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Best Practices to Drive Health Equity in CRC Screening

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Fast Facts

In 2020, **~9.7 million people living in the United States identified as American Indian or Alaska Native**, representing ~3% of the total population.[1]

American Indian/Alaska Native patients have the **highest incidence of colorectal cancer** compared to all other races and ethnicities worldwide[1,2]

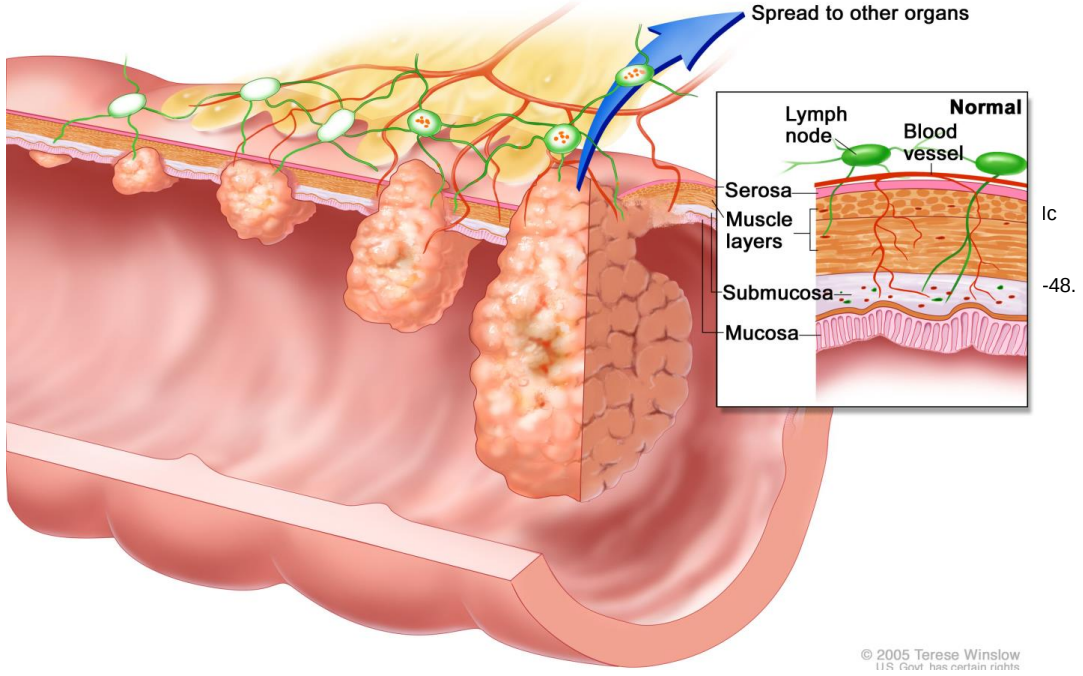
Elevated incidence and mortality may reflect a higher prevalence of risk factors, such as cigarette smoking, obesity and diabetes, differences in diet; **and/or lower receipt of CRC screening**.[1]

1. Kratzer TB, Jemal A Miller KD et al. Cancer statistics for American Indian and Alaska Native individuals, 2022: Including increasing disparities in early onset colorectal can. *CA Cancer J Clin.* 2022;0 1-27 2. Siegel RL, Miller KD, Fuchs HE, Jemal A. Cancer statistics, 2022. *CA Cancer J Clin*. 2022;72(1):7-33.

Disease State Awareness

Typical Progression to Early Stage CRC[1,2]

- Colorectal cancer usually begins as a polyp (Non-cancerous)
  - Note: ~70% of colorectal cancers develop from adenomas
- When a polyp progresses to cancer, it can grow into the wall of the colorectum (Local†)
- It may invade lymph vessels and spread to nearby lymph nodes (Regional†)
- Cancer cells may also be carried via blood vessels to other organs such as liver or lung (Distant†)
- Progression from adenoma to CRC (>10 yrs)



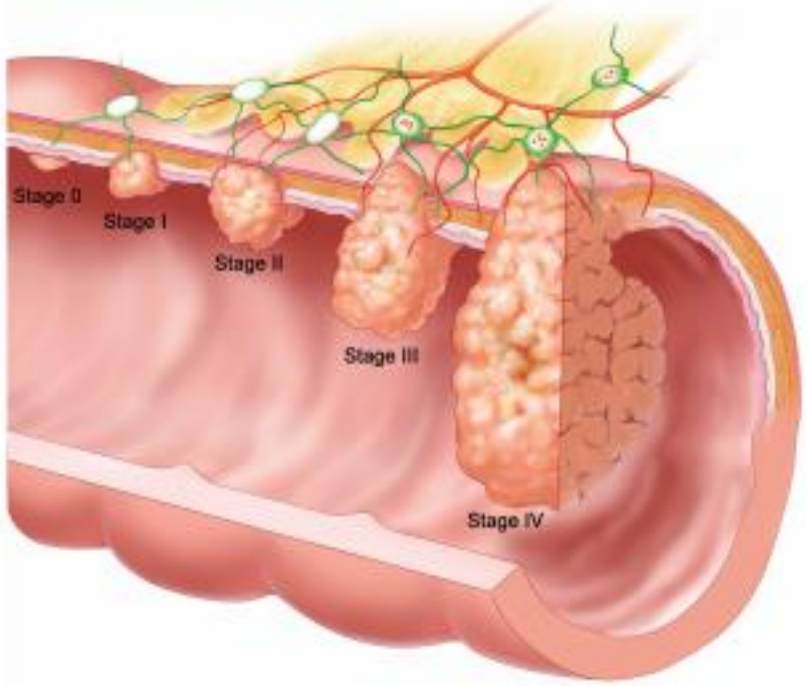
The five-year survival rate for patients diagnosed with stage I/II* colorectal cancer is 91%.[2] † The five-year survival rate for patients diagnosed with stage IV CRC is 14%.[2†]

