Clinomics Europe

Tomorrow's **biotechnology...**

...for today's **challenges**

Preliminary European results on the clinical utility of ColonAiQ, a cell-free DNA methylation-based liquid biopsy assay for colorectal cancer early detection

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6th Central - Eastern European Congress on cell-free DNA and medical practice

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Czech Republic

Epidemiology of colorectal cancer in Europe

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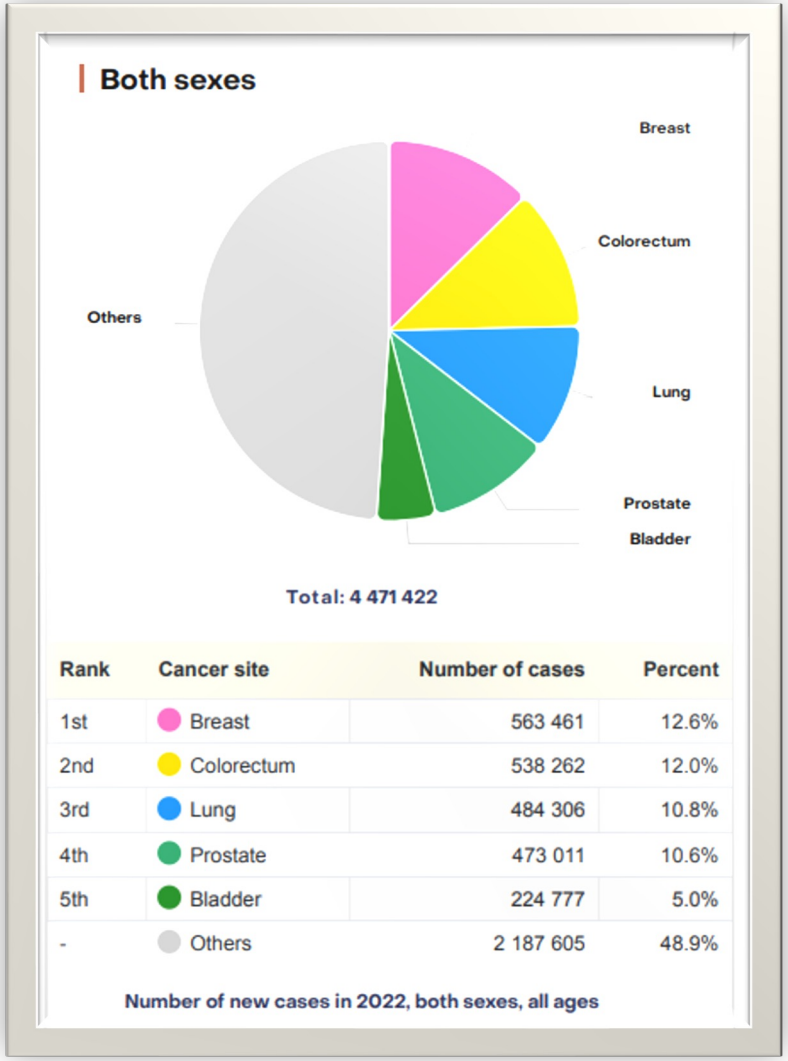


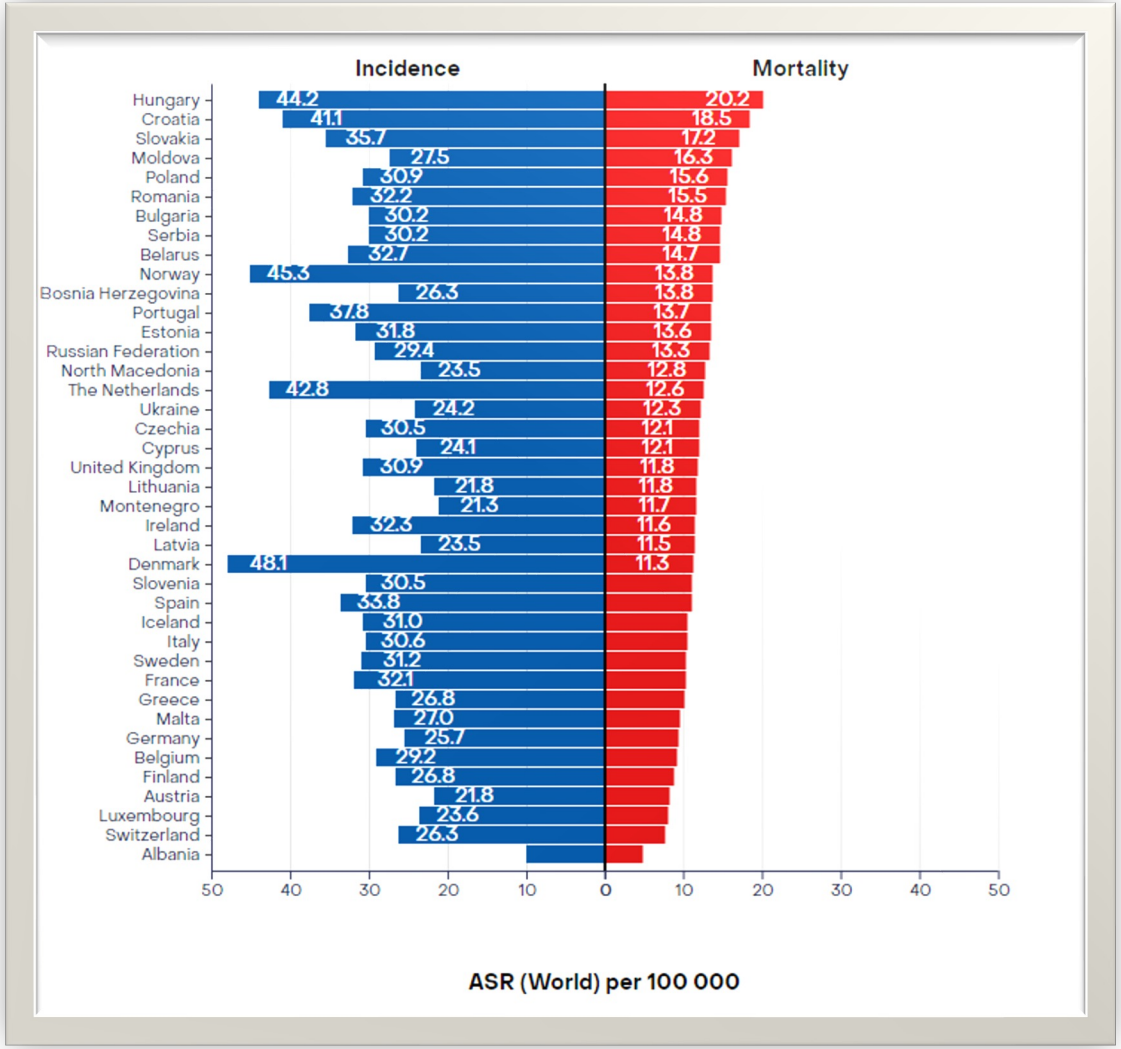
Rank	Cancer site	Number of cases	Percent
1st	Breast	563 461	12.6%
2nd	Colorectum	538 262	12.0%
3rd	Lung	484 306	10.8%
4th	Prostate	473 011	10.6%
5th	Bladder	224 777	5.0%
-	Others	2 187 605	48.9%

Number of new cases in 2022, both sexes, all ages

Age-Standardized Rate (World) per 100 000, Incidence and Mortality, Both sexes, in 2022

