

Cologuard[®] Screening Communication Toolkit

for Healthcare Providers

Supporting awareness and screening for
colorectal cancer (CRC)

Within this toolkit, you'll find customizable letters that aid in patient engagement and colorectal cancer prevention. They cover various stages of the screening process, from initial test orders to repeat screening reminders and insurance-related communications.

These resources can be shared via email or printed, and are readily available for direct download from the toolkit itself.



How-to-use Guidance

Entities using this material are responsible for and should pay close attention to the accuracy of the information about their company and the coverage details that they distribute via these materials or otherwise. This template is provided to any appropriately requesting entity, regardless of the manner in which they cover, recommend, or participate in the ordering of the Cologuard test.

You may adapt the provided content to suit the needs of your organization, including the removal of the Exact Sciences logo and editing any highlighted section to personalize to the recipient and/or sender.

Do not remove or modify the “Important Information” section.

For more information, please contact your Cologuard sales representative or visit cologuardhcp.com/resources

Streamline Communication Between Your Patients and Peers

Healthcare providers face considerable challenges when it comes to screening patients for CRC. While the process is complex, this supportive toolkit is filled with personalized patient communication tools and specialized gastroenterologist (GI) resources that are tailored to address each providers' needs. By utilizing this toolkit, providers have the opportunity to improve patient interactions, increase the number of screenings, and optimize office operations.

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Patients Aged 45-49 Years Screening Letter

Intended audience: Average risk patients, specifically aged 45 to 49 years old, who have not yet screened for CRC.

When to use: To encourage patients aged 45 to 49, who may not be aware they are eligible, to begin colorectal cancer (CRC) screening. The goal is to prompt them to schedule a screening appointment and consider noninvasive options like the Cologuard test.

Patients 45-49 Screening Letter From Provider

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Dear **<Patient Name>**,

More people under age 50 are being diagnosed with colorectal cancer (CRC).¹

Call **<Provider Contact Information>** to make a screening appointment. Learn about CRC screening options, including noninvasive options like the Cologuard® test.

Screening for CRC can save your life.

- CRC kills more men under 50 than any other cancer, including lung cancer.²
- After breast cancer, CRC is the 2nd main cause of cancer death in women under 50.²
- When caught early, we can treat CRC for about 90% of people.³
- The American Cancer Society recommends that people at average risk for CRC start regular screenings at age 45.⁴

The Cologuard test:

- finds signs of cancer (altered DNA and blood) in your poop.⁵
- finds 92% of colorectal cancers, even in early stages.⁵
- can be used by adults 45 years or older, at average risk for CRC.⁶
- is free for most insured patients.⁷

The Cologuard test is simple and easy to use at home.

1. Use your kit (sent from Exact Sciences Laboratories).
2. Collect your sample at home. (No prep, diet change, or time off required!)
3. Return your sample the **same** or **next** day (for free).
4. Your provider will call you when they get your results (usually a couple weeks).

We can talk about all screening options available to you and any questions you have.

<Sign Off>

*Based on 5-year survival



Patient Screening Letter

Intended audience: Eligible patients due for CRC screening

When to use: To prompt eligible patients (typically aged 45 and older) to schedule a colorectal cancer (CRC) screening appointment. This letter is ideal for general outreach to patients who are due or overdue for screening, regardless of prior communication.

Patient Screening Letter From Provider

Entities using this material are responsible for and should pay close attention to the accuracy of the information about their company and the coverage details that they distribute via these materials or otherwise. This template is provided to any appropriately requesting entity, regardless of the manner in which they cover, recommend, or participate in the ordering of the ColoGuard test. You may adapt the provided content to suit the needs of your organization, including the removal of the Exact Sciences logo. However, do not remove or modify the "Important Information" section.

Header as appropriate for mail or email letter:

Dear **Patient Name:**

Call **Provider Contact Information:** to schedule your colorectal cancer (CRC) screening.

Screening has the potential to save your life.

- CRC is projected to kill an estimated 53,000 Americans per year.¹
- When caught in early stages, CRC treatment is more effective in about **90%** of people.²

We can talk about screening options, including **noninvasive** options, like the ColoGuard® test.

The ColoGuard test:

- can find 92% of colorectal cancers, and can even find cancers in early stages.³
- can be used by patients 45 and older at average risk for colorectal cancer.
- is covered by Medicare and most major insurers.⁴

The ColoGuard test is simple and easy to use at home.