***Based on people with CRC in stage I, stage IIa, or stage IIb between 2012 and 2018.**
†Per American Joint Committee on Cancer's (AJCC) staging system: Localized = stage I, IIa, IIb. Regional = stage IIc and III Distant = stage IV.[3]
CRC: colorectal cancer.

1. Rex DK, et al. *Am J Gastroenterol.* 2017;112(7):1016-1030. 2. **Siegel RL, et al. *CA Cancer J Clin*. 2023; 73(1):17-48.** 3. ACS. Survival rates for colorectal cancer. Accessed March 9, 2023.. https://www.cancer.org/cancer/colon-rectal-cancer/detection-diagnosis-staging/survival-rates.html

Screening for colorectal cancer (CRC) on time matters[1]

How CRC develops[1]



- CRC typically starts as a polyp, or growth, on the wall of the colon or rectum. Some polyps may develop into cancer[1]
- Many people with early-stage CRC have no symptoms, but their cancer is detected through screening[1]
- When caught in early stages, CRC is more treatable in 90% of people[2]*

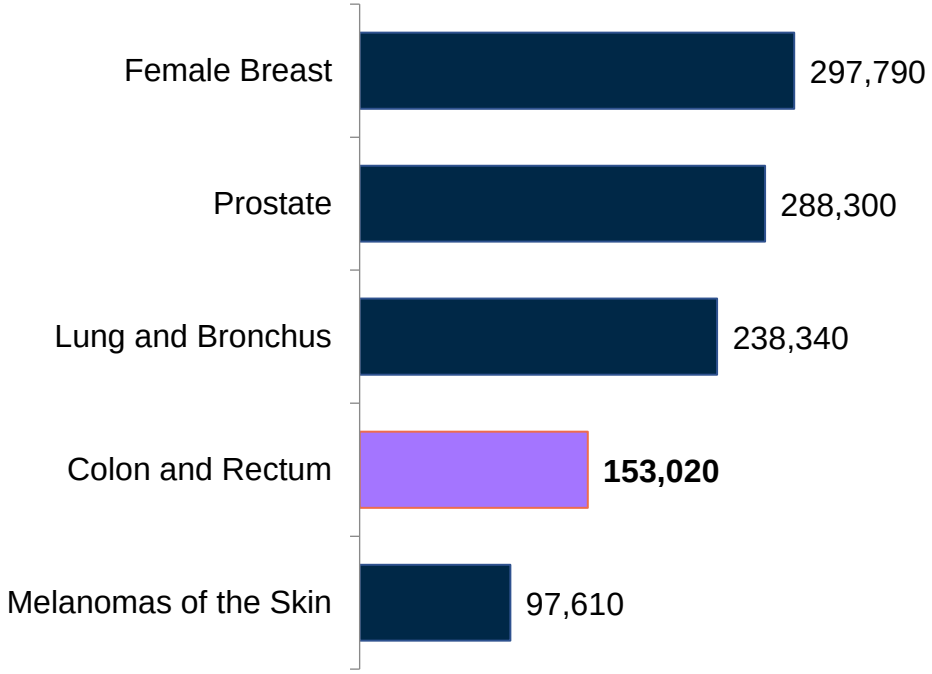
Regular screening can help find CRC in early stages. That's why it's important to screen on time.[1]

*5-year survival.[2]