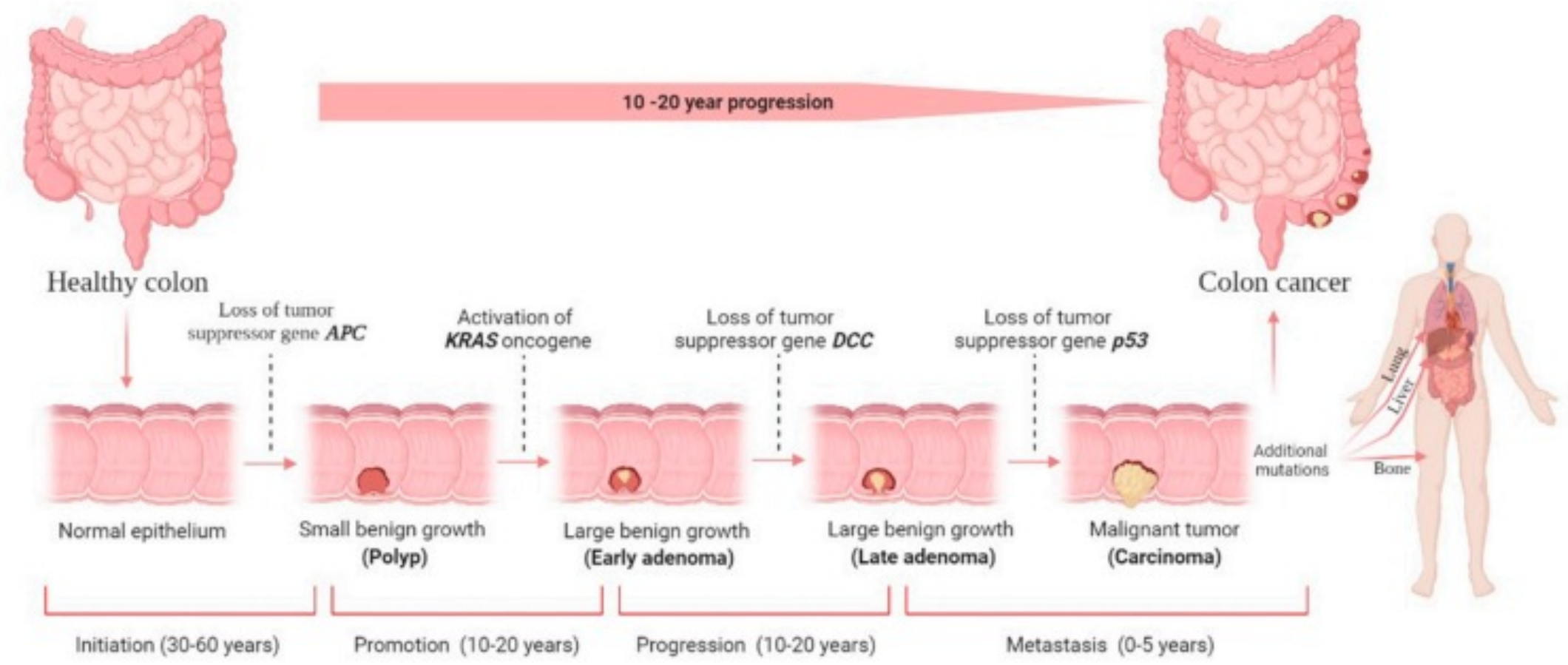
Colorectum

Europe



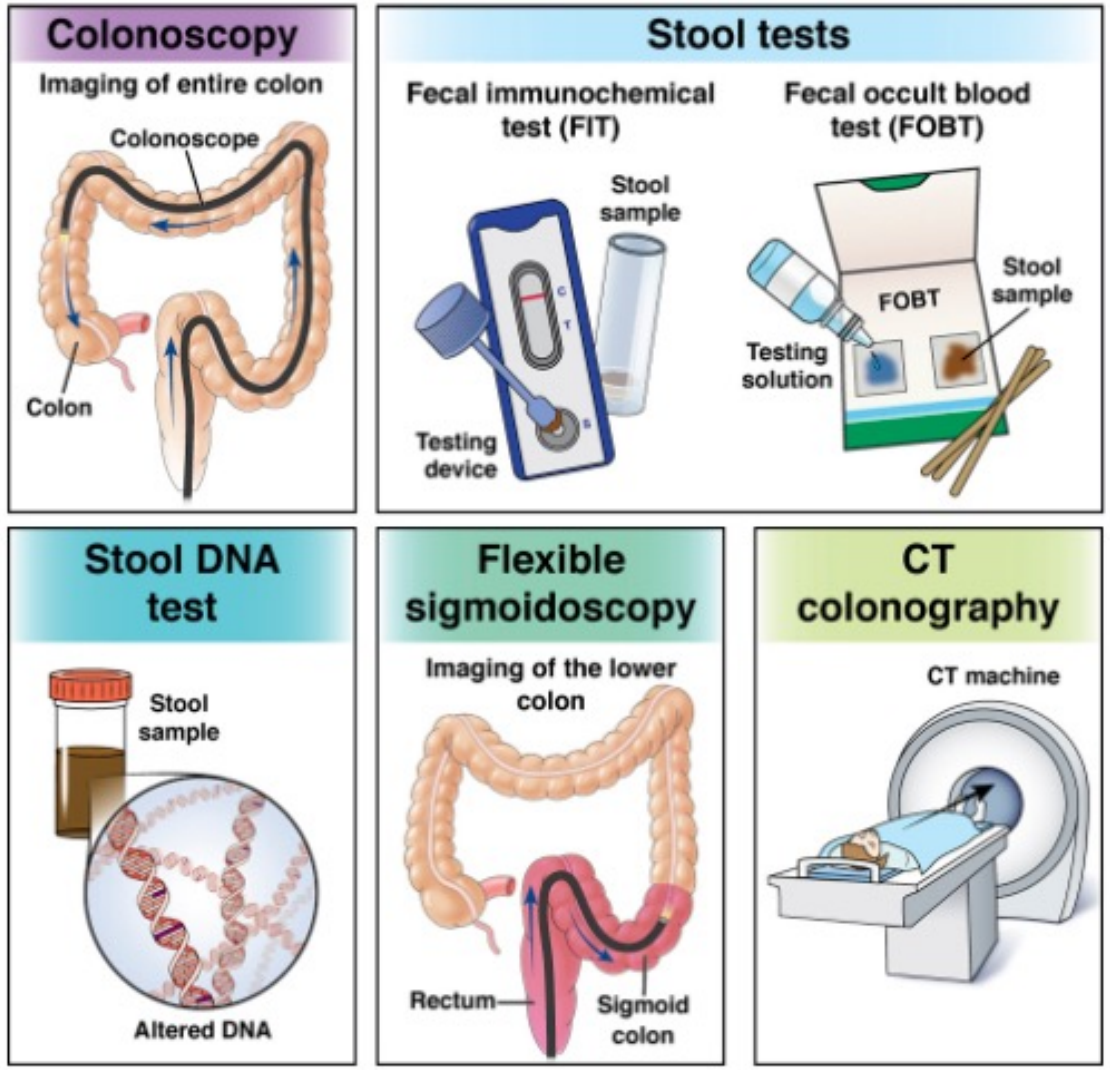
GLOBOCAN: Global Cancer Observatory https://gco.iarc.fr/en

