

Acuamark Diagnostics Announces Two Peer-Reviewed Publications on Sequencing-Free Blood Test for Early Colorectal Cancer

Top models achieved 92% sensitivity at 97% specificity across Stages I-IV colorectal cancer in a validation subset — on a PCR-based assay



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[Acuamark Diagnostics, Inc.](#) ("AcuamarkDx" or "Acuamark"), a molecular diagnostics company developing blood-based tests for early cancer detection, today announced two peer-reviewed publications describing the development and initial clinical evaluation of its sequencing-free cell-free DNA (cfDNA) methylation platform in colorectal cancer (CRC), including early-stage disease.



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Bernard Peperstraete, MD, MBA, Co-Founder and CEO, Acuamark Diagnostics

Strong Initial Performance, Including Early-Stage Disease

The clinical study, published in [Cancer Prevention Research](#), evaluated plasma from 216 participants — 86 people with CRC and 130 healthy controls — using a 40-marker methylation panel read on qPCR. The 216 samples were divided into a 151-sample training subset and a separate 65-sample validation subset. In the study's validation subset, which included CRC cases spanning

Stages I-IV, the top-performing neural-network models achieved 92% sensitivity at 97% specificity. Across all 14 models evaluated, performance was consistent: validation sensitivity ranged from 81% to 92% and specificity from 85% to 97%.

Early-stage performance was a focus of the study. The early-stage validation subset comprised 11 cases with Stage I or II disease. Sensitivity for Stage I and II cases ranged from 90.9% to 100% across the four top-performing models of the 14 evaluated. Since the number of early-stage cases was limited, the authors noted that these figures require confirmation in larger cohorts.

The study also showed that cumulative methylation signals increased progressively from healthy

controls through advancing CRC stages, providing biological support for the methylation markers used by the assay.

The assay was not evaluated for detection of advanced adenomas. Acuamark is preparing a larger clinical verification study that will include evaluation of advanced adenoma detection. Its assays remain investigational and are not approved for clinical use.



“Early cancer detection is both a biology challenge and a deployment challenge,” said Bernard Peperstraete, MD, MBA, Co-Founder and CEO of Acuamark. “Unlocking Stage I and II detection on qPCR and dPCR answers both and puts early-cancer screening within reach of labs already running PCR. Our focus now is advancing to a larger clinical study alongside preparation for commercialization.”

Sequencing-Free by Design

The companion publication, published in the [Journal of Personalized Medicine](#), describes a multiplexed qPCR-based cfDNA methylation assay using enzymatic conversion. The approach avoids conventional bisulfite treatment, which can cause substantial DNA degradation — a particular concern when analyzing the small amounts of fragmented cfDNA found in blood.

The assay evaluates a panel of 40 CpG methylation markers associated with colorectal cancer and is compatible with both quantitative PCR (qPCR) and digital PCR (dPCR). Analytical testing demonstrated detection of methylated DNA at levels below 0.2%, while qPCR and dPCR produced concordant results.

Since the workflow uses PCR-based detection, it does not require sequencing, sequencing-library preparation, or extensive bioinformatic processing. This could ultimately make methylation-based liquid biopsy testing more accessible to laboratories equipped with standard molecular diagnostic instrumentation.

“These publications bring together several years of work aimed at developing a sensitive but practical way to detect cancer-associated methylation in blood,” said Francis Barany, Ph.D., Professor of Microbiology and Immunology at Weill Cornell Medicine, and Co-Founder and Senior Scientific Advisor at Acuamark. “An important feature of this approach is that we can interrogate multiple methylation markers without relying on next-generation sequencing. The results in colorectal cancer, particularly the ability to detect signals in early-stage disease, are

very encouraging and provide a strong rationale for evaluating the technology in larger clinical studies that come next.”

The Publications

□ A Neural Network–Enabled, Enzymatic cfDNA Methylation Assay for Colorectal Cancer Early Detection, Cancer Prevention Research.

<https://doi.org/10.1158/1940-6207.CAPR-26-0072>

□ Establishment and Performance Evaluation of a Multiplexed TET2–APOBEC-Mediated cfDNA Methylation Detection Workflow Using qPCR and dPCR Readouts, Journal of Personalized Medicine.

<https://doi.org/10.3390/jpm16050269>

About Acuamark Diagnostics, Inc.

Acuamark Diagnostics, Inc. is a molecular diagnostics company working to bring accurate, broadly scalable early cancer detection within reach for everyone. Its lead colorectal cancer program detects cancer-associated DNA methylation in blood with qPCR and dPCR readouts rather than sequencing. The assay is built to run on widely available, high-throughput laboratory instrumentation. The platform is being developed for transfer to clinical laboratory systems and future distributed-kit deployment, and is protected by an exclusively licensed, multi-layer patent estate. Acuamark’s assays are investigational and are not approved for clinical use.

For more information, visit www.acuamarkdx.com

Forward-Looking Statements

This release contains forward-looking statements, including statements regarding Acuamark’s plans for the continued development, clinical evaluation, regulatory advancement and potential commercialization of its investigational assays. These statements are based on Acuamark’s current plans, estimates and expectations as of the date of this release and are not guarantees of future performance or results. Forward-looking statements are subject to known and unknown risks and uncertainties that could cause actual results to differ materially from those expressed or implied, including risks relating to assay development, clinical validation, regulatory review, financing and commercialization; the possibility that clinical-study results may not support the intended uses of Acuamark’s assays or be replicated in subsequent studies; the ability to obtain required regulatory approvals or clearances; and the ability to obtain adequate funding. Additional risks and uncertainties may exist. Except as required by applicable law, Acuamark undertakes no obligation to update or revise these statements.

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