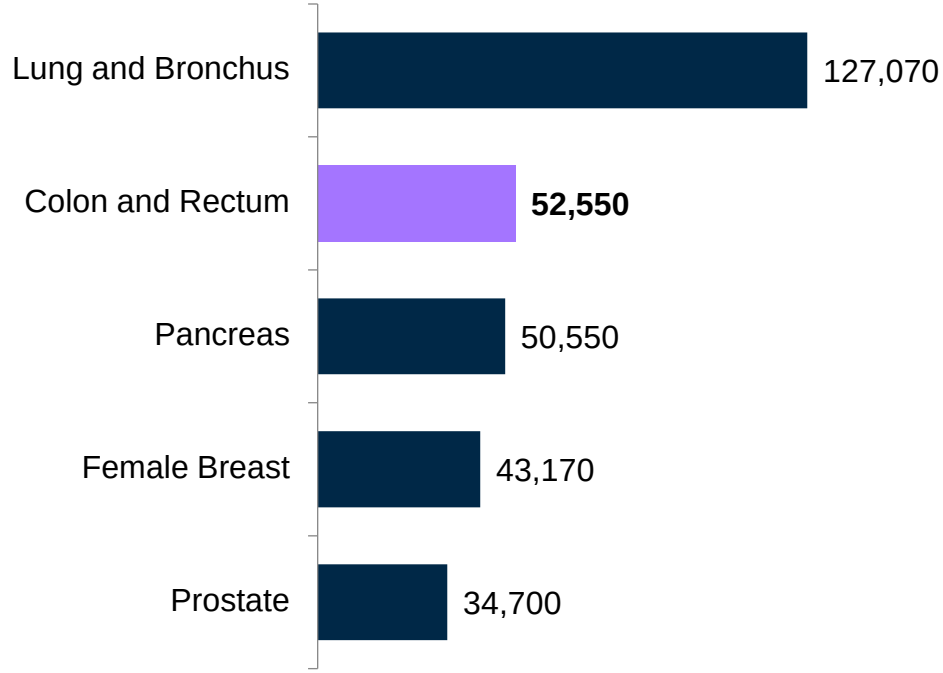
=1. American Cancer Society. Colorectal cancer facts and figures 2022. Atlanta: American Cancer Society, 2022. 2. Siegel RL et al. *CA Cancer J Clin.* 2022; 72(1):7-33. https://doi.org/10.3322/caac.217. 3. SEER cancer stat facts: colorectal cancer. Accessed July 16, 2021. https://seer.cancer.gov/statfacts/html/colorect.html

Estimated*† CRC Incidence and Mortality, US 2023

Top 5 Cancers by Number of New Cancer Cases (US, 2023)



Top 5 Cancers by Number of Cancer Deaths (US, 2023)



Overall Lifetime Risk of CRC:

4.3% for men

3.9% for women

Source: Estimated new cases are based on 2005-2019 incidence data reported by the North American Association of Central Cancer Registries (NAACCR). Estimated deaths are based on 2006-2020 US mortality data, National Center for Health Statistics, Centers for Disease Control and Prevention. *Estimates are rounded to the nearest 10; cases exclude basal cell and squamous cell skin cancers and in situ carcinoma except urinary bladder.
†The 2023 projections are based on currently available incidence and mortality and thus do not reflect reduced access to cancer care because of the COVID-19 pandemic.

COVID-19: coronavirus disease of 2019; **CRC**: colorectal cancer; **US**: United States.

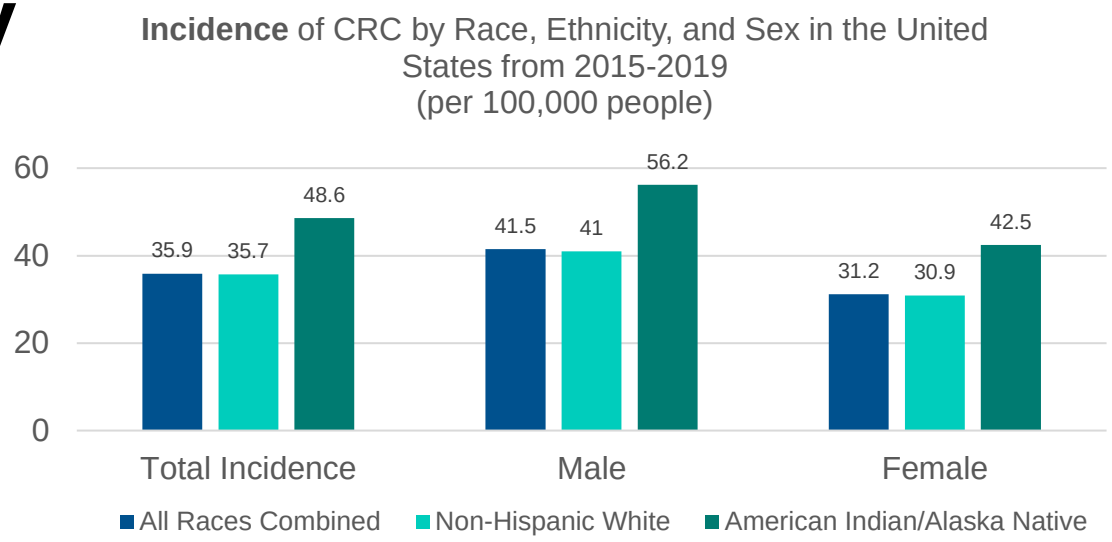
Siegel RL, et al. *CA Cancer J Clin.* 2023;73(1):17-48.

