Ontario Health
Cancer Care Ontario

Transition to Fecal Immunochemical Testing (FIT)

Frequently Asked Questions for Primary Care Providers and Healthcare Administrators

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Overview

Ontario, through the ColonCancerCheck program, has transitioned from the guaiac fecal occult blood test (gFOBT) to the fecal immunochemical test (FIT) for colorectal cancer screening as of June 24, 2019. To support this transition, frequently asked questions (FAQs) have been developed to provide primary care providers with information regarding why, how and when to screen with FIT, changes to the ColonCancerCheck program, and how these changes are expected to impact primary care providers and the screen-eligible public. Please note that the purpose of this document is to prepare primary care providers and healthcare administrators for any potential questions they may receive from their patients or other health care practitioners.

Glossary

Below is a glossary of standard terms used throughout the FAQs.

FIT: fecal immunochemical test

Completed FIT: term used to refer to the collection device once it contains a specimen

gFOBT: guaiac fecal occult blood test

FIT collection device: consists of the probe (grooved plastic stick) used to collect the stool and the buffer solution- containing vial (tube) where the probe is stored and into which the specimen will be placed

FIT kit: term used to refer to the package that the laboratory will send to the screen-eligible participants. The FIT kit includes the FIT collection device and package components (introductory program letter, instructions and return mailing materials)

OHIP: Ontario Health Insurance Plan

Pre-cancerous polyps: polyps that could turn into cancer over time. Pre-cancerous polyps include low risk adenomas, high risk (i.e., advanced) adenomas and sessile serrated adenomas/polyps. Hyperplastic polyps are not considered to be pre-cancerous.

About the fecal immunochemical test (FIT) and why it has been introduced in Ontario

1. What is the fecal immunochemical test (FIT)?

- FIT is a safe and painless stool-based test used for screening people at average risk of developing colorectal cancer*.
- Specifically, FIT checks for the presence of occult blood in the stool, which can be an early sign of colorectal cancer and/or pre-cancerous polyps.
- *As outlined in ColonCancerCheck's screening recommendations, "average risk" refers to people ages 50 to 74 with no first-degree relatives who have been diagnosed with colorectal cancer, and with no personal history of inflammatory bowel disease (i.e., Crohn's disease involving the colon or ulcerative colitis) or pre- cancerous polyps requiring surveillance.

2. Why has Ontario switched from the guaiac fecal occult blood test (gFOBT) to the fecal immunochemical test (FIT)?

Ontario has switched from gFOBT to FIT for several reasons:

- FIT is a more sensitive screening test than gFOBT, which means that it is better at detecting colorectal cancer and high risk adenomas (1, 2).
- FIT is specific for human hemoglobin, which means it will not mistake dietary sources of blood or other substances for human blood.
- Research has shown that people prefer screening with FIT over gFOBT, leading to increases in colorectal cancer screening participation. The benefits of FIT include:
    - The enhanced design of the collection device, which is easy to use and reduces the amount of contact people have with their stool when collecting it;
    - Only one specimen needed;
    - No dietary restrictions, including vitamin C; and
    - No medication restrictions.
    - FIT testing is automated at LifeLabs, which makes the interpretation of test results more consistent.

(1) Lee JK, Liles EG, Bent S, Levin TR, Corley DA. Accuracy of fecal immunochemical tests for colorectal cancer: Systematic review and meta-analysis. Ann Intern Med. 2014; 160(3):171-181.

(2) Canadian Task Force on Preventive Health Care. Screening for colorectal cancer [Internet]. Ottawa, Canada: Canadian Task Force on Preventive Health Care; 2014. Available from: http://canadiantaskforce.ca/guidelines/published-guidelines/colorectal-cancer/

3. Compared to the guaiac fecal occult blood test (gFOBT), how effective is the fecal immunochemical test (FIT) for screening average risk people?

- FIT is a more accurate screening test than gFOBT for detecting a cancer or pre-cancerous polyps in average risk people. Results from systematic reviews show that FIT is more sensitive (i.e., better at detecting a cancer in people who have the disease) than gFOBT (one-time FIT vs. one-time gFOBT (Hemoccult II) has a sensitivity of 82 percent vs. 38 percent) (1, 2). FIT has also been shown to detect twice as many high risk adenomas and cancers as gFOBT (relative risk [RR], 2.15; 95 percent confidence interval [CI], 1.58 to 2.94). (3) Despite this much higher sensitivity, FIT only has a slightly lower specificity (i.e., proportion of negative test results correctly identified as not having the disease) than gFOBT (94 percent vs. 96 percent) (1, 2).
    - A recent systematic review also found that people are more likely to participate in screening when FIT is used compared to gFOBT (RR, 1.16; 95 percent CI, 1.05 to 1.28) (3). This may be due to the fact that diet and medications do not interfere with FIT and sampling is easier.
    - This combination of better test accuracy and higher participation than the gFOBT makes FIT a better screening test for people at average risk for colorectal cancer.

(1) Lee JK, Liles EG, Bent S, Levin TR, Corley DA. Accuracy of fecal immunochemical tests for colorectal cancer: Systematic review and meta-analysis. Ann Intern Med. 2014; 160(3):171-181.

(2) Canadian Task Force on Preventive Health Care. Screening for colorectal cancer [Internet]. Ottawa, Canada: Canadian Task Force on Preventive Health Care; 2014. Available from: http://canadiantaskforce.ca/guidelines/published-guidelines/colorectal-cancer/

(3) Tinmouth J, Vella E, Baxter NN, Dubé C, Gould M, Hey A, et al. Colorectal cancer screening in average risk populations: Evidence summary. Toronto (ON): CCO; 2015 November 11. Program in Evidence-based Care Evidence Summary No.: 15-14.

4. How does screening with the fecal immunochemical test (FIT) compare to screening colonoscopy in persons at average risk?

- There is limited evidence comparing FIT to colonoscopy screening in terms of colorectal cancer incidence and mortality in people at average risk*. However, several large randomized controlled trials (RCTs) are underway to address this question. This includes an RCT in Spain with over 50,000 participants invited to be screened. While final results for colorectal cancer mortality will not be available until the 2020s, preliminary results suggests that FIT offers comparable benefits.

Cancer and pre-cancer detection:

- In 2012, the large RCT currently underway in Spain published results from the first round of screening, which provides some initial information about the effectiveness of FIT vs. colonoscopy (1). In the first round of screening, FIT was as good as colonoscopy at detecting colorectal cancer (33

cancers vs. 30 cancers; P value = not significant) on an "intention to screen" basis (i.e., analyses are based on all participants initially randomized to that arm, regardless of whether or not they complete screening or whether they withdraw from the study—this approach better reflects the "real life" impact of screening as it captures participants' acceptance of the test as well as its accuracy). While the study found that colonoscopy was significantly better at detecting advanced adenomas than the one-time use of FIT (514 vs. 231; p<0.001), this benefit may not be sustained over time because people in the FIT group will be recalled for screening four more times over the course of the study. Although these preliminary findings are of considerable interest, the final results will provide a more definitive answer about how colonoscopy compares to FIT.

Participation:

- People tend to prefer the less invasive FIT to colonoscopy. In the Spanish RCT described above, screening participants were given the option to switch their screening test from FIT to colonoscopy, or colonoscopy to FIT. While 23 percent of people invited for colonoscopy opted to switch to FIT, only one percent of people invited for FIT opted to switch to colonoscopy (crossover rate OR: 16.8; 95% CI, 13.9 to 20.2; p<0.001). Additional studies comparing participation between stool-based tests and colonoscopy are described in the Colorectal Cancer Screening in Average Risk Populations: Evidence Summary (2). While the quality of these studies varies, there is a general trend showing that people prefer stool-based testing over colonoscopy.

Complications:

- In the Spanish RCT described above, among those who screened with FIT, one colorectal cancer was detected for every 18 people with an abnormal FIT result who underwent a colonoscopy, compared to one colorectal cancer being detected for every 191 people who screened with colonoscopy (2). Therefore, screening with FIT reduces the number of people who need a colonoscopy and ensures that only those who are most likely to benefit from the procedure are exposed to its uncommon, but potentially serious, complications.
- In the Spanish RCT, the risk of complications was statistically significantly lower in the FIT arm than in the colonoscopy arm (0.1 percent vs. 0.5 percent; p<0.001). The complications experienced by participants in the FIT group occurred in those with an abnormal FIT result and who underwent a follow-up diagnostic colonoscopy.
- FIT is a safe, non-invasive screening test. While colonoscopy is a generally safe exam, complications can occur, including those related to bowel preparation and sedation. Possible colonoscopy-related complications include (but are not limited to) perforation, post-polypectomy bleeding, cardiac events, syncope/hypotension and death (in rare cases) (3, 4). A Canadian study found that out of approximately 68,000 people in Ontario who had an outpatient colonoscopy in 2002–2003, 101 were admitted to hospital with bleeding and 40 with perforations; five colonoscopies resulted in death, two of which were confirmed to be colonoscopy related and the remainder were possibly colonoscopy related (3).

(1) Quintero E, Castells A, Bujanda L, Cubiella J, Salas D, Lanas Á, et al. Colonoscopy versus fecal immunochemical testing in colorectal cancer screening. The New England Journal of Medicine. 2012; 366(8): 697-706.
(2) Tinmouth J, Vella E, Baxter NN, Dubé C, Gould M, Hey A, et al. Colorectal cancer screening in average risk populations: Evidence summary. Toronto (ON): CCO; 2015 November 11. Program in Evidence-based Care Evidence Summary No.: 15-14.
(3) Rabeneck L, Paszat L, Hilsden R, Saskin R, Leddin D, Grunfeld E, et al. Bleeding and perforation after outpatient colonoscopy and their risk factors in usual clinical practice. Gastroenterology. 2008;135(6):1899-1906.e1.
(4) Hilsden RJ, Dubé C, Heitman SJ, Bridges R, McGregor SE, Rostom A. The association of colonoscopy quality indicators with the detection of screen-relevant lesions, adverse events, and postcolonoscopy cancers in an asymptomatic Canadian colorectal cancer screening population. Gastrointest Endosc. 2015 Nov; 82(5):887-94.

5. Are there any limitations to the fecal immunochemical test (FIT) compared to the guaiac fecal occult blood test (gFOBT)?

- The FIT collection device has a shorter shelf life (12 to 18 months) than the gFOBT card (three years). Therefore, to manage device inventory and avoid the accidental distribution of expired devices, LifeLabs will mail your patient their FIT kit after you send LifeLabs a FIT requisition.
- Once a stool specimen has been collected using the FIT collection device, the specimen is less stable than a gFOBT specimen on a card. Therefore, ColonCancerCheck recommends testing FIT collection devices within 14 days of specimen collection (vs. 21 days for gFOBT). ColonCancerCheck is working with LifeLabs to support timely return of completed tests from participants in all regions across Ontario.

Changes to ColonCancerCheck's screening recommendations

6. Why does ColonCancerCheck no longer recommend the guaiac fecal occult blood test (gFOBT) for screening people at average risk?

- The fecal immunochemical test (FIT) is ColonCancerCheck's recommended screening test for people at average risk of colorectal cancer. As of June 24, 2019, gFOBT is no longer recommended by the ColonCancerCheck program.
- Although there is high-quality evidence to support screening with gFOBT, FIT offers several advantages over gFOBT. Compared to gFOBT, FIT is preferred by participants, easier to use, and is better at detecting colorectal cancer and pre-cancerous polyps.
- According to results from systematic reviews, FIT is more sensitive than gFOBT (1, 2) and has been shown to detect twice as many colorectal cancers and advanced adenomas (immediate precursors to

colorectal cancer) than gFOBT (3). Furthermore, a recent systematic review found that people are more likely to participate in screening when FIT is used than when gFOBT is used (3). This preference may be related to FIT's easier sampling method. For example, FIT requires only one specimen, compared to three for gFOBT, and FIT does not require dietary or medication restrictions.

(1) Lee JK, Liles EG, Bent S, Levin TR, Corley DA. Accuracy of fecal immunochemical tests for colorectal cancer: Systematic review and meta-analysis. Ann Intern Med. 2014; 160(3):171-181.

(2) Canadian Task Force on Preventive Health Care. Screening for colorectal cancer [Internet]. Ottawa, Canada: Canadian Task Force on Preventive Health Care; 2014. Available from: http://canadiantaskforce.ca/guidelines/published-guidelines/colorectal-cancer/

(3) Tinmouth J, Vella E, Baxter NN, Dubé C, Gould M, Hey A, et al. Colorectal cancer screening in average risk populations: Evidence summary. Toronto (ON): CCO; 2015 November 11. Program in Evidence-based Care Evidence Summary No.: 15-14.

7. Has the eligibility criteria for colorectal cancer screening changed with the fecal immunochemical test (FIT)?

- No. Eligibility criteria for screening with FIT are the same as for screening with the guaiac fecal occult blood test (gFOBT). The ColonCancerCheck eligibility criteria are:
    - Being age 50 to 74*;
    - Being at average risk for colorectal cancer†;
    - Being asymptomatic‡;
    - Not having screened for colorectal cancer with FIT in the past two years;
    - Not having had a colonoscopy or flexible sigmoidoscopy in the past 10 years; and
    - Having a valid Ontario Health Insurance Plan number.

