



PROVIDER GUIDE

Fecal Immunochemical Test (FIT)

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ABOUT LETSGETCHECKED

[Client name] has partnered with LetsGetChecked to make it easier for patients to complete recommended screenings. LetsGetChecked is a global healthcare solutions company that helps providers connect patients to better health through testing, accessible health insights, virtual consultations, and medication delivery for a wide range of health and wellness conditions. LetsGetChecked's comprehensive at-home healthcare solutions integrate seamlessly into care offerings to help improve the patient experience and health outcomes.

OVERVIEW

Despite colorectal cancer screening's ability to detect cancer early, screening rates remain low. According to the CDC, only about 7 in 10 US adults aged 50 to 75 are up-to-date with colorectal cancer screening¹.

Increasing screenings is crucial as prolonged screening delays can lead to delayed diagnoses and poor health consequences. At-home colon cancer screenings with LetsGetChecked is one way to encourage your patients to fill a critical gap in their care.

Patients in [Medicare Advantage] program who have been identified with a gap in care for colorectal cancer screening will receive an at-home Fecal Immunochemical Test (FIT) from LetsGetChecked. For more information on eligibility criteria, refer to [Attachment 1](#) – HEDIS Quality Measure: Colorectal Cancer Screening (COL).

Patients who use LetsGetChecked's FIT Test will have a seamless experience as they receive their test, collect their sample, and receive their results – all without leaving their home. Results will be shared with patients and providers to ensure proper follow up care and treatment.

Although the FIT Test is not a replacement for colonoscopies, it plays a vital role in the route to diagnosis. This convenient, noninvasive stool analysis can encourage patients to take the first important step in detecting colorectal cancer early, increasing screening rates and positively affecting health outcomes.

The following document gives you more information on this program and FIT testing. We encourage you to discuss the benefits of this program and all colon cancer screening as relevant for your individual patients. Please don't hesitate to reach out to LetsGetChecked with any questions. [Contact Us](#).

HOW LETSGETCHECKED'S FIT SCREENINGWORKS



Step 1

Client & LGC identify specific patients, i.e., adults aged 45 and older that had no CRC screening.



Step 2

LGC delivers sample collection kits from our ISO 13485 accredited facility to the patient's home.



Step 3

The patient collects the sample and sends it to the lab in the prepaid shipping envelope.



Step 4

Our CLIA approved and CAP-accredited lab processes the sample.



Step 5

Both the patient and their PCP receive results online and/or by mail.

WHAT IS IN THE KIT?



HOW DOES MY PATIENT COMPLETE THE TEST?

The patient receives a sample collection test kit with easy-to-follow instructions. The patient provides a stool sample from the privacy of their home and sends it to our lab partner. LetsGetChecked also has customer support agents available who can walk patients through the step-by-step instructions.

HOW DOES LETSGETCHECKED OVERSEE THE ADMINISTRATION OF THIS TEST?

Our laboratories are CLIA approved and CAP-accredited, which are the highest levels of accreditation. In addition, our labs complete validation studies to ensure accuracy of the test.

Sample collection kits are manufactured within our ISO 13485 accredited facility, the highest level of accreditation for medical devices.

WHAT ARE THE FIT RESULT VALUES?

FIT results are negative or positive. The cutoff value for a positive result is 100 ng hHb/mL.

HOW DO MY PATIENT AND I RECEIVE RESULTS?

ABNORMAL (POSITIVE) RESULT NOTIFICATION

When a lab processes the test and the result is positive, the LetsGetChecked clinical staff will reach out to the patient immediately. In addition, the patient and their primary care provider will receive mailed letters with results. The patient may reach out to you for further guidance and recommendations.

NORMAL (NEGATIVE) RESULT NOTIFICATIONS

Patients and their providers receive mailed result letters. Please see [Attachment 2](#) – Sample Results Letters.

NOTIFICATIONS FOR TESTING NOT PERFORMED

There are instances where the laboratory was unable to run the test. Patients are notified and another test kit is mailed. Patients may call you to inquire about why testing was not performed. Please refer them to LetsGetChecked.

WHAT ARE THE NEXT STEPS IF A TEST RESULT IS POSITIVE?

According to the U.S. Preventive Services Task Force (USPSTF), positive results on stool-based screening tests require follow-up with colonoscopy for the screening benefits to be achieved.²

HOW LONG DOES THE ENTIRE TESTING PROCESS TAKE?