Colorectal cancer stages and development



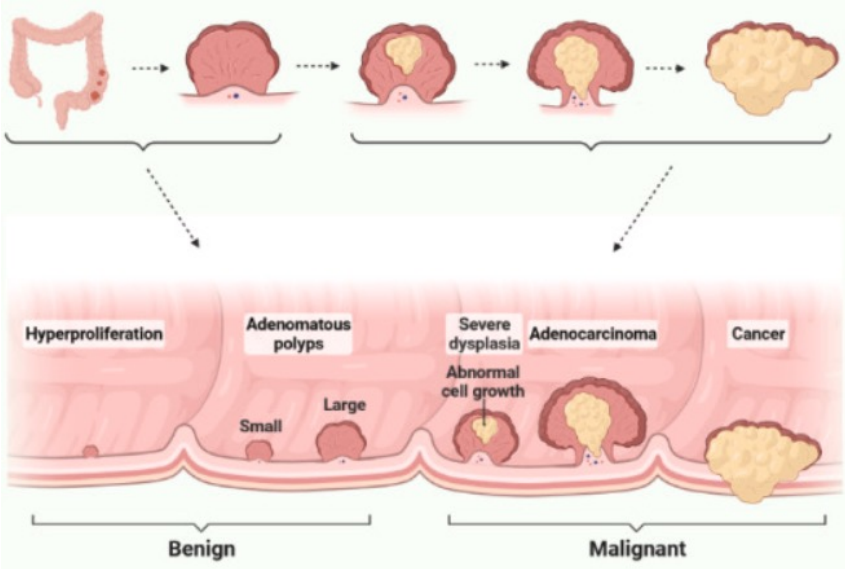
Colorectal Cancer: A Review of Carcinogenesis, Global Epidemiology, Current Challenges, Risk Factors, Preventive and Treatment Strategies. Cancers 2022, 14, 1732

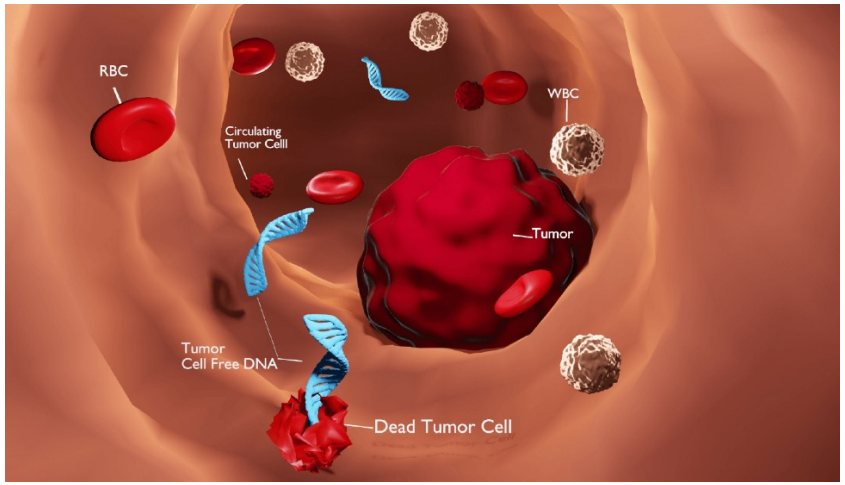
Colorectal cancer screening options



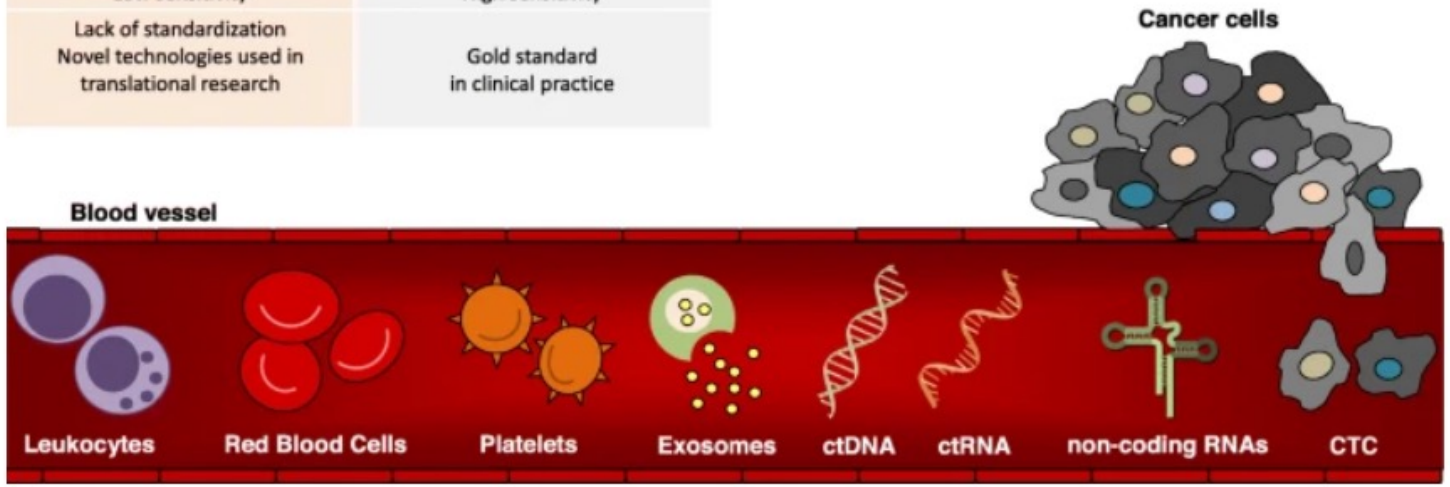
https://patient.gastro.org/crcscreening/

Liquid biopsy has great advantages in CRC early detection





LIQUID BIOPSY	TISSUE BIOPSY
Body fluids (usually blood)	Surgery or needle biopsy
Non-invasive	Invasive and risky
Easy and repeatable	Difficult to repeat
Real time detection of comprehensive cancer profile	Single snapshot over time and space
Low sensitivity	High sensitivity
Lack of standardization Novel technologies used in translational research	Gold standard in clinical practice



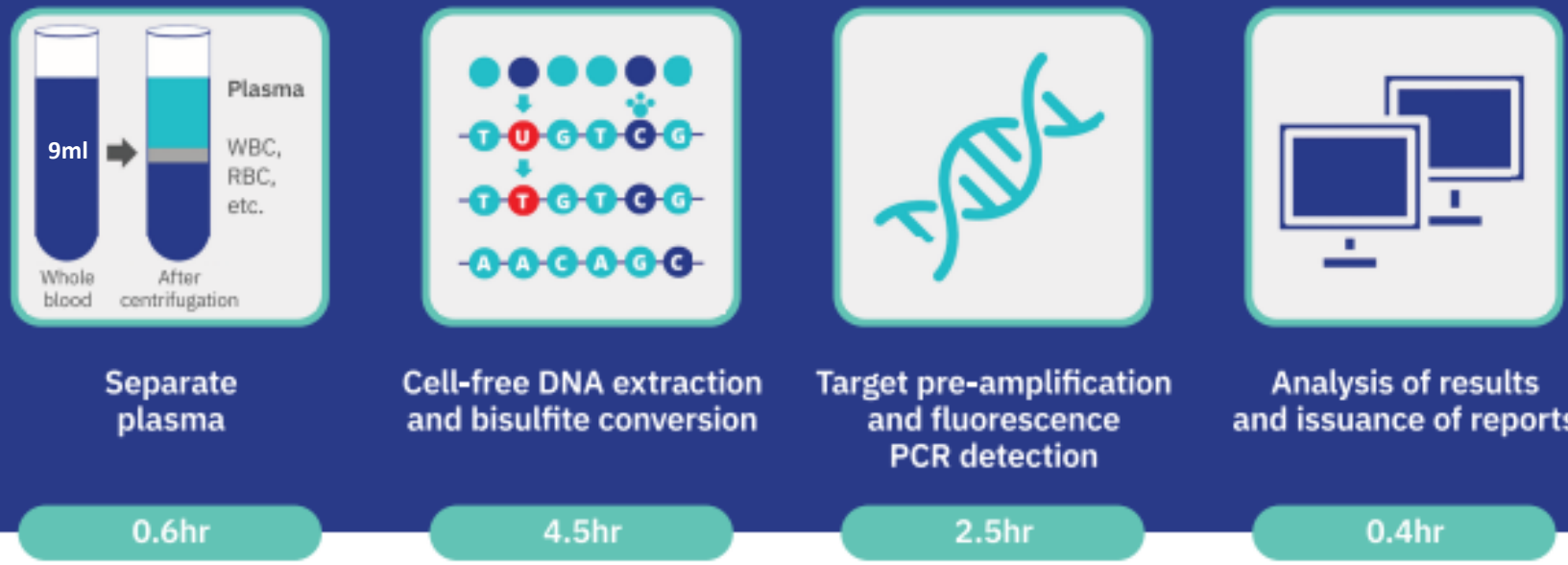
Colon cancer and colorectal cancer: Prevention and treatment by potential natural products, Chem-Biol Int, Vol 368 (2022) https://doi.org/10.1016/j.cbi.2022.110170.
Liquid biopsy and tumor heterogeneity in metastatic solid tumors: the potentiality of blood samples. J Exp Clin Cancer Res 39, 95 (2020). https://doi.org/10.1186/s13046-020-01601-2


