

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 paraffinembedded (FFPE) tissue to liberate DNA for subsequent real-time PCR amplification and detection.

FEATURES

EGFR mutation detection				
Exon 18	G719A G719C G719C G719S	c.2156G>C c.2155G>T c.2154_2155delinsTT c.2155G>A		
Exon 19	Deletion 9	c.2238_2248delinsGC c.2239_2248delinsC c.2240_2248del c.2239_2247del		
	Deletion 12	c.2239_2251delinsC c.2240_2251del		
	Deletion 15	c.2235_2249del c.2236_2250del c.2240_2254del c.2237_2251del c.2235_2252delinsAAT c.2237_2252delinsT c.2234_2248del c.2236_2252delinsCT c.2235_2251delinsAG c.2236_2252delinsCA		



Exon 19	Deletion 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_2256delinsTC
	Deletion 21	c.2238_2258del c.2236_2256del
	Deletion 24	c.2253_2276del
Exon 20	T790M	c.2369C>T c.[2369C>T;2361G>A]
	S768I	c.2303G>T
	InsG	c.2310_2311insGGT
	InsASV(9)	2300_2308dup
	InsASV(11)	c.2309_2310delinsCCAGCGTGGAT
	InsSVD	c.2303_2311dup
	InsH	c.2317_2319dup
Exon 21	L858R	c.2573T>G c.2573_2574delinsGT c.2573_2574delinsGA
	L861Q	c.2582T>A

EGFR Total (acting as Sample Processing Control)

Minimum 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	
Result Reporting		
Report	Qualitative genotype call	
Catalog Number		
ldylla™ EGFR Mutation Assay	A0061/6	

 $Idylla^{\texttt{M}} \, \mathsf{EGFR} \, \mathsf{Mutation} \, \mathsf{Assay} \, \mathsf{is} \, \mathsf{for} \, \mathsf{Research} \, \mathsf{Use} \, \mathsf{Only} \, (\mathsf{RUO}), \, \mathsf{not} \, \mathsf{for} \, \mathsf{use} \, \mathsf{in} \, \mathsf{diagnostic} \, \mathsf{procedures}. \, \mathsf{Biocartis} \, \mathsf{and} \, \mathsf{Idylla^{\texttt{M}}} \, \mathsf{are} \, \mathsf{registered} \, \mathsf{trademarks} \, \mathsf{in} \, \mathsf{Europe}, \, \mathsf{the} \, \mathsf{US} \, \mathsf{and} \, \mathsf{other} \, \mathsf{countries}. \, \mathsf{The} \, \mathsf{Biocartis} \, \mathsf{and} \, \mathsf{Idylla^{\texttt{M}}} \, \mathsf{trademarks} \, \mathsf{and} \, \mathsf{logos} \, \mathsf{are} \, \mathsf{used} \, \mathsf{trademarks} \, \mathsf{owned} \, \mathsf{by} \, \mathsf{Biocartis} \, \mathsf{NV}. \, \mathsf{Idylla^{\texttt{M}}} \, \mathsf{is} \, \mathsf{available} \, \mathsf{for} \, \mathsf{sale} \, \mathsf{in} \, \mathsf{Europe}, \, \mathsf{the} \, \mathsf{US} \, \mathsf{and} \, \mathsf{many} \, \mathsf{other} \, \mathsf{countries}. \, \mathsf{Please} \, \mathsf{check} \, \mathsf{availability} \, \mathsf{with} \, \mathsf{a} \, \mathsf{local} \, \mathsf{Biocartis} \, \mathsf{representative}. \\ @ \, \mathsf{August} \, \mathsf{2024}, \, \mathsf{Biocartis} \, \mathsf{NV}. \, \, \mathsf{All} \, \mathsf{rights} \, \mathsf{reserved}. \\$