Results are typically processed within a few days and then will be sent to the patient and provider via mail.

ABOUT THE FIT SCREENING

WHAT IS A FECAL IMMUNOCHEMICAL TEST (FIT)?

The FIT Test is used to screen for colorectal cancer. Cancer in the colon or polyps in the colon are more likely to bleed than normal colon tissue. This test uses antibodies to check for very small amounts of blood in the stool. This quick and noninvasive test requires patients to collect samples directly from their feces. (The sample is mailed to the laboratory for testing). Patients can collect their samples from the comfort of home with no bowel preparation necessary. The benefits of stool-based testing accrue over frequent, repeated testing, thus requiring commitment and adherence to screening intervals to achieve a substantial benefit in decreased colorectal cancer mortality.²

WHY AT-HOME FIT SCREENING?

There are several options for colorectal cancer screening, and we encourage patients to do the option that is best for them. For many patients at average risk for colon cancer, that's the easy-to-use, non-invasive FIT. Many patients may be more receptive to a

colorectal cancer screening that can be completed from the comfort of their home. We encourage you to discuss options with your patients and urge them to do the screening that’s right for them, which may include the one they’re most likely to complete.

A large research study, published in the BMJ Journal Gut, revealed that FIT screening was found to result in a 34% reduction in advanced-stage colorectal cancer (CRC) and a 40% reduction in death from CRC after 10 years of follow-up.³

WHAT IS THE DIFFERENCE BETWEEN FOBT AND FIT?

Both high-sensitivity gFOBT and FIT detect blood in the stool; however, they use different methods. High-sensitivity gFOBT is based on chemical detection of blood, while FIT uses antibodies to detect blood.²

Screening with high-sensitivity gFOBT requires some dietary and medication restrictions prior to collecting stool samples, while the FIT does not.²

Test specimens can be collected from a single stool sample with FIT while collection of samples from 3 separate bowel movements is required for high-sensitivity gFOBT screening.²

WHAT IS LETSGETCHECKED’S CLINICAL DATA FOR FIT?

VERIFICATION OF FECAL OCCULT BLOOD IN HUMAN STOOL ON THE POLYMEDCO OC-AUTO SENSOR DIANA

Accuracy

A total of forty (40) specimens with varying hemoglobin concentrations were run. Samples were produced from fortified stool proxy matrix provided by the manufacturer, Polymedco. These samples were considered Polymedco’s accuracy validation panel. Qualitative Accuracy passes if the overall concordance $\geq 90\%$. The accuracy test passed with 100% overall concordance.

Summary of Accuracy

Instrument	Concordance Rate	Pass/Fail
OC-Auto SENSOR DIANA	100%	PASS

Precision

The Polymedco-provided installation sample numbers 38 (Negative) and 40 (Positive) were used for precision testing. Sample 40 was combined 1:1 with sample 38 to dilute the hemoglobin concentration to a value closer to the cutoff. Intra-day reproducibility was performed on Day 1 by running each sample in replicates of 20. Inter-day reproducibility was assessed by running testing each sample 5 replicates per day for another 4 days. Total precision was determined by assessing both intra- and inter-day precision studies for a total of 40 points per sample. The total precision should be $\geq 90\%$. The precision verification passed with a total precision of 100%.

Summary of Precision

Instrument	Total Precision	Pass/Fail
OC-Auto SENSOR DIANA	100%	PASS

Correlation

The method comparison study was carried out utilizing samples produced from fortified stool proxy matrix provided by Polymedco. Forty individual correlation samples were tested on the OC-Auto Sensor Diana analyzer. These forty individual correlations samples were of known negative/positive values. The correlation study passes if the agreement is within the 95%

Confidence Interval (CI) and Cohen’s Kappa is >75% and falls within the 95% CI and the symmetry test passes. The correlation study passed with 100% agreement, a Cohen’s Kappa of 100%, and a passing symmetry test.

Summary of Correlation

Instrument	Concordance Rate	Pass/Fail
OC-Auto SENSOR DIANA	100%	PASS

HOW OFTEN SHOULD I TEST MY PATIENT?