- You will continue to assess eligibility of your patients for screening with FIT. In addition, LifeLabs will confirm eligibility based on key parameters, such as age and, when possible, previous fecal test screening status.
- To learn more about the current ColonCancerCheck screening recommendations and eligibility criteria, please visit cancercareontario.ca/CCCrecommendations.

*Although the ColonCancerCheck program does not recommend regular screening for people over age 74, someone may choose to get screened after age 74 if the benefits of screening outweigh the risks. Therefore, you are able to order FIT kits for people ages 75 to 85 who you deem eligible and appropriate for screening.

† "Average risk" refers to people ages 50 to 74 with no first-degree relative who has been diagnosed with colorectal cancer, and with no personal history of inflammatory bowel disease (i.e., Crohn's disease or ulcerative colitis) or pre-cancerous polyps requiring surveillance.

‡ There are no physical symptoms during the early stages of the disease. As colorectal cancer develops over time, someone might experience:

- Unexplained iron deficiency anemia;
- Blood (either bright red or very dark) in the stool;
- Unexplained weight loss;
- New and persistent diarrhea, constipation or feeling that the bowel does not empty completely; and/or
- New and persistent abdominal discomfort.

8. What is the screening interval for the fecal immunochemical test (FIT) for people at average risk of colorectal cancer?

- FIT should be performed every two years in people ages 50 to 74 who are at average risk* of developing colorectal cancer. This is the same screening interval that was previously recommended for gFOBT.
- Following a colonoscopy that is normal, or that only found hyperplastic polyps in the rectum or sigmoid colon, people should resume screening with FIT after 10 years.
- Following a colonoscopy that found low risk adenomas†, people should resume screening with FIT after five years.
- Following a colonoscopy that found high risk adenomas‡ or serrated polyps, people should undergo surveillance colonoscopy
- For more information about surveillance intervals, refer to ColonCancerCheck's Recommendations for Post-Polypectomy Surveillance: cancercareontario.ca/CCCsurveillance.

* "Average risk" refers to people ages 50 to 74 with no first-degree relative who has been diagnosed with colorectal cancer, and with no personal history of inflammatory bowel disease (i.e., Crohn's disease involving the colon or ulcerative colitis) or pre-cancerous colon polyps requiring surveillance.

† Low risk adenomas: One to two tubular adenomas less than 10 millimeters in diameter without high- grade dysplasia.

‡ High risk adenomas: One or more tubular adenomas 10 millimeters or greater, or three or more adenomas of any size, or an adenoma with villous histology, or an adenoma with high-grade dysplasia (also called advanced adenomas).

9. How soon after undergoing colonoscopy should people start screening again with the fecal immunochemical test (FIT) if they have no family history of colorectal cancer in a first-degree relative?

- People at average risk* of colorectal cancer who have had a colonoscopy that is normal, or that only found hyperplastic polyps in the rectum or sigmoid, should resume screening with FIT after 10 years.
- These people should not re-screen with colonoscopy because the ColonCancerCheck program does not recommend screening with colonoscopy for people at average risk.
    - FIT is recommended over colonoscopy because:
        - evidence shows that FIT is as good as colonoscopy at detecting colorectal cancer on an "intention to screen" basis (i.e., analyses are based on all participants initially randomized to that arm, regardless of whether or not they complete screening or whether they withdraw from the study—this approach better reflects the "real life" impact of screening as it captures participants' acceptance of the test as well as its accuracy) (1);
        - evidence reflects that patients prefer FIT over colonoscopy (1,2); and
        - evidence also shows FIT is a safe and non-invasive screening test, and average risk screening with FIT will reduce the risk of complications associated with colonoscopy (1).

* "Average risk" refers to people ages 50 to 74 with no first-degree relative who has been diagnosed with colorectal cancer, and with no personal history of inflammatory bowel disease (i.e., Crohn's disease involving the colon or ulcerative colitis) or pre-cancerous polyps requiring surveillance.

(1) Quintero E, Castells A, Bujanda L, Cubiella J, Salas D, Lanas Á, et al. Colonoscopy versus fecal immunochemical testing in colorectal cancer screening. The New England Journal of Medicine. 2012; 366(8): 697-706.

(2) Tinmouth J, Vella E, Baxter NN, Dubé C, Gould M, Hey A, et al. Colorectal cancer screening in average risk populations: Evidence summary. Toronto (ON): CCO; 2015 November 11. Program in Evidence-based Care Evidence Summary No.: 15-14.

10. Why is screening average risk people with the fecal immunochemical test (FIT) recommended over colonoscopy?

- The ColonCancerCheck program does not recommend screening with colonoscopy for people at average risk*.
- There is limited evidence comparing FIT to colonoscopy screening in terms of colorectal cancer incidence and mortality in people at average risk*. Several large randomized controlled trials (RCTs)

are underway to address this question, with preliminary results suggesting that FIT offers comparable benefits.

- Results from one large ongoing RCT in Spain suggest that FIT is as good as colonoscopy at detecting colorectal cancer (33 cancers vs. 30 cancers; P value = not significant) on an "intention to screen" basis (i.e., analyses are based on all participants initially randomized to that arm, regardless of whether or not they complete screening or whether they withdraw from the study—this approach better reflects the "real life" impact of screening as it captures participants' acceptance of the test as well as its accuracy) (1). While the study found that colonoscopy was significantly better at detecting advanced adenomas than the one-time use of FIT (514 vs. 231; p<0.001), this benefit may not be sustained over time because people in the FIT arm will be recalled for screening four more times over the course of the study; by comparison, those in the colonoscopy arm are not re-invited for screening throughout this 10-year interval. The study also found that 23 percent of people invited for colonoscopy opted to switch to FIT, compared to only one percent of people invited for FIT who switched to colonoscopy (crossover rate OR: 16.8; 95% CI, 13.9 to 20.2; p<0.001), providing further evidence that people prefer screening with FIT over colonoscopy (1).
- Furthermore, unlike colonoscopy, FIT is a non-invasive screening test. While colonoscopy is generally a safe exam, complications can occur, including those related to bowel preparation (e.g., falls, injuries and electrolytic abnormalities) and sedation. Possible colonoscopy-related complications include (but are not limited to) perforation, post-polypectomy bleeding, cardiac events, syncope/hypotension and death (in rare cases) (2, 3). In the Spanish RCT, the risk of complications was statistically significantly lower in the FIT arm than in the colonoscopy arm (0.1% vs. 0.5%; p<0.001).
- Colonoscopy remains the appropriate test for follow-up of abnormal FIT results and for screening people at increased risk of colorectal cancer**.

* "Average risk" refers to people ages 50 to 74 with no first-degree relative who has been diagnosed with colorectal cancer, and with no personal history of inflammatory bowel disease (i.e., Crohn's disease involving the colon or ulcerative colitis) or pre-cancerous polyps requiring surveillance.

** "Increased risk" refers to people with a family history of colorectal cancer that includes one or more first-degree relatives who have been diagnosed with colorectal cancer, but who do not meet the criteria for colorectal cancer hereditary syndromes.

(1) Quintero E, Castells A, Bujanda L, Cubiella J, Salas D, Lanas Á, et al. Colonoscopy versus fecal immunochemical testing in colorectal cancer screening. The New England Journal of Medicine. 2012; 366(8): 697-706.
(2) Rabeneck L, Paszat L, Hilsden R, Saskin R, Leddin D, Grunfeld E, et al. Bleeding and perforation after outpatient colonoscopy and their risk factors in usual clinical practice. Gastroenterology. 2008;135(6):1899-1906.e1.

(3) Hilsden RJ, Dubé C, Heitman SJ, Bridges R, McGregor SE, Rostom A. The association of colonoscopy quality indicators with the detection of screen-relevant lesions, adverse events, and postcolonoscopy cancers in an asymptomatic Canadian colorectal cancer screening population. Gastrointest Endosc. 2015 Nov; 82(5):887-94.

11. Why does ColonCancerCheck not recommend routine screening for people older than age 74?

- The ColonCancerCheck program does not recommend regular screening for people older than age 74. However, the ColonCancerCheck program considers it appropriate to screen some people after age 74 if the benefits of screening outweigh the risks.
- In general, people older than 74 do not benefit as much and are at more risk of having complications when they get screened for colorectal cancer. People who are younger than 75 with severe medical conditions may also experience more risks than benefits from screening.
- It is generally accepted that someone whose life expectancy is less than five years should not be screened. This consideration also applies to people who are younger than 75 who suffer from severe comorbidities.
- There are a number of factors that influence the decision to screen for cancer in older adults ages 75 to 85. The benefits vary, depending on someone's life expectancy and their screening history, while the potential for harm (including complications from diagnostic procedures and psychological distress from screening) increase. In particular, the benefits of screening are greater if someone has never been screened than if someone has regularly screened up until that age.
- For these reasons, adults ages 74 to 85 can be screened for colorectal cancer with FIT at your discretion. The ColonCancerCheck program strongly recommends against colorectal cancer screening among people older than 85. The program will not accept FIT requisitions for adults older than 85 and LifeLabs will not process them.

12. Why does ColonCancerCheck not recommend routine colorectal cancer screening for people younger than age 50?

- High-quality evidence to support initiation of screening earlier than age 50 is limited, in part, because colorectal cancer screening research has traditionally focused on people age 50 and older.
- In Canada, the incidence of colorectal cancer among people ages 40 to 49 has increased, with an annual percent change from 2003 to 2012 of +1.66% for colon cancer and +2.05% for rectal cancer (compared to an annual percent change of -0.54% for colon cancer and +1.11% for rectal cancer among people ages 50 to 55 from 1993 to 2012) (1).
- However, colorectal cancer incidence remains very low among adults younger than age 50. Approximately six percent of new colorectal cancer cases in Canada are diagnosed among people age 49 and younger (2). In Ontario, the projected incidence of colorectal cancer among people ages 45 to

49 is 39.2/100,000 for 2018, compared to 146.1/100,000 for people ages 50 to 74 over the same period (Cancer Care Ontario, 2018, unpublished).

- The ColonCancerCheck program continues to recommend that people at average risk of colorectal cancer begin screening at age 50 due to the lack of high-quality evidence for screening in people younger than age 50, the uncertainty surrounding the clinical benefits of extending these recommendations and the relatively low incidence of cancer among people ages45 to 50.
- ColonCancerCheck is also aware of diagnostic delays among younger people with colorectal cancer (3). ColonCancerCheck advises family doctors and nurse practitioners to be aware of early onset colorectal cancer and to promptly refer people of any age with symptoms suggestive of colorectal cancer to a specialist, if appropriate.*
- The ColonCancerCheck program continues to monitor the emerging evidence in this area, including colorectal cancer incidence trends in Ontario, and will re-evaluate program recommendations as appropriate.

*Visit the following link for more information about symptoms of colorectal cancer: cancercareontario.ca/CCCrecommendations.

(1) Brenner DR, Ruan Y, Shaw E, De P, Heitman SJ, and Hilsden RJ. Increasing colorectal cancer incidence trends among younger adults in Canada. Prev Med. 2017; 105:345-349.

(2) Canadian Cancer Society's Advisory Committee on Cancer Statistics. Canadian cancer statistics 2017. Toronto, ON: Canadian Cancer Society; 2017. Available at: cancer.ca/Canadian-Cancer-Statistics- 2017-EN.pdf (accessed June 7, 2018).

(3) You YN, Xing Y, Feig BW, Cang GJ, Cormier JN. Young-onset colorectal cancer: is it time to pay attention? Arch Intern Med. 2012; 172(3):287.

13. Why are people with symptoms or conditions that may be related to colorectal cancer advised not to have a fecal immunochemical test (FIT)?

- Cancer screening, by definition, means testing people without symptoms or conditions that may be related to cancer to identify those with a higher likelihood of an underlying cancer. Because people with symptoms (e.g., bleeding) or conditions (e.g., iron deficiency anemia) related to colorectal cancer already have a higher likelihood of an underlying colorectal cancer, they should be directly referred to colonoscopy.
- Stool-based testing should not be used to guide the decision to refer or investigate patients with symptoms or iron deficiency anemia.
- Using stool-based testing in people presenting with symptoms suggestive of colorectal cancer or iron deficiency anemia or upper gastrointestinal bleeding has been shown to cause diagnostic delays and inefficiencies (1, 2, 3, 4).

(1) Pochapin MB, Fine SN, Eisorfer RM, Rigas B. Fecal occult blood testing in hospitalized patients. J Clin Gastroenterol. 1994; 19(4):274-277.

(2) Narula N, Ulic D, Al-Dabbagh R, Ibrahim A, Mansour M, Balion C, et al. Fecal occult blood testing as a diagnostic test in symptomatic patients is not useful: A retrospective chart review. Can J Gastroenterol Hepatol. 2014; 28(8): 421–26.
(3) van Rijn AF, Stroobants AK, Deutekom M, Lauppe C, Sturk A, Bossuyt PMM, et al. Inappropriate use of the faecal occult blood test in a university hospital in the Netherlands. Euro J of Gastroenterol and Hepatol. 2012; 24(11):1266-69.
(4) Ip S, Sokoro AA, Kaita L, Ruiz C, McIntyre E, Singh H. Use of fecal occult blood testing in hospitalized patients: results of an audit. Can J Gastroenterol Hepatol. 2014; 28(9): 489-94.

Changes associated with the switch to the fecal immunochemical test (FIT)

14. What changes will participants and primary care providers experience with the introduction of the fecal immunochemical test (FIT)?