1. Use your kit (sent from Exact Sciences Laboratories).
2. Collect your sample at home. (No medicine, diet change, or time off required!)
3. Mail your sample the **same or next day** (for free).
4. Your provider will contact you when they get your results (usually a couple weeks).

If you have any questions, please call us at **Provider contact information:**

Sign Off:

*based on 5-year survival



Patient Order Letter

Intended audience: Patients who have had a Cologuard test ordered for them outside of a point-of-care visit.

When to use: This letter explains that the patient meets the criteria for CRC screening and that a Cologuard kit has already been ordered and will arrive by mail. It outlines the benefits of early detection, describes how the test works, and provides step-by-step instructions for completing and returning the kit.

Patient Cologuard® Order Letter From Provider

Entities using this material are responsible for and should pay close attention to the accuracy of the information about their company and the coverage details that they distribute via these materials or otherwise. This template is provided to any appropriate requesting entity, regardless of the manner in which they cover, recommend or participate in the ordering of the Cologuard test. You may adapt the provided content to suit the needs of your organization, including the removal of the Exact Sciences logo. However, do not remove or modify the "Important Information" section.

Header as appropriate for mail or email letter:

Dear **§Patient Name§**,

I ordered a Cologuard® test for you because you are eligible for colorectal cancer (CRC) screening. CRC is also called colon cancer.

Screening has the potential to save your life:

- CRC is projected to kill an estimated 53,000 Americans per year.¹
- When caught in early stages, CRC treatment is more effective in about **90%** of people.²

The Cologuard test:

- finds signs of colon cancer in your stool (poop).
- is simple and easy to use at home.
- is a noninvasive screening (nothing goes inside of your body).
- can be used by adults 45 years or older, at average risk for colon cancer.
- is covered by Medicare and most major insurers.¹

How do I use the Cologuard test?

1. You will receive the collection kit in the mail (from Exact Sciences Laboratories).
2. Use the kit to collect your sample at home.
3. Mail your sample the **same or next day** (for free).
 - Go to a UPS® store. Find stores and hours at Cologuard.com/UPS.
 - Schedule a UPS pick-up at 1-844-870-8870 or Cologuard.Com/UPS.
4. Your provider will contact you when they get your results within a couple weeks.

If you have any questions about next steps, please call us at **§Provider contact information§**.

Sign Off:



After Visit Summary Letter

Intended audience: Patients after a Cologuard test has been ordered

When to use: Provide this letter to your patients after prescribing the Cologuard test to set expectations once they receive it. You can provide this directly to a patient in the practice during a point-of-care visit or send electronically if a Cologuard test has been ordered outside of a patient appointment.



Colorectal cancer screening with the Cologuard® test

What is the Cologuard® test?
The Cologuard test finds signs of colon cancer in your stool (poop). The Cologuard test is a non-invasive screening. It's fast and easy to use at home.

What's inside your Cologuard collection kit?
You will receive your Cologuard collection kit by mail.



How do I use my Cologuard collection kit?

- Unpack your kit. Read the Patient Guide inside (English and Spanish).
 - Set a calendar reminder in your phone to complete your kit in 8 to 10 days.
- Collect your sample when you can take it to UPS® **the same day or the next day.**
- Send your sample the same day or day after you collect it.
 - Schedule a free UPS pick-up (1-844-870-8870 or Cologuard.com/UPS).
 - Take your kit to UPS. Find stores and hours at Cologuard.com/UPS. Some stores are closed on Sundays or holidays.
- Your healthcare provider will get your result about 2 weeks after Exact Sciences Laboratory receives your sample.












Watch the How to Use Cologuard Video (in 13 languages)
Scan the QR code or go to Cologuard.com/use

Questions?
Please visit Cologuard.com or call Exact Sciences Laboratories at 1-844-870-8870.

Cologuard Test Indications and Important Risk Information
The Cologuard® test is intended for the qualitative detection of colorectal neoplasia associated DNA markers and for the presence of occult hemoglobin in human stool. A positive result may indicate the presence of colorectal cancer (CRC) or advanced adenoma (AA) and should be followed by colonoscopy. The Cologuard test is indicated to screen adults of either sex, 45 years or older, who are at typical average risk for CRC. The Cologuard test is not a replacement for diagnostic colonoscopy or surveillance colonoscopy in high-risk individuals. The Cologuard test is not for high-risk individuals, including patients with a personal history of colorectal cancer and adenomas, have had a positive result from another colorectal cancer screening method within the last 6 months, have been diagnosed with a condition associated with high risk for colorectal cancer such as IBD, chronic inflammatory colitis, Crohn's disease, or have a family history of colorectal cancer, or certain hereditary syndromes. Positive Cologuard results should be referred to colonoscopy. A negative Cologuard test result does not guarantee absence of cancer or advanced adenoma. Following a negative result, patients should continue participating in a screening program at an interval and with a method appropriate for the individual patient. False positives and false negatives do occur. In a clinical study, 3% of patients without colorectal cancer or advanced adenomas received a positive result (false positive) and 8% of patients with cancer received a negative result (false negative). The clinical validation study was conducted in patients 50 years of age and older. Cologuard test performance in patients ages 45 to 49 years was estimated by age-group analysis of near-age groups. Cologuard test performance when used for repeat testing has not been evaluated or established. Rx only.