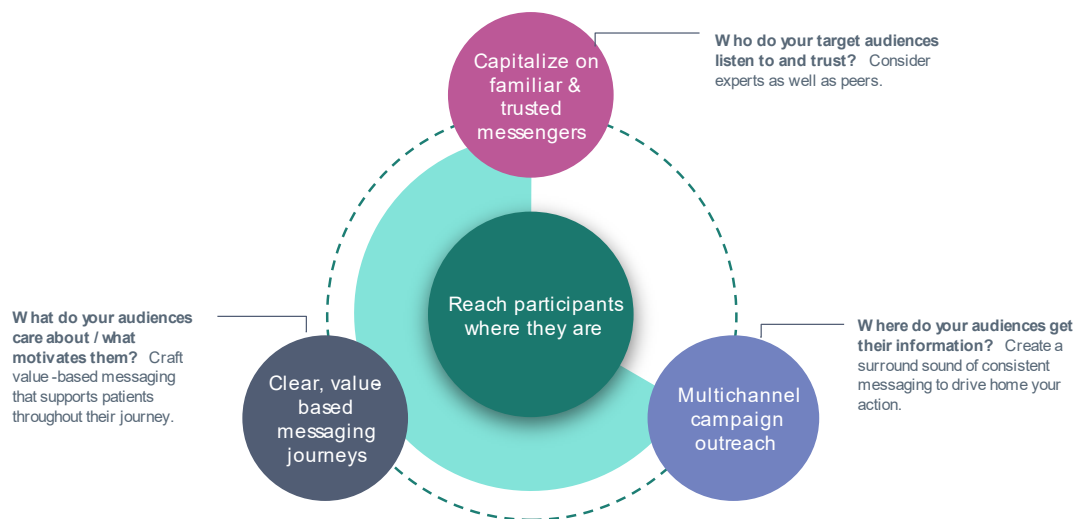
The USPSTF recommends colorectal cancer screening for people aged 45 and older. While there are other screening options available, if a patient chooses the FIT, the test should be completed annually. This recommendation applies to asymptomatic adults 45 years or older who are at average risk of colorectal cancer (i.e., no prior diagnosis of colorectal cancer, adenomatous polyps, or inflammatory bowel disease; no personal diagnosis or family history of known genetic disorders that predispose them to a high lifetime risk of colorectal cancer [such as Lynch syndrome or familial adenomatous polyposis]).²

HOW CAN I ENCOURAGE MY PATIENTS TO PARTICIPATE?

You could discuss the benefits of an annual FIT with your eligible patients during a regular office visit or with a regularly scheduled phone call. Your office staff could also discuss the benefits of the test. Please see [Attachment 3](#) for more information.

In addition, LetsGetChecked will assist you in sharing this important message. We use a multichannel approach to reach participants. See [Attachment 4](#) for sample communications.

LetsGetChecked meets patients where they are in their well-being journey



CONTACT US

 <https://www.letsgetchecked.com/contact-us/>

 1-800-984-9837

ATTACHMENTS

- [**Attachment 1**](#) – HEDIS Quality Measure: Colorectal Cancer Screening (COL)
- [**Attachment 2**](#) – Sample Results Letters
- [**Attachment 3**](#) – Sample Provider-Patient Talking Points
- [**Attachment 4**](#) – Sample Communications

REFERENCES

¹Centers for Disease Control and Prevention. (November 3, 2021). Use of Colorectal Cancer Screening Tests. CDC. <https://www.cdc.gov/cancer/colorectal/statistics/use-screening-tests-BRFSS.htm>.

²US Preventive Services Task Force. (2021, May 18). Final Recommendation Statement Colorectal Cancer: Screening. USPSTF. <https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/colorectal-cancer-screening>.

³Chiu H-M, Jen GH-H, Wang Y-W, et al. (2021, January 25). Long-term effectiveness of faecal immunochemical test screening for proximal and distal colorectal cancers. BMJ Journals. <https://gut.bmj.com/content/70/12/2321>.

Attachment 1 – HEDIS Quality Measure: Colorectal Cancer Screening (COL)

Description

The percentage of members 50–75 years of age who had appropriate screening for colorectal cancer.

Eligible Population

Product lines

Commercial, Medicare (report each product line separately).

For only Medicare, report the following SES stratifications and total:

- **Non-LIS/DE, Nondisability.**
- **LIS/DE.**
- **Disability.**
- **LIS/DE and Disability.**
- **Other.**
- **Unknown.**
- **Total Medicare.**

Note: Stratifications are mutually exclusive and the sum of all six stratifications is the Total population.