Changes to the distribution of FIT kits

- You no longer need to maintain an inventory of, or distribute, colorectal cancer screening tests (e.g., guaiac fecal occult blood test [gFOBT] and FIT).
- You can submit requisitions to LifeLabs (e.g., by fax 1-833-676-1427 or electronic medical record), and LifeLabs will mail FIT kits directly to your patients).
- Centralized distribution of FIT kits from LifeLabs (instead of from providers and pharmacies) will help to address FIT's shorter shelf life and minimize rejected tests through:
    - Barcode labelling of FIT collection devices with patient identifiers, which reduces the information patients have to provide themselves (failure to provide this information can lead to test rejections);
    - Improved inventory management so that participants do not receive expired kits, given the shorter shelf life of the FIT collection device (which expires within 12 to 18 months); and
    - Allowing LifeLabs to confirm patient eligibility before mailing out each FIT kit (which will help to reduce inappropriate use of the FIT).
- Centralized distribution of gFOBT and FIT kits is common practice in many jurisdictions (Nova Scotia, Saskatchewan, Manitoba, New Brunswick, Prince Edward Island, Newfoundland, England, Australia and the Netherlands).
- Ontario Health (Cancer Care Ontario) has sent a sample FIT collection device to primary care providers to give them the opportunity to demonstrate how to complete a FIT with their patients.

Your role in the screening of average risk patients for colorectal cancer

You are responsible for:

- Determining patient eligibility for screening with FIT;

- Validating patient address information and date of birth before completing the requisition form and sending it to LifeLabs—this validation is critical for ensuring that LifeLabs and ColonCancerCheck have up-to-date participant mailing information, so the privacy of patients is not compromised, and so participants can receive their FIT kit and test result notification; LifeLabs may need to check with you regarding completeness and/or accuracy of information on FIT requisitions;
- Specifying in the requisition where the FIT kit should be sent, even if it is somewhere other than your patient's home or mailing address;
- Completing the FIT requisition form and submitting (e.g., faxing) it directly to LifeLabs (you should never give the requisition to your patient); LifeLabs will mail your patient's FIT kit to the address on their FIT requisition—the FIT kit will include the FIT collection device, instructions for completing the FIT and materials for mailing it back to LifeLabs;
- Ensuring that patients with an abnormal FIT result receive timely follow-up—ColonCancerCheck recommends follow-up with a colonoscopy within eight weeks of an abnormal FIT result. Timely follow-up of an abnormal FIT result is particularly important due to the higher likelihood of abnormal findings for follow-up colonoscopies after an abnormal FIT result. Patients with an abnormal FIT result should be referred for colonoscopy to a facility that has the expertise and resources to perform colonoscopies in FIT- positive patients.
- Being aware of any regional strategies to ensure timely access to colonoscopy for your patients with a positive (i.e., abnormal) FIT. A list of facilities funded by Ontario Health (Cancer Care Ontario) to provide colonoscopies for patients with an abnormal FIT result is available at cancercareontario.ca/FITcolonoscopy.

Role of patients

- After you order a FIT for your eligible patient, they will receive the FIT in the mail from LifeLabs and will complete it.
    - Participants will receive simple, picture-based, instructions with their FIT to help them complete the test properly.
    - Copies of FIT instructions are available at cancercareontario.ca/FITinstructions
- Participants must return their completed FIT to LifeLabs by mail or by dropping it off at a specimen collection centre associated with Life Labs (visit locations.lifelabs.com).
- The completed FIT should be returned to LifeLabs as soon as possible after the stool is collected. LifeLabs will contact screening participants if their specimen collection date needs clarification.
- Participants are only required to return their completed FIT with the specimen collection date clearly recorded in the space provided. No additional paperwork has to be returned with a completed FIT.

15. Will Ontario Health (Cancer Care Ontario) continue to send letters to my patients and will the new correspondence differ from the guaiac fecal occult blood test (gFOBT) letters?

- Ontario Health (Cancer Care Ontario) has updated all colorectal cancer screening correspondence letters to reflect that the fecal immunochemical test (FIT), rather than gFOBT, is the recommended test for screening people at average risk. These changes went into effect on the day FIT was launched in Ontario (June 24, 2019) to coincide with the availability of the test.
- However, participants who completed a gFOBT shortly before the switch to FIT will receive a result letter that is specific to their gFOBT result.

16. Why was my patient invited to complete a guaiac fecal occult blood test (gFOBT) now that the fecal immunochemical test (FIT) is available?

- Ontario Health (Cancer Care Ontario) has updated its correspondence letters to invite people to complete a FIT instead of a gFOBT. These changes went into effect on the day FIT was launched in Ontario (June 24, 2019). If your patient was due for colorectal cancer screening before FIT launch, their correspondence letter would have been specific to gFOBT.
- People who received an invitation for gFOBT, but who did not do their test, will be sent a reminder letter encouraging them to screen. If their reminder letter is sent after FIT launch, it will be specific to FIT. In this scenario, people will receive an invitation for gFOBT and a reminder for FIT.
- Because patients are expected to connect with their family doctor, nurse practitioner or Telehealth Ontario before doing their screening test, you should have the opportunity to introduce your patient to the new test before ordering it for them, if appropriate.

17. Now that the fecal immunochemical test (FIT) is available, why does my patient's normal or abnormal guaiac fecal occult blood test (gFOBT) result letter not acknowledge FIT as the new screening test for people at average risk for colorectal cancer?

- Ontario Health (Cancer Care Ontario) has updated colorectal cancer screening correspondence letters to reflect the fact that FIT, rather than gFOBT, is the recommended test for screening people at average risk. These changes went into effect on the day FIT was launched in Ontario (June 24, 2019) to coincide with the availability of the test.
- Participants who complete a gFOBT and get an indeterminate or rejected test result will receive a letter instructing them to complete a FIT (the new screening test recommended for people at average risk).

- Participants who complete a gFOBT and receive a normal or abnormal result will be sent a result letter specific to gFOBT. Abnormal and normal result letters for gFOBT will not acknowledge that FIT is the new screening test. After the appropriate follow-up activities are completed, the participant will receive a recall letter inviting them to screen with FIT as the next appropriate screening interval.

18. What is the cost of the fecal immunochemical test (FIT)?

- The cost of FIT is comparable to the cost of the guaiac fecal occult blood test (gFOBT). Cost-effectiveness studies consistently find that colorectal cancer screening in general is more cost-effective than no screening (1, 2, 3, 4). Two economic evaluations of FIT screening have used Canadian data (1, 2). Heitman et al. used a Markov model to simulate a population of 100,000 average risk people and compared screening for that population with different tests: gFOBT, FIT, flexible sigmoidoscopy every five years and colonoscopy every 10 years (1). Results showed that FIT was more effective and less costly than gFOBT. The lower cost of FIT is related to a decrease in colorectal cancer incidence, leading to decreased costs of colorectal cancer treatment. The study also showed that screening once every two years with FIT was as effective as, and less costly than, colonoscopy.
- In another study, Goede et al. used the MIcrosimulation SCreening Analysis (MISCAN) Colorectal Cancer Model and Ontario population data to run a simulated comparison of screening with FIT versus gFOBT every two years (2). Results from this study also showed that FIT is less costly and more effective than gFOBT (2).
- FIT is available at no cost through the ColonCancerCheck program to people with Ontario Health Insurance Plan coverage.

(1) Heitman S, Hilsden R, Au F, Dowden S, Manns B. Colorectal cancer screening for average risk North Americans: an economic evaluation. PLoS Medicine. 2010;7(11):e1000370.

(2) Goede S, Rabeneck L, van Ballegooijen M, Zauber A, Paszat L, Hoch J et al. Harms, benefits and costs of fecal immunochemical testing versus guaiac fecal occult blood testing for colorectal cancer screening. PLOS ONE. 2017;12(3):e0172864.

(3) Lansdorp-Vogelaar I, Knudsen AB, Brenner H. Cost-effectiveness of colorectal cancer screening. Epidemiol Rev 2011;33:88–100

(4) Knudsen AB, Zauber AG, Rutter CM, Naber SK, Doria-Rose VP, Pabiniak C, et al. Estimation of benefits, burden, and harms of colorectal cancer screening strategies: Modeling study for the US preventive services task force. JAMA. 2016 Jun 21;315(23):2595-609. doi: 10.1001/jama.2016.6828

19. Is the fecal immunochemical test (FIT) available outside of the program?

- Ontario Health (Cancer Care Ontario) is aware that some other laboratories offer FIT in Ontario; however, a FIT from a laboratory other than LifeLabs is not considered part of the ColonCancerCheck program. Therefore, patients who get a FIT from another laboratory will not receive the full benefits of organized screening through ColonCancerCheck.
- Participants receive the following benefits by being screened through the ColonCancerCheck program:
    - Being invited to participate in screening;
    - Being reminded when it is time for their next screening test;
    - Being informed of their test results;
    - Being tracked throughout the screening and diagnostic process; and
    - Participating in a program in which quality and performance are carefully monitored.

20. Is the fecal immunochemical test (FIT) available for colorectal cancer screening in hospitals?

- If you practice in a hospital setting, you can use the new ColonCancerCheck program FIT requisition to order the test for colorectal cancer screening. The FIT requisition is the only requisition that can be used to order a FIT through the ColonCancerCheck program for screen-eligible people at average risk for colorectal cancer. The ColonCancerCheck program FIT cannot be ordered with the Ministry of Health and Long-Term Care Laboratory Requisition or on a hospital laboratory requisition.
- Ontario Health (Cancer Care Ontario) does not recommend using FIT for indications other than colorectal cancer screening (e.g., for diagnostic use, point-of-care testing). Stool-based testing has low sensitivity for the diagnosis of colorectal cancer in people with symptoms (1, 2) and using stool-based testing as a diagnostic tool (e.g., use in the emergency room for patients presenting with symptoms suggestive of gastrointestinal bleeding) has been shown to lead to diagnostic delays and inefficiencies (3, 4, 5).

(1) Farag A, Barkun AN, Martel M. The utility of fecal occult blood testing for clinical indications of suspected gastrointestinal blood loss outside a setting of colorectal cancer screening: A systematic review. Poster session presented at: Digestive Disease Week; 2016 May 22 – 24; San Diego, CA.

(2) Pochapin MB, Fine SN, Eisorfer RM, Rigas B. Fecal occult blood testing in hospitalized patients. J Clin Gastroenterol. 1994; 19(4):274-277.

(3) Narula N, Ulic D, Al-Dabbagh R, Ibrahim A, Mansour M, Balion C, et al. Fecal occult blood testing as a diagnostic test in symptomatic patients is not useful: A retrospective chart review. Can J Gastroenterol Hepatol. 2014; 28(8): 421–26.

(4) van Rijn AF, Stroobants AK, Deutekom M, Lauppe C, Sturk A, Bossuyt PMM, et al. Inappropriate use of the faecal occult blood test in a university hospital in the Netherlands. Euro J of Gastroenterol and Hepatol. 2012; 24(11):1266-69.
(5) Ip S, Sokoro AA, Kaita L, Ruiz C, McIntyre E, Singh H. Use of fecal occult blood testing in hospitalized patients: results of an audit. Can J Gastroenterol Hepatol. 2014; 28(9): 489-94.

Ordering and distribution: general

21. What is the process for ordering a fecal immunochemical test (FIT) kit for my patients?

- You can order a FIT kit for eligible, average risk people by completing a FIT requisition.
- The FIT requisition is a single-test, program-branded requisition. FIT cannot be ordered using the Ministry of Health and Long-Term Care Laboratory Requisition or a hospital laboratory requisition.
- The FIT requisition is available at cancercareontario.ca/pcscreeningprograms.
- You will need to ensure the accuracy of your patient's mailing address information (including an alternative mailing address for the FIT kit, if applicable) and confirm their date of birth. FIT kits will only be mailed within Ontario.
- Complete and submit the FIT requisition directly to LifeLabs (e.g., by fax 1-833-676-1427 or electronic medical record). Do not give your patient the FIT requisition.
- LifeLabs will assess the requisition for completeness and verify patient eligibility. LifeLabs will then mail a FIT kit directly to your patient.
- The requisition has a second address section called "FIT Kit Mailing Address." This section can be used for participants who may require their FIT kit to be sent to an alternative Ontario address, such as a health centre or nursing station. The information in the FIT Kit Mailing Address section will not be used for program correspondence. Ontario Health (Cancer Care Ontario) will use the address provided in the Patient Information section on the requisition as an address source to send patient result letters and correspondence.
- The ColonCancerCheck Guide to Average Risk Screening with FIT in Ontario is a tool that describes how to order a FIT kit for your patient. A copy is at http://www.cancercareontario.ca/CCCrecommendations. If you have any questions for LifeLabs, contact 1-833-676-1426.

22. Can fecal immunochemical test (FIT) kits be stocked by my office?

- No. ColonCancerCheck's FIT kits cannot be stocked by your office or any other provider office. FIT kits are stocked and distributed by LifeLabs to manage FIT collection device inventory. This centralized management of device inventory is necessary to reduce waste from expired FIT kits because FIT has a shorter shelf life than the guaiac fecal occult blood test (gFOBT). It also allows for the use of barcode

labels on FIT collection devices to reduce the rates of rejection from participant mislabeling (e.g., failing to write their name on the device) and provides an opportunity for LifeLabs to confirm eligibility before mailing out kits.

