Cancer Care Ontario

Transition to Fecal Immunochemical Testing (FIT)

Frequently Asked Questions for Primary Care Providers

October 2017
Version 1.1

Ontario
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Overview

Ontario will be transitioning from the guaiac fecal occult blood test (gFOBT) to the fecal immunochemical test (FIT) for colorectal cancer screening in 2018. To support this transition, FAQs have been developed to provide primary care providers with information regarding changes to the ColonCancerCheck program, when Ontario will be transitioning to FIT, and the transition's impact on primary care providers and the screen-eligible public.

Since work to support the transition is ongoing, this list of FAQs does not address all questions that primary care providers may have. Additional FAQs will be developed in early 2018.

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

FIT: fecal immunochemical test

gFOBT: guaiac fecal occult blood test

FIT collection device: consists of the probe (grooved plastic stick) used to collect the stool and the vial (tube) where the probe is stored; also includes a small amount of buffer solution used to stabilize the sample

Inoculated device: term used to refer to the collection device once it contains a stool sample

FIT kit: term used to refer to the entire package that the laboratory/laboratories will send to the screen-eligible participants, including the FIT collection device and package components (e.g., instructions, return mailing materials). The participating laboratory or laboratories have not yet been finalized.

Normal/abnormal: terms used to communicate results to participants

Positive/negative: terms used to communicate results to primary care providers

About the fecal immunochemical test and why it is being 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 lesions.

* 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 or ulcerative colitis) or pre-cancerous colorectal polyps requiring surveillance.

2. 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 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 stool sample needed;
    - no dietary restrictions, including vitamin C; and
    - no medication restrictions.
- FIT processing will be automated at a laboratory/laboratories*, which makes the interpretation of test results more consistent.

* The participating laboratory or laboratories have not yet been finalized.

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-cancer in average risk people**. Results from systematic reviews suggest that FIT is more sensitive (i.e., better at detecting a cancer in people who have the disease) than gFOBT (82 percent vs. 47 percent, after one-time FIT vs. one-time gFOBT). (1,2) FIT has also been shown to detect twice as many advanced 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 positive 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 FIT has no dietary or medication restrictions 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.

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

- Currently, there is limited evidence in terms of colorectal cancer mortality directly comparing FIT to colonoscopy for colorectal cancer screening in people at average risk of developing colorectal cancer. There are several large, randomized controlled trials (RCTs) underway to address this question, including an RCT in Spain with over 50,000 participants invited to be screened, but the final results for colorectal cancer mortality will not be available until the 2020s.

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. (4) **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 comply with or withdraw from the study—this approach better reflects practice and improves generalizability of study findings). While the study found that colonoscopy was significantly better at detecting advanced adenomas than the one-time use of FIT (514 vs. 231; *P* value = <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. Additional studies comparing participation between fecal-based tests and colonoscopy are described in the *Colorectal Cancer Screening in Average Risk Populations: Evidence Summary.* (3) While the quality of these studies varies, there is a general trend showing that people prefer fecal-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 FIT-positive people who underwent a colonoscopy, compared to one colorectal cancer being detected for every 191 people who screened with colonoscopy. (3) **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 rare, but 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* value = < 0.001). The complications experienced by participants in the FIT group occurred in those with a positive 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 the bowel preparation and the use of sedation. Possible colonoscopy-related complications include (but are not limited to) perforation, post-polypectomy bleeding, cardiac events, syncope/hypotension, and death (in rare cases). (5,6) 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. (5)

5. Are there any limitations to the fecal immunochemical test (FIT)?

- The FIT collection device has a shorter shelf life (12 to 18 months) than the guaiac fecal occult blood test (gFOBT) card (three years). Therefore, to manage device inventory and avoid the inadvertent distribution of expired devices, a laboratory/laboratories* will mail FIT kits to participants upon request from their primary care physician.
- Once a stool sample has been collected using the FIT collection device, the specimen is less stable than a gFOBT specimen on a card. Therefore, **ColonCancerCheck recommends processing FIT devices within 14 days of sample collection** (vs. 21 days for gFOBT). ColonCancerCheck will be working with the selected laboratory/laboratories* to support timely return of completed tests from participants in all regions across Ontario.