For each product line, report the following stratifications by race and total, and stratifications by ethnicity and total:

Stratification

- **Race:**
 - **White.**
 - **Black or African American.**
 - **American Indian and Alaska Native.**
 - **Asian.**
 - **Native Hawaiian and Other Pacific Islander.**
 - **Some Other Race.**
 - **Two or More Races.**
 - **Asked but No Answer.**
 - **Unknown.**
 - **Total.**
- **Ethnicity:**
 - **Hispanic/Latino.**
 - **Not Hispanic/Latino.**
 - **Asked but No Answer.**
 - **Unknown.**
 - **Total.**

Note: Stratifications are mutually exclusive and the sum of all categories in each stratification is the Total population.

Administrative Specification

Denominator The eligible population.

Numerator One or more screenings for colorectal cancer. Any of the following meet criteria:

- Fecal occult blood test (FOBT Lab Test Value Set; FOBT Test Result or Finding Value Set) during the measurement year. For administrative data, assume the required number of samples were returned, regardless of FOBT type.
- Flexible sigmoidoscopy (Flexible Sigmoidoscopy Value Set; History of Flexible Sigmoidoscopy Value Set) during the measurement year or the four years prior to the measurement year.
- Colonoscopy (Colonoscopy Value Set; History of Colonoscopy Value Set) during the measurement year or the nine years prior to the measurement year.
- CT colonography (CT Colonography Value Set) during the measurement year or the four years prior to the measurement year.
- FIT-DNA test (FIT DNA Lab Test Value Set; FIT DNA Test Result or Finding Value Set) during the measurement year or the two years prior to the measurement year.

Exclusion (optional)


Either of the following any time during the member’s history through December 31 of the measurement year:

- Colorectal cancer (Colorectal Cancer Value Set).
- Total colectomy (Total Colectomy Value Set; History of Total Colectomy Value Set).

Attachment 2 – Sample Result Letters

Patient

Provider

<p><Member First Name> <Member Last Name> <Address Line 1> <Address Line 2> <City>, <State> <Zip Code></p> <p style="text-align: right;"><Date></p> <p>Dear <Member First Name> <Member Last Name>,</p> <p>Thank you for choosing to take the LetsGetChecked at-home health test provided by your health plan. We have processed your sample, and these are your test results.</p> <p>Your Fecal Immunochemical test (FIT) result has been returned as NEGATIVE on <Result Date>.</p> <p>Your Fecal Immunochemical Test (FIT) result has been returned as NEGATIVE. This means that no blood was detected in your stool at the time of testing. Screening tests should be performed on a regular basis and it is important to discuss with your doctor the best type of screening tests for you. There is a possibility that this test may not identify blood in the stool of someone that has colorectal cancer so it is important to talk to your healthcare provider if you have any symptoms or if you are concerned.</p> <p>Please share these results with your primary care physician. If you have questions about your test, please call LetsGetChecked at <1-XXX-XXX-XXXX> 8am – 8pm ET, Monday to Friday, and we can discuss this result with you and provide advice on your next steps.</p> <p>We are here to help and support you.</p> <p>Sincerely,</p> <p>Robert Mordkin, MD Chief Medical Officer</p> 	<p><PCP First Name Last Name> <PCP Address Line 1> <PCP Address Line 2> <PCP City>, <PCP State> <PCP Zip Code></p> <p style="text-align: right;">Re: <Patient First Name Last Name> <Patient Address Line 1> <Patient Address Line 2> <Patient City> <Patient State> <Patient Zip Code></p> <p>Dear Dr. <PCP Name>,</p> <p>Your patient, <Patient Full Name> (DOB) <Patient DOB>), recently took a LetsGetChecked at-home screening test provided by their health plan. Below are the results:</p> <p><Test name> result has been returned as <Test result> on <TestResultDate>.</p> <p>The patient has been sent these results. Please follow up with your patient to discuss these results and any follow-up testing or treatment needed. If you have any questions, please call LetsGetChecked at <Contact Number> 8am - 8pm ET, Monday to Friday.</p> <p>Sincerely,</p> <p>Robert Mordkin, MD Chief Medical Officer LetsGetChecked</p>
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Attachment 3 – Sample Provider-Patient Talking Points


- According to the CDC, colon cancer is the fourth leading cause of cancer-related deaths in the United States.
- With regular screening, colon cancer may be prevented or found early before symptoms appear. That’s when it’s most treatable.
- Anyone ages 45 and older should complete this test annually. Because screening saves lives!
- With just a small stool sample, this Fecal Immunochemical Test (FIT) looks for blood in the stool, which may be invisible to the naked eye.
- Sample collection is easy and can be done in the privacy, safety, and comfort of your own home.
- There are no dietary or medication restrictions required.
- For most people, it takes about 15-30 minutes to collect their sample.
- No need for scheduling appointments or taking time off from work.
- Reach out to LetsGetChecked to get your free colon cancer screening kit.
- Your kit includes everything you need to collect your sample from home.