Singlera
Clinomics Europe
ColonAiQ®
Multi-Gene Methylation Detection Kit for Colorectal Cancer (PCR-Fluorescence Probing)
ColonAiQ® - Independent innovation product
5 abnormally hypermethylated regions of 4 CRC-related genes
4
CRC-related genes
5
Abnormally hypermethylated regions

Methods

Test process

Simple workflow, easy to perform in a molecular biology laboratory in 8 hours



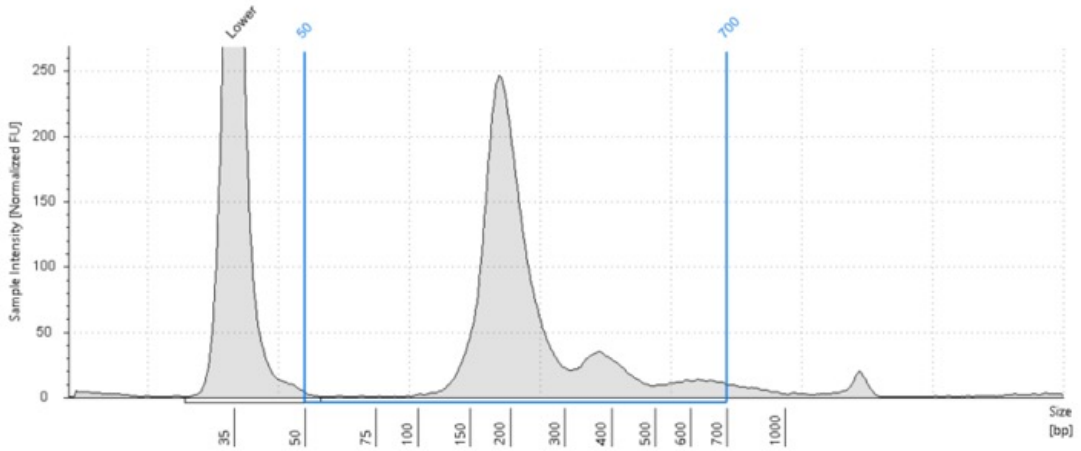
CE IVD

Patient characteristics

	Preoperative patients N (%)	Healthy controls N (%)
Total	24 (100)	23 (100)
Age		
Mean	61.1	55.8
Range	20-85	26-70
Sex		
Female	6 (25)	10 (43.48)
Male	18 (75)	13 (56.52)
Histopathologic subgroups		
Non-neoplastic gastrointestinal disorders	4 (16.67)	
Polyps and adenomas	5 (20.83)	
CRC I-II stages	4 (16.67)	
CRC III stage	11 (45.83)	
Carcinoembryonic Antigen (CEA)		
0-3 µg/L	18 (75)	
>3 µg/L	6 (25)	
Carbohydrate Antigen 19-9 (CA19-9)		
0-37 U/mL	21 (87.5)	
>37 U/mL	3 (12.5)	

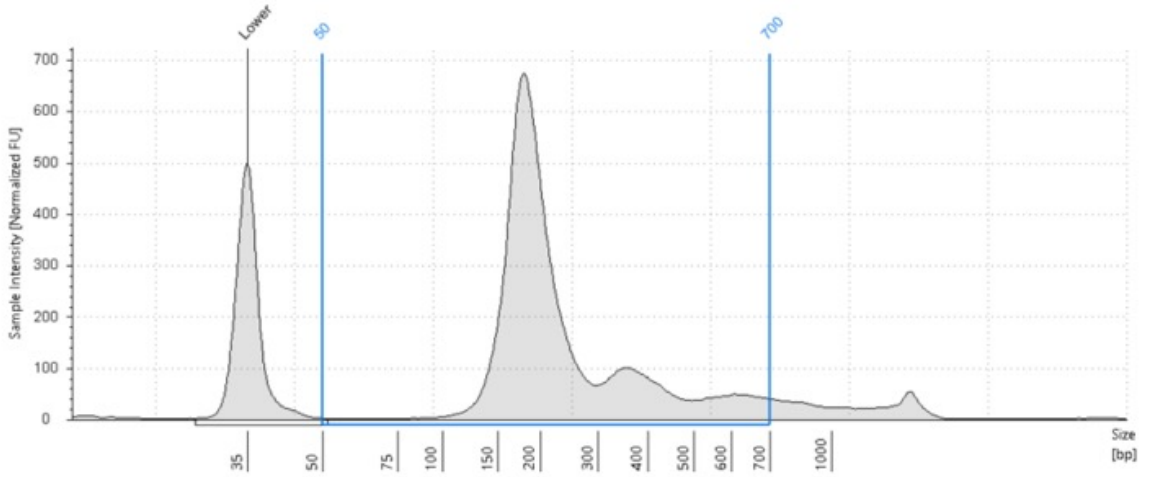
All cell-free DNA passed the quality and quantity criteria

Representative figures of fragment lenght analysis:



Sample Table

Well	%cfDNA	Conc. [pg/µl]	Sample Description	Alert	Observations
A1	94	331	CRC-59-1		



Sample Table

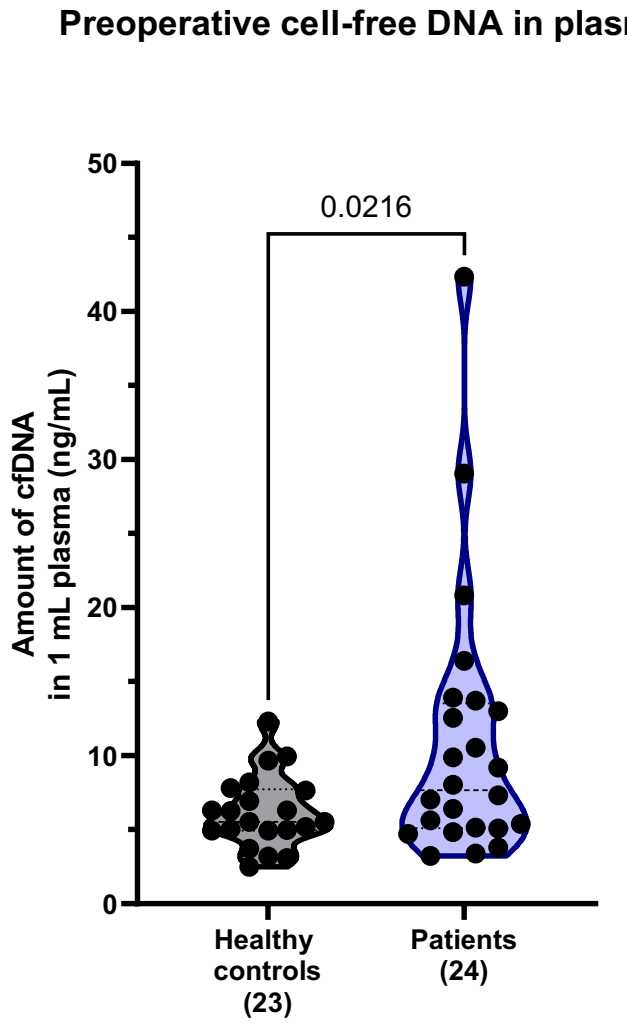
Well	%cfDNA	Conc. [pg/µl]	Sample Description	Alert	Observations
C1	90	1040	CRC-63-1		