* The participating laboratory or laboratories have not yet been finalized.

Changes that can be expected with the implementation of the fecal immunochemical test for screening people at average risk of getting colorectal cancer in Ontario

6. Will the eligibility criteria for colorectal cancer screening change with the fecal immunochemical test (FIT)?

- No. Eligibility criteria to screen with FIT will be the same as it is 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 gFOBT or FIT in the past two years;
    - not having screened for colorectal cancer with colonoscopy or flexible sigmoidoscopy in the past 10 years; and
    - having a valid Ontario Health Insurance Plan (OHIP) number.
- Eligibility for screening with FIT will continue to be assessed by primary care providers. In addition, the laboratory/laboratories§ processing requisitions will confirm eligibility based on key parameters, such as age and, where possible, previous fecal test screening status.
  To learn more about the current ColonCancerCheck screening recommendations and eligibility criteria please visit the Resources for Primary Care Providers website (https://cancercare.on.ca/pcresources).

* 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, primary care providers will be able to order FIT kits for people ages of 75 to 85 who they 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 colorectal polyps requiring surveillance.

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

- unexplained anemia that is caused by a lack of iron;

- 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;
- stools that are narrower than usual; and/or
- new and persistent stomach discomfort.

[§] The participating laboratory or laboratories have not yet been finalized.

7. What is the screening interval for the fecal immunochemical test (FIT)?

- The screening interval for people at average risk* of colorectal cancer will not change after the switch from guaiac fecal occult blood testing (gFOBT) to FIT in Ontario. ColonCancerCheck will recommend screening with FIT every two years for people at average risk.

  * "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 colorectal polyps requiring surveillance.

8. Can I order the fecal immunochemical test (FIT) for my patients today (before the ColonCancerCheck launch of FIT)?

- There is a laboratory in Ontario that offers FIT; however, this test is not covered by the Ontario Health Insurance Plan (OHIP). Therefore, patients who use this test will have to pay out-of-pocket and will be screened outside the ColonCancerCheck program. Being screened within the ColonCancerCheck program provides important benefits to participants, including:
  - 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 that is regularly measured for quality and performance.
- Cancer Care Ontario recommends screening eligible people with the guaiac fecal occult blood test (gFOBT) until FIT is available through the ColonCancerCheck program.

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

- There will be two changes with the introduction of FIT: how you request a FIT for your patients and how the FIT kit is distributed to eligible Ontarians (refer to Appendix A for a summary). These changes are motivated by 1) the shorter shelf life of the FIT collection device (which expires within 12 to 18 months), and 2) the desire to reduce the number of mislabeled collection devices (which will reduce the number of rejected tests and the number of participants not receiving results). The information below provides more detail about these changes.

Primary care providers:

- will determine patient eligibility for screening with FIT;
- will no longer maintain an inventory of, or distribute, colorectal cancer screening tests (e.g., guaiac fecal occult blood test and FIT);
- will complete a FIT requisition form and send it directly to the processing laboratory/laboratories*;
- will be required to validate patient address information before completing the requisition form and sending it to the processing laboratory/laboratories*—this **validation is critical** to ensure that the laboratory/laboratories* and ColonCancerCheck have up-to-date participant mailing information,

so the privacy of patients is **not compromised**, and they can receive their FIT kit and test result notification;
- will be able to specify in the requisition where the FIT kit should be sent, even if it's somewhere other than the patient's home or mailing address, as necessary; and
- will be responsible for ensuring that patients with a FIT-positive result receive timely follow-up—ColonCancerCheck recommends follow-up with a colonoscopy within eight weeks of a positive FIT result. Ensuring timely follow-up of a positive FIT result is particularly important due to the greater likelihood of abnormal findings associated with FIT-positive colonoscopies.