23. Do mobile screening coaches support access to the fecal immunochemical test (FIT)?

- Mobile screening coaches operating in the North West and Hamilton Niagara Haldimand Brant regions support access to colorectal cancer screening with FIT in the regions they serve. Participants can order a FIT kit from the mobile screening coaches. Mobile screening coaches will send FIT requisitions directly to LifeLabs, which is responsible for mailing FIT kits to participants or to an address that is convenient. Mobile screening coaches should not give participants the FIT requisition.

24. Do pharmacists play a role in the distribution of the fecal immunochemical test (FIT)?

- Pharmacists no longer distribute guaiac fecal occult blood test (gFOBT) kits to unattached participants (i.e., people without a primary care provider) and no longer play a role in the ColonCancerCheck program now that it has switched the recommended average risk screening test from the gFOBT to FIT. Unattached participants can call Telehealth Ontario at 1-866-828-9213 to order a FIT kit. Eligibility for a FIT kit can also be discussed with a mobile screening coach staff member in the North West and Hamilton Niagara Haldimand Brant regions.

25. How will people without a primary care provider screen for colorectal cancer with the fecal immunochemical test (FIT)?

- People without a primary care provider (i.e., who are unattached) can access the FIT through Telehealth Ontario and mobile screening coaches. Telehealth Ontario and mobile screening coaches are responsible for submitting FIT requisitions to LifeLabs. LifeLabs will then confirm participant eligibility and mail FIT kits to participants or an alternative address that is convenient. Participants are no longer able to get kits from community pharmacists.
- Unattached participants who have completed a FIT will receive result letters by mail from Ontario Health (Cancer Care Ontario).
- Ontario Health (Cancer Care Ontario) continues to assist participants without a primary care provider who have an abnormal FIT result to connect with a provider for timely follow-up colonoscopy.
- You are encouraged to sign up with Ontario Health (Cancer Care Ontario) to accept new patients who have had an abnormal fecal screening test result and require a follow-up colonoscopy.
    - The Physician Registration for Patient Attachment form can be found at cancercareontario.ca/pcscreeningprograms

- Upon completion, please fax or email this form to: 416-971-6888 or cancerinfo@ontariohealth.ca.

Ordering and distribution: rural and remote & First Nations communities

26. What is the process for ordering and returning a fecal immunochemical test (FIT) kit for patients who live in rural or remote communities?

Ordering FIT:

- Eligible participants who live in rural or remote communities can order a FIT kit through their family doctor or nurse practitioner. If someone does not have a family doctor or nurse practitioner, they can call Telehealth Ontario at 1-866-828-9213 to order a FIT kit. Participants in the North West and Hamilton Niagara Haldimand Brant regions are also able to order a FIT kit through a mobile screening coach (cancercareontario.ca/en/find-cancer-services/mobile-screening). Participants who live on a First Nation reserve also have the option of having a FIT kit ordered through their health centre or nursing station.
- Primary care providers, Telehealth Ontario or nurses from mobile screening coaches must complete a FIT requisition. Do not give your patients the FIT requisition; you should submit the requisition directly to LifeLabs (e.g., by fax 1-833-676-1427 or electronic medical record). LifeLabs will confirm patient eligibility and mail FIT kits directly to your patients.
- It is important to note that the FIT requisition has two address sections. The first address section (Patient Information) should contain the participant's mailing address, as registered with the Ontario Health Insurance Plan. If a patient requires the FIT kit to be mailed to an alternative address (i.e., that is different from the patient's primary mailing address), you can complete the second address section (FIT Kit Mailing Address) on the FIT requisition. For example, patients who live on a First Nation reserve can have their FIT kit sent to a health centre or nursing station.

Returning FIT:

- Participants who live in rural or remote areas can return their completed FIT by dropping it off at a specified LifeLabs Patient Service Centre (see locations.lifelabs.com for details) or by sending it in the mail using the return envelope provided. Participants who live on a First Nation reserve can contact their health centre or nursing station to discuss drop-off options. Participants are asked to mail or drop off their completed test as soon as possible, ideally within two days of collecting their specimen, to ensure that it arrives at LifeLabs within 14 days of specimen collection.
- Because it is important that specimens are tested by LifeLabs within 14 days of specimen collection, Ontario Health (Cancer Care Ontario) has included pre-paid, expedited mailing envelopes in FIT kits for people living in some areas where return time by regular mail can be longer.

27. What is the process for ordering and returning a fecal immunochemical test (FIT) for First Nation patients who live on a reserve, or for fly-in communities?

Ordering FIT:

- Eligible participants can order a FIT kit through their family doctor or nurse practitioner. If someone does not have a family doctor or nurse practitioner, they can call Telehealth Ontario at 1-866-828-9213 to order a FIT kit. Participants in the North West region can also order a FIT kit through the mobile screening coach (tbrhsc.net/programs-services/regional-cancer-care/information-for-patients-and-families/cancer- screening/screen-for-life/).
- Participants living on a First Nation reserve also have the option of having a FIT kit ordered through a health centre or nursing station. If you are a nurse at a health centre or nursing station on a First Nation reserve working with providers in accordance with Health Canada's clinical practice guidelines for nurses in primary care (1), you should complete a FIT requisition for your patient. You should then submit the requisition directly to LifeLabs (e.g., by fax 1-833-676-1427 or electronic medical record) and should never give your patient the FIT requisition. LifeLabs will confirm patient eligibility and mail a FIT kit directly to the address specified on the requisition.
- It is important to note that the FIT requisition has two address sections. The first address section (Patient Information) should contain the participant's mailing address, as registered with the Ontario Health Insurance Plan. If a patient requires their FIT kit to be mailed to an alternative address (i.e., that is different from the patient's primary mailing address), you can complete the second address section (FIT Kit Mailing Address). For example, patients who live on a First Nation reserve can have their FIT kit sent to a health centre or nursing station.

Returning FIT:

- People who live on a First Nation reserve can contact their health centre or nursing station.
- Because it is important that specimens are tested by LifeLabs within 14 days of specimen collection, Ontario Health (Cancer Care Ontario) has included pre-paid expedited mailing envelopes in FIT Kits for people living in some areas where return time in the regular mail is sometimes longer than in other areas.

(1) Government of Canada. Clinical practice guidelines for nurses in primary care. Ottawa. [Accessed July 20, 2018] Available at: canada.ca/en/indigenous-services-canada/services/first-nations-inuit-health/health-care- services/nursing/clinical-practice-guidelines-nurses-primary-care.html

Ordering and distribution: vulnerable populations

28. What is the process for ordering a fecal immunochemical test (FIT) for patients who are homeless or home insecure?

- Eligible patients who are homeless or home insecure can order a FIT kit through their family doctor or nurse practitioner. If someone does not have a family doctor or nurse practitioner, they can call Telehealth Ontario at 1-866-828-9213 to order a FIT kit. Patients in North West or Hamilton Niagara Haldimand Brant regions can also order a FIT kit through a mobile screening coach (cancercareontario.ca/en/find-cancer- services/mobile-screening).
- You must complete a FIT requisition and send it to LifeLabs. LifeLabs will send a FIT kit to your patient in the mail. The FIT requisition allows you to specify an alternative address for where a FIT kit can be delivered, which provides more flexibility for some patients, including those who are homeless or home insecure.
- You should record your patient's primary mailing address in the FIT requisition's Patient Information section. This is where your patient's result letter and other correspondence from Ontario Health (Cancer Care Ontario) will be sent. In many cases, this field should be populated with the address associated with your patient's health card. If your patient is homeless or home insecure and does not have a secure address, this field can be left blank. Please note that given the importance of address accuracy to ensure participants receive result letters from Ontario Health (Cancer Care Ontario), LifeLabs will follow up with providers if this field is blank to ensure that there is no appropriate address to list for the participant. It is important to confirm the accuracy of your patient's address before submitting the requisition to LifeLabs (e.g., by fax 1-833-676- 1427 or electronic medical record). If your patient is homeless or home insecure, Ontario Health (Cancer Care Ontario) recommends that you ensure that you communicate your patient's test result to them in case they do not receive their result letter. This is especially important if the primary address field is left blank, as result letters will not be sent to the FIT Kit Mailing address and Ontario Health (Cancer Care Ontario) may not have an alternative address on record for which to send patient results.
- The FIT requisition has an optional second address section called "FIT Kit Mailing Address." This section provides patients with the option to receive their FIT kit at an alternative Ontario location. People who are currently home insecure or at future risk of being home insecure can have their FIT kit mailed to a family physician's office or primary care provider's clinic/office. It is important to note that if the patient's primary mailing address is left blank, the FIT kit mailing address section must be completed to ensure the patient can receive their FIT kit.

29. What if my patient is uninsured (i.e., does not have Ontario Health Insurance Plan [OHIP] coverage)?

- A patient must have OHIP coverage to participate in screening through the ColonCancerCheck program; this is consistent with the approach used for screening with the guaiac fecal occult blood test (gFOBT) through the ColonCancerCheck program. LifeLabs will not accept FIT requisitions that do not include a valid OHIP number.
- To help your patient get OHIP coverage, visit ontario.ca/page/apply-ohip-and-get-health-card, call Service Ontario toll-free at 1-800-267-8097 or text toll-free TYY at 1-800-268-7095 for more information.
- Please note that if your patient has supplementary health insurance (i.e., private health insurance), but does not have a valid OHIP number, you will not be able to order a FIT kit for them and their FIT requisition will not be accepted by LifeLabs.

Ordering and distribution: eligibility

30. Can I order a fecal immunochemical test (FIT) kit for my patients if they have been screened in the last two years?

- No. The ColonCancerCheck program recommends that people at average risk who are up to date with screening wait until the recommended screening interval (i.e., two years for gFOBT or FIT) to get re- screened for colorectal cancer.
- The screening interval for people at average risk* of colorectal cancer did not change after the switch from the guaiac fecal occult blood test (gFOBT) to FIT in Ontario.
- Although the program's recommended screening interval remains two years, LifeLabs will accept FIT requisitions 21 months after a patient's last stool-based test. This provides some flexibility by allowing a FIT requisition to be submitted to LifeLabs (e.g., by fax 1-833-676-1427 or electronic medical record) slightly before a patient's two-year screening anniversary.
- If a FIT requisition is submitted earlier than 21 months after a patient's last stool-based test, the requisition will not be accepted by LifeLabs.
- Repeating the FIT after an abnormal FIT or gFOBT is not appropriate and can lead to delays in diagnosis and treatment. Ontario Health (Cancer Care Ontario) recommends that patients with an abnormal FIT or gFOBT result follow up with colonoscopy within eight weeks. Requests to repeat FIT after an abnormal FIT result will not be accepted by LifeLabs.
- For further information, refer to ColonCancerCheck's Guide to Average Risk Screening with FIT in Ontario (available at cancercareontario.ca/CCCrecommendations).

*"Average risk" refers to people ages 50 to 74 with no first-degree relative who has been diagnosed with colorectal cancer, and with no personal history of inflammatory bowel disease (i.e., Crohn's disease involving the colon or ulcerative colitis) or pre-cancerous polyps requiring surveillance.

31. What happens if I order a fecal immunochemical test (FIT) kit for a patient outside the recommended screening age range (i.e., ages 50 to 74)?

- The ColonCancerCheck program recommends that people ages 50 to74 who are at average risk* of getting colorectal cancer are be screened with FIT every two years.
- The ColonCancerCheck program does not recommend regular screening for people younger than age 50 with no first-degree relatives who have been diagnosed with colorectal cancer. If you order a FIT kit for any patient under age 49**, the requisition you submitted (e.g., faxed) will be rejected and you will be notified by a LifeLabs report.
    - While the incidence of colorectal cancer in younger adults is increasing in Canada, the absolute numbers of people younger than age 50 that are diagnosed with cancer is still very low. In 2017, there were about 16 times more cases of colorectal cancer in people age 50 and older than in those younger than age 50 (1). Because the risk of colorectal cancer is much higher in people older than age 50, this group will benefit most from screening.
    - However, at any age, people with symptoms or conditions suggestive of colorectal cancer (e.g., rectal bleeding, iron deficiency anemia) need to be assessed and referred to a specialist, if appropriate. It is not appropriate to test people with FIT if they have symptoms or conditions suggestive of colorectal cancer because it may lead to a delay in diagnosis.
- The ColonCancerCheck program does not recommend regular screening for people older than age 74. The decision to screen patients ages 75 to 85 should include an assessment of risks and benefits, and take into consideration current health status, life expectancy and screening history. Someone may choose to get screened after age 74 if the benefits of screening outweigh the risks. It is generally accepted that someone who is expected to live less than five years should not get screened.
- Screening history will affect the decision to screen in people older than age 74. Those who are healthy and have never been screened before are most likely to benefit from colorectal cancer screening.
- If you order a FIT kit for a patient who is age 75 to 85, the requisition you submitted will be accepted by LifeLabs. However, if you order a FIT for someone older than age 85, the requisition you submitted will not be accepted. The ColonCancerCheck program does not recommend that people older than age 85 get screened. Similarly, requisitions will not be accepted by LifeLabs if someone does not meet other eligibility criteria (e.g., Ontario Health Insurance Plan coverage).

* “Average risk” refers to people ages 50 to 74 with no first-degree relative who has been diagnosed with colorectal cancer, and with no personal history of inflammatory bowel disease (i.e., Crohn’s disease involving the colon or ulcerative colitis) or pre-cancerous polyps requiring surveillance.

**While the ColonCancerCheck program is designed for patients ages 50 to 74, Ontario Health (Cancer Care Ontario) will accept, at your discretion, orders for patients age 49 and ages 75 to 85.

