

IDYLLA™ BRAF MUTATION DETECTION ON SOLID AND LIQUID BIOPSIES

BACKGROUND INFORMATION*

Activating mutations in the *BRAF* gene are observed in about 8% of all cancers⁷ and have been associated with sensitivity and resistance to a number of targeted anti-cancer therapeutics.

Cancers in which *BRAF* mutations are observed include: melanoma, colorectal cancer, thyroid cancer, lung cancer, hairy cell leukemia and ovarian cancer.

BRAF testing is recommended in all patients with metastatic melanoma and metastatic colorectal

cancer (mCRC). About 50% of all metastatic melanoma patients harbor mutations in the *BRAF* gene, making them eligible for BRAF or BRAF/MEK inhibitor therapy.⁸ In mCRC, BRAF mutation status should be assessed alongside the assessment of tumor *RAS* mutational status for prognostic assessment (the presence of a *BRAF* mutation indicates poor prognosis). The prevalence of *BRAF* in mCRC is about 8-15%.⁹

*Idylla™ BRAF Mutation Test is validated for use in metastatic melanoma

DIAGNOSTIC PRODUCT

Idylla™ BRAF Mutation Test (CE IVD)



RESEARCH PRODUCT

Idylla™ ctBRAF Mutation Assay (RUO)



Diagnostic use

Research Use Only, not for diagnostic use

approx. 90 min sample-to-result
 < 2 min hands-on time
 7 mutations in codon 600

approx. 85 min sample-to-result
 < 1 min hands-on time
 7 mutations in codon 600

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

Directly on 1 ml plasma

Qualitative genotype call

Semi-quantitative genotype call + Cq values

Mutation detection for **baseline treatment**

Applicable in multiple cancers harboring BRAF mutations

*Prof. B. Neyns, M.D., Ph.D
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“The Idylla™ system has the potential to allow the start of targeted therapy within a time window of less than 24 hours following the diagnosis of metastasis, thereby saving precious time”