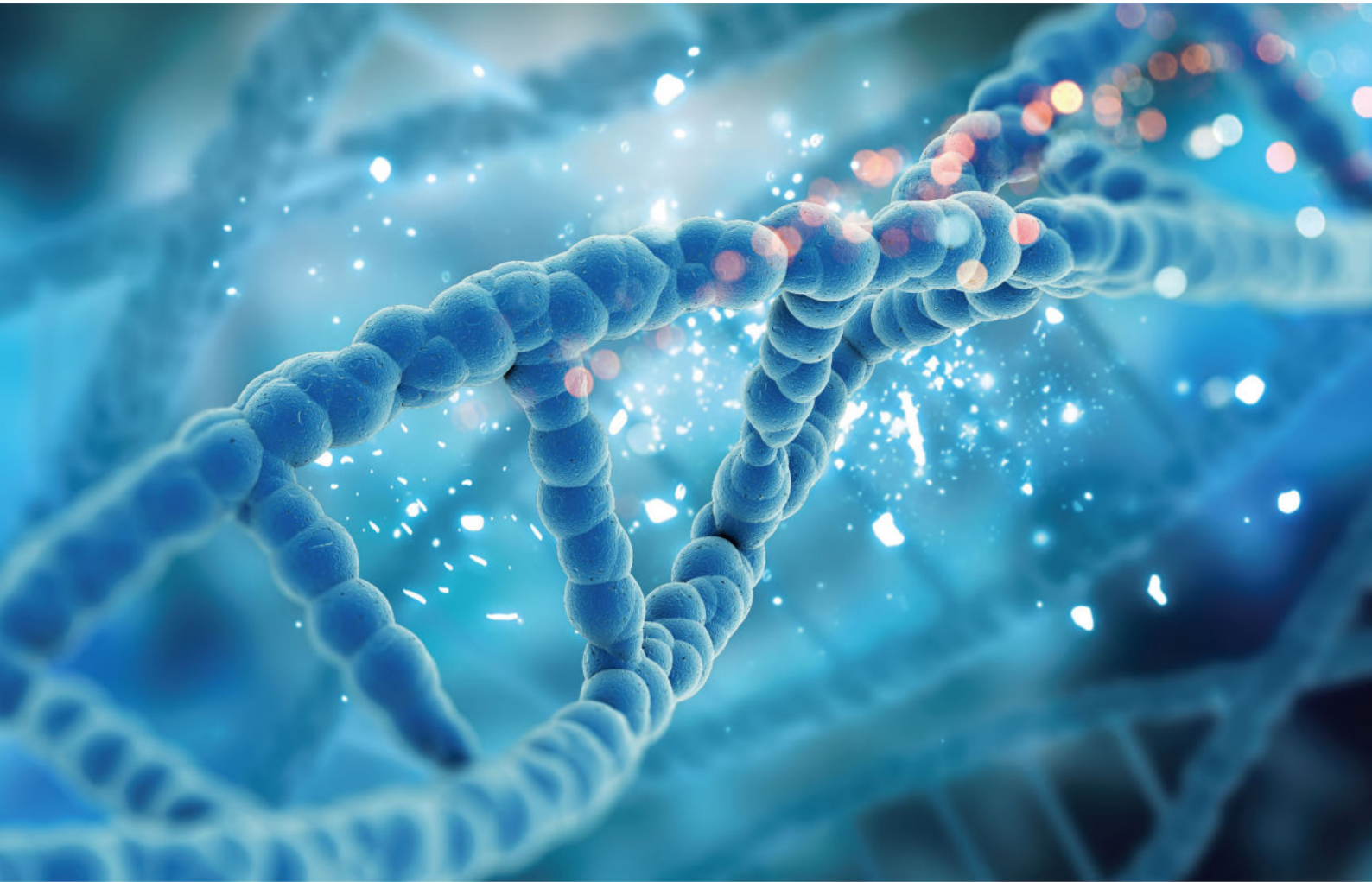


## ColonAiQ®

### ■ Multi-Gene Methylation Detection Kit for Colorectal Cancer (PCR-Fluorescence Probing)



**Colorectal cancer (CRC)** is one of the most common and deadliest cancers worldwide. Survival can be greatly improved if cancerous lesions are **detected early**. ColonAiQ® is a **cost-effective, multilocus** blood test for cancer screening and surveillance, developed for **detecting CRC, advanced adenoma (AA), and CRC early recurrence**. It is the first **blood-based qPCR** test to integrate **five CRC methylation markers in one assay** and **outperform current screening assays**.

