

- Dietel M. et al. A multicenter validation study of the Idylla™ BRAF Mutation Test on FFPE tissue of malignant melanoma. Poster AACCC 2014. Poster AMP 2014.
- Devogelaere B. et al. BRAF V600 mutation testing on FFPE samples using a novel fully integrated molecular diagnostics platform. Poster AACR 2013.
- Janku F. et al. BRAF Mutation Testing with a Novel, Rapid, Fully-Automated Molecular Diagnostics Prototype Platform. Poster AACR 2013.
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- Vandenbroucke I. et al. A rapid and fully automated multiplex assay for KRAS-BRAF mutations with high mutation sensitivity using novel selective amplification and detection technologies. Poster AACR 2014.
- Dietel M. et al. A multicenter validation study of the Idylla™ BRAF Mutation Test on FFPE tissue of malignant melanoma. Poster AACCC 2014. Poster AMP 2014.
- Van der Auwera M. et al. Evaluation of a rapid, sensitive and fully automated Idylla™ BRAF Mutation Test starting directly from FFPE samples. Poster BWP 2014.
- Micalessi I. et al. Evaluation of the Idylla™ BRAF Mutation Test performance using the novel fully-automated Idylla™ System. Poster BWP 2014.
- Janku F. et al. BRAF mutation testing with a rapid, fully integrated molecular. Oncotarget 2015.
- Melchior L. et al. Multi-center evaluation of the novel fully-automated PCR-based Idylla™ BRAF Mutation Test on FFPE tissue of malignant melanoma. J Exp Mol Path 2015.
- Micalessi I. et al. Evaluation of the Idylla™ BRAF Mutation Test performance using the novel fully-automated Idylla™ System on FFPE melanoma samples. Poster EMMD 2015.
- Schiefer A-I. et al. Multicenter Evaluation of a Novel Automated Rapid Detection System of BRAF Status in Formalin-Fixed, Paraffin-Embedded Tissues. J of Molecular Diagnostics 2016
- Alexandre H. et al. Detection of BRAF Mutations Using a Fully Automated Platform and Comparison with High Resolution Melting, Real-Time Allele Specific Amplification, Immunohistochemistry and Next Generation Sequencing Assays, for Patients with Metastatic Melanoma. PLOS ONE 2016.
- Riveiro-Falkenbach E. et al. BRAF V600 mutation detection in tricky melanoma samples using the new Idylla™ BRAF Mutation Test. Poster ESP 2016-

### Research applications

- Schiefer A-I. et al. Evaluation of a novel fully automated PCR-based technique for detection of BRAF-status in FFPE tissues. Poster AMP 2014.
- Colling R. et al. Automated PCR detection of BRAF mutations in colorectal adenocarcinoma. J Clin Path 2015.
- Micalessi I. et al. Evaluation of the Idylla™ BRAF Mutation Test performance using the novel fully-automated Idylla™ System on FFPE colorectal cancer samples. Poster EMMD 2015.
- Yeo MK. et al. The usefulness of a novel fully automated PCR-based Idylla test for detection of the BRAF V600E mutation in thyroid tissue: comparison with PNA-clamping PCR, real-time PCR and pyrosequencing. J Clin Pathol 2016.

### Disclaimer

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## 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		
	BRAF V600E	(c.1799T>A)
	BRAF V600E2	(c.1799_1800delinsAA)
	BRAF V600D	(c.1799_1800delinsAT; c.1799_1800delinsAC)
Codon 600	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 10µm)	
Neoplastic cells	≥50%, if less macrodissection is required	
Tissue area	50-600mm² (5µm) 25-300mm² (10µm)	
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	

**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	<b>89</b>	0	0	<b>4**</b>	93
	BRAF V600 K/R/M	0	<b>17</b>	0	<b>1**</b>	18
	No mutation	0	0	<b>1*</b>	<b>124</b>	125
	<b>Total</b>	<b>89</b>	<b>17</b>	<b>1</b>	<b>129</b>	<b>236</b>

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

\*\* 4/5 mutations called by Idylla™ are confirmed by NGS

↓  
Discordant analysis by NGS

		Pyrosequencing and further analysis by NGS				Total
		BRAF V600E/E2/D	BRAF V600 K/R/M	Other mutation	No mutation	
Idylla™ BRAF Mutation Test	BRAF V600E/E2/D	<b>93</b>	0	0	0	93
	BRAF V600 K/R/M	0	<b>17</b>	0	<b>1</b>	18
	No mutation	0	0	<b>1*</b>	<b>124</b>	125
	<b>Total</b>	<b>93</b>	<b>17</b>	<b>1</b>	<b>125</b>	<b>236</b>

**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	<b>68</b>	<b>1</b>	<b>1</b>	70
	BRAF V600 K/R/M	<b>2</b>	<b>10</b>	<b>6</b>	18
	No mutation	0	0	<b>50</b>	50
	<b>Total</b>	<b>70</b>	<b>11</b>	<b>57</b>	<b>138</b>

\*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)

\*\* Insufficient DNA input not taken into account.

↓  
Discordant analysis by ddPCR or Sanger

		Routine reference methods, including further analysis by ddPCR or Sanger			Total
		BRAF V600E/E2/D	BRAF V600 K/R/M	No mutation	
Idylla™ BRAF Mutation Test	BRAF V600E/E2/D	<b>70</b>	0	0	70
	BRAF V600 K/R/M	<b>2</b>	<b>16</b>	0	18
	No mutation	0	0	<b>50</b>	50
	<b>Total</b>	<b>72</b>	<b>16</b>	<b>50</b>	<b>138</b>

\*Including routine reference tests and confirmation tests, different methods were used: cobas® 4800 BRAF V600 Mutation Test (Roche), BRAF RGQ PCR Kit (Qiagen), BRAF StripAssay® V600E (Viennalab), Sanger sequencing, digital droplet PCR, and several inhouse BRAF tests (based on high-resolution melting, allele-specific and wild-type blocking real-time PCR).

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**Idylla™ BRAF Posters & Publications**

- Devogelaere B. et al. BRAF V600 mutation testing on FFPE samples using a novel fully integrated molecular diagnostics platform. Poster AACR 2013.
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