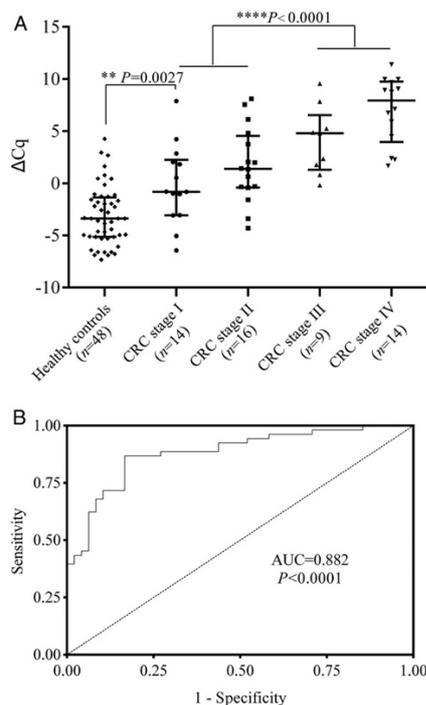


Apostle MiniMax Technology In Novel Liquid Biopsy Method for Detecting and Monitoring Colon Cancer, Published in PNAS

For immediate release

San Jose, CA, February 2, 2021 – Apostle Inc is pleased to announce that the company's Apostle MiniMax technology is used in the recent development of a novel liquid biopsy method for efficient detection and post-surgical monitoring of colon cancer, published in PNAS.



In this clinical research article, Jin et al. have developed a single-tube methylation-specific quantitative PCR assay (mqMSP) that uses 10 different methylation markers and is capable of quantitative analysis of plasma samples with as little as 0.05% tumor DNA. In a cohort of 179 plasma samples from colorectal cancer (CRC) patients, adenoma patients, and healthy controls, the sensitivity and specificity of the mqMSP assay were 84.9% and 83.3%, respectively. In a head-to-head comparative study, the mqMSP assay also performed better for detecting early-stage (stage I and II) and premalignant polyps than a published SEPT9 assay. In an independent longitudinal cohort of 182 plasma samples (preoperative, postoperative, and follow-up) from 82 CRC patients, the mqMSP assay detected ctDNA in 73 (89.0%) of the preoperative plasma samples.

Fig. 2. Quantification of ctDNA by the mqMSP assay in the technical evaluation cohort. (A) Methylation levels of plasma DNA as quantified by the mqMSP assay in CRC patients and healthy controls. The y-axis represents methylation levels ($\Delta Cq = Cq_{\dots} - Cq_{\dots}$), where a higher value represents a higher methylation level. Lines represent median with interquartile range. The methylation levels were significantly higher in CRC patients than in healthy controls, with significantly higher levels in patients in more advanced stages (III and IV) compared with patients in earlier stages (I and II). (B) ROC analysis for separating CRC patients ($n = 53$) and healthy controls ($n = 48$) with an AUC value of 0.882. (Source: <https://www.pnas.org/content/118/5/e2017421118>)

Postoperative detection of ctDNA (within 2 wk of surgery) identified 11 of the 20 recurrence patients and was associated with poorer recurrence-free survival (hazard ratio, 4.20; $P = 0.0005$). With subsequent longitudinal monitoring, 14 patients (70%) had detectable ctDNA before recurrence, with a median lead time of 8.0 mo earlier than seen with radiologic imaging. The mqMSP assay is cost-effective and easily implementable for routine clinical monitoring of CRC recurrence, which can lead to better patient management after surgery.

In this clinical study, plasma DNA extraction was performed using 2 to 5 mL of plasma with the Apostle MiniMax High-Efficiency cfDNA Isolation Kit. “We are very glad to see more and more novel liquid biopsy methods and applications are made available with the integration of the Apostle MiniMax high efficiency cfDNA isolation technology.” Said Dr. David Ge, CEO of Apostle Bio.

About Apostle Inc

Apostle Inc is a biotechnology company in San Jose, CA, a provider of innovative technologies and services for public health and life sciences. Apostle aims to develop innovative technologies in the space of liquid biopsy - the sampling and analysis of non-solid biological tissue, primarily blood, often utilizing circulating free DNA (cfDNA) as a biomarker. Apostle's innovations include Apostle MiniMax, a new scalable and automatable method to efficiently capture cfDNA from a standard blood draw; Apostle MagTouch, a nucleic acids isolation automation system, and Apostle MiniEnrich, a high-resolution DNA size enrichment technology using a magnetic nano-platform.

In 2020, the company responded to the COVID-19 pandemic to help our community fight together with a high quality, low cost, fast, automated, Apostle COVID-19 Viral RNA Isolation System.

More information can be found at www.apostle.bio.
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