# ColonAiQ®

## ColonAiQ® — Independent innovation product

→ 5 abnormally hypermethylated regions of 4 CRC-related genes

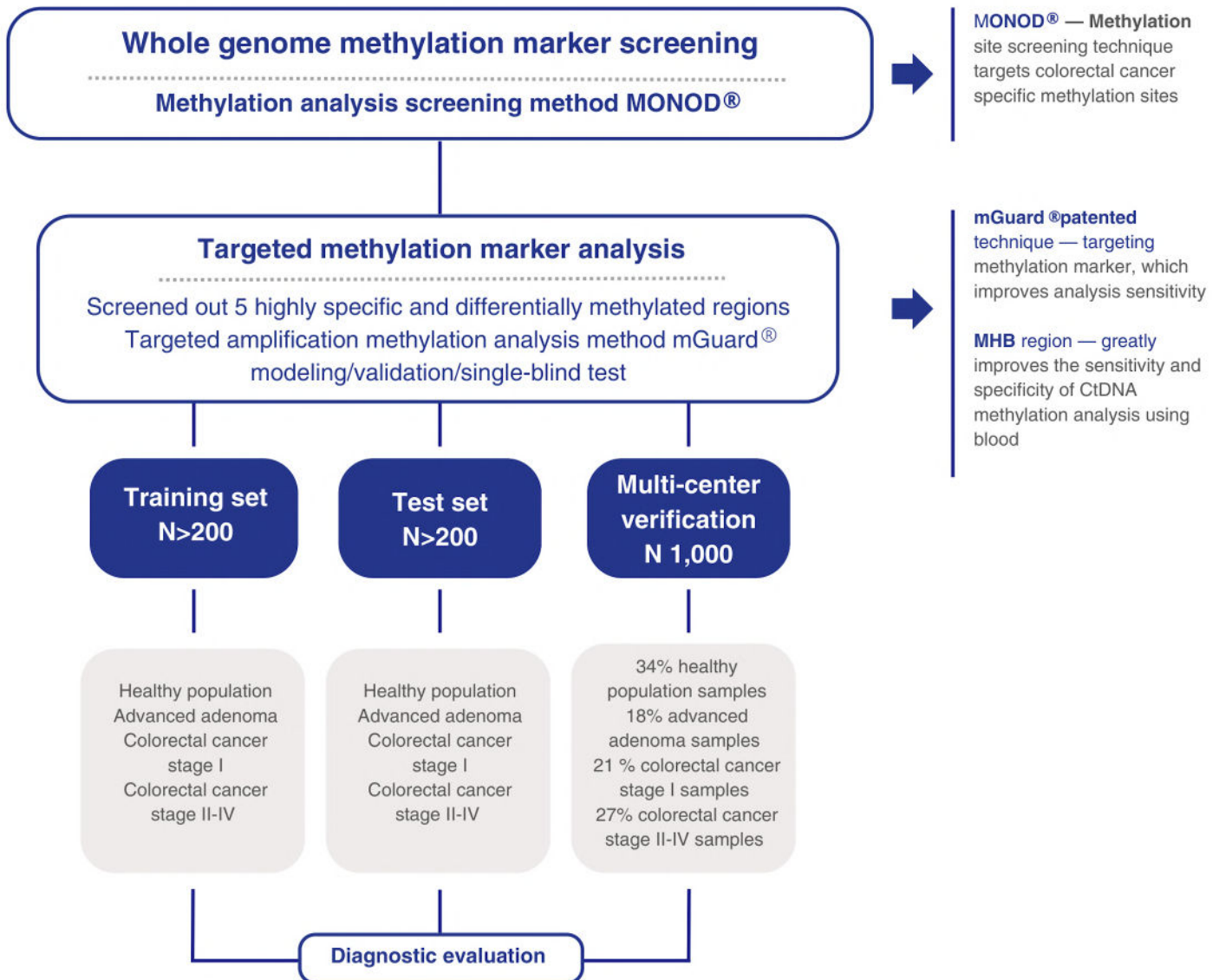


CRC-related genes



Abnormally hypermethylated regions

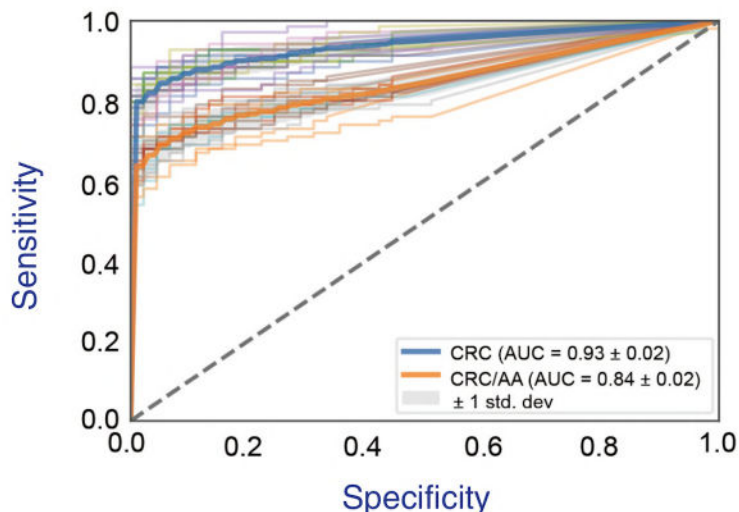
→ Scientific and rigorous screening process



# ColonAiQ®

**ColonAiQ® is used for early diagnosis of colorectal cancer**

➔ Average AUC in CRC detection: 0.93 | Average AUC in AA detection: 0.84



CRC: colorectal cancer  
AA: advanced adenoma

➔ **ColonAiQ® had an overall sensitivity of 86% (149/173) for detecting colorectal cancer (stage I-IV)**

➔ **The test specificity of a healthy population in the control group was 92% (125/136)**

➔ **The test sensitivity of advanced adenoma was 42% (45/107)**

Diagnostic result	Number of cases	ColonAiQ® verification test (n=507)			
