ctNRAS3 RUO

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 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™ 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 research applications use 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 | (c.436G>A) | |
| | A146V | (c.437C>T) | |

NRAS Total (acting as Sample Processing Control)

| ctBRAF 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)



| ctEGFR mutation detection | | |
|---------------------------|-----------------|--------------------------|
| Codon 492 | S492R S492R2 | (c.35G>A) (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 + Cq values | | |

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