



# ColonSentry™

Help Improve Patient Compliance with Cancer Screening



## The Problem:

- 33% 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.
- 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.<sup>1-2</sup>
- If the ColonSentry score is elevated, there is an increased probability of the patient having a pre-cancerous lesion or colorectal cancer.<sup>1-2</sup>

## 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 America<sup>1-2</sup>
- Negative predictive value is 99.6%<sup>1-2</sup>
- 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 s found early, the five-year survival rate is 92%.<sup>3</sup>
  - When CRC is found late, the five-year survival rate drops to 11%.<sup>3</sup>
- Young adults with colon cancer have a statistically higher risk of advanced disease at the time of operation.<sup>7</sup>

## How Do I Get Started?

- Request a new account form and submit it to client relations at info@oncorepharma.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 our partner Innovative Diagnostic Laboratory.



### How To Read A Lab Report

**ColonSentry®**  
**LABORATORY RESULTS**

<b>Name:</b> STUDY CASE	<b>Phone #:</b> (555) 555-0000	<b>Patient ID #:</b> T15-000-000	<b>Collection Time:</b> 11:30 AM	<b>Specimen ID:</b> T1602200001	<b>Requesting Provider:</b> TEST PHYSICIAN
<b>Fasting Status:</b> NON-FASTING	<b>Gender:</b> Male	<b>Birthdate:</b> 01/01/1962	<b>Age:</b> 55	<b>Collection Date:</b> 06/16/2017	<b>Report Type:</b> COMPLETE
<b>Height:</b>	<b>Weight:</b>	<b>BMI:</b>	<b>Prev. BMI:</b>	<b>Received Date:</b> 06/17/2017	<b>Report Date:</b> 06/21/2017
			<b>Provider:</b>	<b>Client ID:</b> T001	

**Test Results and Interpretation**

The patient has an **Elevated** risk of having colorectal cancer, 3X than the average risk<sup>†</sup>.

<sup>†</sup> 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.

**Gene Expression**

Gene	Cycle Threshold
ANXA3* (ΔCt)	1.1
CLEC4D* (ΔCt)	0.5
TNFAIP6* (ΔCt)	1.6
LMNB1* (ΔCt)	0.3
PRRG4* (ΔCt)	1.2
VNN1* (ΔCt)	1.1
IL2RB (Ct)	24.6

\* Difference with respect to IL2RB

**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 (or 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.

**What to do next?**

According to USPSTF<sup>††</sup>, 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 adenoma 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.<sup>†††</sup>

††† 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

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