(1) Canadian Cancer Society’s Advisory Committee on Cancer Statistics. Canadian cancer statistics 2017. Toronto, ON: Canadian Cancer Society; 2017.

Ordering and distribution: requisition

32. Why is there a new requisition for the fecal immunochemical test (FIT)?

- The ColonCancerCheck guaiac fecal occult blood test was previously administered by the Ministry of Health and Long-Term Care, which is why the Ministry of Health and Long-Term Care Laboratory Requisition was used. With the implementation of FIT as the screening test for the ColonCancerCheck program, funding accountability has been transferred to Ontario Health (Cancer Care Ontario).
- A new requisition is required to support obtaining information that will help eligible Ontarians successfully obtain a FIT. As a result, the Ministry of Health and Long-Term Care Laboratory Requisition or a hospital requisition cannot be used to order a ColonCancerCheck program FIT.
- Since LifeLabs will be mailing FIT kits directly to your patients, the new FIT requisition includes features such as an optional FIT kit mailing address that is meant to promote equitable access to the test for all Ontarians.
- To promote proper use of the FIT, eligibility criteria are included on the new requisition.
- It is important to complete the requisition accurately to prevent delays in patients receiving their FIT.

33. Where can I find the fecal immunochemical test (FIT) requisition and can I access this requisition in my electronic medical record (EMR)?

- The FIT requisition is available at cancercareontario.ca/pcscreeningprograms.
- The FIT requisition is available in all OntarioMD-Certified EMRs. Please add the FIT requisition to your library of custom forms in your EMR. If you are unable to find the requisition in your EMR, you can manually upload it or email support@ontariomd.com for support.

34. Do I have to manually sign the requisition?

- Primary care providers are required to sign and date the fecal immunochemical test (FIT) requisition.
- Similar to other forms that require a signature, a digitized image of a primary care provider's signature will be accepted under the following condition: eSignatures must be generated by an electronic medical record (EMR) software.

35. Why do I need to confirm my patient's addresses on the fecal immunochemical test (FIT) requisition every two years?

- To ensure that LifeLabs and Ontario Health (Cancer Care Ontario) have the most up-to-date participant mailing information, you are required to confirm that your patient's address is accurate when you order them a FIT kit. This address check is important because your patient's address may have changed over the two-year period between screens (e.g., your patient moves to a different location in Ontario).
- In addition, confirming your patient's address information is critical for ensuring that they receive their test result letter from Ontario Health (Cancer Care Ontario) and for protecting patient privacy.
- It is important to note that if the address information provided on the FIT requisition is incomplete or inaccurate, your patient may experience a delay in receiving a FIT kit or may not receive a kit at all. LifeLabs will follow up with you if your patient's address information is incomplete or missing. Validating patient address information up front will help to reduce the need for you to work with LifeLabs later to correct this information.

36. What is the difference between the patient information address and the fecal immunochemical test (FIT) kit mailing address on the FIT requisition?

- The address information provided in each of these address sections will determine where your patient's FIT kit and result letter will be sent.
- The FIT requisition includes a Patient Information section. This address is where your patient's FIT kit, result letter and other correspondence from Ontario Health (Cancer Care Ontario) will be sent. In most cases, this field should be populated with the address associated with your patient's health card. It is important to confirm the accuracy of your patient's address before submitting (e.g., faxing) the requisition to LifeLabs.
- The FIT requisition has an optional second address section called "FIT Kit Mailing Address." This section provides patients with the option to receive their FIT kit at an alternative Ontario location if necessary. For example, patients who live on a First Nation reserve can have their FIT kit mailed to a health centre or nursing station. People who are currently home insecure or at future risk of being home insecure can have their FIT kit mailed to a family physician's office or primary care provider's

clinic/office. If no FIT kit mailing address is specified, the FIT kit will be mailed to the address in the Patient Information section.

- Note that any address information on the requisition must be complete and accurate. A requisition will not be accepted if address information is incomplete, which could result in delays in sending your patient a FIT kit.

37. How long will it take for patients to receive a fecal immunochemical test (FIT) kit once the FIT requisition is sent to the laboratory?

- LifeLabs will mail your patient's FIT kit within two days of receiving a fully complete and accurate FIT requisition from you.
- It is very important to take time to check a patient's address information for accuracy before submitting (e.g., faxing) the FIT requisition to LifeLabs to avoid mailing delays. LifeLabs will use an address cleansing service to ensure that the patient addresses provided on FIT requisitions meet Canada Post's criteria for "mailability".
- If your patient's address information is incomplete, inaccurate or does not meet Canada Post's mailing criteria, LifeLabs will make at least three attempts to contact you (e.g., by phone or fax) to confirm or retrieve information. If the information cannot be retrieved by the third contact attempt, LifeLabs will let you know that the requisition has not been accepted.
- Once mailed from LifeLabs, in general, most participants can expect to receive their FIT kit from Canada Post, generally within five to 10 days (standard local mail).

38. How will I know if my patient received their fecal immunochemical test (FIT) kit?

- You will not receive a confirmation of FIT kit delivery from LifeLabs, Ontario Health (Cancer Care Ontario) or Canada Post.
- However, you will be notified by LifeLabs if your patient did not complete their FIT within six months of the requisition being sent to the laboratory. After these six months, the FIT requisition will expire, the test will be cancelled, and a new requisition must be completed and submitted to LifeLabs to request another FIT kit for your patient. You will also be notified if your patient contacts LifeLabs and declines to complete the test. In this situation, you may choose to contact your patient to address any questions or concerns.
- Once mailed from LifeLabs, in general, most patients can expect to receive their FIT kit from Canada Post, generally within five to 10 days (standard local mail).
- If your patient tells you that they did not receive their FIT kit (i.e., it is lost in mail), you should confirm that you have their correct address information on file, which includes the participant mailing address and alternative FIT kit mailing address, if provided. If the address information is

correct and a participant has been waiting for their FIT kit longer than expected (more than two weeks from the date of requisition submission), you or your patient should call LifeLabs for assistance at 1-833-676-1426.

Completing the fecal immunochemical test (FIT)

39. My patient is experiencing rectal bleeding and is due for colorectal cancer screening. Should they be screened for colorectal cancer?

- Regardless of your patient's age or whether they are due for screening, patients experiencing uninvestigated symptoms need to be investigated. It is not appropriate to screen symptomatic patients with FIT.
- For people experiencing rectal bleeding that has not been investigated, it is important to perform a digital rectal examination (DRE) as part of a thorough physical examination. It is not appropriate to perform an office-based guaiac fecal occult blood test.
- People experiencing rectal bleeding should be evaluated by a specialist even if the DRE reveals a benign source of bleeding (e.g., fissure).

40. My patient is bleeding intermittently from a previously investigated benign source (e.g., investigated hemorrhoids), menstruation, or dental and is due for colorectal cancer screening. Can they complete a fecal immunochemical test (FIT)?

- People who have undergone dental work that resulted in bleeding should wait three days before completing a FIT.
- People who are bleeding from a previously investigated benign source or from menstruation can get screened with FIT if they complete the FIT three days after the bleeding has stopped.
- For people who cannot screen with FIT because their bleeding is more frequent than every three days, flexible sigmoidoscopy is an acceptable screening test (1).
- People who have a previously investigated benign source of bleeding, but experience a change in symptoms should be thoroughly investigated and should not complete the FIT.
- People with bleeding from a non-confirmed source should be investigated. Do not use FIT or any fecal occult blood test for these patients.

(1) Tinmouth J, Vella E, Baxter NN, Dubé C, Gould M, Hey A, et al. Colorectal cancer screening in average risk populations: Evidence summary. Toronto (ON): CCO; 2015 November 11. Program in Evidence-based Care Evidence Summary No.: 15-14.

41. Can my patient still do the fecal immunochemical test (FIT) if they are taking iron?

- Yes, people taking iron are able to complete the FIT without any changes to their diet or supplementation because FIT detects blood in the stool using antibodies specific for human globin (1). FIT does not detect iron. Therefore, dietary iron or dietary sources of non-human hemoglobin will not cause false-positives.

(1) Tinmouth J, Lansdorp-Vogelaar I, Allison JE. Faecal immunochemical tests versus guaiac faecal occult blood tests: what clinicians and colorectal cancer screening programme organisers need to know. Gut. 2015; 64:1327-1337.

42. If my patient is on non-steroidal anti-inflammatory drugs (NSAIDs), can they do the fecal immunochemical test (FIT)?

- Yes, people taking NSAIDs or oral anti-coagulants (OACs) can do the FIT without any changes to their use of these medications. This decision is supported by several recent systematic reviews and meta-analyses (1, 2, 3).

(1) Nieuwenburg SAV, Vuik FER, Kruip MJHA, Kuipers EJ, Spaander MCW. Effect of anticoagulants and NSAIDs on accuracy of faecal immunochemical tests (FITs) in colorectal cancer screening: a systematic review and meta-analysis. Gut. 2018. doi: 10.1136/gutjnl-2018-316344. [Epub ahead of print]

(2) De Klerk CM, Vendrig LM, Bossuyt PM, Dekker E. Participant-related risk factors for false-positive and false-negative fecal immunochemical tests in colorectal cancer screening: Systematic review and meta- analysis. Am J Gastroenterol. 2018. https://doi.org/10.1038/s41395-018-0212-7

(3) Wong MCS, Ching, JYL, Chan VCW, Lam TYT, Luk AKC, Ng SSM et al. Factors associated with false-positive and false-negative fecal immunochemical test results for colorectal cancer screening. Gastrointestinal Endoscopy. 2015; 81(3)596-607.

43. Can patients with hemoglobinopathies do the fecal immunochemical test (FIT)?

- FIT detects blood in the stool using polyclonal antibodies that recognize different sites on the human globin molecule.
- A hemoglobinopathy is a condition characterized by abnormal synthesis of one or more of hemoglobin's four chains, resulting in the production of hemoglobin variants. Based on the limited literature examining this question (1), FIT seems to adequately detect blood in the majority of tested cases with hemoglobin (Hb) variants (e.g., HbC, HbD, HbE, sickle cell trait, sickle cell disease, sickle C and beta-thalassemia carrier). The available literature suggests that FIT has a reduced ability to detect hemoglobin in beta- thalassemia major and hemoglobin F (HbF) (1). However, due to frequent

blood transfusions in adults with these conditions, the proportion of abnormal hemoglobin variants is unlikely to be significant.

- There is therefore not enough evidence to suggest that patients with common hemoglobin variants should refrain from screening with FIT. ColonCancerCheck recommends screening with FIT for eligible patients with these conditions. The ColonCancerCheck program will continue to monitor the evidence in this area and will revise program recommendations as appropriate.

(1) Caroll MRR, John C, Manto D, Djedovic NK, Benton SC. An assessment of the effect of haemoglobin variants on detection by faecal immunochemical tests. Ann Clin Biochem. 2018 Jan 1:4563218778716. doi: 10.1177/0004563218778716. [Epub ahead of print]

44. Are there any stability considerations for a completed fecal immunochemical test (FIT)?

- The stability considerations for FIT are primarily related to hemoglobin degradation in the stool specimen once it has been taken. Studies show that degradation occurs over time and as temperature increases (1, 2).
- FIT is most stable at four degrees Celsius; however, the ColonCancerCheck program does not encourage participants to delay returning their completed FIT by storing it in the fridge. Instead, participants should promptly return completed FITs to LifeLabs to ensure that specimens are viable for testing.
- As a result of the stability concerns for FIT, the return time for sending a completed device to LifeLabs has been shortened from 21 days for the guaiac fecal occult blood test (gFOBT) to 14 days for FIT. The ColonCancerCheck program recommends that participants mail or drop off their completed FIT to LifeLabs as soon as possible, ideally within two days of specimen collection, to ensure that it arrives at LifeLabs within 14 days. Returning the completed test quickly will help to reduce the risk of hemoglobin degradation over time. Participants should avoid exposing their completed FIT to high temperatures (e.g., leaving their device in a hot car). Participants are also encouraged to plan taking their stool sample at a time when they can return their test to the laboratory as soon as possible. Planning can include finding out where their closest LifeLabs Patient Service Centre (drop-off location) is and taking into account any mailing delays that may apply, such as during a long weekend or holiday.
- In partnership with LifeLabs, the ColonCancerCheck program is monitoring return times by geographic area and is providing participants in selected areas with expedited mailing options to prevent delays between specimen collection and testing at LifeLabs.
- While FIT collection devices should be tested at the laboratory within 14 days of specimen collection, LifeLabs will still test FIT collection devices returned 15 to 30 days after specimen collection. Results below the positivity threshold are reported as “invalid” for FIT collection devices returned 15 to 30 days after specimen collection. Results at or above the positivity threshold will be reported as positive (i.e., abnormal).

- The clinical significance of hemoglobin degradation during transit to LifeLabs is likely to be minimal. However, on a seasonal basis, LifeLabs will monitor temperatures that completed FIT collection devices and specimens will be exposed to during the mailing and transportation processes and the results of these FITs after being exposed to those temperatures. This monitoring will allow for the ongoing evaluation of the impact of temperature on specimen stability.
  (1) Tinmouth J, Baxter N, Paszat L, Rabeneck L, Randell E, Sutradhar R, et al. Report on pilot evaluation of fecal immunochemical test (FIT) in Ontario. The Ontario FIT pilot. Final report submitted July 5 2013. Revised Jan 29, 2014.
  (2) Catomeris P, Baxter NN, Boss SC, Paszat LF, Rabeneck L, Randell E, et al. Effect of temperature and time on fecal hemoglobin stability in 5 fecal immunochemical test methods and one guaiac method. Arch Pathol Lab Med. 2018;142:75–82.