Processing laboratory/laboratories*:

- will mail the patients' FIT kits to the address on the requisition—each FIT kit will include the FIT collection device, instructions for completing the FIT and materials for mailing it back to the laboratory/laboratories*;
- may need to check with the primary care provider regarding completeness and/or accuracy of information on FIT requisitions; and
- before mailing FIT kits, will apply a barcode label (including participant identifiers) to each FIT collection device (reducing the likelihood of repeat tests due to labelling errors) and mail the kits directly to participants.

Participants:

- will be required to return their inoculated device to the laboratory/laboratories* by mail or by dropping it off at a specimen collection centre associated with the processing laboratory/laboratories†—inoculated devices should be returned to the laboratory/laboratories* as soon as possible after the stool is collected and the laboratory/laboratories* will contact participants if their collection date needs clarification.

* The participating laboratory or laboratories have not yet been finalized.

† The participating laboratory or laboratories have not yet been finalized. The option to drop specimens off at collection centres will depend on the participating laboratory/laboratories and will be confirmed at a later date.

10. 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) will be able to access the FIT through authorized organizations, including Telehealth Ontario and mobile screening coaches. Prior to FIT launch, primary care providers will be provided further information. Authorized organizations will inform the laboratory/laboratories* of the request for a FIT kit, and the laboratory/laboratories* will mail the FIT kit to the participant or to an address that is convenient. People will no longer be able to get a kit from community pharmacists.
- Unattached people who have completed a FIT will continue to receive result letters by mail from Cancer Care Ontario.
- Cancer Care Ontario will continue to assist people without a primary care provider who have a positive FIT result to connect with a physician for timely follow-up.
- With the implementation of FIT, physicians will continue to be encouraged to sign up with Cancer Care Ontario to accept new patients who have had a positive fecal screening test result and require a follow-up colonoscopy. Physicians will also be encouraged to accept new patients who have self-identified as increased risk for developing colorectal cancer due to their family history. Primary care providers who are part of a patient enrolment model and roster new patients referred from Cancer Care Ontario can claim the Q043A New Patient Fee FOBT

Positive/Colorectal Cancer Increased Risk. Cancer Care Ontario anticipates that a related code will be available for FIT.

* The participating laboratory or laboratories have not yet been finalized.

11. How will the fecal immunochemical test (FIT) be processed and how will results be communicated to patients and primary care providers?

- FIT processing will be completed by the laboratory/laboratories* after receiving the inoculated device.
- Primary care providers will continue to receive results directly from the processing laboratory/laboratories*, in addition to recommendations to arrange colonoscopy for patients with positive results. Primary care providers will continue to be responsible for communicating test result information to their patients and for ensuring that their patients with a positive FIT result receive timely follow-up. ColonCancerCheck recommends follow-up with a colonoscopy within eight weeks of a positive FIT result. Ensuring timely follow-up of a positive FIT result is particularly important due to the greater likelihood of positive findings associated with FIT-positive colonoscopies.
- Participants will continue to receive result letters from Cancer Care Ontario.
- FIT results will be provided to primary care providers and their patients qualitatively (negative/positive, normal/abnormal, respectively).

* The participating laboratory or laboratories have not yet been finalized.

12. Why does the current method of distribution for the guaiac fecal occult blood test (gFOBT) have to change with the fecal immunochemical test (FIT)?

- A centralized distribution approach is being adopted for screening with FIT. The processing laboratory/laboratories* will receive FIT requisitions from primary care providers and mail FIT kits directly to participants.
- Centralized distribution of FIT kits from the laboratory/laboratories* (instead of from physicians and pharmacies) has several advantages for patients, including:
    - 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 patients do not receive expired kits, which is particularly important because FIT has a much shorter shelf life; and
    - reducing inappropriate use of FIT because the processing laboratory/laboratories* will confirm the patient's eligibility before mailing out each FIT kit.
- Centralized distribution for 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).