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- | | | | |
|--|--|---|---|
|  English |  Spanish |  Arabic |  Chinese Traditional |
|  French |  Haitian Creole |  Hindi |  Korean |
|  Polish |  Portuguese |  Russian |  Tagalog/Filipino |
|  Vietnamese | | | |

Unreturned Kit Reminder Letter

Intended audience: Patients who have received their Cologuard kit but have not yet returned it for processing.

When to use: To follow up with patients who have received a Cologuard test kit but have not yet completed or returned it. The goal is to prompt action by reminding them of the importance of screening and how easy it is to complete the test.

Unreturned Kit Reminder Letter From Provider

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RETURNING YOUR COLOGUARD® COLLECTION KIT

Dear <Patient name>

Did you receive the Cologuard® colorectal cancer screening kit <Provider/Network Office Name> ordered for you?

The Cologuard test is simple and easy to use at home.

1. Receive your kit (sent from Exact Sciences Laboratories).
2. Collect your sample at home.
 - No prep, diet change, or time off required!
3. Return your sample the **same** or **next** day (for free).
 - Schedule a free UPS® pick-up at 1-844-870-8870 or Cologuard.com/UPS.
 - Take it to a UPS store. Find locations and hours at Cologuard.com/UPS. (Some stores are closed on Sundays or holidays.)
4. Your provider will contact you when they get your results (usually a couple weeks).

Screening can save your life

- CRC is projected to kill an estimated 53,000 Americans per year, more than breast or prostate cancer.¹
- When caught in early stages, CRC treatment is more effective in about 90% of people.²
- People at average risk of CRC are recommended to start regular screenings at 45 years of age (American Cancer Society).³

Call <Provider contact information> if you have questions. You can learn more about Cologuard at www.cologuard.com.

<Sign-off>



Cologuard Repeat Screening Letter

Intended audience: Patients who have completed a Cologuard test three years or more ago, received a negative result and are now due for their next CRC screening.

When to use: To prompt patients who are due for screening with the Cologuard test again to take action by contacting their provider to request a new test. This letter is used when a new kit has not been automatically ordered, and the patient needs to initiate the process.

Patient Cologuard® Rescreening Letter from Provider

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Header as appropriate for mail or email letter

Dear **Patent Name**,

It's time to rescreen for colorectal cancer (CRC).

Get your Cologuard® prescription today! Call your provider at **Provider Contact Information**.

Rescreening has the potential to save your life.

- CRC is projected to kill an estimated 53,000 Americans per year, more than breast or prostate cancer.¹
- When caught in early stages, CRC treatment is more effective in about 90% of people.²
- Rescreening is recommended 3 years after a negative Cologuard result.³
- The Cologuard test finds signs of early cancer (altered DNA and blood) in your poop.

The Cologuard® test is fast and easy to use at home.

1. You receive the collection kit by mail.
2. Use the kit to collect your sample. No medication, diet changes, bowel preparation, or time off work needed.
3. Use the prepaid UPS® package to send your sample the **same or next day**.
4. Your provider will get your results within a couple weeks.

If you have any questions, please call us at **Provider contact information**.

Sign Off:

*Based on 5-year survival



Cologuard Repeat Screening Order Letter

Intended audience: Patients who have completed a Cologuard test three years or more ago, received a negative result, are now due for their next CRC screening.

When to use: To notify patients who previously completed a Cologuard test and are now due to screen again that a new kit has already been ordered on their behalf. The goal is to prompt them to complete the test promptly and maintain adherence to CRC screening guidelines.

Patient Cologuard® Rescreen Order Letter from Provider

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Header as appropriate for mail or email letters

Dear **Patient Name**,

Our records show that you might be due for your next colorectal cancer (CRC) screening.