45. Is it acceptable to screen patients with the fecal immunochemical test (FIT) in the summer?

- Yes, the ColonCancerCheck program recommends screening patients for colorectal cancer year-round.
- Hemoglobin will degrade in the stool specimen over time and as temperature increases (1, 2). While evidence from population-based colorectal cancer screening programs suggests that the positivity rate for FIT is reduced during summer months, the clinical significance of this reduction in positivity is uncertain (3, 4, 5, 6). Many population-based screening programs continue to operate throughout the year and existing evidence is not sufficient to warrant only screening for colorectal cancer in certain seasons (7).
- The ColonCancerCheck program recommends that participants mail or drop off their completed FIT to a LifeLabs Patient Service Centre as soon as possible, ideally within two days of specimen collection, to ensure that it arrives at the laboratory within 14 days. Returning the completed FIT quickly will help to reduce the risk of hemoglobin degradation over time. Participants should avoid exposing their specimen to high temperatures (e.g., leaving their device in a hot car). Participants are also encouraged to plan taking their stool sample at a time when they can return their test to the laboratory as soon as possible. Planning can include finding out where their closest drop-off location is and taking into account any mailing delays that may apply, such as during a long weekend or holiday.
- In partnership with LifeLabs, the ColonCancerCheck program is monitoring return times by geographic area and is providing participants in selected areas with expedited mailing options to prevent delays between specimen collection and testing at the laboratory.
- While FIT collection devices should be tested at the laboratory within 14 days of specimen collection, LifeLabs will still test FIT collection devices returned 15 to 30 days after specimen collection. Results below the positivity threshold (i.e., negative test results) will be reported as “invalid” for FIT collection devices returned 15 to 30 days after specimen collection.

- The clinical significance of hemoglobin degradation during transit to the laboratory (as recommended by the ColonCancerCheck program) is likely to be minimal. However, on a seasonal basis, LifeLabs will monitor temperatures that completed FIT collection devices and specimens will be exposed to during the mailing and transportation processes, and will assess the impact of temperature on specimen stability.

(1) Tinmouth J, Baxter N, Paszat L, Rabeneck L, Randell E, Sutradhar R, et al. Report on pilot evaluation of fecal immunochemical test (FIT) in Ontario. The Ontario FIT pilot. Final report submitted July 5 2013. Revised Jan 29, 2014.

(2) Catomeris P, Baxter NN, Boss SC, Paszat LF, Rabeneck L, Randell E, et al. Effect of temperature and time on fecal hemoglobin stability in 5 fecal immunochemical test methods and one guaiac method. Arch Pathol Lab Med. 2018;142:75–82.

(3) Cha JM, Suh M, Kwak MS, Sung NY, Choi KS, Park B, et al. Risk of interval cancer in fecal immunochemical test screening significantly higher during the summer months: Results from the National Cancer Screening Program in Korea. Am J Gastroenterol 2018; 113:611–621.

(4) Young GP, Symonds EL, Allison JE, Cole SR, Fraser CG, Halloran SP et al. Advances in fecal occult blood tests: the FIT revolution. Dig Dis Sci 2015;60:609–622.

(5) Grazzini G, Ventura L, Zappa M, Ciatto S, Confortini M, Rapi S, et al. Influence of seasonal variations in ambient temperatures on performance of immunochemical faecal occult blood test for colorectal cancer screening: observational study from the Florence district. Gut 2010;59:1511-5.

(6) Symonds ET, Osborne JM, Cole SR, Bampton PA, Fraser RJ, Young GP, Factors affecting faecal immunochemical test positive rates: demographic, pathological, behavioural and environmental variables. J Med Screen 2015;22(4):187-93.

(7) Robertson DJ, Lee JK, Boland CR, Dominitz JA, Giardiello FM, Johnson DA, et al. Recommendations on fecal immunochemical testing to screen for colorectal neoplasia: A consensus statement by the US Multi-Society Task Force on Colorectal Cancer. Gastroenterology. 2017;152(5):1217-37.e3.

46. Should my patient be concerned about putting their fecal immunochemical test (FIT) in the mailbox?

- No, your patients should not be concerned about putting their completed FIT in the mailbox, as long as they follow the kit instructions.
- The ColonCancerCheck program recommends that participants mail their completed FIT to LifeLabs as soon as possible, ideally within two days of specimen collection, to ensure that it arrives at the laboratory within 14 days.
- Participants can also drop off their completed FIT to a LifeLabs Patient Service Centre as soon as possible, ideally within two days, to ensure that it arrives at the laboratory within 14 days.

Participants who live on a First Nation reserve can contact their health centre or nursing station to discuss drop-off options.

(1) Tinmouth J, Baxter N, Paszat L, Rabeneck L, Randell E, Sutradhar R, et al. Report on pilot evaluation of fecal immunochemical test (FIT) in Ontario. The Ontario FIT pilot. Final report submitted July 5 2013. Revised Jan 29, 2014.

(2) Catomeris P, Baxter NN, Boss SC, Paszat LF, Rabeneck L, Randell E, et al. Effect of temperature and time on fecal hemoglobin stability in 5 fecal immunochemical test methods and one guaiac method. Arch Pathol Lab Med. 2018;142:75–82.

47. Is it acceptable to keep a fecal immunochemical test (FIT) specimen in the fridge?

- Yes. While it is not necessary to store a completed FIT in the fridge, if your patient will be delayed in returning their FIT, they can put their completed FIT in its sealed return envelope in the refrigerator. Even if participants store their specimen in the fridge, it must still be received at LifeLabs within 14 days of the specimen collection date.
- Participants are encouraged to plan sampling so they can get their completed FIT back to LifeLabs as soon as possible. Planning can include finding out where their closest LifeLabs Patient Service Centre is and taking into account any mailing delays that may apply, such as during a long weekend or holiday.
- If your patient has questions about how to do the FIT or how to return it, they can contact LifeLabs at 1- 833-676-1426

48. How long can my patient keep the fecal immunochemical test (FIT) collection device at home before completing it?

- Participants should complete the FIT as soon as possible after receiving it and no longer than six months from when the kit was requested (the requisition is only valid for six months). The FIT device has an expiry date printed on it, but it should not expire during the time the requisition remains active. People who do not plan to complete their FIT right away should ensure that they know when the device expires.
- FIT manufacturers recommend storing the FIT collection device (before specimen collection) at or below room temperature, and recommend against freezing.
- Exposing the FIT collection device to high temperatures (e.g., leaving the device in a hot car) before specimen collection presents less of a concern than exposing a FIT collection device to high temperatures after specimen collection.

49. What is the risk of contaminating a fecal immunochemical test (FIT) during sampling (i.e., with urine, water or chemicals) and how can my patient minimize this risk?

- If the stool that is sampled does not come into contact with chemicals or urine, there are no concerns of contamination. To be safe, participants should flush the toilet before completing the FIT to remove any chemicals or urine from the toilet. Participants who use a cleaning product that stays in the toilet bowl (e.g., a puck or other built-in toilet cleaner) should consider removing the toilet cleaner first or using another toilet.
- Participants should urinate and flush the toilet before taking the test to prevent specimen dilution.
- The FIT kit includes a thin piece of paper (stool collection paper) that should be placed in the toilet before the participant goes to the bathroom to prevent their stool from being fully submerged. The collection paper can be flushed afterwards.
- When completing the FIT, participants should collect a sample from the part of their stool that is not in contact with the toilet water to prevent the sample from being diluted.

50. How should patients prevent their stool from being submerged in the toilet water?

- The FIT kit includes a thin piece of paper that should be placed in the toilet before the participant goes to the bathroom to prevent their stool from being fully submerged. The collection paper can be flushed afterwards.
- When completing the FIT, participants should take a sample from the part of their stool that is not in contact with the toilet water to prevent the sample from being diluted. The instructions provided in the FIT kit show how to use the collection paper and prevent the stool from being submerged in water; consider reviewing the instructions with your patients.

Lost and damaged fecal immunochemical test (FIT) kits

51. What should I do if a patient reports that their fecal immunochemical test (FIT) kit was damaged or misplaced?

- If a participant tells you that their FIT kit is lost or damaged, you can order them a replacement FIT kit. To order another FIT kit, send a new FIT requisition to LifeLabs and be sure to check the box at the top of the requisition indicating that a new FIT is required. You may also call LifeLabs directly at 1-833-676-1426. LifeLabs will also accept calls for replacement kits from patients.
- LifeLabs will send a new FIT kit to your patient, provided the original requisition is still valid. FIT requisitions will remain valid for six months from the date the requisition is received by LifeLabs.

52. What should I do if a patient reports that they never received their fecal immunochemical test (FIT) kit?

- LifeLabs will mail the FIT kit within two days of receiving the fully complete and accurate requisition. Once mailed by LifeLabs, in general, most participants can expect to receive their FIT kit from Canada Post, generally within five to 10 days (standard local mail).
- If a participant tells you that they did not receive their FIT kit (i.e., it is lost in mail), you should confirm that you have their correct address information on file, which includes the participant mailing address and alternative FIT kit mailing address, if provided.
- If the address information is correct and a participant has been waiting for their FIT kit longer than expected (more than two weeks from the date of requisition submission), you or your patient should call LifeLabs for assistance at 1-833-676-1426. If your patient's address is incorrect, you can call LifeLabs or send a new FIT requisition to LifeLabs with the correct address. Be sure to check the box at the top of the requisition indicating that a new FIT is required.
- LifeLabs will send a new FIT kit to your patient, provided the original requisition is still valid. FIT requisitions will remain valid for six months from the date the requisition is received by LifeLabs.
- It is your responsibility to ensure that the address fields on the FIT requisition are accurate and complete before submitting the requisition to LifeLabs (e.g., by fax 1-833-676-1427 or electronic medical record). Having accurate address information will prevent privacy breaches and ensure that the FIT kit reaches your patient in a timely manner.

Results

53. How is the fecal immunochemical test (FIT) analyzed and how are results communicated to my patients and me?

- You will get results directly from LifeLabs and a recommendation for next steps. You are responsible for communicating test result information to your patients and for ensuring that your patients with abnormal FIT results receive timely follow-up. ColonCancerCheck recommends follow-up with a colonoscopy within eight weeks of an abnormal FIT result. Ensuring timely follow-up of an abnormal FIT result is particularly important due to the higher likelihood of abnormal findings at colonoscopy following an abnormal FIT result.
- Your patients will receive result letters from Ontario Health (Cancer Care Ontario), including guidance on what to do next. For example, patients with a normal FIT result will receive a letter letting them know that no further action is needed and that they will be recalled to screen with FIT again in two years. Patients with an abnormal FIT result will receive a letter instructing them to follow up with you and explaining that you will recommend follow-up with a colonoscopy.

- FIT results are provided to you and your patients qualitatively (i.e., normal, abnormal, rejected or invalid).

54. How are fecal immunochemical test (FIT) results reported to primary care providers and how will I know what to do next?

- Laboratory reports to providers include standard messaging for FIT results and recommended next steps. FIT results are reported to you qualitatively as normal, abnormal, invalid* or rejected**. You are encouraged to become familiar with the qualitative result categories that will appear in the laboratory reports.
- If the result is normal, re-screen your patient with FIT in two years if they continue to meet the ColonCancerCheck eligibility criteria for colorectal cancer screening in average risk persons.
- If the result is abnormal, refer your patient to colonoscopy as soon as possible. The colonoscopy should be completed within eight weeks of the abnormal FIT result.
- If the result is invalid or the FIT collection device is rejected, the report will provide the specific reason for the unsatisfactory test result. You should promptly submit a new FIT requisition for your patient (e.g., by fax 1-833-676-1427 or electronic medical record), if appropriate, and counsel them if they need help completing their next test successfully.
- You are responsible for communicating test result information to your patients and for ensuring that patients with an abnormal FIT result receive timely follow-up with colonoscopy within eight weeks.
- If you are practicing in a patient enrolment model (PEM), you will continue to receive a summary of your enrolled/rostered patients' colorectal cancer screening results in the screening activity report (SAR).
- The SAR is an online tool available to primary care physicians who practice as part of a PEM or practice in the Sioux Lookout Municipality and Sioux Lookout Zone (27 First Nation communities). It provides screening data for breast, cervical and colorectal cancers to help physicians improve their cancer screening rates and appropriate follow-up. It also helps physicians better understand Ontario Health (Cancer Care Ontario)'s cancer screening guidelines. The report platform is interactive, allowing physicians to quickly find specific cancer screening information for each patient.
- If you are a non-PEM physician servicing the Sioux Lookout municipality and zone (27 First Nations) using postal codes that have been confirmed with these communities, you will receive a summary of your patients' colorectal cancer screening results in the new Sioux Lookout and Zone SAR. The SAR will reflect FIT results and patient screening status. If you are in a PEM but not signed up for the SAR, instructions on how to do so can be found at the following link: cancercareontario.ca/en/guidelines-advice/treatment- modality/primary-care/screening-activity-report.

