

# **Quantitative and Serial Fecal Immunochemical Testing as a Means of Additional Risk Stratification in Colorectal Cancer Screening Programs**

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## **Background:**

Fecal Immunochemical Testing (FIT) is currently used in a number of Canadian provinces to screen for colorectal cancer. The aim of this study is to assess the effectiveness of various FIT cut-offs and combinations of FIT cut-offs in predicting adenomas and colorectal cancer.

## **Methods:**

Data for this study was obtained in a prospective fashion using the Newfoundland and Labrador Colon Cancer Screening Program. Those enrolled in the study were between the ages of 50-74 at average risk for colon cancer. Participants were provided with two FIT tests – if a minimum of one test was  $\geq 100\text{ng/mL}$ , participants were further evaluated via colonoscopy. Data on the patient's age, gender, FIT value, presence of adenoma, pathology, and other variables were collected.

## **Results:**

Of the 21,371 FIT kits mailed out, 16,152 (75.6%) were returned, of which, 2694 (16.7%) had at least one FIT value  $\geq 100\text{ng/mL}$ . At the time of analysis, 1831 participants had been further evaluated by colonoscopy. Of those who had a colonoscopy, 73 (4.0%) were found to have colorectal cancer and 1092 (59.6%) were found to have an adenoma. The positive predictive value for both adenomas and colorectal cancer increased with increasing FIT values and serial positive values. Those with two FIT values  $\geq 5000\text{ng/mL}$  had the highest adenoma detection rate (100.0%) and highest rate of colorectal cancer (53.8%), which was significantly higher than those with one FIT value  $\geq 100\text{ng/mL}$  (p-values 0.002 and  $\leq 0.001$ , respectively).

## **Conclusions:**

Patients with two FIT positive results are more likely to have colon cancer or an adenoma compared to patients with only one FIT positive result. Further triaging of colonoscopy wait lists could be considered based on quantitative

FIT values and number of positive tests, thus reducing the time to diagnosis for patients most likely to have colorectal cancer.

**Table 1.** Colonoscopy Results by FIT Cutoff

	<b>1 FIT ≥ 100</b>	<b>2 FIT ≥ 100</b>	<b>1 FIT ≥ 200</b>	<b>2 FIT ≥ 200</b>	<b>1 FIT ≥ 1000</b>	<b>2 FIT ≥ 1000</b>	<b>1 FIT ≥ 5000</b>	<b>2 FIT ≥ 5000</b>
<b># of CSPY</b>	1831	748	1106	289	290	84	62	12
<b>CRC</b>	73 (4.0%)	61 (8.2%)	66 (6.0%)	45 (15.6%)	40 (13.8%)	20 (23.8%)	15 (24.2%)	7 (58.3%)
<b>Adenoma</b>	1092 (59.6%)	538 (71.9%)	740 (66.9%)	228 (78.9%)	208 (71.7%)	68 (81.0%)	48 (77.4%)	12 (100%)

CSPY = colonoscopy; CRC = Colorectal Cancer