TO RESULT VS. REFERENCE METHOD
Brohawn et al. 2018[1]	In-house PCR	< 160 minutes vs. 35 hours 5 minutes (13 times faster than reference method)
Ghigna et al. 2017[7]	Send-out NGS	≤ 1 week (88%) / same day (37%) vs. ≤ 3 weeks (69%)/ > 8 days (100%)
Mackinnon et al. 2019[8]	In-house NGS	1-2 days vs. 2-15 days*

* Data shown as average for Idylla™ KRAS, BRAF, NRAS-BRAF and EGFR Mutation Assays

The Idylla™ EGFR Mutation Assay is able to analyze samples which do not have sufficient quantity or quality for NGS testing or have failed on previous NGS testing platforms

STUDY	REFERENCE METHOD	VALID RESULTS IN % (# OF SAMPLES) VS. REFERENCE METHOD
De Luca et al. 2018[2]	Ion Torrent NGS	93% (63/68) vs. 63% (43/68)
Al-Turkmani et al. 2018[6]	Ion Torrent NGS	98% (39/40) vs. 85% (34/40)
Mackinnon et al. 2019[8]	Ion Torrent NGS	25 NGS QNS samples: valid Idylla™ results in all cases, including actionable results in 8 cases

IDYLLA™ EGFR MUTATION DETECTION

EGFR is a key component regulating tumor cell proliferation and growth and it is frequently mutated in different types of human cancers including lung cancer.[9]

The Idylla™ EGFR Mutation Assay provides qualitative detection of exon 18 (G719A/C/S), exon 21 (L858R, L861Q), exon 20 (T790M, S768I) mutations, exon 19 deletions and exon 20 insertions in the EGFR oncogene.

Exon 18	G719A G719S G719C	c.2156G>C c.2155G>A c.2155G>T; c.2154_2155delinsTT
Exon 19	Del 9	c.2238_2248delinsGC; c.2239_2248delinsC; c.2240_2248del; c.2239_2247del
	Del 12	c.2239_2251delinsC; c.2240_2251del
	Del 15	c.2235_2249del; c.2236_2250del; c.2239_2253del; c.2240_2254del; c.2238_2252del; c.2237_2251del; c.2235_2252delinsAAT; c.2237_2252delinsT; c.2234_2248del; c.2236_2253delinsCTA; c.2237_2253delinsTA; c.2235_2251delinsAG; c.2236_2253delinsCAA; c.2230_2249delinsGTCAA
	Del 18	c.2240_2257del; c.2237_2255delinsT; c.2239_2256del; c.2236_2253del; c.2239_2258delinsCA; c.2237_2254del; c.2238_2255del; c.2237_2257delinsTCT; c.2236_2255delinsAT; c.2236_2256delinsATC; c.2237_2256delinsTT; c.2237_2256delinsTC; c.2235_2255delinsGGT
	Del 21	c.2238_2258del; c.2236_2256del
	Del 24	c.2253_2276del
Exon 20	T790M	c.2369C>T
	S768I	c.2303G>T
	insG	c.2310_2311insGGT
	insASV9	c.2307_2308insGCCAGCGTG
	insASV11	c.2309_2310delinsCCAGCGTGGAT
	insSVD	c.2311_2312insGCGTGGACA
	insH	c.2319_2320insCAC
Exon 21	L858R	c.2573T>G; c.2573_2574delinsGT; c.2573_2574delinsGA
	L861Q	c.2582T>A

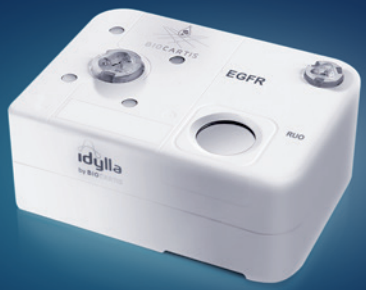
THE IDYLLA™ ADVANTAGE

The fully automated Idylla™ EGFR Mutation Assay provides fast and reliable information on EGFR mutation status directly from FFPE tissue.[1-7]

The Idylla™EGFR Mutation Assay shows high concordance to reference methods across a variety of different samples types.[1-6]

The Idylla™ EGFR Mutation Assay provides high accuracy with low sample input showing a reduced failure rate compared to reference technologies.[2,6,8]

The fast turnaround time and ease of use makes the Idylla™ solution suitable for any lab - as a cost effective, quick and accurate in-house system for small centers that lack highly trained staff and molecular expertise as well as a reliable STAT solution complementing comprehensive NGS profiling at larger centers.



REFERENCES

(1) Brohawn DG et al. (2019) Journal of Diagnostic Techniques and Biomedical Analysis; 7:2.
(2) De Luca et al. (2018) Journal of Clinical Pathology; 71:745-750.
(3) De Montpréville et al. (2017) Pathology - Research and Practice; 213,7:793-798.
(4) Arcila M et al. (2018) Journal of Molecular Diagnostics; 20:6. Abstract #ST027.
(5) Al-Turkmani M (2018) Journal of Molecular Diagnostics; 20:6. Abstract # TT060.
(6) Al-Turkmani M (2018) Journal of Molecular Diagnostics; 20:6. Abstract # ST125.
(7) Ghigna M et al. (2018) Journal of Thoracic Disease; 10(7):4653-4658.
(8) Mackinnon A et al. (2019) Accepted for publication in Journal of Molecular Diagnostics.
(9) Sigismund S et al. (2018) Molecular Oncology; 12(1):3–20.

Contact details
Biocartis US Inc.
2 Pierce Place Suite 1510
Itasca, IL 60143
1-844-4-IDYLLA (1-844-443-9552)
www.biocartis.com/US
customerserviceUS@biocartis.com

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