



ColonSentry™

Help Improve Patient Compliance with Cancer Screening

The Problem:

- 40% of average risk patients eligible for colorectal cancer (CRC) screening are non-compliant with colonoscopy, imaging and/or stool-based screening tests.

Why Should I Use the Test in My Practice?

- ColonSentry is a blood test with a 95% in-office compliance rate that motivates patients to comply with CRC screening.
- Data shows that patients with elevated ColonSentry scores are likely to move forward with Colonoscopy.*
- Get your eligible, average-risk patients who are non-compliant screened for CRC.
- Meet the National Colorectal Cancer Roundtable's 80 by 18 goal of getting people screened for CRC.
- Find colorectal cancer early when survival rates are highest.

The ColonSentry™ Solution:

- ColonSentry is a 7-gene, blood-based biomarker panel that can stratify subjects according to their current, relative risk of having colorectal cancer in an average-risk population.¹⁻²
- If the ColonSentry score is elevated, there is an increased probability of the patient having a pre-cancerous lesion or colorectal cancer.¹⁻²

The Science Behind the Test:

- ColonSentry measures the expression levels of six genes (ANXA3, CLEC4D, LMNB1, PRRG4, TNFAIP6, and VNN1). Each gene is paired with the expression level of a 7th gene, IL2RB, to create a genetic signature by which patients are stratified for CRC risk.
- Validated in a study of 10,000 patients in North America¹⁻²
- Negative predictive value is 99.6%¹⁻²
- Utilized on over 100,000 patients in the United States

The ColonSentry Patient Profile:

- ColonSentry is for patients who are asymptomatic and at average risk for CRC who have not proceeded with CRC screening.
- ColonSentry should not be used on patients who are at higher risk, such as those with inflammatory bowel disease or a personal or family history of polyps or colon cancer.

The Patient Benefit

- Finding Colorectal Cancer early saves lives.
 - When CRC is found early, the five-year survival rate is 92%.³
 - When CRC is found late, the five-year survival rate drops to 11%.³
- Young adults with colon cancer have a statistically higher risk of advanced disease at the time of operation.⁷

How Do I Get Started?

- Fill out a new account form and submit it to client relations clientrelations@myinnovativelab.com.
- Upon completion of new account form, a starter kit(s) will be shipped based upon your testing needs.
- Schedule training of your staff through an onboarding call with Innovative Diagnostic Laboratory.



ColonSentry®
LABORATORY RESULTS

Name: STUDY CASE	Phone #: (555) 555-0900	Patient ID #: T15-000-000	Collection Time: 11:30 AM	Specimen ID: T16082200031	Requesting Provider: TEST PHYSICIAN
Fasting Status: NON-FASTING	Gender: Male	Birthdate: 01/01/1962	Age: 55	Collection Date: 06/16/2017	Report Type: COMPLETE
Height:	Weight:	BMI:	Prev. BMI:	Received Date: 06/17/2017	Report Date: 06/21/2017
				Provider:	Client ID: T901

Test Results and Interpretation

The patient has an **Elevated** risk of having colorectal cancer, 3X than the average risk[†].

† Average risk of CRC is 0.7%

Test Description

Test results are reported with a 95% CI (Confidence Interval). The ColonSentry® test measures the expression of 7 gene biomarkers in whole blood to help determine a patient's Current Risk for having colorectal cancer (CRC) relative to the current risk in an average risk population.

Clinical Recommendations

The results indicate that the patient's current risk is elevated (2X or more), the patient should be referred for further evaluation with procedures such as colonoscopy. Average risk scores for the ColonSentry® test do not rule out colon cancer. When caught early, colon cancer is both treatable and beatable.

Average Risk: recommendation** for FIT, FIT-DNA, flexible sigmoidoscopy, CT colonography, or colonoscopy.
 Elevated Risk: recommendation** for colonoscopy.

** Screening for Colorectal Cancer: US Preventive Services Task Force Recommendation Statement. JAMA Jun 21, 2016; 315(23):2564-2575.

Gene Expression

Gene	Relative Expression
ANKK3* (LCI)	1.1
CLEC4D* (LCI)	0.5
TNFAIP6* (LCI)	1.6
LMNB1* (LCI)	0.3
PRRG4* (LCI)	1.2
YNN1* (LCI)	1.1
IL2RB (CI)	24.6

* Difference with respect to IL2RB

What to do next?

According to USPSTF[†], an average risk patient is a man or woman who is at least 50 years old, is asymptomatic for CRC, has no personal history of benign colorectal polyps, colorectal adenomas, CRC or inflammatory bowel disease, and does not have a first-degree relative with CRC. The presence of conditions such as pancreatic cancer, systemic sclerosis or CLL might affect the risk score.

Screening for colorectal cancer reduces mortality through detection and treatment of early-stage cancer and detection and removal of adenomatous polyps. The degree to which each of these mechanisms contributes to a reduction in mortality is unknown, although it is likely that the largest reduction in colorectal cancer mortality during the 10 years after initial screening comes from the detection and removal of early-stage cancer. Colonoscopy is a necessary step in any screening program that reduces mortality from colorectal cancer.^{†††}

††† Screening for Colorectal Cancer: US Preventive Services Task Force Recommendation Statement. JAMA Jun 21, 2016; 315(23):2564-2575.

Disclaimer

This test is not recommended for patients that have previous history of colorectal cancer, or pre-cancerous (e.g. adenomatous) polyps, or familial or inherited colon polyp syndromes, or inflammatory bowel disease, or have received chemotherapy and/or radiation.

- All patient demographics appear at the top of each page.
- BMI calculation based on reported height and weight.
- Test Results—the patient's relative risk for colorectal cancer is signified by the "Current Risk" score. It is recommended that patients with an Average Risk result (<2) be referred for FIT, flexible sigmoidoscopy or colonoscopy while patients with an Elevated Risk (≥2X) be referred for colonoscopy in accordance with USPSTF recommendations.
- Gene Expressions are for technical purposes and are used within the algorithm to determine the patient's relative risk for CRC. As individual entities they provide no significant value.
- Clinical recommendations based on the patient's individual score

What Do I Do with The Results?

- Patients with elevated ColonSentry scores should be encouraged to have a colonoscopy.
- Patients with average ColonSentry scores should continue to comply with USPSTF guidelines.

References

- Liew CC, Ma J, Tang HC, et al. The peripheral blood transcriptome dynamically reflects system wide biology: a potential diagnostic tool. J Lab Clin Med. 2006 Mar;147(3):126-32.
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