  *Invalid FIT result: The FIT collection device was tested but a valid result could not be obtained (e.g., too much sample [instrument cannot read], result below the positivity threshold with no specimen

collection date). A new FIT requisition is required and your patient should repeat the FIT within the next few weeks.

**Rejected FIT collection device: The FIT collection device was not accepted for testing by LifeLabs (e.g., specimen leaking, FIT collection device not opened [no sample]). A new FIT requisition is required and your patient should repeat the FIT within the next few weeks.

55. How will I receive laboratory result reports for fecal immunochemical test (FIT) results?

- FIT results are available through a variety of channels including mail, fax, Ontario electronic medical record (EMR) systems, and LifeLabs' online result portal (i.e., Launchpad) for healthcare providers. LifeLabs will also submit result data to the Ontario Laboratory Information System (OLIS) that will feed into additional channels (e.g., eHealth clinical viewers and the eHealth portal), some of which you can access through the ONEID Account. To register for a ONE ID account:
    - Please send a registration request to: ONEIDBusinessSupport@ehealthontario.on.ca
    - Please indicate your name and College of Physicians and Surgeons of Ontario (CPSO) number in your email request
    - Registration appointments will be scheduled based on location and/or date of your request
- If you currently have a relationship with LifeLabs you will continue to receive laboratory reports through these processes. Call LifeLabs at 1-833-676-1426 if you do not routinely receive laboratory supplies or test results from them.

56. Will fecal immunochemical test (FIT) data be included in my screening activity report (SAR) and how can I access these results?

- If you are practicing in a patient enrolment model (PEM), you can continue to access colorectal cancer screening results in the SAR. For more information on how to sign-up for the SAR, please visit: cancercareontario.ca/en/guidelines-advice/treatment-modality/primary-care/screening-activity-report?redirect=true
- FIT data is reflected in the SAR as of June 24, 2019.
- The SAR includes a summary of your patients' colorectal cancer screening results, including FIT results and patient screening status.
- The SAR reflects up-to-date data captured from patients who completed either ColonCancerCheck gFOBT or FIT. Completion of a ColonCancerCheck gFOBT will not be included in the up to date for screening category after December 23, 2021.

57. Can my patients receive their fecal immunochemical test (FIT) results in their LifeLabs Patient Portal (MyResults)?

- No, FIT results are not available in the LifeLabs Patient Portal (MyResults).
- Participants receive result letters from Ontario Health (Cancer Care Ontario), including guidance on what to do next. For example, participants with a normal FIT result will receive a letter letting them know that no further action is needed, and that they will be recalled to screen with FIT again in two years. Participants with an abnormal FIT result will receive a letter instructing them to follow up with you and explaining that you will recommend follow-up with a colonoscopy.

58. How long will it take for results to be available once LifeLabs receives a fecal immunochemical test (FIT) at LifeLabs' testing location?

- LifeLabs will complete testing within two days from the day that the test is received at the LifeLabs test facility. You can expect to receive results shortly after testing takes place.
- For questions about receiving results and result reports, call LifeLabs at 1-833-676-1426.

59. Can I find out if my patient did not complete the fecal immunochemical test (FIT) in the six-month time frame (i.e., before their requisition expires)?

- You will receive a notification from LifeLabs if your patient does not return their FIT or declines to complete their test. This a key ColonCancerCheck program improvement for FIT compared to the guaiac fecal occult blood test (gFOBT).
- If your patient does not return their completed FIT to LifeLabs within six months of the requisition being sent, LifeLabs will send you a report indicating that the test has been cancelled. You will need to complete and submit a new FIT requisition for your patient.
- Please advise your patient to complete the new FIT and mail it back to the laboratory (or drop it off) as soon as possible, ideally within two days of specimen collection, to ensure that it arrives at the laboratory within 14 days of specimen collection.
- You will also be notified if your patient contacts LifeLabs and declines to complete the test. In this situation, you may choose to contact your patient to address any questions or concerns.

Abnormal results and timely follow-up

60. What do I do if my patient receives an abnormal fecal immunochemical test (FIT) result?

- Ontario Health (Cancer Care Ontario) recommends that participants with an abnormal FIT result have a colonoscopy within eight weeks.
- Participants should be counselled on the importance of a follow-up colonoscopy because only colonoscopy can determine whether they have colorectal cancer. It is important to counsel participants and answer any questions they might have on what to expect before, during and after the colonoscopy to relieve any fear or anxiety. It is also important to identify whether they need assistance before or after the procedure.
- Repeating the FIT after an abnormal FIT or guaiac fecal occult blood test (gFOBT) is not appropriate and can lead to delays in diagnosis and treatment. Requests to repeat FIT after an abnormal FIT result will not be accepted by LifeLabs.

61. Why is it important that my patients with abnormal fecal immunochemical test (FIT) results have follow-up colonoscopy within eight weeks?

- Ontario Health (Cancer Care Ontario) recommends that participants with an abnormal FIT result follow-up with colonoscopy within eight weeks. The eight-week benchmark was set by the Canadian Association of Gastroenterology Wait Time Consensus Group (1) and aligns with recommendations set by the Canadian Partnership Against Cancer's National Colorectal Cancer Screening Network (2).
- Following an abnormal FIT result, a prompt colonoscopy is required. This is because there is a higher likelihood that the patient has colorectal cancer compared to those who are referred to colonoscopy for average risk screening or most of those who are referred with symptoms. Diagnostic delays following an abnormal FIT result could allow the disease to progress to a more advanced stage*, and may lead to delays in receiving treatment.
- Participants with abnormal FIT results are likely to feel anxious and concerned as they wait for their follow- up (4). To help manage anxiety, you should promptly refer patients for colonoscopy so that the procedure can be completed within eight weeks of the abnormal FIT result.

  *A recent study published by Corley et al. (3) found that, compared to people who had a colonoscopy within eight to 30 days following their result, those who had their colonoscopy after 10 months had a higher risk of colorectal cancer and advanced-stage disease at diagnosis. This finding demonstrates the importance of promptly sending patients with abnormal FIT results for colonoscopy.

(1) Paterson WG, Depew WT, Paré P, Petrunia D, Switzer C, Veldhuyzen van Zanten SJ, et al. Canadian consensus on medically acceptable wait times for digestive health care. Can J Gastroenterol. 2006; 20(6): 411-423.
(2) Canadian Partnership Against Cancer. Quality determinants and indicators for measuring colorectal cancer screening program performance in Canada. Toronto: The Partnership, 2012.
(3) Corley DA, Jensen CD, Quinn VP, Doubeni CA, Zauber AG, Lee JK et al. Association between time to colonoscopy after a positive fecal test result and risk of colorectal cancer and cancer stage at diagnosis. JAMA 2017; 317(16): 1631-1641
(4) Canadian Partnership Against Cancer. Living the cancer journey: A report on the patient experience. 2017 (in progress).

62. How do I ensure that my patients with abnormal fecal immunochemical test (FIT) results receive a follow-up colonoscopy within the recommended eight-week timeframe?

- To ensure that your patients receive timely follow-up colonoscopies, you should complete and submit (e.g., fax) a referral for them as soon as possible after receiving their abnormal FIT result.
- Be sure to consult your Regional Cancer Program for information on processes that may be in place in your region to help your patients access timely follow-up colonoscopy.
- Be aware of any regional strategies to ensure timely access to colonoscopy for your patients with a positive (i.e., abnormal) FIT. A list of facilities funded by Ontario Health (Cancer Care Ontario) to provide colonoscopies for patients with an abnormal FIT result is available at cancercareontario.ca/FITcolonoscopy.

63. Where and how should I refer my patients with abnormal FIT results?

- Follow-up colonoscopies in those with an abnormal FIT results are expected to require more time, expertise and equipment, given the higher likelihood of advanced neoplasias (including colorectal cancer and high risk adenomas) in these patients.
- For this reason, not all facilities will offer FIT-positive colonoscopies and usual routes for referral may not apply. Ontario's Regional Cancer Programs have been working with colonoscopy services in each region to identify which facilities will be performing FIT-positive colonoscopies.
- Contact your Regional Cancer Program for information on which facilities are best positioned to perform colonoscopies for patients with abnormal FIT results.
- Be aware of any regional strategies to ensure timely access to colonoscopy for your patients with a positive (i.e., abnormal) FIT. A list of facilities funded by Ontario Health (Cancer Care Ontario) to provide colonoscopies for patients with an abnormal FIT result is available at cancercareontario.ca/FITcolonoscopy.

64. Will the rate of abnormal fecal immunochemical test (FIT) results increase compared to the guaiac fecal occult blood test (gFOBT)?

- Compared to gFOBT, FIT is a more sensitive screening test, which means it is better at detecting colorectal cancer and advanced adenomas (1,2).
- FIT is specific for human hemoglobin, which means it will not mistake dietary sources of blood or other substances for human blood.
- Research has shown that people prefer screening with FIT over gFOBT, leading to increases in colorectal cancer screening participation. The benefits of FIT include:
    - The enhanced design of the collection device, which is easy to use and reduces the amount of contact people have with their stool when collecting it;
    - Only one specimen needed;
    - No dietary restrictions, including vitamin C; and
    - No medication restrictions.
- For these reasons, we expect more abnormal FIT results than gFOBT results, which has been observed in other jurisdictions (1,2).

(1) Lee JK, Liles EG, Bent S, Levin TR, Corley DA. Accuracy of fecal immunochemical tests for colorectal cancer: Systematic review and meta-analysis. Ann Intern Med. 2014; 160(3):171-181.

(2) Canadian Task Force on Preventive Health Care. Screening for colorectal cancer [Internet]. Ottawa, Canada: Canadian Task Force on Preventive Health Care; 2014. Available from: http://canadiantaskforce.ca/guidelines/published-guidelines/colorectal-cancer/

65. Why are colonoscopy procedures following abnormal fecal immunochemical test (FIT) results more complex?

- In general, colonoscopies in persons with abnormal FIT results are expected to be more challenging procedures than those performed for most other indications, with a higher burden of colonic polyps. Compared to the guaiac fecal occult blood test (gFOBT), ColonCancerCheck's previous screening test, FIT is expected to have higher participation rates and detect twice as many important lesions, including advanced adenomas and colorectal cancers (1).
- In addition, FIT will result in the identification of larger polyps that are more challenging to remove. Therefore, the proportion of polypectomies required is expected to increase, as well as the proportion of procedures requiring a surgical referral (2). Because lesions found at follow-up colonoscopies in patients with an abnormal FIT tend to be more challenging to remove, it is necessary to ensure that endoscopists performing these follow-up colonoscopies and nurses who are assisting in these procedures have the advanced skill sets necessary to manage these lesions, to ensure patient safety and to avoid referrals for repeat procedures.

(1) Tinmouth J, Vella E, Baxter NN, Dubé C, Gould M, Hey A, et al. Colorectal cancer screening in average risk populations: Evidence summary. Toronto (ON): CCO; 2015 November 11. Program in Evidence-based Care Evidence Summary No.: 15-14.
(2) Forzani-Macphail. Colon Cancer Screening Centre: First year experience with the fecal immunochemical test (FIT). CCSC 2014 FIT Report. June 2015.

66. My patient had an abnormal fecal immunochemical test (FIT) result and their colonoscopy was normal. How soon should they re-screen and what test should they use?

- If the follow-up colonoscopy was normal (meaning either hyperplastic polyps found in the rectum or sigmoid colon only, or no polyps), people should return to average risk screening with FIT 10 years after their follow-up colonoscopy.

67. My patient had an abnormal fecal immunochemical test (FIT) result and the follow-up colonoscopy found that they had one or more polyps. What happens next?

- The next steps will depend on the size and histology of the polyps.
- ColonCancerCheck's Recommendations for Post-Polypectomy Surveillance (cancercareontario.ca/CCCsurveillance) describe the recommended surveillance or screening intervals based on the findings at the baseline colonoscopy:
    - Following a colonoscopy that was normal, or that found hyperplastic polyps in the rectum or sigmoid, people should resume screening with FIT after 10 years.
    - Following a colonoscopy that found low risk adenomas*people should resume screening with FIT after five years.
    - Following a colonoscopy that found high risk adenomas† or serrated polyps‡, surveillance is recommended and the surveillance interval will depend on the colonoscopy findings (refer to recommendations).

*Low risk adenomas: One to two tubular adenomas less than 10 millimeters in diameter without high-grade dysplasia.

† High risk adenomas: One or more tubular adenomas 10 millimeters or greater, or three or more adenomas of any size, or an adenoma with villous histology, or an adenoma with high-grade dysplasia (also called advanced adenomas).

‡ Either sessile serrated polyps (SSPs) (also called "sessile serrated adenoma" [SSA], "sessile serrated adenoma/polyp" [SSA/P]) or traditional serrated adenoma (TSA). Most serrated polyps

will not have any dysplasia; serrated polyps with dysplasia are considered advanced. Traditional serrated adenomas are uncommon and are often protuberant and left-sided (1,2,3).

(1) Bettington ML, Chetty R. Traditional serrated adenoma: an update. Hum Pathol. 2015;46(7):933-8.
(2) Ferlitsch M, Moss A, Hassan C, Bhandari P, Dumonceau JM, Paspatis G, et al. Colorectal polypectomy and endoscopic mucosal resection (EMR): European Society of Gastrointestinal Endoscopy (ESGE) Clinical Guideline. Endoscopy. 2017;49(3):270-97.
(3) Longacre TA, Fenoglio-Preiser CM. Mixed hyperplastic adenomatous polyps/serrated adenomas: a distinct form of colorectal neoplasia. Am J Surg Pathol. 1990;14(6):524-37.

