

University of Arizona Leads Landmark Clinical Study Evaluating EPISSEK Pleural Fluid Liquid Biopsy Cancer Test

University of Arizona Pulmonary Division Leads Landmark Clinical Study Evaluating Precision Epigenomics' Pleural Fluid (EPISSEK-MPE) Cancer Detection Test

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Billie Bixby, MD

molecular diagnostics company developing innovative epigenetic liquid biopsy technologies, today announced the launch of the CAMEO (Cell-free Analysis of Methylation in Effusion for Oncology) study in collaboration with the [Division of Pulmonary, Allergy, Critical Care and Sleep Medicine](#) at the [University of Arizona College of Medicine – Tucson](#).

The CAMEO study is the first real-world clinical utilization study designed to evaluate the performance of Precision Epigenomics' EPISSEK-Malignant Pleural Effusion (EPISSEK-MPE) liquid biopsy test designed for earlier cancer

detection. The study will enroll approximately 200 participants presenting with benign, indeterminate, and malignant pleural effusions — an accumulation of fluid between the lung and chest wall often caused by cancer. The primary objective of the study is to evaluate the clinical sensitivity and specificity of the EPISSEK-MPE test for detecting malignancy in pleural effusion samples across multiple cancer types and disease stages, particularly in cases where standard diagnostic approaches may yield inconclusive results.

Pleural effusions are a common clinical problem in patients with suspected malignancy, yet conventional diagnostic methods — including cytology and imaging — lack sensitivity in certain cases. The EPISSEK-MPE test analyzes cell-free DNA methylation signatures in pleural fluid, offering a novel molecular approach that may improve diagnostic accuracy and assist clinicians in distinguishing malignant from benign effusions. The test represents the culmination of more than two years of research and assay development conducted in partnership with the University of Arizona. The platform is supported by data generated from test-development studies involving more than 300 participants, funded in part through the National Cancer Institute Small Business Innovation Research Program. Precision Epigenomics anticipates that the EPISSEK-MPE

test will become commercially available in 2027, pending completion of clinical validation and regulatory considerations.

The CAMEO study represents an important step toward generating clinical evidence to support the adoption of a molecular liquid biopsy approach for evaluating pleural effusions in routine medical practice. “Our goal is to generate rigorous clinical evidence that supports reimbursement for this new diagnostic approach while improving patient care,” said Billie Bixby, MD, director of the Interventional Pulmonology Program at Banner – University Medical Center Tucson and an assistant clinical professor in the U of A Pulmonary Division. “Evaluating this technology in real-world clinical settings will help determine how molecular diagnostics can complement existing tools and improve diagnosis for patients with pleural effusions.”

“Precision Epigenomics is committed to advancing innovative liquid biopsy tests that address important unmet needs in cancer patient care,” said Richard Bernert, MD, Chief Operating Officer and Vice President of Precision Epigenomics. “Collaborating with leading academic medical centers such as the University of Arizona is essential to understanding how our technology performs in real-world clinical practice. The CAMEO study will help inform new molecular approaches to cancer detection and address gaps in standard-of-care procedures.”

About Precision Epigenomics

Precision Epigenomics, with headquarters in Tucson, Arizona, operates a CLIA-certified and CAP-accredited clinical laboratory, ensuring its diagnostic tests meet rigorous standards for quality, analytical performance, and reliability.

Forward-Looking Statements

This press release contains forward-looking statements regarding the development, clinical evaluation, and potential commercialization of diagnostic tests developed by Precision Epigenomics, including the EPISSEK-MPE test and the outcomes of the CAMEO study. These statements are based on current expectations and assumptions and are subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied. Factors that may affect such outcomes include clinical study results, regulatory considerations, reimbursement decisions, and other risks associated with the development and commercialization of diagnostic technologies. Precision Epigenomics undertakes no obligation to update forward-looking statements except as required by applicable law.

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