Attachment 4 – Sample Communications

Welcome (‘In-Kit’) Letter

Putting your health first just got easier



CLIENT COMPANY LOGO


Complete your colon cancer screening

This sample collection kit allows you to screen for colon cancer from the comfort of your home. It's provided to you at no cost by [Client] and LetsGetChecked.

This screening test, called a Fecal Immunochemical Test (FIT), checks a small sample of your stool for blood, which may be invisible to the naked eye. If blood is found, then a follow up-test such as a colonoscopy is usually recommended.

Colon cancer is the fourth leading cause of cancer related deaths in the United States. It's recommended that everyone aged between 45 and 75 be screened regularly for colon cancer. Screening recommendations vary depending on your individual risk. Talk to your healthcare provider about the most suitable screening tests for you.

With regular screening, colon cancer may be prevented or found at an early stage before symptoms appear. That's when treatment can be most effective.

How to get started

 <p style="font-size: 9px;">Follow the step-by-step instructions inside the kit or scan the QR code to watch a video: [Link].</p>	 <p style="font-size: 9px;">Collect your sample on a weekday. Keep the kit in the bathroom as a reminder to complete it.</p>	 <p style="font-size: 9px;">Return your sample to the lab using our prepaid shipping method.</p>
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When your results are ready, we'll contact you, and your primary care provider (PCP), with your confidential results. Please call your PCP to schedule an appointment to go over the results together.

We're here to help

Call us if you have questions about this test at 1-XXX-XXX-XXXX (TTY 711), Monday through Friday, 8 a.m. to 8 p.m. ET.

Healthy regards,

LetsGetChecked in partnership with [Client]

Robert Mordkin, MD
Chief Medical Officer
LetsGetChecked

Announcement Letter

CLIENT COMPANY LOGO 

Your free sample collection kit is on its way.
Making it easier to screen for colon cancer.



Hello [First Name],

[Client] has partnered with LetsGetChecked to make it easy for you to complete your health screenings. You will be receiving a sample collection kit to help you complete your colon cancer screening from the comfort of home.

This screening, called a Fecal Immunochemical Test (FIT), tests a small sample of your stool for blood, which may be a sign of cancerous or precancerous growths in the colon. This blood is often invisible to the naked eye.

Why the Centers for Disease Control and Prevention (CDC) recommend this [test](#)



According to the CDC, colon cancer is the fourth leading cause of cancer related deaths in the United States.



With regular screening, colon cancer may be prevented or found at an early stage before symptoms appear.



The CDC recommends anyone age 45 and older completes this simple test annually.

It only takes a few minutes to collect your sample. And by collecting it at home you avoid doctor visits or appointments.


We're here to help

Call us if you have questions about this test at 1-XXX-XXX-XXXX (TTY 711), Monday through Friday, 8 a.m. to 8 p.m. ET.

Healthy regards,


LetsGetChecked in partnership with [Client]

Kit Return Reminder Letter

CLIENT COMPANY LOGO 

How to return your sample

Scan this QR code with your phone's camera to watch a helpful video. Or visit [\[link\]](#)




Hello [First Name],


We sent a sample collection kit to you on behalf of [Client] to help you complete a colon cancer screening. Looks like our lab hasn't received your sample. Do you have questions or [need](#) help? If you recently sent your stool sample to the lab, thank you. If not, try to return your sample this week. It's important.

According to the CDC, colon cancer is the fourth leading cause of cancer-related deaths in the United States. With regular screening, colon cancer may be prevented or found early before symptoms appear. That's when treatment can be most effective.


Remember:



Your kit includes everything you need to collect your sample from home.



For most people, it takes about 15-30 minutes to collect their sample.



LetsGetChecked's care team is ready to help you if you need us.

Make sure to collect your sample and return it to the lab (postage-free). Take advantage of this easy-to-do option to screen for colon cancer from home.

We're here to help

Call us if you have questions about this test at 1-XXX-XXX-XXXX (TTY 711), Monday through Friday, 8 a.m. to 8 p.m. ET.

Healthy regards,

LetsGetChecked in partnership with [Client]