## TECHNICAL SHEET IDYLLA™ ctNRAS-BRAF-EGFR S492R MUTATION ASSAY

The Idylla™ ctNRAS-BRAF-EGFR S492R Mutation Assay, performed on the Biocartis Idylla™ System, is a molecular assay for the semi-quantitative 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™ ctNRAS-BRAF-EGFR S492R Mutation Assay extracts and amplifies NRAS, BRAF and EGFR circulating tumor DNA (ctDNA) from 1 ml of plasma. The assay is a **sample-to-result** real-time PCR, intended for use in research applications only.

## **FEATURES**

ctNRAS 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 A146V	(c.436G>A) (c.437C>T)
•••••••••••••••••••••••••••••••••••••••	••••••	•••••••••••••••••••••••••••••••••••••••

NRAS Total (acting as Sample Processing Control)



ctBRAF mutation detection		
	BRAF V600E	(c.1799T>A; c.1799_1800delinsAA)
Codon 600	BRAF V600D	(c.1799_1800delinsAC)
	BRAF V600K	(c.1798_1799delinsAA)
	BRAF V600R	(c.1798_1799delinsAG)

BRAF Total (acting as Sample Processing Control)

ctEGFR mutation detection		
Codon 492	S492R	(c.1476C>A)
00011492	S492R2	(c.1474A>C)

EGFR Total (acting as Sample Processing Control)

Specimen requirements	
Sample Type	1 ml of plasma
Supported blood collection tubes	
EDTA tubes	Blood must be centrifuged within 4 hours after collection
Cell-free DNA BCT® tubes (Streck)	Blood must be centrifuged within 3 days after collection
Total turnaround time	
Time	Approx. 110 minutes
Result Reporting	
Report	Qualitative genotype call and Cq values



Biocartis trademark and logo are trademarks belonging to Biocartis and are used and registered in Europe. Idylla is a registered trademark in the United States (US) and other countries. Idylla trademark and logo are used trademarks belonging to Biocartis. Idylla<sup>™</sup> platform is a CE-marked IVD in Europe. The Idylla<sup>™</sup> ctNRAS-BRAF-EGFR S492R Mutation Assay is available for Research Use Only (RUO), not for use in diagnostic procedures.

REF: ONCO\_TS\_CTNRAS\_US\_201812