

Enabling personalized cancer care

Oncobit™ PM for personalized monitoring of melanoma

Imaging data is often difficult to interpret and may not accurately reflect disease progression. Clinical studies have shown that circulating tumor DNA can improve the understanding of patient prognosis and is an appropriate biomarker for monitoring disease recurrence, progression and response to therapy.*

Oncobit™ PM is a digital PCR platform technology consisting of optimized PCR reagents and a proprietary analysis software. This complete solution enables the sensitive detection of specific cancer markers in circulating tumor DNA, as well as an unbiased and automatic report generation, providing a quantitative measure of circulating tumor DNA including the mutant allele frequency.

- **Fully validated with clinical samples according to European guidelines**
- **Unbiased and automatic data analysis and reporting**
- **High accuracy demonstrated with > 1 000 patient samples**
- **Precise quantification, e.g. standard error of 0.23% at 1.5% MAF** for BRAFV600E*****
- **High sensitivity, detecting as low as 2 copies per 10,000 wild-type copies (equivalent to 0.02% MAF**)**

Target gene	Single-plex assays for	Limit of Blank (molecules)	Typical Indication
<i>BRAF</i>	V600E/K/R/E2/D	2.8/2.8/1.4/2.7/2.5	Cutaneous melanoma
<i>NRAS</i>	Q61K/L/R	1.8/1.8/1.8	Cutaneous melanoma
<i>GNAQ</i>	Q209P/L	1.8/1.8	Uveal melanoma
<i>GNA11</i>	Q209L	1.8	Uveal melanoma
<i>SF3B1</i>	R625H/C	5.7/7.5	Uveal melanoma

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* Please find references on the back
** Mutant allele frequency
*** Input material of 18ng cfDNA



For professional use only.
According to the In Vitro
Diagnostic Regulation (EU
2017/746).



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