

TECHNICAL SHEET IDYLLA™ ctEGFR MUTATION ASSAY



The **Idylla™ ctEGFR Mutation Assay**, performed on the Biocartis Idylla™ System, is an assay for the qualitative detection of **exon 18 (G719A/C/S), exon 20 (T790M, S768I) and exon 21 (L858R, L861Q) mutations, exon 19 deletions, and exon 20 insertions** in the *EGFR* gene. The Idylla™ ctEGFR Mutation Assay extracts and amplifies *EGFR* circulating tumor DNA (ctDNA) from 2 ml of plasma. The Assay is **sample-to-result** real-time PCR, intended for research applications use only.

FEATURES

ctEGFR mutation detection - Gene <i>EGFR</i>				
Exon 18	G719A	p.Gly719Ala	c.2156G>C	G719A/C/S
	G719C	p.Gly719Cys	c.2155G>T	
	G719C	p.Gly719Cys(2)	c.2154_2155delinsTT	
	G719S	p.Gly719Ser	c.2155G>A	
Exon 19	Del9	p.Leu747_Ala750delinsPro	c.2238_2248delinsGC c.2239_2248delinsC	Exon 19 deletion
		p.Leu747_Ala750delinsSer	c.2240_2248del	
		p.Leu747_Glu749del	c.2239_2247del	
	Del12	p.Leu747_Thr751delinsPro	c.2239_2251delinsC	
		p.Leu747_Thr751delinsSer	c.2240_2251del	
	Del15	p.Glu746_Ala750del	c.2235_2249del c.2236_2250del	
		p.Leu747_Thr751del	c.2239_2253del c.2240_2254del c.2238_2252del	
		p.Glu746_Thr751delinsAla	c.2237_2251del	
		p.Glu746_Thr751delinsIle	c.2235_2252delinsAAT	
		p.Glu746_Thr751delinsVal	c.2237_2252delinsT	
		p.Lys745_Ala750delinsThr	c.2234_2248del	
		p.Glu746_Thr751delinsLeu	c.2236_2253delinsCTA	
		p.Glu746_Thr751delinsVal	c.2237_2253delinsTA	
		p.Glu746_Thr751delinsAla	c.2235_2251delinsAG	
		p.Glu746_Thr751delinsGln	c.2236_2253delinsCAA	
p.Ile744_Ala750delinsValLys	c.2230_2249delinsGTCAA			

ctEGFR mutation detection - Gene *EGFR* continued

Exon 19	Del18	p.Leu747_Pro753delinsSer	c.2240_2257del	Exon 19 deletion		
		p.Glu746_Ser752delinsVal	c.2237_2255delinsT			
		p.Leu747_Ser752del	c.2239_2256del			
		p.Glu746_Thr751del	c.2236_2253del			
		p.Leu747_Pro753delinsGln	c.2239_2258delinsCA			
		p.Glu746_Ser752delinsAla	c.2237_2254del			
		p.Glu746_Ser752delinsAsp	c.2238_2255del			
		p.Glu746_Ser752delinsIle	c.2236_2256delinsATC			
		p.Glu746_Ser752delinsVal	c.2237_2256delinsTT c.2237_2256delinsTC c.2235_2255delinsGGT			
Del21	Del21	p.Leu747_Pro753del	c.2238_2258del			
		p.Glu746_Ser752del	c.2236_2256del			
Exon 20	InsG	p.Ser752_Ile759del	c.2253_2276del	Exon 20 insertion		
		T790M	p.Thr790Met		c.2369C>T	T790M
		S768I	p.Ser768Ile		c.2303G>T	S768I
		InsG	p.Asp770_Asn771insGly		c.2310_2311insGGT	
		InsASV9	p.Val769_Asp770insAlaSerVal		c.2307_2308insGCCAGCGTG	
		InsASV11	p.Val769_Asp770insAlaSerVal		c.2309_2310delinsCCAGCGTGGAT	
		InsSVD	p.Asp770_Asn771insSerValAsp		c.2311_2312insGCGTGGACA	
Exon 21	InsH	p.His773_Val774insHis	c.2319_2320insCAC			
		L858R	p.Leu858Arg		c.2573T>G c.2573_2574delinsGT c.2573_2574delinsGA	L858R
		L861Q	p.Leu861Gln		c.2582T>A	L861Q

EGFR Total (acting as Sample Processing Control)

Specimen requirements

Sample Type The Assay is optimized using 2 ml plasma specimens collected from blood in EDTA blood collection tubes. Proteinase K (20 µl of 20 mg/ml (stock concentration) is also added to the cartridge before processing.

Supported blood collection tubes

EDTA tubes Blood must be centrifuged within 4 hours after collection

Total turnaround time

Time Approx. 160 minutes

Hands on time

Time Approx. 2 minutes (excluding plasma preparation steps)

Result reporting

Report Genotype call, Cq values and quality status

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