		Number of positive cases	Number of negative cases	Sensitivity (95% confidence interval)	Specificity (95% confidence interval)
Unknown stage of colorectal cancer	12	12	0	100 (69.9-100)	
Colorectal cancer stage I	23	18	5	78.3 (55.8-91.7)	
Colorectal cancer stage II	50	41	9	82.0 (68.1-91.0)	
Colorectal cancer stage III	72	62	10	86 (75.5-92.8)	
Colorectal cancer stage IV	16	16	0	100 (75.9-100)	
<b>Total</b>	<b>173</b>	<b>149</b>	<b>24</b>	<b>86.1 (79.9-90.7)</b>	
Advanced adenoma	107	45	62	42.1 (32.7-52.0)	
No advanced adenoma	58	8	50		86.2 (74.1-93.4)
Other benign lesions*	33	6	27		81.8 (63.9-92.4)
Healthy population	136	11	125		91.9 (85.7-95.7)
<b>Total</b>	<b>227</b>	<b>25</b>	<b>202</b>		<b>89.0 (84.0-92.6)</b>

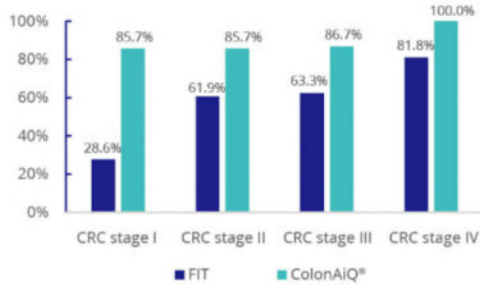
\* Other benign lesions include: non-neoplastic polyps, mainly inflammatory and hyperplastic polyps, and enteritis.