* The participating laboratory or laboratories have not yet been finalized.

13. Will fecal immunochemical test (FIT) kits be stocked by physician offices?

- No. ColonCancerCheck's FIT kits will not be stocked by physician offices. FIT kits will be stocked and distributed by a laboratory/laboratories* 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 the laboratory/laboratories* to confirm eligibility before mailing out kits.

* The participating laboratory or laboratories have not yet been finalized.

14. Will the mobile screening coaches support access to the fecal immunochemical test (FIT)?

- The mobile screening coaches that currently operate in the North West and Hamilton Niagara Haldimand Brant regions will continue to support access to colorectal cancer screening in the regions they serve. Participants can request a FIT kit from the mobile screening coaches. Mobile screening coaches will then send FIT requisitions to the processing laboratory/laboratories*, which will be responsible for mailing FIT kits to participants or to an address that is convenient.

  * The participating laboratory or laboratories have not yet been finalized.

Availability of the fecal immunochemical test in Ontario

15. When will Ontario be switching to the fecal immunochemical test (FIT)?

- Cancer Care Ontario is working to make changes to the ColonCancerCheck program for the transition to screening with FIT. Once these changes are completed in 2018, FIT will be available for screening average risk people in Ontario.
- Cancer Care Ontario will be communicating with physicians regularly leading up to the launch of FIT. Over the course of 2017 and 2018, Cancer Care Ontario will be presenting at conferences, sharing communications with professional associations and Regional Cancer Programs, and posting resources and updates on the FIT resource hub (https://cancercare.on.ca/FITHub).
- Until FIT is launched in 2018, the guaiac fecal occult blood test (gFOBT) remains the recommended colorectal cancer screening test in Ontario for people at average risk of getting colorectal cancer. FIT is not yet covered by the Ontario Health Insurance Plan (OHIP) and people are advised to continue using gFOBT until FIT becomes available through the ColonCancerCheck program. While FIT is available as a user-pay test from one laboratory in Ontario, Cancer Care Ontario recommends against screening people outside the program. As part of its organized screening program, ColonCancerCheck provides people with additional benefits, including letters inviting and reminding them to participate in screening and notification of results.

16. Why won't the fecal immunochemical test (FIT) be available for colorectal cancer screening until late 2018?

- Transitioning from the use of the guaiac fecal occult blood test (gFOBT) to FIT for colorectal cancer screening requires a number of large-scale changes to the ColonCancerCheck program and its supporting infrastructure.
- To ensure a successful transition from gFOBT to FIT, Cancer Care Ontario will have to make changes to the ColonCancerCheck program that impact FIT kit distribution, information technology, quality assurance, provider education and communications.

17. Should primary care providers wait to screen their patients for colorectal cancer until the fecal immunochemical test (FIT) becomes available?

- No, they should continue to screen their eligible patients with the guaiac fecal occult blood test (gFOBT) until FIT is available through the ColonCancerCheck program.
- Cancer Care Ontario does not recommend changing the screening interval during the transition period from gFOBT to FIT. Regular screening is important because it detects cancer and pre-cancerous lesions early when they are easier to treat.
- Cancer Care Ontario recommends fecal testing every two years, either with the gFOBT or FIT, depending on which is available. For example, people who are due for screening before FIT is available through the ColonCancerCheck program should screen with gFOBT. People who are up to date with screening should wait until the appropriate interval and screen with FIT.

Support for primary care providers during the transition to using the fecal immunochemical test in Ontario

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

- To learn more about FIT, you can visit the FIT resource hub (https://cancercare.on.ca/FITHub).
- For more information about the current ColonCancerCheck program (including current colorectal cancer screening recommendations), visit the Resources for Primary Care Providers website (https://cancercare.on.ca/pcresources).