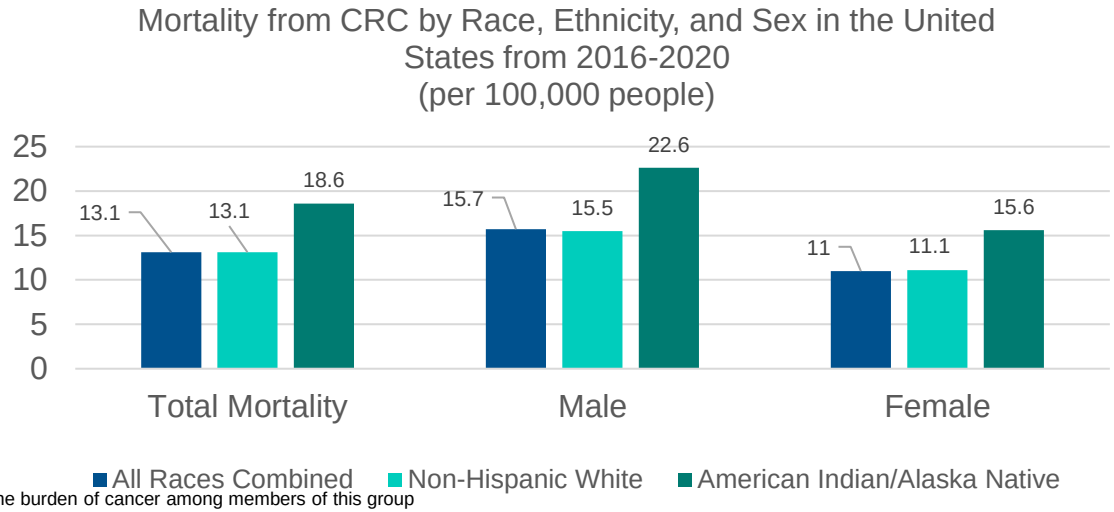
Colorectal Cancer Epidemiology

American Indian/Alaska Native people **have the highest incidence** of colorectal cancer than any other race or ethnicity and are **more likely to die** from colorectal cancer than people from all other races and ethnicities[1*]

Colorectal Cancer in Alaska

- Second leading cause of cancer among men[2*]
- Men have a **2.23-2.47x greater risk** of developing colorectal cancer[2,3*†]
- Women have a **2.96-2.99x greater risk** of developing colorectal cancer[2,3*‡]
- Colorectal cancer is more common among women than men[2-4]
- >**35-41%** of eligible Alaska Native people have not been screened for colorectal cancer and rates vary across Tribal health regions[5,6]





Abbreviation: **CRC:** Colorectal cancer

* AI/AN population has the highest racial misclassification in health data of any racial or ethnic group in the U.S., likely contributing to an underestimation of the burden of cancer among members of this group

† Compared to White men

‡ Compared to White women

1. Siegel RL, Miller KD, Waggle NS, Jemal A. Cancer statistics, 2023. CA: *Cancer J Clin*. 2023; 73(1):17-48. https://doi.org/10.3322/caac.21763 2. Melkonian SC, Weir HK, Jim MA, Preikschat B, Haverkamp D, White MC. Incidence of and Trends in the Leading Cancers With Elevated Incidence Among American Indian and Alaska Native Populations, 2012-2016. *Am J Epidemiol.* 2021;190(4):528-538. 3. Kratzer TB, Jemal A, Miller KD, Nash S, Wiggins C, Redwood D, Smith R, Siegel RL. Cancer statistics for American Indian and Alaska Native individuals, 2022: Including increasing disparities in early onset colorectal cancer. CA Cancer J Clin. 2022 Nov 8. doi: 10.3322/caac.21757. Epub ahead of print. PMID: 36346402. 4. Haverkamp D, Redwood D, Roik E, Vindigni S, Thomas T. Elevated colorectal cancer incidence among American Indian/*Alaska* native persons in *Alaska* compared to other populations worldwide. *Int J Circumpolar Health*. 2023;82(1):2184749. 5. Alaska Department of Health and Social Services. Alaska Behavioral Risk Factor Surveillance System. 2019. 6. Indian Health Service. Alaska Area Aggregate GPRA (Government Performance and Results Act of 1993) Clinical Performance Report, CRS (Clinical Reporting System), Version 18.0. 2017

Colorectal Cancer Epidemiology and Screening Adherence

Between 2012 and 2016, racial disparities accounted for 1,079 excess cases of colorectal cancer among American/Alaska Native people.[1]

Northern Plains

288[1]

- 4th leading cause of cancer among men[1]*
- 5th leading cause of cancer among women[1]*
- Screening adherence: 33-48%±

Alaska

248[1]

- 2nd leading cause of cancer among men and women[1]*
- Screening adherence: 59%±

Southwest

59[1]

- 5th leading cause of cancer among men[1]*
- Screening adherence: 30-43%±

Southern Plains

365[1]

- 5th leading cause of cancer among men[1]*
- 6th leading cause of cancer among women[1]*
- Screening adherence: 52%±

Pacific Coast

119[1]

