

Technical sheet

Idylla™ EGFR Mutation Assay

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) tissue 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)
Exon 19	Del9	c.2238_2248delinsGC c.2239_2248delinsC
		c.2240_2248del
		c.2239_2247del
	Del12	c.2239_2251delinsC
		c.2240_2251del
		c.2235_2249del
	Del15	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.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
Exon 20	Del21	c.2237_2256delinsTT
		c.2237_2256delinsTC
		c.2235_2255delinsGGT
		(c.2238_2258del; c.2236_2256del)
Exon 20	Del24	(c.2253_2276del)
		T790M
		(c.2369C>T)
		S768I
		(c.2303G>T)
		insG
		(c.2310_2311insGGT)
Exon 20	insASV9	(c.2308_2309insGCCAGCGTG)
		insASV11
		(c.2308_2311delinsCCAGCGTGGAT)
		insSVD
		(c.2311_2312insGCGTGGACA)
		insH
		(c.2319_2320insCAC)
Exon 21	L858R	c.2573T>G
		c.2573_2574delinsGT
		c.2573_2574delinsGA
Exon 21	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	
Result Reporting		
Report	Qualitative genotype call	

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