# ColonAiQ®

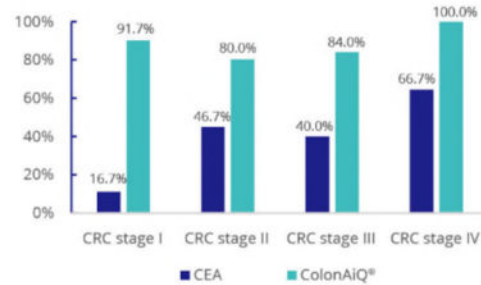
## Performance of ColonAiQ®

Outperforms FIT, CEA, and SEPT9 detection

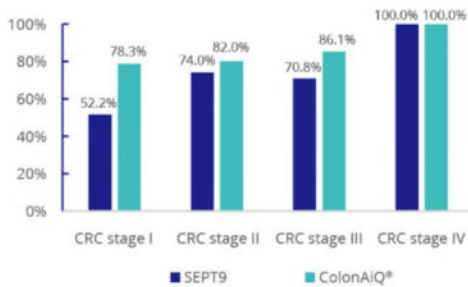
Compared with the sensitivity of FIT in CRC (stage I-IV)  
Overall sensitivity 59.2% vs. 88.2% (N=76)



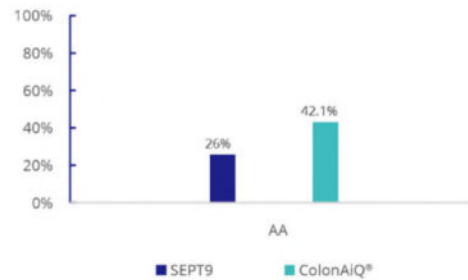
Compared with the sensitivity of CEA in CRC (stage I-IV)  
Overall sensitivity: 38.2% vs. 85.5% (N=55)



Compared with the sensitivity of SEPT9 in CRC (stage I-IV)  
Overall sensitivity: 72.0% vs. 85.1% (N=161)

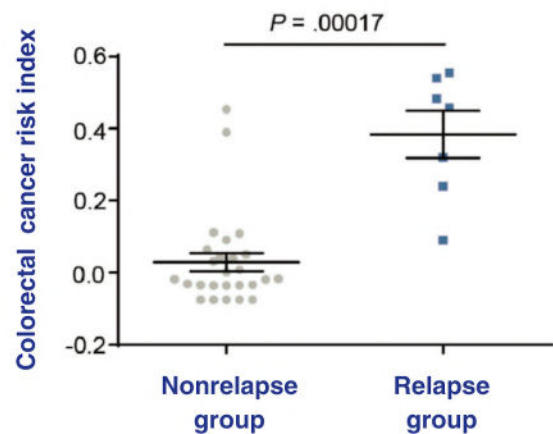
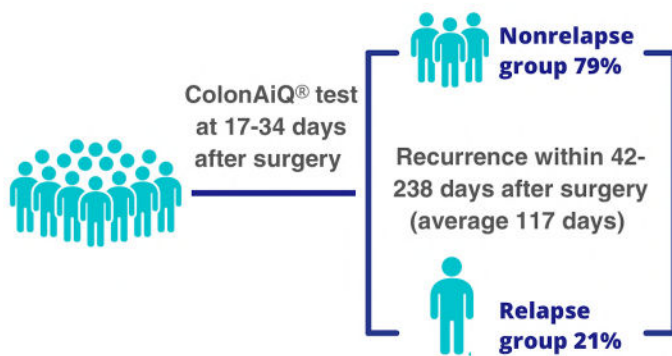


Compared with the sensitivity of SEPT9 in AA 26.0% vs. 42.1% (N=107)



## ColonAiQ® is used for predicting early relapse of colorectal cancer [1]


There was a significant difference in the ColonAiQ® score among the postoperative samples between the relapse and the nonrelapse groups