Here's why it's important to screen for colorectal cancer:

- It's often considered the most preventable, yet least prevented form of cancer¹
- When caught in early stages, CRC treatment is more effective in about 90% of people²
- Regular screening should be part of your health care routine

You may remember using the Cologuard® test for your last CRC screening. The American Cancer Society guidelines recommend screening again three years after a negative Cologuard result.³ Based on the information at the bottom of this letter, you are eligible to screen again with the Cologuard test.

The Cologuard collection kit is an easy-to-use, noninvasive screening option. The kit is conveniently shipped directly to your home. No special planning, diet, change in medication or time off is needed. When you get the kit, try to collect your sample and return it to UPS® on the same day or the next day using the prepaid label.

We will contact you to discuss your results once we receive them from Exact Sciences Laboratories, within a couple weeks of when the lab receives the kit.

Most patients with insurance pay \$0.⁴ Cologuard is covered by Medicare and most major insurance plans. Nationwide, ~96% of Cologuard patients have no out-of-pocket cost for screening!⁵

If you have any questions about next steps, please contact us this week at **Provider contact information**.

Sign Off

*Based on 5 year survival
COLOGUARD® IMPORTANT RISK INFORMATION



Cologuard Repeat Screening Advance Order Letter

Intended audience: Patients who have completed a Cologuard test three years or more ago, received a negative result, are now due for their next CRC screening.

When to use: To inform patients that they are approaching the recommended rescreening interval for colorectal cancer (CRC) and that a new Cologuard test has already been pre-ordered for them. The goal is to prepare the patient for the upcoming screening and encourage timely completion once the kit arrives.

Patient Cologuard® Advance Order Letter From Provider

Entities using this material are responsible for and should pay close attention to the accuracy of the information about their company and the coverage details that they distribute via these materials or otherwise. This template is provided for any appropriate requesting entity, regardless of the manner in which they cover, recommend or participate in the ordering of the Cologuard test. You may adapt the provided content to suit the needs of your organization, including the removal of the Exact Sciences logo. However, do not remove or modify the "Important Information" section.

Header as appropriate for mail or email letters

Dear **patient name**,

Our records show that you may be due for another colorectal cancer (CRC) screening in the next **xx** months.

Last time, you screened with the Cologuard® test. This test looks for changes in DNA and blood in your stool, which can be signs of CRC or precancer.

Guidelines from the American Cancer Society guidelines recommend screening again three years after a negative Cologuard result. Based on the information below, you are eligible to use Cologuard again.

I have placed an order and your Cologuard collection kit will be mailed to you via UPS® when you are eligible to be screened.

The Cologuard test is simple and easy to use at home.

1. Receive your kit (sent from Exact Sciences Laboratories).
2. Collect your sample at home.
 - No prep, diet change, or time off required!
3. Return your sample the **same or next day** (for free).
 - Schedule a free UPS® pick-up at 1-844-870-8870 or Cologuard.com/UPS.
 - Take it to a UPS store. Find locations and hours at Cologuard.com/UPS. (Some stores are closed on Sundays or holidays.)

If you'd like to do the test sooner or have any questions, please contact us at **Provider contact information** or reach out to Exact Sciences at 1-844-870-8870.

Sign Off



Patient Cologuard Order Letter

Intended audience: Eligible patients due for CRC screening.

When to use: A letter template that GIs can share with eligible patients who may have missed or cancelled their last CRC screening colonoscopy.

Patient Cologuard® Order Letter From GI

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Header as appropriate for mail or email letter:

Dear **Patient Name:**

Our records indicate that you have missed or declined your scheduled routine colonoscopy.

I ordered a Cologuard® test for you because you are eligible for colorectal cancer (CRC) screening. CRC is also called colon cancer.

Screening has the potential to save your life:

- CRC is projected to kill an estimated 53,000 Americans per year.¹
- CRC is often considered the most preventable, yet least prevented form of cancer.²
- When caught in early stages, CRC treatment is more effective in about **90%** of people.³

The Cologuard test:

- finds signs of colon cancer in your stool (poop).
- is simple and easy to collect a sample at home.
- is a noninvasive screening (nothing goes inside of your body).
- can be used by adults 45 years or older, at average risk for colon cancer.
- is covered by Medicare and most major insurers.⁴

How do I use the Cologuard test?

1. You will receive the collection kit in the mail (from Exact Sciences Laboratories).
2. Use the kit to collect your sample at home.
3. Mail your sample the **same or next day** (for free).
4. Your provider will contact you when they get your results within a couple weeks.