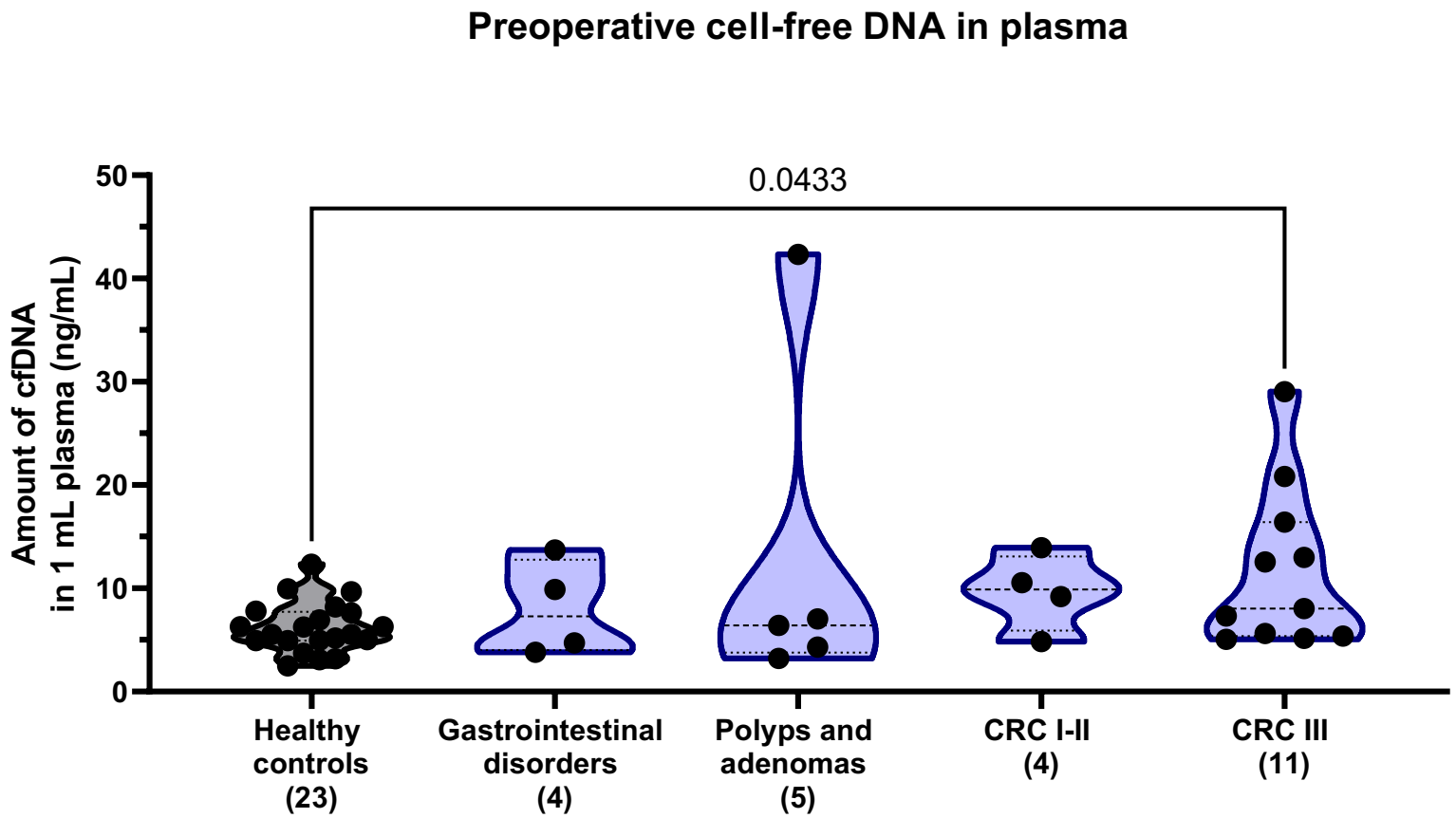
- minimum of 80% cfDNA-specific fragments

