



# Three-year Update of Real-World Evaluation of ColonAiQ for Colorectal Cancer Screening in Asymptomatic Individuals

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Abstract  
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## BACKGROUND

- Colorectal cancer (CRC) has emerged as a major public health concern in Yangzhou city due to the rapid development of local economy, the aging of population and the change of life style.
- Cancer screening, cancer and precancerous lesions early detection and offering early treatment are cost-effective measures to reduce the burden of colorectal cancer.
- Expert Consensus on community-based colorectal cancer screening in China recommends that the multi-locus blood-based assay targeting circulating tumor DNA methylation could be the preliminary CRC screening method for community individuals, and followed by colonoscopy for those with positive tests.

## OBJECTIVES

- The three-year PreC cohort study aims to assess the efficiency of ColonAiQ<sup>®</sup>, a blood-based assay targeting circulating tumor DNA methylation, in stratifying the risk for CRC and advanced adenoma (AA).
- Clinical trial identification: NCT05336539

## METHOES

- From January 2021 to December 2023, participants aged 40 to 80, residing in the local community of Yangzhou city, were recruited. The ColonAiQ<sup>®</sup> test, long with a risk questionnaire, served as the primary screening tool for all participants. Those individuals with a positive primary result were recommended to undergo colonoscopy.
- The numbers of positive ColonAiQ<sup>®</sup> test, colonoscopy compliance rate, and positive predictive values (PPV) for AA and/or CRC were evaluated.

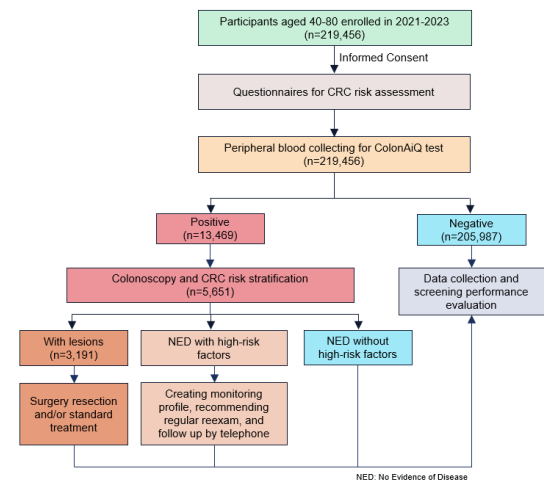


Figure1. Study Design and Enrollment

## OVERALL ENROLMENT

- Overall, 219,456 participants were invited and enrolled during three years.
- Of these, 13,469 (6.14%) tested positive with the ColonAiQ<sup>®</sup> assay.
- And then, 5,651 (41.96%) underwent colonoscopy, leading to pathological confirmation.
- Among the whole, 159,454 questionnaires for CRC risk assessment were completed and collected.
- The validated data from questionnaires was presented.

Table1. Population Characteristics

Factors	ColonAiQ <sup>®</sup> Positive	ColonAiQ <sup>®</sup> Negative
	N(%)	N(%)
<b>Sex</b>		
Male	6459(48.28)	72761(37.64)
Female	6919(51.72)	120557(62.36)
<b>Age</b>		
40-49	1284(9.94)	25147(14.20)
50-59	3456(26.75)	55929(31.57)
60-69	4206(32.56)	54816(30.95)
≥70	3972(30.75)	41238(23.28)
<b>Body Mass Index (BMI) *</b>		
Weight loss (<18.5)	219(2.82)	3173(3.19)
Normal (18.5≤BMI<25)	6175(79.43)	82316(82.88)
Overweight (25≤BMI<30)	1281(16.48)	12995(13.08)
Obese (BMI≥30)	99(1.27)	843(0.85)

\* The classifications for BMI are used by World Health Organization (WHO) for adults.

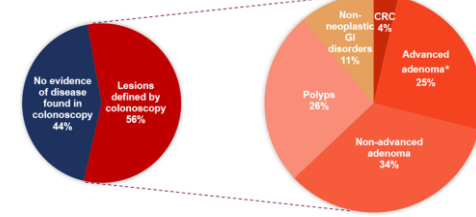


Figure2. Colonoscopy findings with pathological confirmation

- Advanced adenoma included tubular adenoma ≥10 mm in the largest dimension, adenoma of any size with villous features, high-grade dysplasia and sessile serrated lesions.
- Early colorectal neoplasm included advanced adenoma and stage 0-I CRC.
- All lesions detected by colonoscopy were counted proportionally.

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## RESULTS

- Among participants underwent colonoscopy, 3,191 (56.47%) participants had confirmed colonoscopy findings, including 117 (2.07%) cases of CRC, 806 (14.26%) cases of AA, 1086 (19.22%) cases of non-advanced adenoma, 824 (14.58%) cases of small polyps, and 358 (6.34%) cases of non-neoplastic colorectal disorders.
- Notably, the diagnosis rate of early colorectal neoplasm<sup>[1]</sup> reached 89.71%.
- PPV were estimated at 2.07% for CRC and 33.48% for adenoma (14.26% for AA), respectively.

## CONCLUSIONS

- The three-year real-world study confirms the utility of ColonAiQ<sup>®</sup> test in stratifying the risks of CRC and adenoma among the average-risk population.
- It significantly improved the compliance rate of colonoscopy, achieving 41.96% compared to the average rate of 17.25% in Cancer Screening Program in Urban China<sup>[2]</sup>.
- ColonAiQ<sup>®</sup> test demonstrates its potential to identify asymptomatic patients with neoplasm who may benefit from early treatments, such as endoscopic resection or surgery excision.
- These findings from the ongoing PreC study underscore the cost-effectiveness of a two-step screening strategy in community populations, which may influence future cancer screening policy.

- References**
  - Li Xiao et al. China Cancer, 2021, 30(5): 340-345.
  - Shi Jin et al. China Cancer, 2021, 30(8):591-599.
- Disclosures**  
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