19. Will continuing professional development be offered in relation to the fecal immunochemical test (FIT)?

- Yes. Cancer Care Ontario will be offering a continuing professional development module for primary care providers about FIT and colorectal cancer screening in Ontario. This module will be available regionally through face-to-face presentations hosted by Regional Primary Care Leads from all 14 Local Health Integration Networks in Ontario.

References

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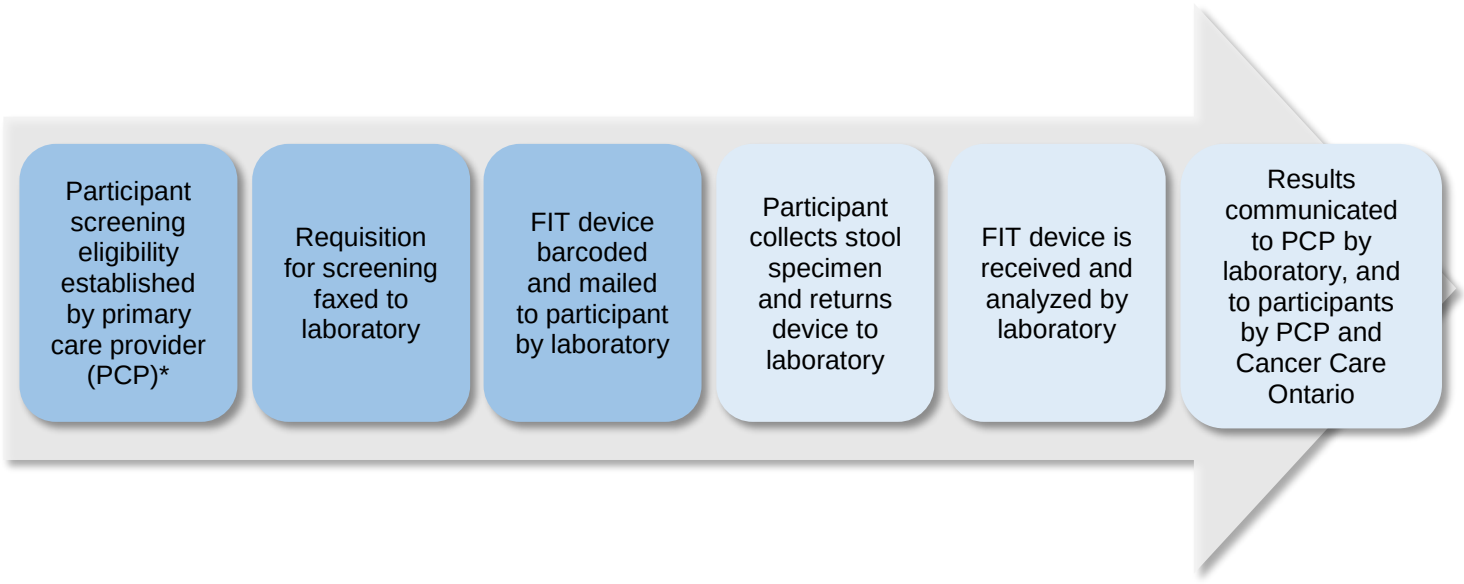
Appendix A: Fecal immunochemical test (FIT) screening pathway



ORDERING AND DISTRIBUTION

- PCPs will continue patient counselling and recruitment
- **NEW:** PCPs will no longer provide kit to their patients or maintain test kit inventory
- **NEW:** FIT requisition faxed directly to laboratory (central intake)
- **NEW:** Laboratory will validate participant eligibility and requisition completeness
- **NEW:** Centralized distribution of FIT kit by laboratory

*People without a PCP can get a requisition from Telehealth Ontario or a mobile screening coach

RECEIVING, TESTING AND REPORTING

- Completed kits returned to laboratory by mail
- **NEW:** Drop-off within 7–14 days when returning completed kit to laboratory
- **NEW:** Laboratory will refrigerate specimen upon receipt
- **NEW:** Laboratory will contact participant if collection date requires clarification
- **NEW:** Testing to be completed within 2 calendar days