If you have any questions about next steps, please call us at **SCI contact information:**

Sign Off:

*Based on 5-year survival



Patient Cologuard Repeat Screening Letter

Intended audience: Patients who are now due for their next CRC screening.

When to use: To notify patients that they are due, or approaching the time, for their next colorectal cancer (CRC) screening, and to encourage them to complete it. The goal is to prompt action, whether the patient previously screened with a Cologuard test or another method.

Patient Cologuard® Rescreening Letter from GI

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Header as appropriate for mail or email letter:

Dear **Patient Name:**

Our records show that you might be due for your next colorectal cancer (CRC) screening. CRC is also called colon cancer.

Use if patient previously screened with method other than the Cologuard test: The last time you screened for colon cancer, you **used a screening method**. This year, if you are still between the ages of 45-75 and at average risk for colon cancer, the Cologuard® test may be an appropriate alternative screening method.

Rescreening has the potential to save your life.

- CRC is often considered the most preventable, yet least prevented form of cancer!
- When caught in early stages, CRC treatment is more effective in about **90%** of people*
- CRC is projected to kill an estimated 53,000 Americans per year, more than breast or prostate cancer.*

Use if patient previously screened with the Cologuard test: You may remember using the Cologuard test for your last CRC screening. The American Cancer Society guidelines recommend screening again three years after a negative Cologuard result.* Based on the information at the bottom of this letter, you are eligible to screen again with the Cologuard test.

The Cologuard test is fast and easy to use at home.

1. You receive the collection kit by mail.
2. Use the kit to collect your sample. No medication, diet changes, bowel preparation, or time off work needed.
3. Use the prepaid UPS® package to send your sample the **same or next day**.
4. Your provider will get your results in within a couple weeks.

If you have any questions, please call us at **GI contact information**.

Sign Off:

*Based on 5-year survival



Cologuard Alignment Letter

Intended audience: Any healthcare provider.

When to use: To reassure and inform primary care providers (PCPs) that their local gastroenterologist (GI) supports the use of Cologuard for appropriate patients. The goal is to encourage PCPs to confidently prescribe the Cologuard test for average-risk patients and help expand access to CRC screening.

Cologuard® GI Alignment Letter

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Header, as appropriate for mail or email letter:

Dear **Primary Care Provider Name:**

As healthcare providers, we know how important early detection is in the fight against colorectal cancer (CRC), which remains the most preventable, yet least prevented, cancer.^{1,2}

Together, we can close the CRC screening gap.

For patients at average risk for CRC who are 45 years or older, the non-invasive screening option I recommend is the **Cologuard®** test. The Cologuard test has demonstrated superior sensitivity over fecal immunochemical test (FIT)³ in detecting CRC and advanced precancerous polyps.^{1,4}

The Cologuard test is an effective screening option for eligible patients. It is not for patients at increased risk of CRC due to family history of CRC, personal history of CRC or adenoma, IBD, or certain hereditary syndromes. Cologuard is also not a replacement for diagnostic or surveillance colonoscopy. With the Cologuard test, there is a chance for false positives and false negatives.⁵

By offering the Cologuard test for average risk patients, we can get more eligible patients screened for CRC, while helping to prioritize colonoscopy for those who need it most.

Let's work together to close the screening gap.

Please feel free to contact me if you have any questions. **GI contact information:**

Sign Off:

Declined Colonoscopy Letter

Intended audience: Healthcare providers that need to be notified when their referred patient declined a colonoscopy.

When to use: To inform the referring primary care provider that their patient either declined or missed their scheduled colonoscopy. The goal is to prompt the PCP to follow up with the patient and consider offering an alternative, non-invasive screening option like the Cologuard test.



Declined Colonoscopy Letter From GI

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Header as appropriate for mail or email letter:

To: **Office Name**
Attn: **Provider Name**

I want to let you know that the patient you referred to our office, **Patient Name - (DOB xx/xx/xxxx)**, has declined their colonoscopy at this time. **OR** I want to let you know that the patient you referred to our office, **Patient Name - (DOB xx/xx/xxxx)**, was not present at their appointment for a colonoscopy.

Based on what we know about the importance of early detection¹ in CRC, improving screening rates has never been more important. That is why I am informing you of **Patient Name's** screening status.

I encourage you to follow up with them to gain a clearer understanding of the barriers preventing them from being screened for CRC, and perhaps to offer them a non-invasive option.

