

PRESS RELEASE

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Austrian Company Wholomics Reports High Early-Stage Sensitivity in Blinded Validation of Multi-Cancer Blood Test

Locked serum-based assay detected 95.0% of Stage I cancers and 93.1% of cancers overall at 99.0% specificity across ten solid tumor types in an independent blinded validation presented at ASCO 2026; results have not yet been peer-reviewed

RIED IM INNKREIS, Austria – Wholomics GmbH, an Austrian biotechnology company developing a serum-based multi-cancer early detection test, today reported results from an independent blinded validation study presented at the 2026 Annual Meeting of the American Society of Clinical Oncology (ASCO) in Chicago, Abstract 10536.

The validation showed high sensitivity for early-stage disease, including Stage I cancers, which remain among the most challenging targets for blood-based cancer detection. In the study, the Wholomics assay detected 38 of 40 Stage I cancers, corresponding to a Stage I sensitivity of 95.0%.

Unlike many multi-cancer early detection assays currently in development, which are based primarily on circulating cell-free DNA, the Wholomics test measures metabolomic, lipidomic, and proteomic features in serum. The approach is designed to capture systemic biological signals associated with early tumor development.

Before testing began, the full diagnostic assay was locked, including sample profiling, quality control procedures, the biomarker feature set, the machine-learning model, and the decision threshold. The locked assay was then applied to a blinded cohort of 216 samples provided by the Masaryk Memorial Cancer Institute. The cohort included 116 cancer cases across ten solid tumor types, including pancreatic, colorectal, gastric, and gynecological cancers, as well as 100 controls with screening-relevant conditions.

Key results from the blinded validation included:

- **99.0% specificity**, corresponding to one false-positive result among 100 controls
- **93.1% overall sensitivity** across ten solid tumor types
- **95.0% Stage I sensitivity**, with 38 of 40 Stage I cancers detected
- **Area under the receiver operating characteristic curve of 0.991**

The results come from a blinded case-control validation study. Prospective studies are underway to evaluate the assay's performance in real-world clinical settings. The findings have not yet undergone peer review.

Early-stage detection remains a central challenge for blood-based cancer screening. Several multi-cancer early detection approaches have shown more limited sensitivity in early disease, particularly in prospective settings. If confirmed in larger prospective studies, the Wholomics results could represent an important step toward blood-based detection of multiple cancers at a stage when treatment is often more effective.

WHOLOMICS

“Detecting cancer early is where a blood test could have the greatest clinical impact, and it is also where the field has faced some of its greatest challenges,” said Patrick Strasser, CEO and co-founder of Wholomics. “These blinded validation results are an encouraging early signal. Our focus now is on confirming the findings in prospective studies.”

The validation was conducted in collaboration with the Masaryk Memorial Cancer Institute and the Medical University of Graz. Study co-author Luke R. Pike, MD, DPhil, of Memorial Sloan Kettering Cancer Center, contributed to the analysis and interpretation of the results.

The company’s development cohort included more than 1,400 individuals and more than 13 cancer types across multiple European centers. Wholomics is now inviting clinicians and cancer centers to collaborate on prospective evaluations of the assay in screening and high-risk monitoring settings.

About Wholomics

Wholomics GmbH is an Austrian biotechnology company developing a next-generation, serum-based multi-cancer early detection test. The company operates across Austria and the United States.

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