

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	Del 9	c.2238_2248delinsGC
		c.2239_2248delinsC
		c.2240_2248del c.2239_2247del
Exon 19	Del 12	c.2239_2251delinsC
		c.2240_2251del
		Exon 19
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		

Exon 19	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
	T790M	c.2369C>T
Exon 20	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

EGFR Total (acting as Sample Processing Control)

Specimen requirements

Sample Type	1 x 5 µm FFPE tissue section
Neoplastic cells	≥10%, if less macrodissection is required

Total turnaround time

Time	150 minutes
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Result Reporting

Report	Qualitative genotype call
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