

Colorectal Cancer Control Program FAQ

What is the Cologuard® test?

The Cologuard test is indicated to screen adults of either sex, 45 years or older, who are at typical, or average risk for colorectal cancer (CRC) and is included in both the US Preventive Services Task Force and American Cancer Society CRC screening guidelines, as well as major quality measures, such as [HEDIS®](#) and the [UDS](#) measure. The Cologuard test detects both DNA markers associated with colorectal cancer and the presence of hemoglobin (blood) in human stool. As such, 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 not a replacement for diagnostic colonoscopy or surveillance colonoscopy in high-risk individuals. See [here](#) for risk as defined by the American Cancer Society.

What is the Cologuard test's sensitivity and recommended interval?

The Cologuard test has the highest [sensitivity](#) of currently recommended non-invasive average-risk screening tests for CRC sensitivity (92%) and advanced precancerous lesions (42%) (at 90% specificity to negative colonoscopy)¹. Based on clinical performance studies, the Cologuard test is recommended for use at a [3-year interval](#).

How widespread is the Cologuard test's coverage?

Nationwide, >96% of all Cologuard test patients 45 years and older pay \$0 for screening cost-sharing for most insurance plans [Commercial, Medicare, Medicaid]. For the few remaining states where the Cologuard test is not covered or enrolled by Medicaid, Medicaid patients are automatically enrolled in our patient financial assistance program, meaning patients will be able to complete a Cologuard test without cost sharing. For patients needing a follow-up colonoscopy procedure after a positive stool test, by [federal policy](#), insurers should not be imposing cost-sharing for follow up colonoscopy on most insured patients.

Further, Exact Sciences assumes the financial risk of sending out test kits and neither clinical practices nor patients are charged until a test is resulted.

Do you have a patient financial assistance program for the uninsured?

Exact Sciences' Patient Financial Assistance Program helps patients with financial constraints receive Cologuard test screening at no cost. The program has been revamped in recent years to provide a better experience for patients in need of assistance. Most patients who are uninsured FQHC patients will automatically qualify for financial assistance. Beyond FQHC patients, Exact Sciences also works with un- or underinsured patients from other sites of care to qualify them for the program. Exact Sciences is continually trying to improve this program and feedback is appreciated. For answers to all patient and provider questions, the Customer Care Center is available at [1-844-870-8870](tel:1-844-870-8870).

What are the roles of the various Exact Sciences staff I encounter?

CDC grantees are likely to encounter a number of team members from Exact Sciences, each with a different role aimed at supporting clinics and patients in their colorectal cancer screening needs. The team works together to ensure grantee needs are met from a relationship management perspective. Below are some of the team members you may encounter and the role they play.

Position	Role
Health Equity Managers	Primary CDC Grantee contact. Health equity managers aim to understand and address grantee needs and challenges with respect to colorectal cancer screening in underserved settings.
Sales Representatives	Introduce or educate health care providers on product information, product ordering and workflow support.
Market Development Leaders (formerly Screening Advocates)	Explore how the Cologuard test can be a solution for increasing CRC screening rates at a system or institution level.
Medical Science Liaison	Address clinical and scientific questions about the Cologuard test or screening at a more robust level; discuss emerging literature.
Patient and Provider support staff	Support patients and providers to help ensure Cologuard kits are ordered and completed.

These team members have an array of expertise and professional experience, each filling a different role. For simplicity, your assigned Health Equity Manager (see the list below) can be your first point of contact to the broader team and can direct you accordingly.

What does Exact Sciences offer in terms of Culturally Responsive Trainings & Resources?

Exact Sciences is continually innovating to improve the assistance and reminders we offer to patients to aid them in completing their colorectal screening. There are a number of trainings and education that our team can provide, as well as lower literacy and translated resources (Email healthequity@exactsciences.com). Our patient support line (1-844-870-8870) can connect patients with support for greater than 200 languages. Exact Sciences is continually trying to improve in this area and is very open to feedback. If your patients have specific needs that are not being met, please direct them to your assigned Health Equity Manager.

How can you best help patients with low literacy or language barriers?

This is an area in which we are striving to improve. Our in-kit instructions are now in English and Spanish. We also recently released a one-page “Quick Start” guide (in English and Spanish) for patients with simplified language and pictures to walk

patients through the kit completion process. Additionally, on our website, we have [How To Videos](#) in 12 languages describing how to complete the test. Having said that, we understand that some patients benefit from “de-mystifying” the kit and appreciate having live interactions with their providers. As such, grantees can request demo kits from their health equity manager to help educate patients on how the kit works.

What does Exact offer in terms of Navigation Services?

Exact Sciences is committed to ensuring that patients complete their at-home colorectal cancer screening test. As such, every patient who receives an order for a Cologuard test will receive navigation support, unless they opt out. Our navigation services process (inclusive of digital messaging) ensures patients are supported in completing and returning their samples for processing and includes reminders, language support, insurance navigation, and free door-to-door UPS® delivery and pick up. Additionally, we are piloting work with FQHCs at which we can offer onsite Cologuard distribution and drop-off, while also ensuring patients who receive kits in this manner still benefit from our navigation services.