68. Why am I responsible for navigating my patient's follow-up of abnormal fecal immunochemical test (FIT) results?

- If you order a FIT for a patient, you are responsible for ensuring that they have their test result information and for referring them for timely follow-up if they have abnormal test results*.
- When a FIT kit is ordered through Telehealth Ontario or the North West mobile coach (i.e., unattached patients), Ontario Health (Cancer Care Ontario) will communicate test results (as it does for attached patients), and will also help the participant connect with a primary care physician to arrange for appropriate follow-up.
- You are encouraged to complete the Physician Registration for Patient Attachment form (cancercareontario.ca/pcscreeningprograms) if you are willing to accept new patients with abnormal FIT results into your practice.

*It is recommended that patients with an abnormal FIT undergo colonoscopy within eight weeks of their abnormal result.

gFOBT during the FIT transition and decommissioning

69. How soon after a guaiac fecal occult blood test (gFOBT) should my patient screen with a fecal immunochemical test (FIT) kit?

- People who have screened with gFOBT should wait two years before screening with FIT. The screening interval for people at average risk* of colorectal cancer did not change with the switch from gFOBT to FIT in Ontario. People who were due for screening before FIT was available through the ColonCancerCheck program should have screened with gFOBT.
- Although the program's recommended screening interval remains two years, LifeLabs will accept FIT requisitions 21 months after a patient's last stool-based test, which allows you to order a FIT kit for your patients shortly before they are due for screening.

- LifeLabs will not accept FIT requisitions for participants who have completed a FIT within the past 21 months.
- Ontario Health (Cancer Care Ontario) will send FIT-specific correspondence to participants who previously screened with gFOBT when they are next due for screening.
- Repeating the FIT after an abnormal FIT or CCC gFOBT is not appropriate and can lead to delays in diagnosis and treatment. Requests to repeat FIT after an abnormal FIT result will not be accepted by LifeLabs. Participants with an abnormal FIT or CCC gFOBT should follow-up with a colonoscopy within eight weeks, as per the CCC Screening Recommendations Summary (1).

  *As outlined in ColonCancerCheck's screening recommendations, "average risk" refers to people ages 50 to 74 with no first-degree relatives who have been diagnosed with colorectal cancer, and with no personal history of inflammatory bowel disease (i.e., Crohn's colitis or ulcerative colitis) or pre-cancerous polyps requiring surveillance.

  (1) cancercareontario.ca/CCCrecommendations

70. When do I stop screening my patients with the guaiac fecal occult blood test (gFOBT)?

- As of June 24, 2019, the fecal immunochemical test (FIT) is the recommended screening test for patients at average risk of developing colorectal cancer.
- Use the new FIT requisition for all eligible patients and do not distribute unused CCC gFOBT kits.

71. What should I do with my remaining ColonCancerCheck (CCC) guaiac fecal occult blood test (gFOBT) kits?

- CCC gFOBT laboratory providers will arrange the removal of unused CCC gFOBT kits from primary care provider offices on and after June 24, 2019. For more information, please contact your CCC gFOBT laboratory provider.

72. How long will the ColonCancerCheck (CCC) guaiac fecal occult blood test (gFOBT) laboratory providers continue to test CCC gFOBT kits?

- CCC gFOBT laboratory providers will continue to test CCC gFOBT kits until December 23, 2019. This will ensure that most participants who have not yet completed their CCC gFOBT kit after the fecal immunochemical test (FIT) became available can still receive their CCC gFOBT result. CCC gFOBT laboratory providers will reject CCC gFOBT kits returned after December 23, 2019 and will notify you directly of this rejection. You should encourage your patients to complete and return their CCC gFOBT kits as soon as possible. Now that FIT is available, do not distribute unused CCC gFOBT kits.

73. Can participants at average risk for colorectal cancer still submit their completed ColonCancerCheck (CCC) guaiac fecal occult blood test (gFOBT) now that FIT is available?

- CCC gFOBT laboratory providers will not test CCC gFOBT specimens received after December 23, 2019. CCC gFOBT laboratory providers will notify you directly of this rejection.

74. What updates will be made to the Ministry of Health and Long-Term Care Laboratory Requisition related to the ColonCancerCheck (CCC) guaiac fecal occult blood test (gFOBT)?

- The CCC gFOBT checkbox has been removed from the Ministry of Health and Long-Term Care Laboratory Requisition. A new separate fecal immunochemical test (FIT) requisition form is available to order FIT kits as part of the CCC program. You can access the new FIT requisition form through your certified electronic medical record (EMR) or on the Ontario Health (Cancer Care Ontario) website at cancercareontario.ca/pcscreeningprograms.

75. How are fee codes related to the ColonCancerCheck (CCC) guaiac fecal occult blood test (gFOBT) changing?

- Information on fee code changes for laboratories or physicians have been communicated by the Ministry of Health and Long-Term Care through an Ontario Health Insurance Plan INFOBulletin (http://health.gov.on.ca/en/pro/programs/ohip/bulletins/11000/bul11210.aspx). Please check this website for any updates regarding fee code changes.

76. What happens if my patient receives an unsatisfactory (i.e., indeterminate or rejected) ColonCancerCheck (CCC) guaiac fecal occult blood test (gFOBT) within six months from when the fecal immunochemical test (FIT) became available as the screening test for people at average risk for colorectal cancer?

- Participants who complete a CCC gFOBT within the six month overlap period and get an indeterminate or rejected test result will receive a letter instructing them to complete a FIT (the new screening test for people at average risk for colorectal cancer).
- You will need to submit a FIT requisition to Lifelabs for your patient to receive a FIT. Please advise your patient to complete a FIT and mail it back to Lifelabs (or drop it off) as soon as possible, ideally within two days of specimen collection, to ensure that it arrives at Lifelabs within 14 days of specimen collection.

77. Will occult blood testing not associated with the ColonCancerCheck (CCC) program still be available now that the fecal immunochemical test (FIT) is available as the screening test for people at average risk for colorectal cancer?

- Occult blood testing (e.g., gFOBT or FIT) not associated with the CCC program will continue to be available after FIT becomes available as the screening test for people at average risk for colorectal cancer.
- The CCC program recommends that gFOBT should not be used for screening people at average risk once FIT becomes available.
- The CCC program recommends using the CCC program FIT because it is more user-friendly and is a more sensitive screening test than gFOBT.
- The CCC program does not recommend colorectal cancer screening outside of the CCC program. People who complete a non-program occult blood test are not considered part of the CCC program.
- Participants receive the following benefits by being screened through the ColonCancerCheck program:
    - Being invited to participate in screening;
    - Being reminded when it is time for their next screening test;
    - Being informed of their test results;
    - Being tracked throughout the screening and diagnostic process; and
    - Participating in a program in which quality and performance are carefully monitored.
- The CCC program does not recommend using occult blood testing for investigating symptoms (e.g., bleeding) or conditions (e.g., iron deficiency anemia) that may be related to colorectal cancer. People with symptoms or conditions that may be related to colorectal cancer should be promptly referred directly for colonoscopy. Due to their low sensitivity for colorectal cancer in this context (1,2), occult blood tests can lead to diagnostic delay and inefficiencies (3,4,5).

(1) Farag A, Barkun AN, Martel M. The utility of fecal occult blood testing for clinical indications of suspected gastrointestinal blood loss outside a setting of colorectal cancer screening: A systematic review. Poster session presented at: Digestive Disease Week; 2016 May 22 – 24; San Diego, CA.

(2) Pochapin MB, Fine SN, Eisorfer RM, Rigas B. Fecal occult blood testing in hospitalized patients. J Clin Gastroenterol. 1994; 19(4):274-277.

(3) Narula N, Ulic D, Al-Dabbagh R, Ibrahim A, Mansour M, Balion C, et al. Fecal occult blood testing as a diagnostic test in symptomatic patients is not useful: A retrospective chart review. Can J Gastroenterol Hepatol. 2014; 28(8): 421–26.

(4) van Rijn AF, Stroobants AK, Deutekom M, Lauppe C, Sturk A, Bossuyt PMM, et al. Inappropriate use of the faecal occult blood test in a university hospital in the Netherlands. Euro J of Gastroenterol and Hepatol. 2012; 24(11):1266-69.

(5) Ip S, Sokoro AA, Kaita L, Ruiz C, McIntyre E, Singh H. Use of fecal occult blood testing in hospitalized patients: results of an audit. Can J Gastroenterol Hepatol. 2014; 28(9): 489-94.

Resources and support for primary care providers during the transition to using the fecal immunochemical test (FIT) in Ontario

78. Where can I learn more about the fecal immunochemical test (FIT) and the ColonCancerCheck program?

- For more information about FIT and the ColonCancerCheck program, visit the FIT resource hub at cancercareontario.ca/CCCrecommendations.

79. Is continuing professional development offered for the fecal immunochemical test (FIT)?

- Yes. Ontario Health (Cancer Care Ontario) is offering a continuing professional development module for primary care providers on FIT and colorectal cancer screening in Ontario. This module is available regionally through face-to-face presentations hosted by Regional Primary Care Leads from all 14 Local Health Integration Networks (LHIN) in Ontario.
- To learn more about the continuing professional development module presentations for FIT, please contact your local LHIN (lhins.on.ca)

80. Where can I find a copy of the fecal immunochemical test (FIT) instructions?

- FIT instructions are available online at cancercareontario.ca/FITinstructions in 32 languages.
- The FIT instructions are included in English and French in the FIT kits that are mailed to screening participants.
- The FIT instructions are designed to be 'word light', so that they are participant-friendly and easy to follow.

81. How do I encourage and support my patients to complete the fecal immunochemical test (FIT)?

- Explain to your patients that FIT is better at detecting colorectal cancer and pre-cancerous polyps than the guaiac fecal occult blood test (gFOBT). FIT is better because it is a more sensitive screening test than gFOBT, which was previously used in ColonCancerCheck for screening persons at average risk for colorectal cancer.

- Let your patients know that finding pre-cancerous polyps is important because polyps are abnormal growths on the lining of the colon that may develop into cancer over time.
- Tell your patients that when colorectal cancer is caught early, nine out of every 10 people with the disease can be cured (1). If colorectal cancer is caught later, it can be treated, but cure is less likely. About one out of every 10 people with a colorectal cancer that is diagnosed at a later stage will be cured.
- Review the benefits of FIT with your patients to help ensure informed decision-making:
    - Safe and painless;
    - Simple and accurate way to check for colorectal cancer;
    - Only takes a few minutes;
    - Can be done at home;
    - No need to change what you eat, including vitamin C; and
    - No medication restrictions.
- In addition, on an "intention to screen" basis (i.e., analyses are based on all participants initially randomized to that arm, regardless of whether or not they complete screening or whether they withdraw from the study—this approach better reflects the "real life" impact of screening as it captures participants' acceptance of the test as well as its accuracy), FIT is as effective as colonoscopy at detecting colorectal cancer. FIT is non-invasive and can be done in the privacy and comfort of a patient's home.
- Consider showing patients the ColonCancerCheck Guide to Average Risk Screening with FIT in Ontario (available at: cancercareontario.ca/CCCrecommendations). Although it is targeted to primary care providers, it can help reinforce the benefits of FIT and that FIT is the screening test recommended by Ontario Health (Cancer Care Ontario) for people at average risk of colorectal cancer.
- Sign up for physician-linked correspondence to improve screening participation (cancercareontario.ca/en/guidelines-advice/treatment-modality/primary-care/physician-linked-correspondence). Physician-linked correspondence includes physician names on personalized letters generated by Ontario Health (Cancer Care Ontario) inviting and reminding their patients to get screened.
    - Research has shown that people who receive a personal recommendation from their family physician are more motivated to get screened for cancer than those who do not.
    - Physician-linked correspondence is available for colorectal cancer screening to all patient enrolment model physicians in the province.

(1) Cancer Care Ontario. Ontario cancer statistics 2018 report. Toronto, ON: Cancer Care Ontario; 2018.

82. Will Ontario Health (Cancer Care Ontario) be providing me with any materials to support conversations with my patients about screening with the fecal immunochemical test (FIT)?

- FIT instructions are available at cancercareontario.ca/FITinstructions to help facilitate discussions with patients.
- Consider showing patients ColonCancerCheck's Guide to Average Risk Screening with FIT in Ontario (available at: cancercareontario.ca/CCCrecommendations). Although this document is targeted to primary care providers, the information is simplified and shows the key steps involved in getting screened with FIT. This document can help to explain the benefits of FIT and that FIT is the screening test recommended by Ontario Health (Cancer Care Ontario) for people at average risk of colorectal cancer.
- Ontario Health (Cancer Care Ontario) has sent a sample FIT collection device to primary care providers to give them the opportunity to demonstrate how to complete a FIT with their patients.

83. How is Ontario Health (Cancer Care Ontario) educating patients and increasing their awareness of the fecal immunochemical test (FIT)?

- Ontario Health (Cancer Care Ontario)'s ColonCancerCheck program correspondence will reflect the switch from the guaiac fecal occult blood test to FIT. Participants will continue to be sent letters from Ontario Health (Cancer Care Ontario) inviting and reminding them to get screened at two-year intervals.
- ColonCancerCheck has also developed an insert to let participants know that the test has changed to FIT. This insert will be included during the first two years after FIT launch with all letters inviting patients and reminding them to get screened with FIT.