

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



Features

EGFR mutation detection		
Exon 18	G719A	(c.2156G>C)
	G719S	(c.2155G>A)
	G719C	(c.2155G>T; c.2154_2155delinsTT)
Del9		c.2238_2248delinsGC
		c.2239_2248delinsC
		c.2240_2248del c.2239_2247del
Del12		c.2239_2251delinsC
		c.2240_2251del
		c.2235_2249del c.2236_2250del c.2239_2253del c.2240_2254del
Exon 19	Del15	c.2238_2252del c.2237_2251del c.2235_2252delinsAAT c.2237_2252delinsT c.2234_2248del c.2236_2253delinsCTA c.2237_2253delinsTA c.2237_2253delinsTC c.2235_2251delinsAG c.2236_2253delinsCAA c.2230_2249delinsGTCAA

Exon 19	Del18	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		
Del21	(c.2238_2258del; c.2236_2256del)	
Del24	(c.2253_2276del)	
Exon 20	T790M	(c.2369C>T)
	S768I	(c.2303G>T)
	insG	(c.2310_2311insGGT)
	insASV9	(c.2308_2309insGCCAGCGTG)
	insASV11	(c.2308_2311delinsCCAGCGTGGAT)
	insSVD	(c.2311_2312insGCGTGGACA)
Exon 21	L858R	c.2573T>G
		c.2573_2574delinsGT
		c.2573_2574delinsGA
L861Q	(c.2582T>A)	
EGFR Total (acting as Sample Processing Control)		
Specimen requirements		
Sample Type	1 x 5µm FFPE tissue section	
Neoplastic cells	≥10%, if less macrodissection is required	
Total turnaround time		
Time	150 minutes	

Idylla™ EGFR Posters & Publications

- Troncone G. et al. EGFR mutation detection on lung cancer cytological specimens by the rapid and fully integrated Idylla™ molecular diagnostics system. Poster ASCO 2016.
- De Luca C. et al. EGFR mutation detection on lung cancer cytological specimens by the novel fully automated PCR-based Idylla EGFR Mutation Assay. J Clin Pathol 2016.

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