- 4th leading cause of cancer among men[1]*
- 5th leading cause of cancer among women[1]*
- Screening adherence: 38-42%±

Abbreviation: **CRC:** Colorectal cancer

* Note that the AI/AN population has the highest racial misclassification in health data of any racial or ethnic group in the U.S., likely contributing to an underestimation of the burden of cancer among members of this group

† Compared to White men

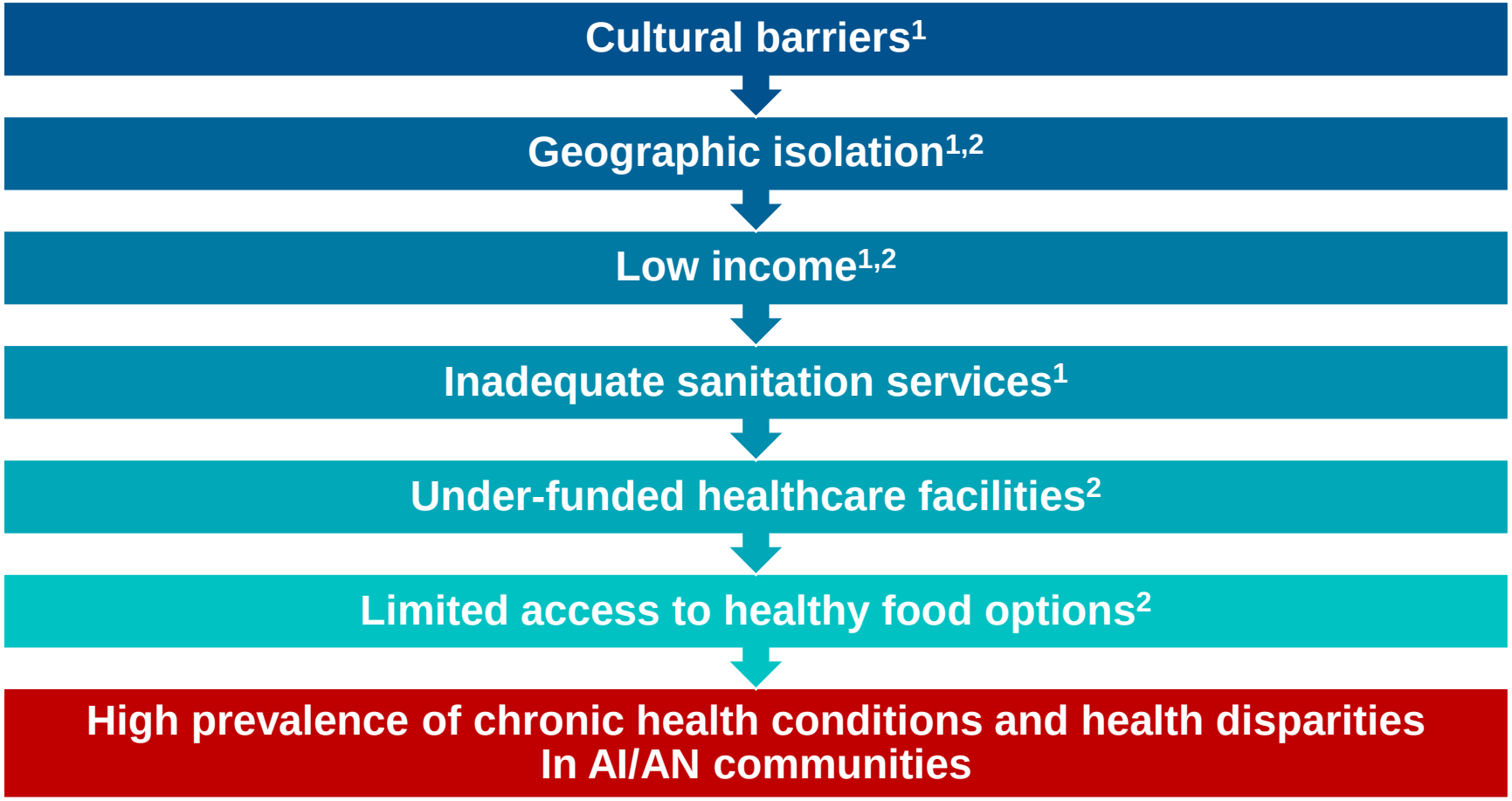
‡ Compared to White women

± Among individuals aged 50-75 years by Purchased/Referred Care Delivery Area region and Indian Health Service area, 2017

1. Melkonian SC, Weir HK, Jim MA, Preikschat B, Haverkamp D, White MC. Incidence of and Trends in the Leading Cancers With Elevated Incidence Among American Indian and Alaska Native Populations, 2012-2016. *Am J Epidemiol.* 2021;190(4):528-538. 2. Kratzer TB, Jemal A, Miller KD, et al. Cancer statistics for American Indian and Alaska Native individuals, 2022: Including increasing disparities in early onset colorectal cancer. *CA Cancer J Clin.* 2023;73(2):120-146. doi:10.3322/caac.21757

Focus on Social Determinants of Health

American Indian/Alaska Native individuals frequently encounter issues that limit access to quality medical care:



For more information on social determinants of health, please see the following resource:
https://exactsciences.app.box.com/file/1034461049062?s=am1onbh8gj1mdzwpcq59xdamng1kldp9

1. HHS. Profile: American Indian/Alaska Native. January 11, 2022. July 29, 2022. https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=3&lvlid=62. 2. Kratzer TB, Jemal A Miller KD et al. Cancer statistics for American Indian and Alaska Native individuals, 2022: Including increasing disparities in early onset colorectal can. *CA Cancer J Clin.* 2022;0 1-27.

