KRAS ctKRAS

IDYLLA™ KRAS MUTATION DETECTION ON SOLID AND LIQUID BIOPSIES

BACKGROUND INFORMATION*

Activating mutations in the *RAS* genes are observed in 9-30% of all cancers and have been associated with sensitivity and resistance to a number of targeted anti-cancer therapeutics.[12] Cancers in which *KRAS* mutations are observed include: colorectal cancer, lung cancer and pancreatic cancer.

According to ESMO[9], NCCN[14], ASCO[16] and CAP/AMP/ASCO guidelines[15], genotyping of clinically actionable mutations at a sensitivity of 5% in *RAS* genes exon 2 (codons 12 and 13), exon 3 (codons 59 and 61) and exon 4 (codons 117 and 146) is now mandatory on tumor tissue (either primary or metastasis) of all metastatic colorectal cancers, since the presence of these mutations correlate with the lack of response to certain anti-EGFR antibody therapies[9]. About 46% of all metastatic colorectal tumors harbor mutations in exons 2, 3 and 4 of the *KRAS* gene.[13] Several studies are ongoing to define the predictive impact of *KRAS* mutations on therapy decision for non-small-cell lung cancer (NSCLC) patients.[18,19,20] Currently there is evidence that *KRAS* in lung cancer has a prognostic value, indicating poor survival for patients with NSCLC, compared to the absence of *KRAS* mutations.[11]

Using liquid biopsies for *KRAS* testing is minimally invasive, fast and easy to perform and can be used as an alternative or complement to tissue testing to determine the *RAS* mutation status at diagnosis.

*Idylla™ RAS Mutation Tests are validated for use in mCRC

DIAGNOSTIC PRODUCT

Idylla™ **KRAS** Mutation Test (CE IVD)

KRAS

Diagnostic use

approx. 120 min	< 2 min	21 in codons 12,13,59 61,117, 146
sample-to-result	hands-on time	mutations

FFPE

Directly on FFPE tissue sections (5-10 µm) from **metastatic colorectal cancer**

Qualitative genotype call

Mutation detection for **baseline treatment**

DIAGNOSTIC PRODUCT

Idylla™ **ctKRAS** Mutation Test (CE IVD)

ctKRAS

Diagnostic use

approx. 130 min	< 1 min	21 in codons 12,13,59 61,117, 146
sample-to-result	hands-on time	mutations

plasma

Directly on 1 ml plasma from mCRC patients

Qualitative genotype call + Cq values

Mutation detection for **baseline treatment**

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"Idylla™ allows very quick results with little hands-on time"