# ColonAiQ<sup>®</sup>


## ColonAiQ<sup>®</sup> test process


### ➔ Sampling process

- 

1 Collect the blood sample in an EDTA Tube or Cell-Free DNA Collection Tube (a minimum of 8 ml).
- 

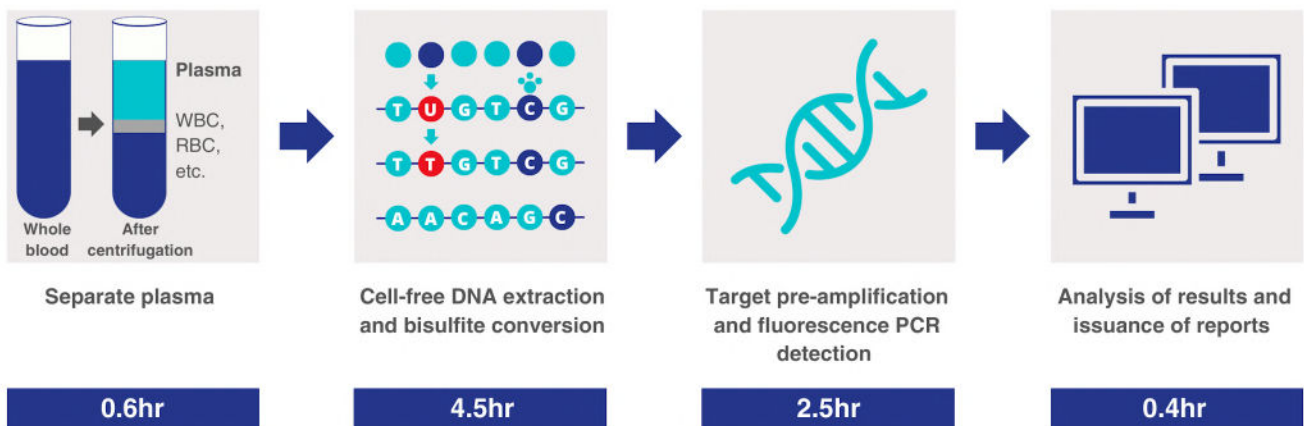
2 Store the EDTA Tube at room temperature for up to 6 hours, or at 2-8°C for 24 hours (do not freeze). / Store the Cell-Free DNA Collection Tube at room temperature for up to 96 hours (do not refrigerate or freeze).
- 

3 Separate plasma using two-step centrifugation.
- 

4a Process the plasma.
- 

4b Store plasma for later processing (at -20°C for up to 4 weeks, or at -80°C for up to 1 year).

### ➔ Test process: Simple workflow, easy to perform in a molecular biology laboratory in 8 hours



## Clinomics Europe, Ltd.

### Company profile

Clinomics Europe was established in 2021 as the first EU subsidiary of Clinomics Inc, Korea. Our multiomics-based research and development company specializes in developing liquid biopsy solutions for precision medicine and oncology. The company develops novel molecular diagnostic tools based on cutting-edge technologies such as liquid biopsy, NGS (next-generation sequencing), real-time qPCR, dPCR, and more. Besides research development activities, Clinomics Europe also provides diagnostic services in its well-equipped molecular genetics laboratory and is a distributor of molecular biology products within the EU.



## Singlera Medical Technology Co., Ltd. Company profile

Founded in 2014, Singlera Genomics Inc. is a world leader in liquid biopsy and early cancer detection. By leveraging the deep expertise and broad experience in Genome Technology, Singlera offers a wide range of products and solutions covering Cancer Early Screening, Diagnosis, and Prognostic Monitoring for multiple types of cancers.



Reference:

[1] Cai G, Cai M, Feng Z, et al. A Multilocus Blood-Based Assay Targeting Circulating Tumor DNA Methylation Enables Early Detection and Early Relapse Prediction of Colorectal Cancer[Li]. *Gastroenterology*, 2021, 161 (6): 2053-2056. e2.



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**Clinomics Europe, Ltd.**

Address: Mihákovics Street 10, Budapest 1094, Hungary  
Tel:+36 30 233 6991, E-mail: office@clinomicseurope.com



**Singlera Medical Technology Co.,Ltd.**

Address: 3rd & 4th Floor, Building 20, Block 500 Furonghua Road,  
Pudong New District, Shanghai, People's Republic of China  
Tel: +86-400 920 4888, E-mail: intl-market@singlera.com

EC REP

**SUNGO Europe B.V.**

Address: Olympisch Stadion 24, 1076DE Amsterdam,Netherlands  
Tel/Fax: +31 (0)2021 11106, E-mail: ecrep@sungogroup.com



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