Preventing Colorectal Cancer Through Screening

Colorectal Cancer is Preventable

Screening is the most effective way to prevent colorectal cancer.

What is screening? Screening is used to detect cancer in people who do not have symptoms of colorectal cancer.

Why is screening important?

- It may detect pre-cancerous growths (polyps). **Detecting and removing polyps can prevent cancer. We must catch them early before they become cancerous. It can save your patient's life.**
- It can detect cancerous growths at an early stage when they're easy to remove and when cancer treatment is more effective.

Who should get screened for colorectal cancer?

- **Everyone aged 45 and older**
- People with a higher risk of developing colorectal cancer may be screened at a younger age.
- Not everyone who should be screened, has been screened. Compared to non-Hispanic White adults, fewer Hispanic adults 45 years and older have been screened for colorectal cancer.

Wolf AMD, et al. *CA Cancer J Clin*. 2018;68(4):250-281.

There are many screening options available.

The best test is the test you or your patients will complete.

NCCRT. 2019 Colorectal Cancer Screening Messaging Guidebook: Recommended Messages To Reach The Unscreened. 2019.

Common Colorectal Cancer Screening Tests

Visual screening test

Stool-based screening test

Test Characteristic	Colonoscopy	FIT/gFOBT	mt-sDNA (Cologuard®)
Invasive (medical instrument inside the body)	✓		
Uses a camera to look for cancerous or precancerous growths	✓		
Growths may be removed at the time of screening	✓		
Looks for microscopic blood in the stool		✓	✓
Looks for altered DNA that may indicate the presence of cancer or precancer			✓
Recommended every year		✓	
Recommended every 1-3 years			✓
Recommended every 10 years	✓		
Test is done at home		✓	✓
Can be prescribed by your doctor or anyone who can write a prescription	✓	✓	✓
Requires anesthesia, bowel cleansing, and fasting	✓		
Positive test result requires a colonoscopy		✓	✓

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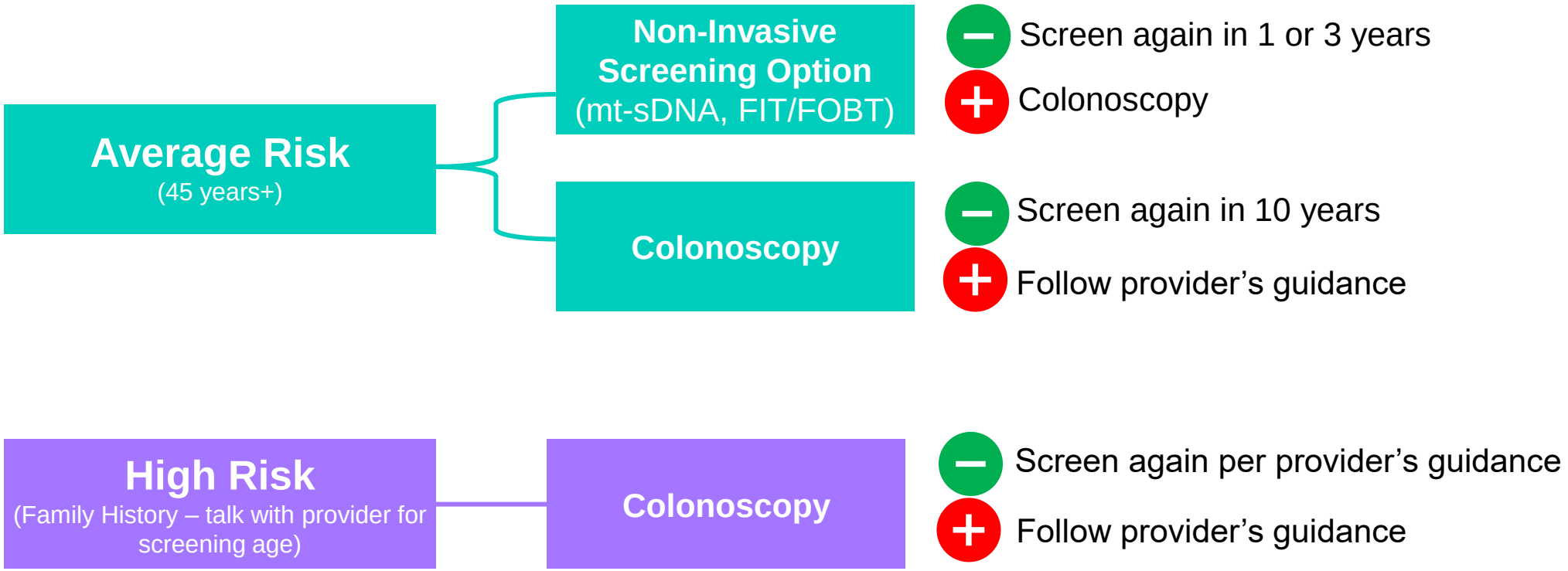
American Cancer Society. Colorectal Cancer Screening Tests. June 29, 2020. Accessed February 28, 2022. https://www.cancer.org/cancer/colon-rectal-cancer/detection-diagnosis-staging/screening-tests-used.html

