

Simple, rapid, highly sensitive diagnostics at hand

**BRAF**



# Idylla™

## BRAF Mutation Test

# BRAF

About 50 percent of all melanomas harbor mutations in the *BRAF* oncogene. Idylla™, Biocartis' fully automated, real-time PCR, offers fast and easy access to high-quality biomarker data. Idylla™ BRAF Mutation Test allows detection of BRAF mutations directly from FFPE <sup>(1)</sup> tissue sections in 90 minutes with less than 2 minutes hands-on time. A game-changing technology when time matters most.

**"Idylla™ gives you an answer in an absolutely unprecedented time frame."**

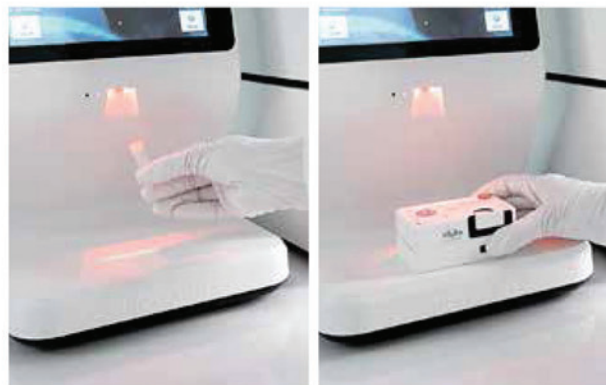
**Filip Janku, M.D., Ph.D.**

Oncologist at MD Anderson  
Cancer Center, Texas

(1) Formalin-fixed paraffin-embedded

## Outstanding ease of use

-  Less than 2 minutes hands-on time
-  90 minutes total turnaround time
-  Directly from FFPE tissue sections



① Scan sample and cartridge



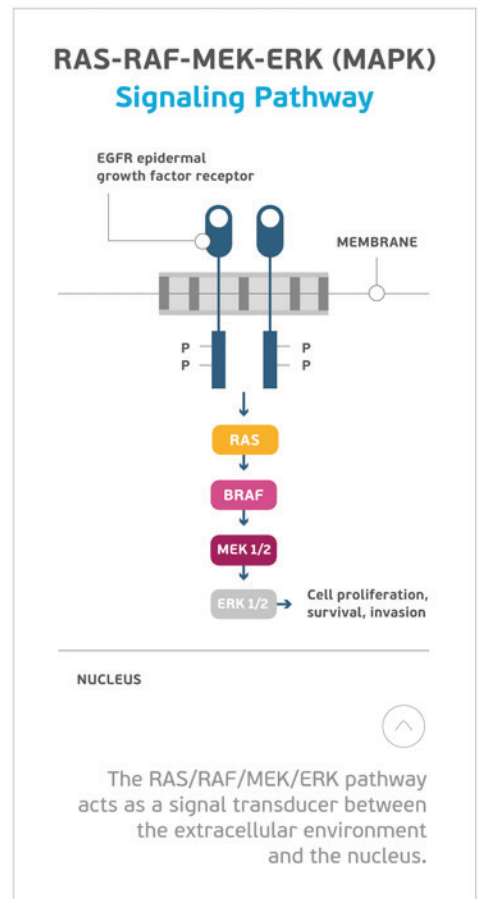
② Load sample into the cartridge



③ Insert the cartridge into the Idylla™ system

# About BRAF

- BRAF is a member of the RAF family of serine/threonine kinases. The RAS/RAF/MEK/ERK pathway acts as a signal transducer between the extracellular environment and the nucleus. Extracellular signals, such as hormones and growth factors, interact with their receptors to activate members of the RAS family. Active BRAF signals through MEK activate ERK, which in turn activates downstream transcription factors that induce processes like cell proliferation, growth and apoptosis.
- Mutations in the *BRAF* gene are found in approximately 7% of cancers.<sup>1</sup>
- BRAF mutations can induce the progression of several types of cancers, including melanoma. About 50% of melanoma patients harbor BRAF mutations. In more than 90% of the cases, BRAF mutations are located in the BRAF V600 codon (V600E and V600K).<sup>2</sup>
- Targeted therapies have shown response rates in up to half of metastatic melanomas harboring these BRAF V600 mutations.<sup>3</sup>
- Tumor mutation status is usually assessed starting from FFPE tumor tissue material. Currently the process from sample to result is labor-intensive, requiring multiple steps. Most laboratories do not perform these tests in-house, but send them out to specialized centers, where samples are batched in order to optimize costs.





# Highly sensitive and standardized

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 uses DNA liberated from formalin-fixed paraffin-embedded (FFPE) tissue sections from human melanoma tumor cells. The test is a sample-to-result real-time PCR.<sup>4</sup>

The **Idylla™ BRAF Mutation Test** has demonstrated excellent analytical sensitivity. It can detect BRAF V600E, E2, D, K, R and M mutations at an analytical sensitivity of 1% of mutant in wild type background in FFPE samples. Studies demonstrated excellent concordance with Illumina MiSeq deepsequencing technology (100%), with Roche's Cobas® BRAF V600 Mutation Test (96.7%) and with CLIA laboratory PCR-based sequencing and Sequenom™ MassARRAY (98%).<sup>5,6,7</sup> A clinical validation study comparing Idylla™ with Pyrosequencing™ showed 97.9% agreement between both assays.<sup>8</sup> (see below)

Allele detection	BRAF V600E (c.1799T>A) BRAF V600E2 (c.1799_1800TG>AA) BRAF V600D (c.1799_1800TG>AT, c.1799_1800TG>AC)	
	BRAF V600K (c.1798_1799GT>AA) BRAF V600R (c.1798_1799GT>AG) BRAF V600M (c.1798G>A)	
	BRAF wild type (c.1799T)	
	Sample Processing Controls	
Sample type	FFPE tissue sections (5µm to 10µm glass mounted FFPE slides or FFPE slices)	
Analytical sensitivity	1% mutant in wild type background	
Between laboratory reproducibility (240 results at 3 sites)	BRAFV600E low positive (3.5%) BRAF V600K low positive (5%)	100% agreement 100% agreement
Total turnaround time	90 minutes	

Idylla™ BRAF Mutation Test	Pyrosequencing				
	V600E/E2/D mutation detected	V600K/R/M mutation detected	Mutation detected G *	No mutation detected	Total
V600E/E2/D mutation detected	89	0	0	4	93
V600K/R/M mutation detected	0	17	0	1	18
No mutation detected	0	0	1	124	125
Total	89	17	1	129	236

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

## References

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# About Idylla™

Biocartis' fully automated, real-time PCR-based molecular system offers fast and easy access to high-quality biomarker data.

- FFPE tissue 'sample to result' in 90 minutes
- Less than 2 minutes hands-on time
- All reagents integrated within the cartridge
- Contamination-controlled design
- No manual deparaffinization required
- Sample processing controls in all PCR chambers
- High specificity & sensitivity
- Detection of most frequent V600 mutations: V600E/E2/D and V600K/R/M



**Order information**

Idylla™ BRAF Mutation Test CE-IVD	6 cartridges/box	Catalog# A0010/6
Idylla™ Instrument CE-IVD	1 unit	Catalog# P0010
Idylla™ Console CE-IVD	1 unit	Catalog# P1010

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Idylla™ and Idylla™ BRAF Mutation Test are CE-marked IVDs.  
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