EGFR A0270/6 CE 2797 IVD IVDR

idylla by BIOCARTIS

TECHNICAL SHEET IDYLLA™ EGFR MUTATION TEST

Intended use

The Idylla™ EGFR Mutation Test is a fully automated real-time PCR test for the qualitative detection of defined mutations of the epidermal growth factor receptor (EGFR) gene. The Idylla™ EGFR Mutation Test uses formalin-fixed paraffin-embedded (FFPE) tumor tissue sections from adult patients diagnosed with non-small cell lung cancer (NSCLC). The Idylla™ EGFR Mutation Test covers the entire process from FFPE sample to result, including fully integrated sample preparation, liberation of nucleic acids, real-time PCR amplification and detection, data analysis and result reporting.

Indications for use

The Idylla™ EGFR Mutation Test, which detects EGFR mutations (L858R and exon 19 deletions), is intended to be used by healthcare professionals as a companion diagnostic to aid in selecting NSCLC patients who are most likely to benefit from treatment with EGFR Tyrosine Kinase Inhibitors (TKI), in accordance with the approved therapeutic product labelling. The activating EGFR mutations and the related TKIs are listed in the table. Safe and effective use has not been established for selecting therapies using this device for mutations other than those in the table.

EMA authorized TKIs	Activating EGFR mutations
Iressa® (gefitinib)	L858R and exon 19 deletions
Tarceva® (erlotinib)	
Tagrisso® (osimertinib)	

The Idylla™ EGFR Mutation Test also detects other less common EGFR mutations, i.e., G719A/C/S, S768I, L861Q, and exon 20 insertions. Analytical performance using NSCLC specimens has been established for these variants. The test results of these uncommon EGFR mutations are intended to aid healthcare professionals in making informed decisions regarding disease management of NSCLC patients. The results obtained are intended to be used in conjunction with other clinical and laboratory findings to guide patient management strategies and optimize patient outcomes in accordance with the established NSCLC guidelines. The test results are not prescriptive or conclusive for labeled use of any specific therapeutic product.

The Idylla™ EGFR Mutation Test is not intended to diagnose NSCLC disease or to be used for patient monitoring or testing upon progression.

FEATURES

Primary EGFR mutations			Genotype call
Exon 18	G719A	c.2156G>C	G719A/C/S
	G719C	c.2155G>T	
	G719S	c.2155G>A	
Exon 19	Deletion 9	c.2239_2248delinsC	Exon 19 deletion
	Deletion 12	c.2239_2251delinsC	
	Deletion 15	c.2235_2249del	
		c.2236_2250del	
	Deletion 18	c.2240_2257del	

Primary EGFR mutations - continued			Genotype call
Exon 19	Deletion 21	c.2238_2258del	Exon 19 deletion
		c.2236-2256del	
	Deletion 24	c.2253-2276del	
Exon 20	S768I	c.2303G>T	S768I
	InsG	c.2310_ 2311insGGT	Exon 20 insertion
	InsASV(9)	c.2300_2308dup	
	InsASV (11)	c.2309_2310del-insCCAGCGTGGAT	
	InsSVD	c.2303_2311dup	
	InsH	c.2317_2319dup	
Exon 21	L858R	c.2573T>G	L858R
	L861Q	c.2582T>A	L861Q

Inclusive EGFR mutations			Corresponding genotype call
Exon 18	c.2154_2155delinsTT		G719A/C/S
Exon 19	c.2240_2254del		Exon 19 deletion
	c.2238_2248delinsGC		
	c.2237_2255delinsT		
	c.2237_2256delinsTC		
	c.2239_2256del		
	c.2237_2251del		
	c.2235_2251delinsAG		
	c.2236_2253del		
	c.2240_2251del		
	c.2240_2248del		
	c.2239_2247del		
	c.2235_2252delinsAAT		
	c.2239_2258delinsCA		
	c.2238_2255del		
	c.2237_2254del		
	c.2237_2257delinsTCT		
	c.2236_2255delinsAT		
	c.2236_2256delinsATC		
	c.2237_2252delinsT		
	c.2234_2248del		
	c.2236_2252delinsCT		
	c.2236_2252delinsCA		
Exon 21	c.2573_2574delinsGT		L858R
	c.2573_2574delinsGA		

Minimum specimen requirements

Sample type	2 x 5-10 µm FFPE tissue sections
Neoplastic cell content	≥ 20% neoplastic cells; if less, macrodissection is required

Total turnaround time

Time	150 minutes

Analytical performance

Analytical sensitivity	LoD for the primary mutations ≤ 5% for the majority of mutations
Between laboratory reproducibility (600 FFPE results at 3 sites)	100% agreement for EGFR L861Q at 10% AF 100% agreement for EGFR Deletion 15 at 10% AF 100% agreement for L858R at 10% AF 100% agreement for G719S at 10% AF 100% agreement for EGFR Wild type at 10% AF
Between lot reproducibility (300 FFPE results on 3 lots)	100% agreement for EGFR L861Q at 10% AF 100% agreement for EGFR Deletion 15 at 10% AF 100% agreement for G719S at 10% AF 100% agreement for L858R at 10% AF 100% agreement for EGFR Wild type at 10% AF

Clinical performance

An overall agreement of 99.1% was achieved for both CDx targets (exon 19 deletions and L858R), and 98.7% for all EGFR targets, in a clinical performance study comparing the Idylla™ System with the cobas® EGFR Mutation Test v2, a PCR-based reference method.

Concordance (PPA, NPA and OPA) between Idylla™ EGFR Mutation Test and cobas® EGFR Mutation Test v2 for the detection of EGFR mutations in NSCLC FFPE tumor tissue specimen.

Mutation	Measure	Rate (N)	% Agreement	95% CI (%) [Lower limit, upper limit]
Exon 19 deletion or L858R	PPA	131/132	99.2%	[95.9%, 100%]
	NPA	100/101	99.0%	[94.6%, 100%]
	OPA	231/233	99.1%	[96.9%, 99.9%]
All EGFR mutations (aggregate)	PPA	137/138	99.3%	[96.0%, 100%]
	NPA	93/95	97.9%	[92.6%, 99.7%]
	OPA	230/233	98.7%	[96.3%, 99.7%]

Concordance between Idylla™ EGFR Mutation Test and cobas® EGFR Mutation Test v2 for the detection of EGFR mutations in NSCLC FFPE tumor tissue specimen at genotype level.

IDYLLA™ EGFR MUTATION TEST	COBAS® EGFR MUTATION TEST V2											
	Ex19DEL	Ex19DEL +T790M	Ex19DEL +L861Q	Ex20INS	G719X	G719X +S768I	L858R	L858R +T790M	L861Q	T790M	NO MUTATION DETECTED	TOTAL
Ex19DEL	**65**	**2**	**1**	0	0	0	0	0	0	0	0	**68**
Ex20INS	0	0	0	**1**	0	0	0	0	0	0	1	**2**
G719X	0	0	0	0	**1**	0	0	0	0	0	0	**1**
G719X +S768I	0	0	0	0	0	**2**	0	0	0	0	0	**2**
L858R	0	0	0	0	0	0	**59**	**4**	0	1	0	**64**
L861Q	0	0	0	0	0	0	0	0	**2**	0	0	**2**
NO MUTATION DETECTED	1	0	0	0	0	0	0	0	0	0	**93**	**94**
TOTAL	**66**	**2**	**1**	**1**	**1**	**2**	**59**	**4**	**2**	**1**	**94**	**233**

Catalog number

Idylla™ EGFR Mutation Test	A0270/6

Regulatory status

Regulatory status	CE IVD - IVDR certified

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