

TECHNICAL SHEET IDYLLA™ ctKRAS MUTATION ASSAY

The Idylla™ ctKRAS Mutation Assay, performed on the Biocartis Idylla™ System, is an assay for the qualitative detection of 21 mutations in codons 12, 13, 59, 61, 117 and 146 of the KRAS gene.

The Idylla™ ctKRAS Mutation Assay extracts and amplifies KRAS circulating tumor DNA (ctDNA) from 1 ml of plasma. The assay is a sample-to-result real-time PCR, intended to use for research applications only.

FEATURES

| ctKRAS mutation detection | | |
|---------------------------|----------------|-------------------------------|
| Codon 12 (exon 2) | G12C | (c.34G>T) |
| | G12R | (c.34G>C) |
| | G12S | (c.34G>A) |
| | G12A | (c.35G>C) |
| | G12D | (c.35G>A) |
| | G12V | (c.35G>T) |
| Codon 13 (exon 2) | G13D | (c.38G>A) |
| Codon 59 (exon 3) | A59E | (c.176C>A) |
| | A59G A59T | (c.176C>G) (c.175G>A) |
| Codon 61 (exon 3) | Q61K | (c.181C>A; c.180_181delinsAA) |
| | Q61L | (c.182A>T) |
| | Q61R | (c.182A>G) |
| | Q61H | (c.183A>C; c.183A>T) |
| Codon 117 (exon 4) | K117N | (c.351A>C; c.351A>T) |
| Codon 146 (exon 4) | A146P | (c.436G>C) |
| | A146T A146V | (c.436G>A) (c.437C>T) |
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KRAS 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. 130 minutes | | |
| Result Reporting | | | |
| Report | Qualitative genotype call and Cq values | | |



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