For patients at average risk for CRC who are 45 years or older, the non-invasive screening option I recommend is the **Cologuard®** test, and here's why:

- **High performance:** The Cologuard test demonstrated superior sensitivity over fecal immunochemical test (FIT)² in detecting CRC and advanced precancerous polyps.³
- **High adherence:** 71% of eligible patients adhere to the Cologuard test.⁴ Patients are highly likely to adhere to future screenings as well as a follow-up colonoscopy after receiving a positive Cologuard test result.⁵
- **Broadly covered:** >96% of all Cologuard patients 45+ have no out-of-pocket costs for screening.⁶

CRC remains the most preventable, yet least prevented, cancer.⁷ By offering the Cologuard test to average risk patients, we can work together to close the CRC screening gap on the estimated 60 million eligible unscreened patients.⁸

Please feel free to contact me if you have any questions. **GI contact information:**

Sign Off:

Unsuccessful Scheduling Attempt

Intended audience: Healthcare providers that need to be notified when their referred patient has been unable to schedule for a colonoscopy.

When to use: To notify the referring primary care provider that multiple attempts to schedule a colonoscopy with their patient have been unsuccessful. The goal is to prompt the PCP to re-engage the patient and consider offering an alternative screening method, such as a Cologuard test.

Unsuccessful Scheduling Attempt From GI

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<Header as appropriate for mail or email letter>

To: <Office Name>
Attn: <Provider Name>

According to our records, your patient, <Patient Name - (DOB xx/xx/xxxx)>, was referred to our practice on <Date xx/xx/xxxx> for colorectal cancer (CRC) screening via colonoscopy. After several attempts to reach this patient, we have been unsuccessful in scheduling their procedure.

<GI Group Name / Provider Name> believes that based on what we know about the importance of early detection in CRC, improving screening rates has never been more important.

That is why we are informing you of <Patient Name>'s screening status. I encourage you to follow up with them to gain a clearer understanding of the barriers preventing them from being screened for CRC, and perhaps to offer them a non-invasive option.

For patients at average risk for CRC who are 45 years or older, the non-invasive screening option I recommend is the **Cologuard®** test, and here's why:

- **High performance:** The Cologuard test demonstrated superior sensitivity over fecal immunochemical test (FIT)¹ in detecting CRC and advanced precancerous polyps.²
- **High adherence:** 71% of eligible patients adhere to the Cologuard test.³ Patients are highly likely to adhere to future screenings as well as a follow-up colonoscopy after receiving a positive Cologuard test result.³
- **Broadly covered:** >96% of all Cologuard patients 45+ have no out-of-pocket costs for screening.⁴

CRC remains the most preventable, yet least prevented, cancer.⁵ By offering the Cologuard test to average risk patients, we can work together to close the CRC screening gap on the estimated 60 million eligible unscreened patients.⁶

Please feel free to contact me if you have any questions. <GI contact information>

<Sign Off>

Important Information about the Cologuard products

Indications for Use

The Cologuard® and Cologuard Plus® tests are intended for the qualitative detection of colorectal neoplasia associated DNA markers and for the presence of occult hemoglobin in human stool. A positive result may indicate the presence of colorectal cancer (CRC) or advanced adenoma (AA)/advanced precancerous lesions (APL) and should be followed by a colonoscopy. The Cologuard test and Cologuard Plus test are indicated to screen adults of either sex, 45 years or older, who are at average risk for CRC. These tests are not a replacement for diagnostic colonoscopy or surveillance colonoscopy in high-risk individuals.

Contraindications

The Cologuard products are not for high-risk individuals, including patients who have the following:

- a personal history of colorectal cancer or adenomas
- a positive result from another colorectal cancer screening method within that test's recommended screening interval
- have been diagnosed with a condition associated with high risk for colorectal cancer such as inflammatory bowel disease (IBD), chronic ulcerative colitis (UC), Crohn's disease
- have a first-degree family history of colorectal cancer, or certain hereditary syndromes

Warnings and Precautions

All positive results should be referred to colonoscopy.

The Cologuard products may produce false positive and false negative results. A false positive result occurs when a result is positive, even though a colonoscopy will not find CRC or APL. A false negative result occurs when a result is negative, even when a colonoscopy identifies APL or CRC.

A negative result does not guarantee the absence of colorectal cancer or advanced adenoma. Following a negative result, patients should continue participating in a screening program at an interval and with a method appropriate for the individual patient. Performance when used for repeat testing has not been established.

Refer to the [Cologuard test Clinician Brochure](#) or the [Cologuard Plus test Clinician Brochure](#) for additional information about the benefits and risks of using each version of the Cologuard product for CRC screening.

RX only.