Pathway of Colorectal Cancer Screening Options



Wolf AMD, et al. *CA Cancer J Clin*. 2018;68(4):250-281.

Shared Decision Making

In Shared Decision Making, Health Care Providers Offer Options and Describe Their Risks and Benefits, and Patients Express Their Preferences and Values[1]

National Guidelines Recommend Shared Decision Making to Improve Screening Adherence

US Preventive Services Task Force (USPSTF) 2021[2]	"Several recommended screening tests are available. Clinicians and patients may consider a variety of factors in deciding which test may be best for each person" "Discussion with patients may help better identify screening tests that are more likely to be completed by a given individual"
American Cancer Society (ACS) 2018[3]	"The importance of offering a choice between structural or stool-based testing is included in this guideline in recognition of the role of patient values and preferences and as a practical implementation strategy to improve adherence"
American College of Gastroenterology (ACG) 2021[4]	"The 'ideal' screening test should be noninvasive, have high sensitivity and specificity, be safe, readily available, convenient, and inexpensive. For CRC screening, there are multiple approved tests and strategies, each with its strengths and weaknesses. In some instances, the 'best' screening test can be considered the one that is acceptable to the patient and gets completed."

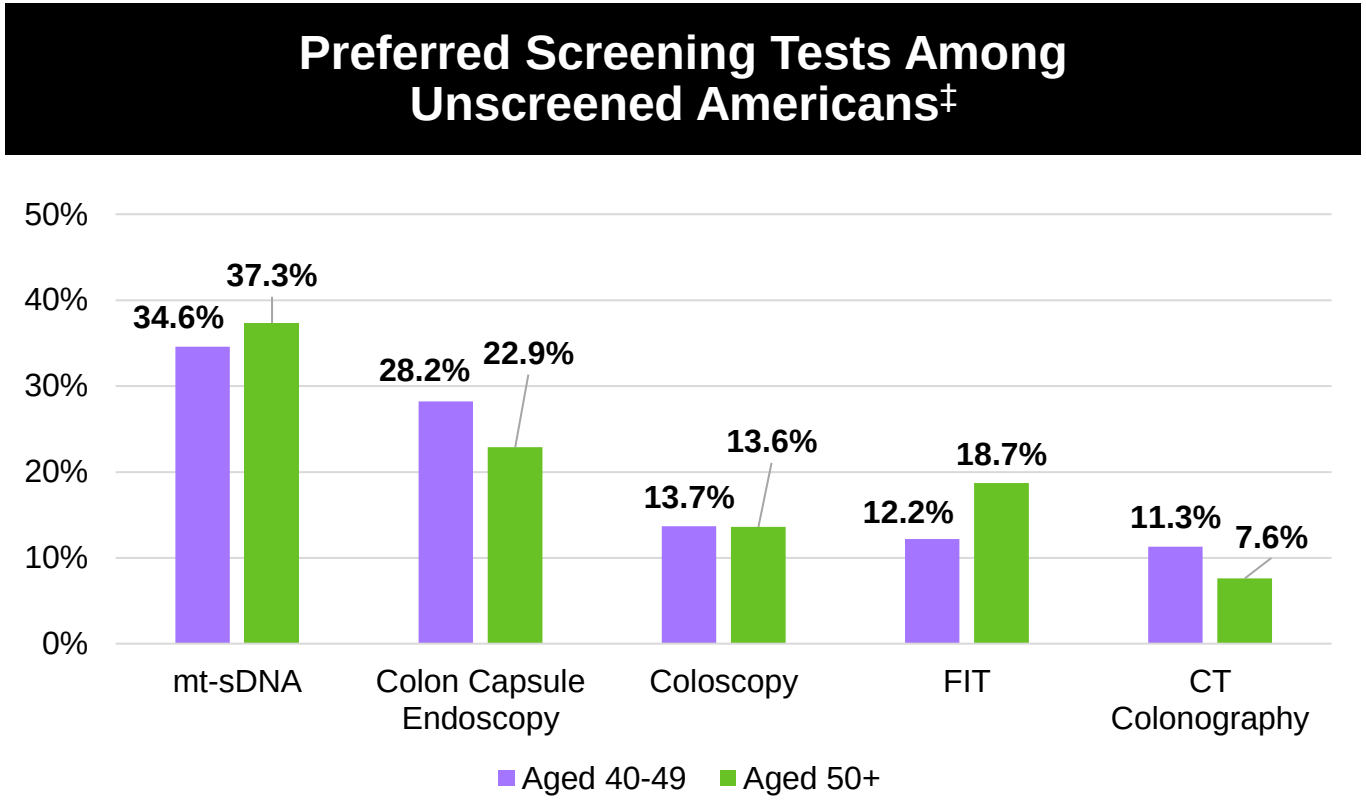
1. Barry MJ, et al. *N Engl J Med*. 2012;366(9):780-781. 2. Davidson KW, et al. *JAMA*. 2021;325(19):1965-1977. 3. Wolf AMD, et al. *CA Cancer J Clin*. 2018;68(4):250-281. 4. Shaukat et al. 2021 *Am J Gastroenterol*. 2021;116:458-479.

