



Transition to Fecal Immunochemical Testing: Frequently Asked Questions for Primary Care Providers and Healthcare Administrators

1. Why is Ontario switching from the guaiac fecal occult blood test (gFOBT) to the fecal immunochemical test (FIT)?

Ontario is switching 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 will be automated at LifeLabs, which will make 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/>

2. 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, Lanás 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.

3. 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 will 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 will 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).
- 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 Cancer Care Ontario to provide colonoscopies for patients with an abnormal FIT result will be available at cancercareontario.ca/FITcolonoscopy when FIT is launched.

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 can be found at cancercareontario.ca/FIThub.
- 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.

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

- Once FIT is launched, 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 can be found at cancercareontario.ca/FIThub.
- 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.
- You will 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. 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 can be found at cancercareontario.ca/FIThub.
- If you have any questions for LifeLabs, contact **1-833-676-1426**.

5. 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 can be found at cancercareontario.ca/FIThub.
- The FIT requisition will be 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.

6. How will the fecal immunochemical test (FIT) be analyzed and how will results be 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 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 will be provided to you and your patients qualitatively (i.e., normal, abnormal, rejected or invalid).
7. **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.
8. **What do I do if my patient receives an abnormal fecal immunochemical test (FIT) result?**
- 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.
9. **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, 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**.
10. **When should I stop screening my patients with the guaiac fecal occult blood test (gFOBT)?**
- You should continue to screen your eligible patients with gFOBT until the fecal immunochemical test (FIT) is available through the ColonCancerCheck program.
 - When a patient at average risk for colorectal cancer is due for screening, they should complete the screening test that is currently recommended by the ColonCancerCheck program. Screening your patients for colorectal cancer should not be delayed until FIT is available.
11. **Where can I learn more about the fecal immunochemical test (FIT) and the ColonCancerCheck program?**
- For more information about the FIT and the ColonCancerCheck program, visit the FIT resource hub at **cancercareontario.ca/FIThub**.