- minimum of 10ng cfDNA in total volume

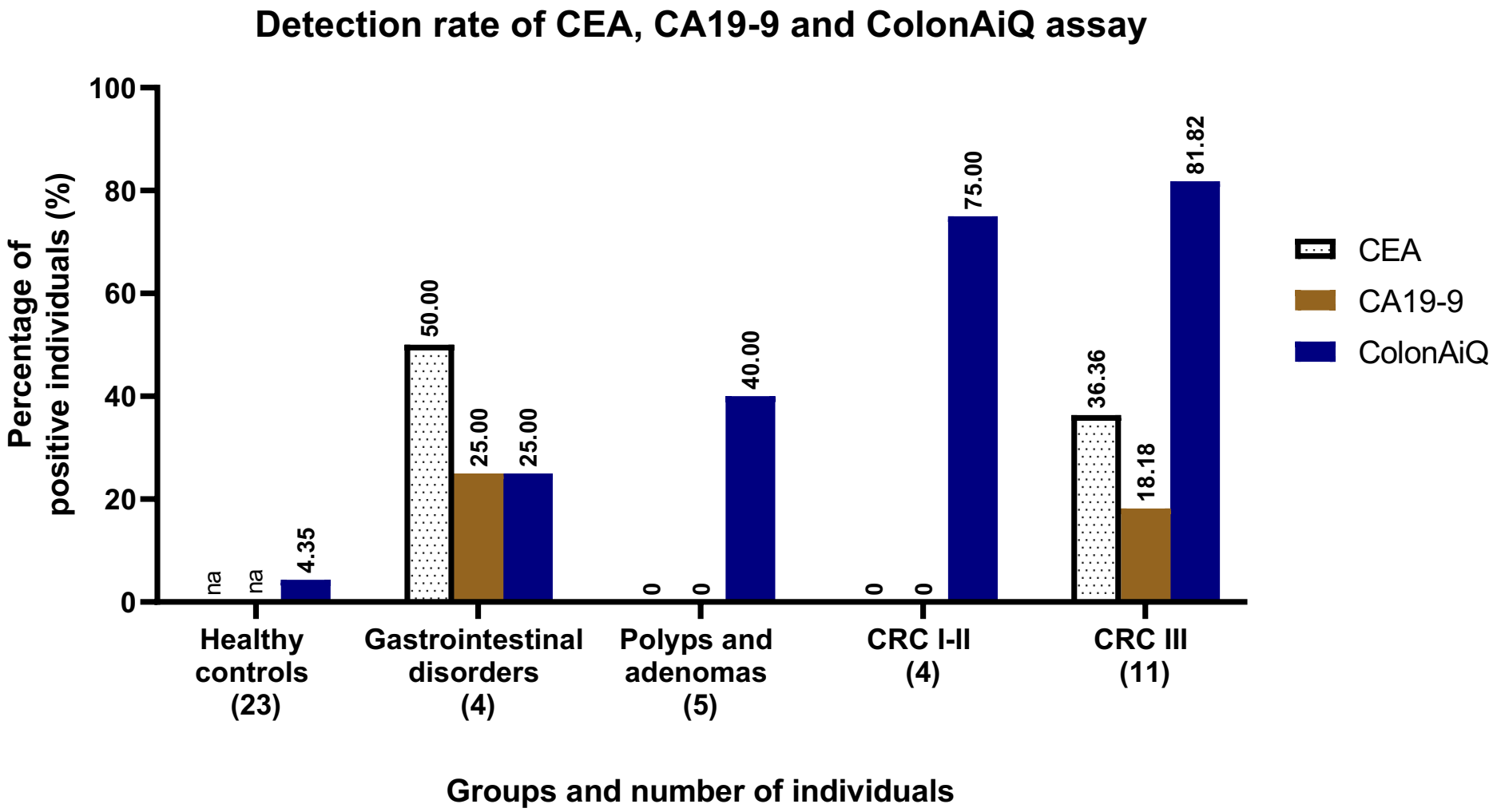
Further processing ✓

The amount of cell-free DNA did not separate non-malignant and CRC early stages from healthy controls





ColonAiQ is highly sensitive in adenomas and all CRC stages



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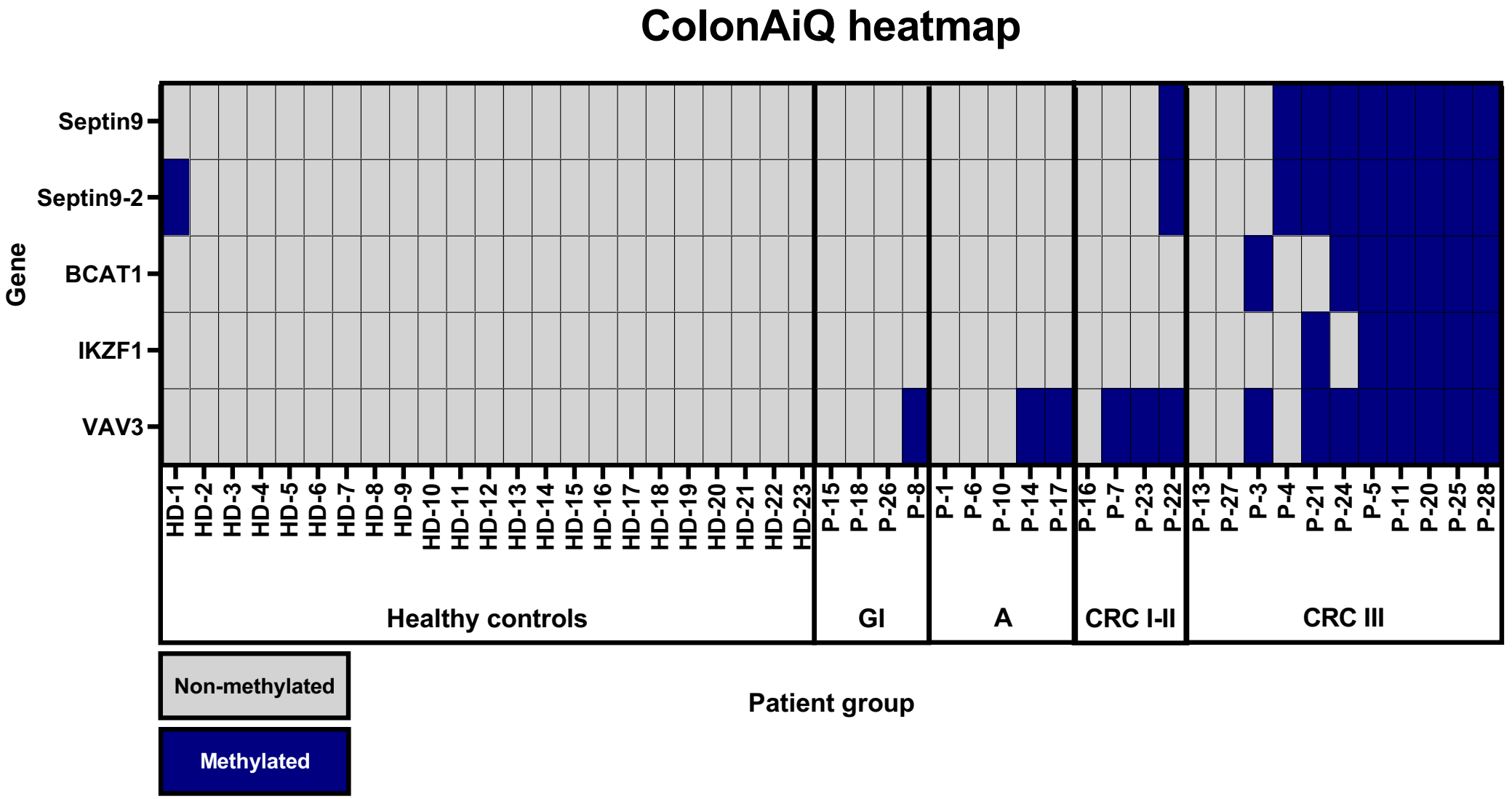
Elevated co-methylation pattern is limited to the advanced CRC stage



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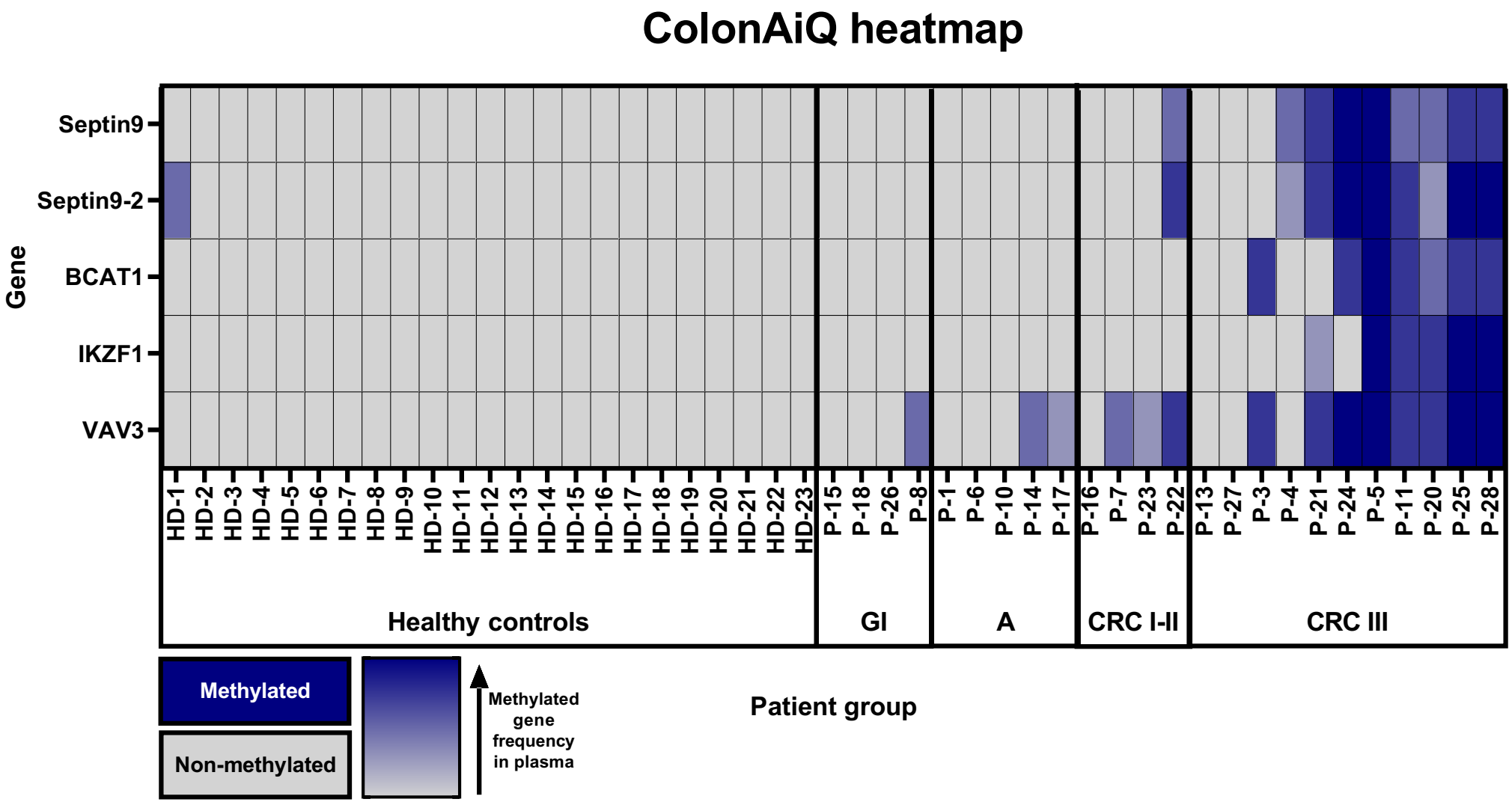
The frequency of methylated cfDNA is stage-dependent



