



Press Release

Oncobit Receives European Regulatory Approval (IVDR Certification) for Melanoma ctDNA Monitoring Tests

Zurich, Switzerland - 10.06.2024 - Oncobit AG, a MedTech spin-off from the University of Zurich developing cancer monitoring assays to improve personalized cancer care, proudly announces its In Vitro Diagnostic Regulation (IVDR) certification, which allows Oncobit to CE mark its Oncobit™ PM melanoma test suite and offer it for clinical use. Oncobit™ PM is designed to detect specific cancer markers in the tumor-derived fraction of circulating cell-free DNA (ctDNA) isolated from the blood of melanoma patients. Oncobit™ PM tests detect specific cancer hot spot mutations in the genes *BRAF*, *NRAS*, *GNAQ*, *GNA11*, and *SF3B1*, critical for cutaneous and uveal melanoma.

IVDR certification confirms that Oncobit™ PM meets stringent European regulatory requirements for safety, quality, and performance, underlining the company's commitment to delivering reliable and state-of-the-art cancer monitoring solutions, and is not only critical for market entry in Europe but also Australia.

Oncobit™ PM leverages advanced digital PCR technology to provide high sensitivity and specificity in the detection and quantification of ctDNA from blood samples. The product includes proprietary digital PCR reagents and software enabling a robust and standardized data analysis and interpretation. Oncobit™ PM is minimally invasive, cost-effective, has a rapid turnaround time and is designed for personalized monitoring of disease progression and treatment response in melanoma patients.

"Achieving IVDR certification is a significant milestone for Oncobit, especially as IVDR certification can be challenging, and we are thrilled to offer the first IVDR-certified ctDNA monitoring solution for these melanoma markers," said Dr. Claudia Scheckel, CEO of Oncobit. "This certification not only validates the robustness and reliability of our assays but also underscores our dedication to enhancing personalized cancer care. We are committed to providing healthcare professionals with the precise tools they need to make informed decisions and improve patient outcomes."

Web links:

<https://oncobit.com>

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