

October 29, 2025



ProPhase Labs Announces Publication of BE-Smart Esophageal Cancer Study in the Official Journal of the American College of Gastroenterology

Peer-Reviewed Study Conducted in Collaboration with Mayo Clinic Demonstrates 100% Sensitivity and Strong Predictive Power for Esophageal Cancer Progression

Early Access Programs and Physician Onboarding Initiatives Expected to Begin in Early 2026

UNIONDALE, NY, Oct. 29, 2025 (GLOBE NEWSWIRE) -- ProPhase Labs, Inc. (NASDAQ: PRPH) today announced that its study, "Assessing Risk of Progression in Barrett's Esophagus Using a Mass-Spectrometry-Based Proteomic Panel," has been published online in *Clinical and Translational Gastroenterology*, the official journal of the American College of Gastroenterology (ACG).

The publication presents full clinical validation data supporting BE-Smart, an 8-protein, mass-spectrometry-based proteomic assay developed for risk stratification of patients with Barrett's Esophagus (BE). Conducted in collaboration with the Mayo Clinic, the study demonstrates that BE-Smart provides a highly accurate, molecularly driven method for identifying BE patients most likely to progress to high-grade dysplasia or esophageal adenocarcinoma. These findings position BE-Smart as a next-generation molecular screening tool ready for broad clinical adoption and reimbursement discussions.

Key findings include:

- 100% sensitivity for identifying patients who later developed esophageal adenocarcinoma, indicating that BE-Smart successfully detected all patients who ultimately progressed to esophageal cancer, with no false negatives observed.
- BE-Smart demonstrated strong predictive performance across multiple analyses, with an overall area under the curve (AUC) of 0.75, indicating solid diagnostic accuracy in distinguishing progressors from non-progressors. In the independent test cohort, the model achieved an AUC of 0.89, showing excellent reproducibility and generalizability. Most notably, for patients who progressed within three years, the test reached an AUC of 1.0, meaning it perfectly identified every individual who later developed advanced disease.
- Hazard ratio of 66.1 ($p = 0.00012$), meaning that patients classified as high-risk by BE-Smart were approximately 66 times more likely to progress to esophageal cancer than low-risk patients, demonstrating exceptionally strong predictive power and correlation with real-world clinical outcomes.
- The greatest clinical benefit was observed among patients with non-dysplastic Barrett's

Esophagus, individuals who show no histologic evidence of dysplasia yet still face unpredictable cancer risk. In this population, traditional histopathology offers limited prognostic insight, often leading to either overtreatment or delayed intervention. BE-Smart provided clear molecular risk stratification in these patients, identifying those silently trending toward disease progression while reassuring others at genuinely low risk.

Unlike legacy tissue-based assays that often require large biopsy volumes to generate sufficient analyte, BE-Smart delivers comprehensive molecular profiling from a minimal amount of tissue—requiring as little as one-tenth the material needed by existing tests. The assay is compatible with both forceps and brush biopsy specimens, accommodating the gastroenterologist's preferred method of tissue retrieval without altering the clinical workflow. Furthermore, it can be performed from standard formalin-fixed samples and evaluates novel protein signatures of cellular proliferation and immune signaling rather than long-established and non-specific histologic markers. By using a next-generation proteomic approach, BE-Smart delivers quantitative, reproducible results that complement and often outperform traditional histopathology methods that have remained largely unchanged for more than a century.

"Publication in the official journal of the American College of Gastroenterology underscores both the scientific rigor and clinical impact of BE-Smart," said **Ted Karkus**, CEO of ProPhase Labs. "ACG's other flagship journal previously published a landmark study that helped define the molecular screening era for esophageal disease. We believe BE-Smart represents the next evolution, offering a more precise, scalable, and tissue-efficient solution for gastroenterologists seeking to bring molecular precision into everyday care."

"You don't even need a microscope for our test," added Dr. Joe Abdo, Scientific Advisor at ProPhase Labs. "BE-Smart uses high-fidelity mass spectrometry that can detect and quantify dozens of biomarkers simultaneously from a single slice of tissue, generating a comprehensive molecular profile of the diseased esophageal microenvironment. We are excited to bring this high-throughput, multiplex platform into the fight against esophageal cancer by augmenting early detection."

ProPhase Labs is now advancing BE-Smart toward broad commercialization and clinical integration, focusing on laboratory partnerships, payer engagement, and expanded real-world studies in collaboration with leading gastroenterology networks. The company expects to begin early access programs and physician onboarding initiatives in early 2026.

Each year, more than twenty thousand Americans are diagnosed with esophageal cancer, a disease that often goes undetected until its later stages. By advancing tools like BE-Smart, ProPhase Labs aims to enable earlier identification of at-risk patients and improve outcomes through precision screening.

About BE-Smart

BE-Smart is a multiplex proteomic assay developed using quantitative mass spectrometry on microdissected esophageal biopsy specimens. It quantifies the expression of eight proteins associated with the risk of progression in Barrett's Esophagus and is fully compatible with routine FFPE tissue. BE-Smart represents the first publication from ProPhase Labs' **STLA (Stratify-to-Limit-Advance)** precision oncology pipeline.

About ProPhase Labs Inc.

ProPhase Labs Inc. (Nasdaq: PRPH) ("ProPhase") is a next-generation biotech, genomics and consumer products company. Our mission is to build a healthier world through bold innovation and actionable insight. We're revolutionizing healthcare with industry-leading Whole Genome Sequencing solutions, groundbreaking diagnostic development, such as our potentially life-saving test for the early detection of esophageal cancer, and a world class direct-to-consumer marketing platform for cutting edge OTC dietary supplements. We develop, manufacture, and commercialize health and wellness solutions to enable people to live their best lives. We are committed to executional excellence, smart diversification, and a synergistic, omni-channel approach. ProPhase Labs' valuable subsidiaries, their synergies, and significant growth underscore our potential for long-term value. www.ProPhaseLabs.com

Forward-Looking Statements

Except for the historical information contained herein, this document contains forward looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including statements regarding our strategy, plans, objectives and initiatives, including our expectations regarding the future revenue growth potential of each of our subsidiaries, our expected timeline for commercializing our BE-Smart Esophageal Cancer Test, our expectations regarding future liquidity events, the success of our efforts to collect accounts receivables and anticipated timeline for any payments relating thereto, and our ability to successfully transition into a consumer products company. Management believes that these forward-looking statements are reasonable as and when made. However, such forward-looking statements involve known and unknown risks, uncertainties, and other factors that may cause actual results to differ materially from those projected in the forward-looking statements. These risks and uncertainties include but are not limited to our ability to obtain and maintain necessary regulatory approvals, general economic conditions, consumer demand for our products and services, challenges relating to entering into and growing new business lines, the competitive environment, and the risk factors listed from time to time in our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q and any other SEC filings. These forward-looking statements are subject to risks and uncertainties and actual results may differ materially. Details about these risks and uncertainties can be found in our filings with the SEC. The Company undertakes no obligation to update forward-looking statements except as required by applicable securities laws. Readers are cautioned that forward-looking statements are not guarantees of future performance and are cautioned not to place undue reliance on any forward-looking statements.

This press release does not constitute an offer to sell or the solicitation of an offer to buy any securities.

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Source: ProPhase Labs, Inc.