Personalis Enables Global Biopharma Support with CE-IVD Marked Specimen Collection Kits

June 9, 2026

Regulatory milestone for specimen collection kits enables global deployment of Personalis' ultrasensitive MRD detection (Next Personal®) for drug development programs

FREMONT, Calif.--(BUSINESS WIRE)--Jun. 9, 2026-- Personalis, Inc. (Nasdaq: PSNL), a leader in advanced genomics for precision oncology, today announced that its Personalis EDTA Blood Collection Kit and Personalis cfDNA Blood Collection Kit have obtained Class A CE-IVD marking in compliance with the European Union's In Vitro Diagnostic Regulation (IVDR).

The CE Mark represents an important regulatory milestone, ensuring that clinical trial sites throughout the European Union and Great Britain can use these collection kits for interventional studies. These kits are specifically designed to maintain the integrity of blood samples required for high-performance genomic analysis, including the company's ultrasensitive Minimal Residual Disease (MRD) testing with NeXT Personal.

"Our biopharma partners are looking for more than just data; they are looking for a global partner capable of supporting their clinical trials," said Chris Hall, CEO of Personalis. "Securing CE-IVD marking of the specimen collection kits is an important milestone that signals that Personalis is poised to support large-scale, global clinical trials. By standardizing the pre-analytical phase of testing, we ensure that the unprecedented sensitivity of NeXT Personal is available to drug developers on a global level, providing the clear, reliable signals they need to bring new therapies to patients faster."

About Personalis, Inc.

At Personalis, we are transforming the active management of cancer through breakthrough personalized testing. We aim to drive a new paradigm for cancer management, guiding care throughout the patient journey. Our highly sensitive assays combine tumor-and-normal profiling with proprietary algorithms to deliver advanced insights even as cancer evolves over time. Our products are designed to detect minimal residual disease (MRD) and recurrence at the earliest timepoints, enable selection of targeted therapies based on ultra-comprehensive genomic profiling, and enhance biomarker strategy for drug development. Personalis is based in Fremont, California. To learn more, visit www.personalis.com and connect with us on LinkedIn and X (Twitter).

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements include all statements that are not historical facts, including statements relating to: the attributes, advantages and sensitivity of the NeXT Personal test, our ability to drive a new paradigm for cancer management and support large-scale global clinical trials, and the design of Personalis' products. Such forward-looking statements involve known and unknown risks and uncertainties and other factors that may cause actual results to differ materially from any anticipated results or expectations expressed or implied by such statements, including the risks, uncertainties and other factors that relate to Personalis' ability to demonstrate attributes or advantages of the NeXT Personal test, including the NeXT Personal MRD assay remaining unique in its ability to detect traces of cancer in the ultrasensitive range; the availability of NeXT Personal to drug developers globally and its ability to help them bring new therapies to patients faster; the rate of adoption and use of the NeXT Personal test; changes in health care policy, which could increase Personalis' costs, decrease Personalis' revenue, and impact sales of and reimbursement for Personalis' tests; the impact of competition and macroeconomic factors on Personalis' business; the partnering and/or collaboration arrangements that Personalis has entered into or may enter into in the future may not be successful, or may terminate, which could adversely impact Personalis' business or affect its ability to develop and commercialize its services and products; having a limited number of suppliers; and customer concentration. These and other potential risks and uncertainties that could cause actual results to differ materially from the results predicted in these forward-looking statements are described under the captions "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" in Personalis' Annual Report on Form 10-K for the year ended December 31, 2025, filed with the Securities and Exchange Commission (SEC) on February 26, 2026, and Quarterly Report on Form 10-Q for the quarter ended March 31, 2026, filed with the SEC on May 7, 2026. All information provided in this release is as of the date of this press release, and any forward-looking statements contained herein are based on assumptions that we believe to be reasonable as of this date. Undue reliance should not be placed on the forward-looking statements in this press release, which are based on information available to us on the date hereof. Personalis undertakes no duty to update this information unless required by law.

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