

Technical sheet Idylla™ NRAS-BRAF Mutation Test

NRAS **BRAF** CE IVD

The **Idylla™ NRAS-BRAF Mutation Test**, performed on the Biocartis Idylla™ system, is an *in vitro* diagnostic Test for the qualitative detection of 18 mutations in **codons 12, 13, 59, 61, 117, 146** of the *NRAS* gene and 5 mutations in **codon 600** of the *BRAF* gene. The Idylla™ NRAS-BRAF Mutation Test, from **sample-to-result**, starts with formalin-fixed, paraffin-embedded (FFPE) human tissue from metastatic colorectal cancers to liberate DNA for subsequent real-time PCR amplification and detection.



Features

NRAS mutation detection	
Codon 12 (exon 2)	G12C (c.34G>T)
	G12S (c.34G>A)
	G12D (c.35G>A)
	G12A (c.35G>C)
	G12V (c.35G>T)
Codon 13 (exon 2)	G13D (c.38G>A)
	G13V (c.38G>T)
	G13R (c.37G>C)
Codon 59 (exon 3)	A59T (c.175G>A)
Codon 61 (exon 3)	Q61K (c.181C>A)
	Q61L (c.182A>T)
	Q61R (c.182A>G)
	Q61H (c.183A>C; c.183A>T)
Codon 117 (exon 4)	K117N (c.351G>C; c.351G>T)
Codon 146 (exon 4)	A146T (c.436G>A)
	A146V (c.437C>T)
NRAS Total (acting as Sample Processing Control)	
BRAF mutation detection	
Codon 600	BRAF V600E (c.1799T>A; c.1799_1800delinsAA)
	BRAF V600D (c.1799_1800delinsAC)
	BRAF V600K (c.1798_1799delinsAA)
	BRAF V600R (c.1798_1799delinsAG)
BRAF Total (acting as Sample Processing Control)	

Specimen requirements		
Sample Type	FFPE tissue sections (5 to 10µm)	
Neoplastic cells	≥10%, if less macrodissection is required	
Tissue area	50-600mm ² (5µm) 25-300mm ² (10µm)	
Performance		
Analytical Sensitivity	LOD ≤5% for most prevalent NRAS and BRAF mutations	
Between Laboratory Reproducibility (600 results at 3 sites)	100% agreement for 10% NRAS G12D	
	100% agreement for 10% NRAS G12V	
	100% agreement for 10% NRAS Q61K	
	100% agreement for 10% NRAS Q61R	
Between Lot Reproducibility (300 results on 3 lots)	100% agreement for 10% BRAF V600E	
	100% agreement for 10% NRAS G12D	
	100% agreement for 10% NRAS G12V	
	100% agreement for 10% NRAS Q61K	
Total turnaround time	100% agreement for 10% NRAS Q61R	
	100% agreement for 10% BRAF V600E	
	Time	120 minutes

Accuracy - Clinical Performance Evaluation

99.6% and 100% overall diagnostic agreement for the *NRAS* and *BRAF* gene, respectively, was obtained during the clinical performance evaluation comparing Idylla™ with a sequencing-based reference method.

99.6% overall concordance		Reference Method											Total
	NRAS	G12A	G12V	G12C	G12D	G12S	G13D	Q61H	Q61K	Q61L	Q61R	No mutation	Total
Idylla™ NRAS-BRAF Mutation Test	G12A/V	1	4										5
	G12C			2									2
	G12D				8							1*	9
	G12S					0							0
	G13D						1						1
	Q61H							1					1
	Q61K								7				7
	Q61L									3			3
	Q61R										6		6
	No mutation											201	201
Total		1	4	2	8	0	1	1	7	3	6	202	235

* ddPCR confirmed the G12D result (<5% allelic frequency)

100% overall concordance	Reference Method			
	BRAF	V600E	No mutation	Total
Idylla™	V600E/D	50		50
NRAS-BRAF	No mutation		185	185
Mutation Test	Total	50	185	235

↓ Discordant analysis by ddPCR

100% overall concordance	Reference Method and further analysis by ddPCR												
	NRAS	G12A	G12V	G12C	G12D	G12S	G13D	Q61H	Q61K	Q61L	Q61R	No mutation	Total
Idylla™	G12A/V	1	4										5
NRAS	G12C			2									2
Mutation Test	G12D				9								9
	G12S					0							0
	G13D						1						1
	Q61H							1					1
	Q61K								7				7
	Q61L									3			3
	Q61R										6		6
	No mutation											201	201
	Total	1	4	2	9	0	1	1	7	3	6	201	235

Idylla™ NRAS Poster

- Vercauteren E. et al. Ultra-rapid, sensitive, and fully automated extended RAS testing for metastatic colorectal cancer – evaluation of an NRAS-BRAF-EGFR S492R method. Ann. Oncology 2016; 27, Suppl. 6, Poster 1175P. doi:10.1093/annonc/mdw380

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