

TECHNICAL SHEET IDYLLA™ NRAS-BRAF-EGFR S492R MUTATION ASSAY

The Idylla[™] NRAS-BRAF-EGFR S492R Mutation Assay, performed on the Biocartis Idylla[™] System, is a molecular assay for the qualitative detection of 18 mutations in codons 12, 13, 59, 61, 117, 146 of the *NRAS* gene, 5 mutations in codon 600 of the *BRAF* gene and 2 mutations in codon 492 of the *EGFR* gene. The Idylla[™] NRAS-BRAF-EGFR S492R Mutation Assay, 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 BRAF V600D	(c.1799T>A; c.1799_1800delinsAA) (c.1799_1800delinsAC)
	BRAF V600K BRAF V600R	(c.1798_1799delinsAA) (c.1798_1799delinsAG)

BRAF Total (acting as Sample Processing Control)



EGFR mutation detection		
Codon 492	S492R	(c.1476C>A)
	S492R2	(c.1474A>C)

EGFR Total (acting as Sample Processing Control)

Specimen requirements	
Sample Type	FFPE tissue sections (5 to 10 µm)
Neoplastic cells	≥10%, if less macrodissection is required
Tissue area	50-600 mm² (5 μm) 25-300 mm² (10 μm)
Total turnaround time	
Time	120 minutes



Biocartis and Idylla[™] are registered trademarks in Europe, the United States and other countries. The Biocartis and the Idylla trademark and logo are used trademarks owned by Biocartis. Idylla[™] platform is CE-marked IVD in Europe. Idylla[™] NRAS-BRAF-EGFR S492R Mutation Assay is available for Research Use Only (RUO), not for use in diagnostic procedures. Idylla[™] is available for sale in EU, USA and some other countries. Please check availability with the local Biocartis sales representative.

GL.FL015.EN.R1.10/2018