



Caris Life Sciences Submits Application to New York State Department of Health for Caris Assure Blood-Based Testing Authorization

May 8, 2026

IRVING, Texas, May 8, 2026 /PRNewswire/ -- [Caris Life Sciences](#)® (NASDAQ: CAI), a leading patient-centric next-generation AI TechBio company and precision medicine pioneer, today announced that it has submitted an application to the New York State Department of Health (NYSDOH) Clinical Laboratory Evaluation Program (CLEP), administered through the Wadsworth Center, seeking authorization to perform Caris Assure®, its blood-based molecular profiling test, on specimens originating from New York State.

Caris Assure is a blood-based molecular profiling test designed to support comprehensive biomarker analysis using a minimally invasive blood sample. Caris Assure uses circulating nucleic acids sequencing (cNAS) to analyze the whole exome (DNA) and whole transcriptome (RNA) of 22,000 genes. This comprehensive test identifies tumor alterations, clonal hematopoiesis (CH) and inherited variants, pharmacogenomic alterations, microsatellite instability (MSI) and tumor mutational burden (TMB).

The submission initiates the formal review process required by New York State for clinical laboratories seeking to perform testing on specimens collected from New York patients. Through the Wadsworth Center, CLEP conducts comprehensive reviews of laboratory permits and laboratory-developed tests to evaluate analytical validation, quality systems, personnel qualifications and compliance with applicable state regulations.

"Caris is committed to meeting the highest standards for laboratory quality, validation and regulatory compliance," said [David Spetzler](#), MS, PhD, MBA, President of Caris Life Sciences. "This submission of Caris Assure for review through the New York State Department of Health's Wadsworth Center reflects our disciplined approach to expanding access to our technologies in a manner that demonstrates the rigor, responsibility and focus on the patient that define Caris Life Sciences and guide our work in the markets we serve."

At this time, no determination has been made by NYSDOH, and Caris Assure is not authorized for use on blood-based specimens originating from New York State unless and until CLEP authorization is granted.

Caris operates a CAP-accredited, CLIA-certified clinical laboratory and performs testing in jurisdictions where it is authorized to do so, in accordance with all applicable federal, state, and local regulations. Any future availability of Caris Assure in New York State will be contingent upon completion of the CLEP review process administered by the Wadsworth Center and receipt of the appropriate authorization.

About Caris Life Sciences

Caris Life Sciences® (Caris) is a leading, patient-centric, next-generation AI TechBio company and precision medicine pioneer actively developing and commercializing innovative solutions to transform healthcare. Through comprehensive molecular profiling (Whole Genome, Whole Exome and Whole Transcriptome Sequencing), advanced AI and machine learning, Caris has created the large-scale, multimodal clinico-genomic database and computing capability needed to analyze and further unravel the molecular complexity of disease. This convergence of next-generation sequencing, AI and machine learning technologies and high-performance computing provides a differentiated platform for developing the latest generation of advanced precision medicine diagnostic solutions for early detection, diagnosis, monitoring, therapy selection and drug development.

Caris was founded with a vision to realize the potential of precision medicine to improve the human condition. Headquartered in Irving, Texas, Caris has offices in Phoenix, New York, Cambridge (MA), Tokyo, Japan and Basel, Switzerland. Caris or its distributor partners provide services in the U.S. and other international markets.

Forward Looking Statements

This press release contains forward-looking statements, within the meaning of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. All statements other than statements of historical facts contained in this press release are forward-looking statements, including statements regarding our business, solutions, plans, objectives, goals, industry trends, financial outlook and guidance. In some cases forward-looking statements can be identified by words such as "may," "will," "should," "would," "expect," "plan," "anticipate," "could," "intend," "target," "project," "potential," "contemplate," "believe," "estimate," "predict," or "continue" or similar expressions.

You should not rely upon forward-looking statements as predictions of future events. Although we believe that the expectations

reflected in these forward-looking statements are reasonable based on information currently available to us, we cannot guarantee that the future results, discoveries, levels of activity, performance or events and circumstances reflected in forward-looking statements will be achieved or occur. Forward-looking statements involve known and unknown risks and uncertainties, some of which are beyond our control. Risks and uncertainties that could cause our actual results to differ materially from those indicated or implied by the forward-looking statements in this press release include, among other things: our future financial performance, results of operations or other operational results or metrics; development, analytical and clinical validation, timing and performance of future solutions by us and our competitors; commercial market acceptance for our solutions, including acceptance of preventive as well as diagnostic testing paradigms, and our ability to meet resulting demand; the rapidly evolving competitive environment in which we operate; third-party payer reimbursement and coverage decisions related to our solutions; risks related to data management, storage, and processing capabilities and our ability to integrate and deploy artificial intelligence and advanced data analytics technologies; our ability to protect and enhance our intellectual property; regulatory requirements, decisions or approvals (including the timing and conditions thereof) related to our solutions, including our application for New York State Department of Health approval for Caris Assure; reliance on third-party suppliers; risks related to data security, patient privacy, and compliance with healthcare data protection regulations as well as potential cybersecurity threats to our data platforms; our compliance with laws and regulations; the outcome of government investigations and litigation; risks related to our indebtedness; and our ability to hire and retain key personnel as well as risks, uncertainties; and other factors described in the section titled "Risk Factors" and elsewhere in our Annual Report on Form 10-K filed on March 3, 2026, and in our other filings we make with the SEC from time to time. We undertake no obligation to update any forward-looking statements to reflect changes in events, circumstances or our beliefs after the date of this press release, except as required by law.

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