

## TECHNICAL SHEET IDYLLA™ EGFR MUTATION TEST



The **Idylla™ EGFR Mutation Test**, performed on the Biocartis Idylla™ System, is an *in vitro* diagnostic test for the qualitative detection of **exon 18 (G719A/C/S), exon 21 (L858R, L861Q), exon 20 (T790M, S768I) mutations, exon 19 deletions and exon 20 insertions** in the *EGFR* oncogene. The Idylla™ EGFR Mutation Test, from **sample-to-result**, starts with formalin-fixed, paraffin-embedded (FFPE) human tissue from non-small cell lung cancer (NSCLC) to liberate DNA for subsequent real-time PCR amplification and detection.

### FEATURES

EGFR mutation detection		
Exon 18	G719A	c.2156G>C
	G719C G719S	c.2155G>T; c.2154_2155delinsTT c.2155G>A
Exon 19	Del9	c.2238_2248delinsGC c.2239_2248delinsC c.2240_2248del cc.2239_2247del
	Del12	c.2239_2251delinsC c.2240_2251del
	Del15	c.2235_2249del 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

<b>Exon 19</b>	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
	T790M	c.2369C>T
<b>Exon 20</b>	S768I	c.2303G>T
	insG	c.2310_2311insGGT
	insASV9	c.2308_2309insGCCAGCGTG
	insASV11	c.2308_2311delinsCCAGCGTGGAT
	insSVD	c.2311_2312insGCGTGGACA
insH	c.2319_2320insCAC	
<b>Exon 21</b>	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

### Performance

Analytical Sensitivity	LOD ≤5% for most prevalent <i>EGFR</i> mutations
Between Laboratory Reproducibility (600 results at 3 sites)	100% agreement for 10% EGFR G719S 100% agreement for 10% EGFR Del15 100% agreement for 10% EGFR T790M 100% agreement for 10% EGFR L858R 100% agreement for 10% EGFR L861Q

Between Lot  
 Reproducibility  
 (300 results on 3 lots)

100% agreement for 10% EGFR G719S  
 100% agreement for 10% EGFR Del15  
 100% agreement for 10% EGFR T790M  
 100% agreement for 10% EGFR L858R  
 100% agreement for 10% EGFR L861Q

**Total turnaround time**

Time 150 minutes

**ACCURACY - CLINICAL PERFORMANCE EVALUATION**



95.9% overall agreement for the *EGFR* gene was obtained during the clinical performance evaluation comparing Idylla™ with Therascreen (Qiagen), a PCR-based reference method.

**95.9% overall concordance**

Therascreen: Idylla™	DelEx19	DelEx19, T790M	L858R	L867Q	G719X	G719X, S768I	L858R, T790M	InsEx20	No mutation detected	Totals without invalids	Invalids	Totals
DelEx19	18		–	–	–	–	–	–	–	18	8	26
InsEx20	–	–	–	–	–	–	–	–	–	–	1	1
DelEx19,T790M	–	4		–	–	–	–	–	–	4	–	4
L858R	–	–	20		–	–	1	–	–	21	2	23
L861Q	–	–	–	2		–	–	–	–	2	–	2
G719X	–	–	–	–	1		–	–	–	1	–	1
G719X,S768I	–	–	–	–	–	1		–	–	1	–	1
L858R,T790M	–	–	–	–	–	–	1		–	1	–	1
T790M	–	1		–	–	–	–	–	1	2	2	4
DelEx19, S768I	1	–	–	–	–	–	–	–	–	1	–	1
S768I	–	–	–	–	–	–	–	–	–	0	1	1
No mutation detected	–	1	2	–	1	–	–	1	66	71	30	101
Totals without invalids	19	6	22	2	2	1	2	1	67	<b>122</b>	–	/
Invalids	–	1	–	–	–	–	–	–	2	–	10	13
Totals	19	7	22	2	2	1	2	1	69	/	54	<b>179</b>

After discordant analysis by NGS and/or ddPCR (excluding invalids) the **overall concordance** was **97.9%**.

## IDYLLA™ EGFR PUBLICATIONS

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