

The first and only fully automated liquid biopsy assay

**ctBRAF**

**Revolution**  
in liquid biopsy  
cancer research

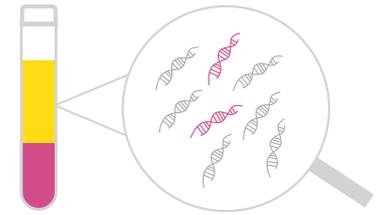


# Idylla™

## ctBRAF Mutation Assay

The easiest solution to implement liquid biopsy testing

# The potential of liquid biopsy



The use of liquid biopsies has the potential to transform cancer diagnostics and extend the application from disease confirmation to **patient monitoring** and even **early diagnosis**.

Taking a tissue biopsy is an invasive method of obtaining a patient sample, with an increased risk for complications compared to a blood draw. Moreover, a tissue biopsy only represents a single location of the primary tumor or a single metastasis and doesn't represent heterogeneity found in different nodules or areas of the tumor.

A less invasive, more convenient, rapid and cost-effective way of obtaining this information is using plasma samples for the diagnosis and management of cancer. In the plasma of most cancer patients, circulating tumor DNA (ctDNA) can be found with the same biomarker profile as the tumor tissue, making this the ideal sample type for a wide range of applications like mutation detection and disease monitoring<sup>1</sup>. Some tissue biopsies are difficult to reach or provide insufficient material for genotyping<sup>2</sup>. In these cases, liquid biopsies could become the primary solution for proper diagnosis. During or after effective treatment, where the tumor is hardly or not detectable, liquid biopsies would be exquisitely suited for monitoring treatment efficacy and early detection of relapse<sup>3,4,5</sup>.



## Mutation detection

Detection of mutated ctDNA in plasma can complement, or even replace, in certain situations, tissue mutation detection.



## Monitoring

Monitoring of treatment by means of ctDNA in plasma is a convenient way of regular testing of genetic changes, which is not practically feasible by means of solid biopsies. First, the rate of reduction of targeted mutations can be analysed and patients can be categorized in rapid and slow responders to treatment. Secondly, the emergence of the original targeted mutations and/or new upcoming resistance mutations can be monitored in responding patients. Finally, patients with complete responses can be further monitored for minimal residual disease.

**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 by analyzing tumor or ctDNA, thereby saving precious time."**

# ctBRAF, the first and only fully automated liquid biopsy assay

- Activating mutations in the *BRAF* gene are observed in about 8% of all cancers<sup>6</sup> 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, lung cancer, thyroid cancer, colorectal cancer, hairy cell leukemia and ovarian cancer.
- These cancers associated BRAF mutations can now be studied in plasma using the Idylla™ ctBRAF Mutation Assay, an assay which allows the detection of BRAF mutations directly from 1 ml of plasma in approximately 100 minutes with less than 1 minute hands-on time. The assay detects 2 different mutations in codon 600 of the *BRAF* oncogene, which can result in any of 7 codon changes in the BRAF protein: V600E, E2, D, D2 and V600 K, R, M.

Easy and accessible liquid biopsy testing is now within reach with the Idylla™ ctBRAF Mutation Assay.

Discover the benefits:

- ◆ Directly from 1 ml plasma sample into the cartridge
- ◆ Less than 1 minute hands-on time
- ◆ Total turnaround time of around 100 minutes
- ◆ All BRAF V600 mutations present in 1 cartridge, no need to develop different assays for each mutation.
- ◆ All mutations detected in duplicate
- ◆ Semi-quantitative results
- ◆ Highly sensitive and standardized



① Scan sample and cartridge



② Pipet plasma sample into the cartridge



③ Insert the cartridge into the Idylla™ system

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# Highly standardized

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The **Idylla™ ctBRAF Mutation Assay**, performed on the Biocartis Idylla™ System, is a for “Research Use Only” Assay for the semi-quantitative detection of V600E/E2/D and V600K/R/M mutations in codon 600 of the *BRAF* gene. The Idylla™ ctBRAF Mutation Assay extracts and amplifies BRAF circulating tumor DNA (ctDNA) from 1 ml of plasma. The Assay is a sample-to result real-time PCR.

Allele detection	V600E (c.1799T>A) V600E2 (c.1799_1800TG>AA) V600D (c.1799_1800TG>AC, c.1799_1800TG>AT)
	V600K (c.1798_1799GT>AA) V600R (c.1798_1799GT>AG) V600M (c.1798G>A)
	BRAF wild type (c.1799T)
Sample type	1 ml of EDTA plasma (prepared within 4 hours after blood collection)
Total turnaround time	approx. 100 minutes
Result Reporting	Genotype call and Cq values

## References

- 1 Genotyping cell-free tumor DNA in the blood to detect residual disease and drug resistance. Giulia Siravegna and Alberto Bardelli; *Genome Biology* 2014, 15:449
- 2 Detection of Circulating Tumor DNA in Early- and Late-Stage Human Malignancies. Chetan Bettegowda et al.; *Science Translational Medicine* 2014, Vol 6 Issue 224
- 3 Actionable Mutations in Plasma Cell-Free DNA in Patients with Advanced Cancers Referred for Experimental Targeted Therapies. Janku et al; *Oncotarget* 2015, Vol. 6 No. 15
- 4 Liquid biopsy: monitoring cancer-genetics in the blood. Crowley E. et al; *Nature Reviews Clinical Oncology* 2013 10, 472-484
- 5 Analysis of circulating DNA and protein biomarkers to predict the clinical activity of regorafenib and assess prognosis in patients with metastatic colorectal cancer: a retrospective, exploratory analysis of the CORRECT trial. Tabernero et al.; *The Lancet Oncology* 2015, Vol. 16 No. 8
- 6 Mutations of the BRAF gene in human cancer. Helen Davies et al.; *Nature* 2002, 417, 949-954



# About Idylla™

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

- Maximum flexibility:
  - FFPE and plasma testing on the same platform
- All reagents integrated within the cartridge
- Contamination-controlled design
- All processing steps in one cartridge (lysis, extraction, real-time PCR)
- Random access, no batching needed/required
- Standardized way of working
- Scalable, up to 8 instruments can be connected to one console
- High sensitivity & specificity



## Order information

Idylla™ ctBRAF Mutation Assay RUO	6 cartridges/box	Catalog# A0071/6
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

[www.biocartis.com](http://www.biocartis.com)

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