Colon AiQ

SAMPLE INFORMATION

Name	-	**Date Received**	-
Medical ID	-	**Date Of Report**	-
Date Of Birth	-	**Req. Physician**	-
Location	-	**Barcode**	-
Material	PLASMA		

RESULTS

Negative: No methylation signal detected

- This analysis did not detect any significant DNA methylation signals associated with colorectal cancer (CRC) in the cell-free DNA (cfDNA) isolated from the patient's blood specimen.
- This negative result does not rule out a clinical diagnosis of CRC or precancerous conditions such as polyps and adenomas, nor does it reduces the patient's lifetime risk of being affected with CRC.

RECCOMENDATIONS

Medical screening and management should rely on clinical findings and family history. Consider other tests such as stool-based screening tests or colonoscopy for more comprehensive colorectal cancer screening. It is recommended to evaluate the result with the attending physician and to repeat the ColonAiQ examination in one year.

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METHODOLOGY

Free circulating DNA was isolated from the examined sample (QIAamp Circulating Nucleic Acid Kit, Qiagen). DNA modification was performed with sodium bisulfite. This was followed by methylation analysis in the promoter of Septin9, IKZF1, BCAT1 and VAV3 genes by preamplification and fluorescent quantitative PCR, using the ColonAiQ CE-IVD test.

INFORMATION ABOUT THE TEST

Colorectal cancer (CRC) is one of the most common and deadly cancers worldwide. 5-year survival for CRC ranges from 91% (localized) when detected early to 13% (distant) when diagnosed late (SEER database). American Cancer Society recommends people with average CRC risk to start regular screening at age 45. Circulating cell-free DNA (cfDNA) in biological fluids such as blood (plasma/serum) contains circulating tumor DNA (ctDNA) which shows epigenetic alterations associated with cancer development. Several studies have demonstrated that DNA-methylation profiling in cfDNA isolated from blood plasma can be effectively utilized in early cancer detection (PMID: **32694610, 34176681**). Using the methylation signature of ctDNA released from colorectal cancer, this CRC early detection assay showed a sensitivity of 86% and a specificity of 92% in a published study including 173 CRC patients (Stages I to IV), 107 patients with advanced adenomas (AA), and 136 colonoscopy-negative controls (PMID: **34487783**) .

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LIMITATIONS OF THE TEST

- 50% of positive patients will have a positive colonoscopy. A Positive signal cannot be used to diagnose colon cancer without positive findings on colonoscopy. Some patients without colon cancer may have a detectable signal.
- The test cannot detect all patients with colon cancer.
- A negative result cannot be used to rule out a diagnosis of colon cancer.
- The test does not replace other colon cancer screening tests recommended by a healthcare provider
- Each molecular analysis has an internal error probability of 0.5-1%. This is due to rare molecular events and factors related with sample preparation and analysis.

REFERENCES

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2. Mo S, Ye L, Wang D, Han L, Zhou S, Wang H, Dai W, Wang Y, Luo W, Wang R, Xu Y, Cai S, Liu R, Wang Z, Cai G. **Early Detection of Molecular Residual Disease and Risk Stratification for Stage I to III Colorectal Cancer via Circulating Tumor DNA Methylation.** *JAMA Oncol. 2023 Jun 1;9(6):770-778. doi: 10.1001/jamaoncol.2023.0425.* PMID: **37079312**.
3. Ding Y, Liu J, Liu R, Zhang Y, Li Y, Li F, Wang C, Jia H, Pan W, Yang H, Luo H, Li Y. **Real-world evaluation of clinical utility of ColonAiQ, a blood-based assay for colorectal cancer (CRC) early detection.** *Annals on Oncology,2022 DOI:https://doi.org/10.1016/j.annonc.2022.04.451*.