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Conclusion

Detection rate (%)	Healthy controls	Non-neoplastic gastrointestinal disorders	Polyps and adenomas	CRC I-II stages	CRC III stage
ColonAiQ	**4.35**	**25**	**40**	**75**	**81.82**
CEA	NA	50	0	0	36.36
CA19-9	NA	25	0	0	18.18

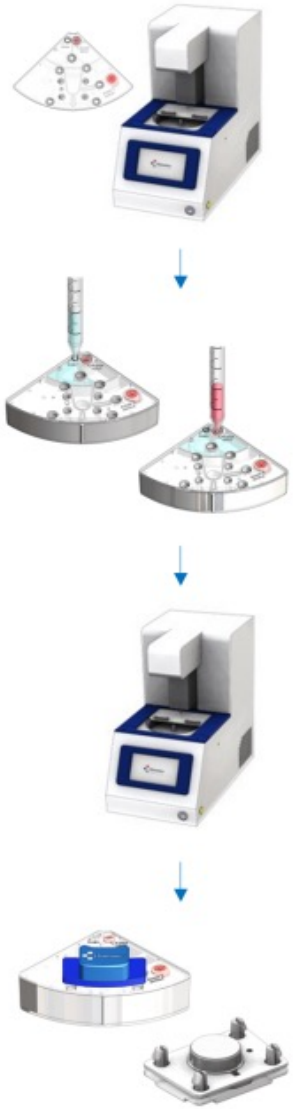
We demonstrated the clinical utility of ColonAiQ, a blood-based assay for detecting colorectal cancer (CRC) in a European subpopulation.

The ColonAiQ assay is a liquid biopsy workflow that can be easily implemented in the clinic, potentially reducing the morbidity and mortality of CRC.

Future perspectives

Further investigations are planned on a larger patient cohort and follow-up samples.

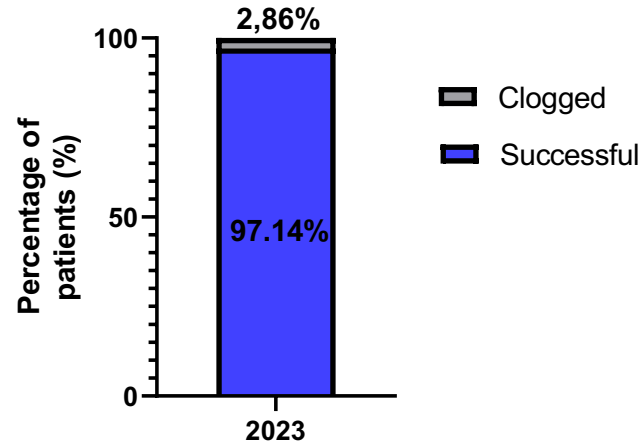
CD-PRIME™



Circulating tumor cell (CTC) analysis for diagnosis and prognosis:

- CTC **gene expression** measurement by **digital PCR**
- Methylated gene detection in CTCs by **ColonAiQ**

CTC enrichment by CD-PRIME and FAST-Auto disc



23 healthy control, 75 CRC samples

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Thank you for your attention!

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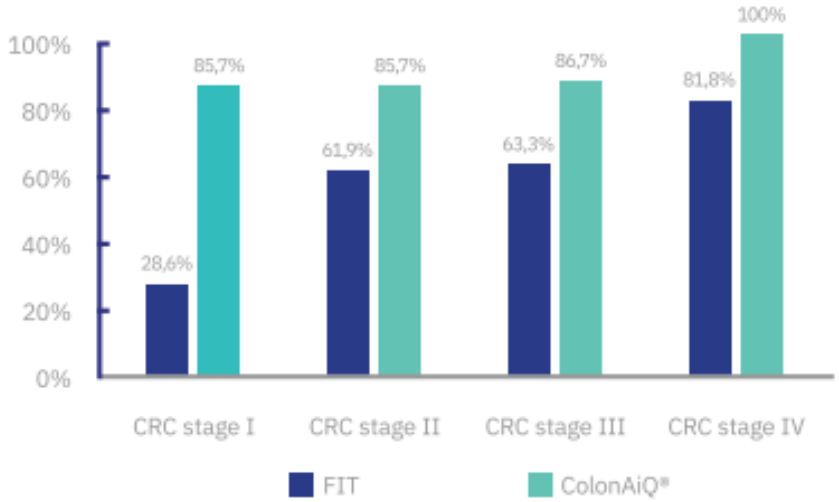
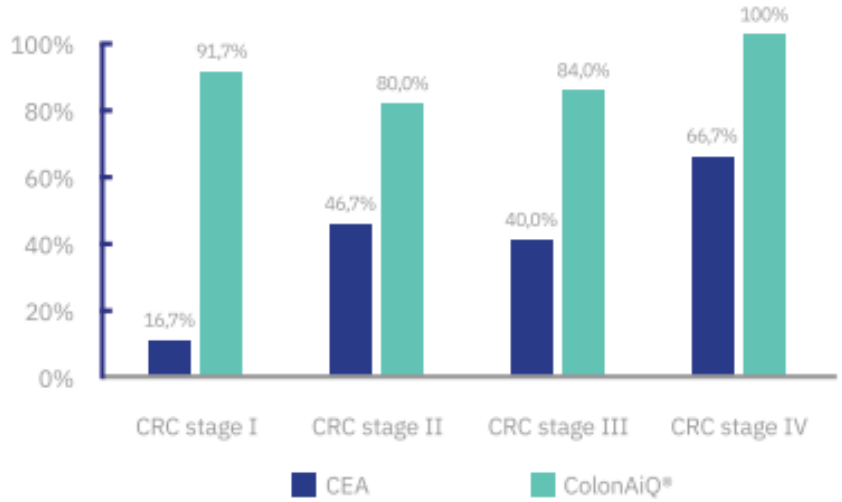
Let's meet at our exhibition place!