Our internal data shows that patients who receive our navigation services have a 22% higher kit return rate than those who do not. Importantly, we are continually striving to improve our support for patients. For example, in addition to the “Quick Start” guide mentioned above, we recently improved our [Results](#) page to ensure the action steps for patients who test positive are clear and direct.

Your feedback is welcomed and can be directed to your health equity manager.

For more information see [here](#).

What happens if my program also has a navigation program?

We welcome you to continue to use your navigation protocols in tandem with the Exact program. Some [data](#) suggest that overlaying the Exact navigation program with tailored clinic-level navigation results in higher overall patient adherence in underserved populations. A longer-term goal of Exact's is to provide more guidance on how on-the-ground navigation can best enhance Exact's navigation efforts and vice versa. Please contact your Health Equity Manager to better understand Exact's protocols and to explore how to best support each other's efforts.

How long does a patient have to return an unused Cologuard kit?

Unused Cologuard kits expire after one year, meaning a patient has a full year to complete and return their Cologuard kit. Once the sample has been collected, patients should return their kit as soon as possible.

How long does a patient have to return the Cologuard kit once the sample is collected?

We recently improved our processes so that patients now have 96 hours (vs 72 hours) for their completed Cologuard kit to arrive at our lab in Madison, once the sample is collected. Clinics can help by emphasizing a sense of urgency in kit return particularly after the sample has been collected. We are constantly working to improve the test to lengthen the return window.

What are ways to help ensure a sample is sufficient in size?

Roughly, the sample should be at least as large as a walnut and no larger than the size of the bottle that is included in the kit. Note that the liquid preservative does not have to fully cover the stool sample. CDC grantees can request demo kits from their health equity manager to help educate patients on how the kit works and what they need to do.

The Cologuard Test Gap Closure Programs

A significant barrier in the public health effort to increase CRC screening rates is the challenge of screening patients who do not regularly go in to see their provider. In 2023, Exact Sciences worked with several insurance plans to ensure covered individuals received a screening test. The goal of the program is to facilitate access to screening for those who otherwise might not complete screening by shipping mt-sDNA tests to patients the plans had identified as in need of screening. Exact Sciences has great respect for the provider-patient relationship. As such, if patients have a provider attached to their medical record, providers are notified in advance of the at home kit being ordered for their patient. The process has since evolved to empower health systems using this program to notify patients and providers that a Cologuard kit is on the way. Internal data has shown that the program is making a difference in screening patients who may otherwise not get screened. Exact is continually striving to work with payers and providers to improve the program. Please provide feedback to your Health Equity Manager to help us further improve this effort to screen patients who are not up-to-date with screening.

Learn More About ECL

Epic Care® Link™ (ECL) is our free, internal portal by which orders are placed for Exact Sciences tests. Integrating ECL to electronic medical record software likely incurs a fee. Accessing your systems dashboard is free and allows you to track orders from order fulfillment to patient result. Health Equity Managers can assist you with getting your link established and any troubleshooting required.

Do you provide grant funding to support colorectal cancer screening?

Twice a year, Exact Sciences opens a Request for Proposal (RFP) for Funding Opportunities for CRC Screening Uptake Strategies, also known as the "FOCUS" Program. This initiative, led by Exact Sciences, aims to support innovative projects in clinics and communities focused on increasing colorectal cancer (CRC) screening uptake. Applications are evaluated by an internal Exact Sciences committee based on pre-defined metrics to ensure a fair and unbiased award process. Should you have any questions please do not hesitate to reach out to Meg Fischer (mfischer@exactsciences.com) or if interested in receiving the RFP announcement organizations can [complete this form](#).

Please see the Cologuard clinician brochure at www.cologuardhcp.com.

Grantee & Health Equity Manager Point of Contact:

<p>Alaska Native Tribal Health Consortium Alaska Primary Care Association AltaMed Health Services Corporation Oregon Health Authority Washington Department of Health</p>	<p>Colorado Department of Public Health Kansas Department of Health Michigan Department of Health and Human Services University of Missouri University of Texas Health Science Center at Houston University of Utah</p>
<p>Jenica Palmer jpalm@exactsciences.com</p>	<p>Tara Schroeder tschroeder@exactsciences.com</p>
<p>Connecticut Peer Review Organization (Qualidigm) District of Columbia Department of Health Maine Department of Health and Human Services Mary Hitchcock Memorial Hospital Maryland Department of Health Massachusetts Department of Public Health New York Department of Health Rhode Island Department of Health Vermont Agency of Human Services West Virginia University</p>	<p>Kentucky State Cabinet for Health Louisiana State University Health Sciences Center Florida Department of Health Georgia Center for Oncology Research and Education Inter-Tribal Council of Michigan Iowa Department of Public Health Minnesota Department of Health Nebraska Department of Health North Carolina Department of Health & Human Services Quality Health Associates of North Dakota South Dakota Department of Health University of Arkansas System University of Chicago Medicine University of South Carolina</p>
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