

TECHNICAL SHEET IDYLLA™ BRAF MUTATION TEST



The **Idylla™ BRAF Mutation Test**, performed on the Biocartis Idylla™ System, is an *in vitro* diagnostic Test for the qualitative detection of **V600E/E2/D** and **V600K/R/M** mutations in **codon 600** of the *BRAF* gene. The Idylla™ BRAF Mutation Test, from **sample-to-result**, starts with formalin-fixed paraffin-embedded (FFPE) human tissue from metastatic melanoma to liberate DNA for subsequent real-time PCR amplification and detection.

FEATURES

BRAF mutation detection

Codon 600	BRAF V600E	(c.1799T>A)
	BRAF V600E2	(c.1799_1800delinsAA)
	BRAF V600D	(c.1799_1800delinsAT; c.1799_1800delinsAC)
	BRAF V600K	(c.1798_1799delinsAA)
	BRAF V600R	(c.1798_1799delinsAG)
	BRAF V600M	(c.1798G>A)
	BRAF Wild Type	(c.1799T)

RNaseP (acting as Sample Processing Control)

Specimen requirements

Sample Type	FFPE tissue sections (5 to 10 µm)
Neoplastic cells	≥50%, if less macrodissection is required
Tissue area	50-600 mm ² (5 µm) 25-300 mm ² (10 µm)

Performance

Analytical Sensitivity	1% mutant in wild type background
Between Laboratory Reproducibility (240 results at 3 sites)	100% agreement for 3.5% BRAF V600E 100% agreement for 5% BRAF V600K
Between Lot Reproducibility (120 results on 3 lots)	98.3% agreement for 3.5% BRAF V600E 100% agreement for 5% BRAF V600K

Total turnaround time

Time	90 minutes
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ACCURACY - CLINICAL PERFORMANCE EVALUATION

97.9% overall percent agreement was obtained during the clinical performance evaluation comparing Idylla™ with Pyrosequencing.

		Pyrosequencing				Total
		BRAF V600E/E2/D	BRAF V600 K/R/M	Other mutation	No mutation	
Idylla™ BRAF Mutation Test	BRAF V600E/E2/D	89	0	0	4**	93
	BRAF V600 K/R/M	0	17	0	1***	18
	No mutation	0	0	1*	124	125
	Total	89	17	1	129	236

* Idylla™ BRAF Mutation Test is not designed for the detection of V600G mutation

** All cases confirmed by NGS in favour of Idylla™

*** Mutation not confirmed by NGS

MULTI-CENTER EVALUATION OF THE NOVEL FULLY-AUTOMATED PCR-BASED IDYLLA™ BRAF MUTATION TEST ON FORMALIN-FIXED PARAFFIN-EMBEDDED TISSUE OF MALIGNANT MELANOMA.

Melchior L. et al. Experimental and Molecular Pathology 2015.

		Routine reference methods***			Total
		BRAF V600E/E2/D	BRAF V600 K/R/M	No mutation	
Idylla™ BRAF Mutation Test	BRAF V600E/E2/D	68	1	1**	70
	BRAF V600 K/R/M	2	10	6**	18
	No mutation	0	0	50	50
	Total	70	11	57	138

* Insufficient DNA input not taken into account

** All mutations confirmed by ddPCR or Sanger

*** Different routine reference methods were used: cobas® 4800 BRAF V600 Mutation Test (Roche), BRAF RGQ PCR Kit (Qiagen), BRAF StripAssay® V600E (Viennalab), Sanger sequencing, and several in-house BRAF tests (based on high-resolution melting, allele specific and wild-type blocking real-time PCR)

IDYLLA™ BRAF PUBLICATIONS

Check our website: <https://www.biocartis.com/publications/articles-posters> and subscribe to receive our newest publications.



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