Outperforms FIT, CEA, and SEPT9 detection

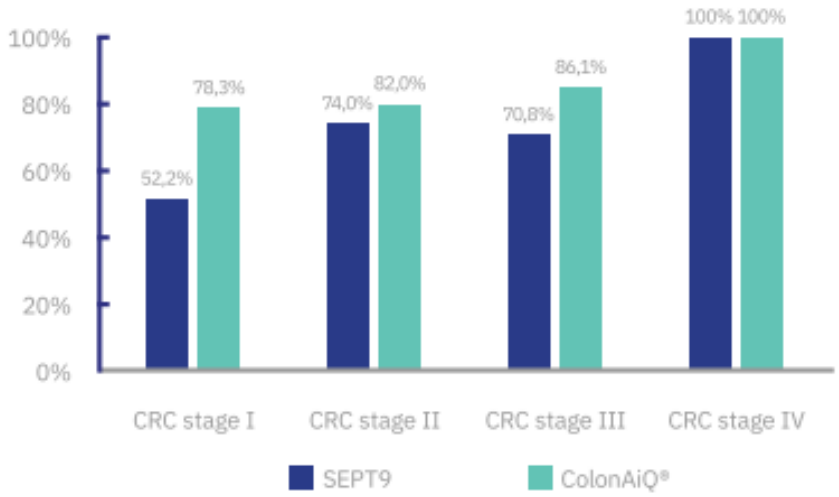
Compared with the sensitivity of FIT in CRC (stage I-IV)
Overall sensitivity 59.2% vs. 88.2% (N=76)



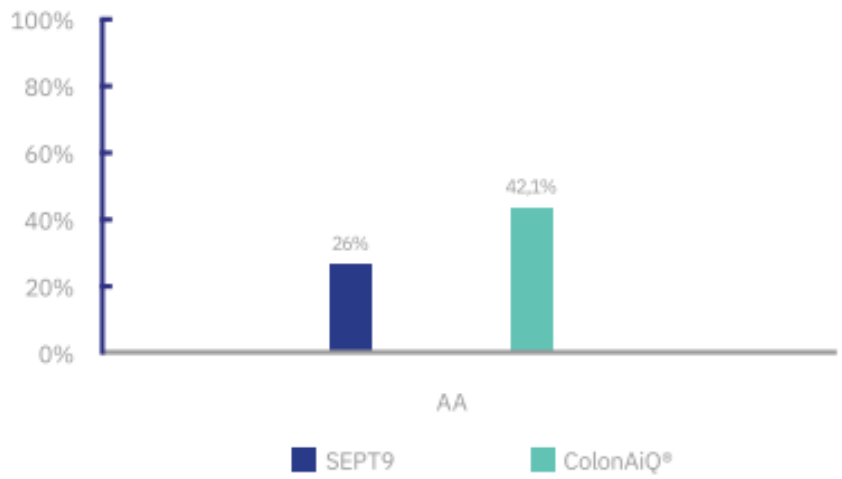
Compared with the sensitivity of CEA in CRC (stage I-IV)
Overall sensitivity: 38.2% vs. 85.5% (N=55)



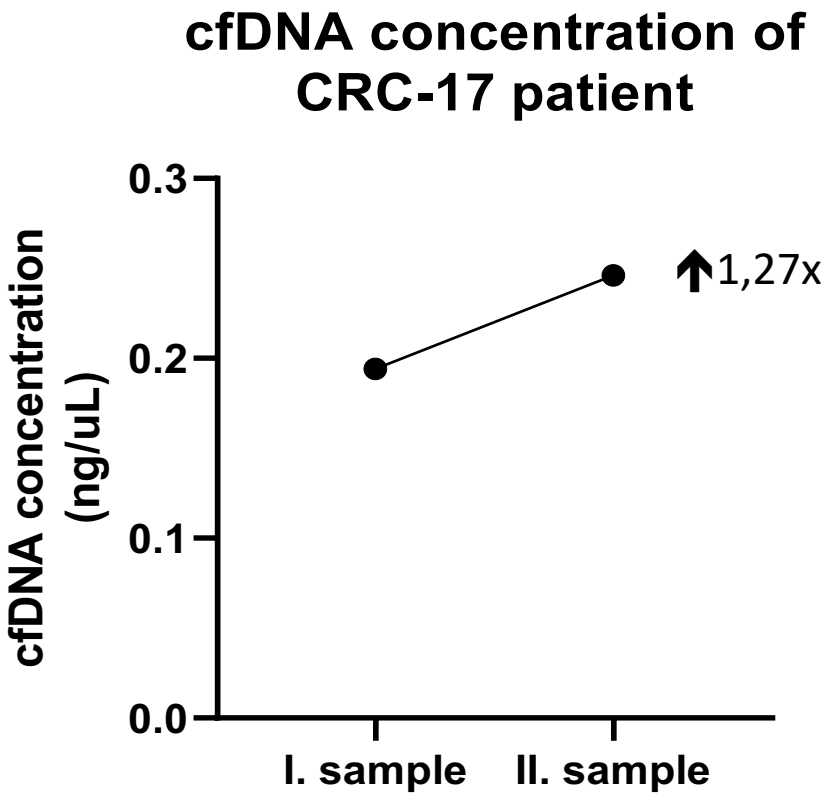
Compared with the sensitivity of SEPT9 in CRC (stage I-IV)
Overall sensitivity: 72.0% vs. 85.1% (N=161)

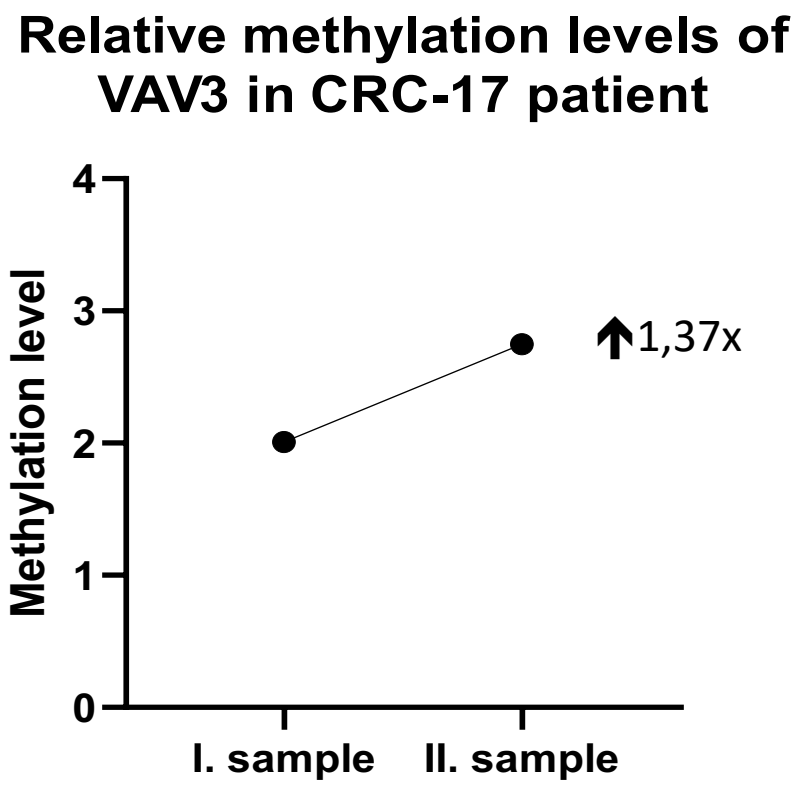


Compared with the sensitivity of SEPT9
in AA 26.0% vs. 42.1% (N=107)



Two samples before surgery characterize the progression of the disease





Good concordance between cfDNA concentration and VAV3 gene relative methylation level.

2 months difference between I. and II. samples.