Shared Decision Making

In one survey study (n=1,000), when presented with a choice, **patients often preferred stool-based screening options‡**

When presented with a choice between colonoscopy and stool-based fecal immunochemical testing (FIT), patients overwhelmingly preferred FIT†

Screening Modality	Preference (45-49 years)	Preference (≥50 years)
Colonoscopy (invasive)	31%	23%
FIT (non-invasive)	69%	77%



†Note that the study included individuals below the recommended age of screening initiation for individuals of average risk in order to capture data on patients soon-to-be eligible for screening

‡Patients were asked to select a test based on the recommended screening intervals (colonoscopy every 10 years, capsule endoscopy every 5 years, CT colonography every 5 years, annual FIT, or triennial mt-sDNA)

Makaroff KE, et al. *Clin Gastroenterol Hepatol*. 2023;21(2):520-531.e10.

Cologuard Indications and Important Risk Information

Contraindications

Cologuard is intended for use with patients, age 45 years and older, at average risk who are typical candidates for CRC screening. Cologuard was not clinically evaluated for the following types of patients:

Patients with a history of colorectal cancer, adenomas, or other related cancers.

Patients who have had a positive result from another colorectal cancer screening method within the last 6 months.

Patients who have been diagnosed with a condition that is associated with high risk for colorectal cancer. These include but are not limited to:

- Inflammatory Bowel Disease (IBD)
- Chronic ulcerative colitis (CUC)
- Crohn's disease
- Familial adenomatous polyposis (FAP)
- Family history of colorectal cancer

Patients who have been diagnosed with a relevant familial (hereditary) cancer syndrome, such as Hereditary non-polyposis colorectal cancer syndrome, (HNPCCC or Lynch syndrome), Peutz-Jeghers Syndrome, MYH-Associated Polyposis (MAP), Gardner's syndrome, Turcots (or Crails) syndrome, Cowden's syndrome, Junveile Polyposis, Cronkhite-Canada syndrome, Neurofibromatosis, or Familial Hyperplastic Polyposis

Cologuard Indications and Important Risk Information

Warnings and Precautions

The performance of Cologuard has been established in a cross sectional study (i.e., single point in time). Programmatic performance of Cologuard (i.e., benefits and risks with repeated testing over an established period of time) has not been studied. Performance has not been evaluated in adults who have been previously tested with Cologuard. Non-inferiority or superiority of Cologuard programmatic sensitivity as compared to other recommended screening methods for CRC and AA has not been established.

The clinical validation study was conducted in patients 50 years of age and older. ACS Guidelines recommend screening begin at age 45. Cologuard performance in patients ages 45 to 49 years was estimated by sub-group analysis of near-age groups.

CRC screening guideline recommendations vary for persons over the age of 75. The decision to screen persons over the age of 75 should be made on an individualized basis in consultation with a healthcare provider. Cologuard test results should be interpreted with caution in older patients as the rate of false positive results increases with age.

A negative Cologuard test result does not guarantee absence of cancer or advanced adenoma. Patients with a negative Cologuard test result should be advised to continue participating in a colorectal cancer screening program with another recommended screening method. The screening interval for this follow-up has not been established.

Cologuard may produce false negative or false positive results. A false positive result occurs when Cologuard produces a positive result, even though a colonoscopy will not find cancer or precancerous polyps. A false negative result occurs when Cologuard does not detect a precancerous polyp or colorectal cancer even when a colonoscopy identifies the positive result.

Cologuard Indications and Important Risk Information

Warnings and Precautions

Patients should not provide a sample for Cologuard if they have diarrhea or if they have blood in their urine or stool (e.g., from bleeding hemorrhoids, bleeding cuts or wounds on their hands, rectal bleeding, or menstruation).

To ensure the integrity of the sample, the laboratory must receive the patient specimens within 96 hours of collection. Patients should send stool samples to the laboratory according to the instructions stated in the Cologuard Patient Guide.

Patients should be advised of the caution listed in the Cologuard Patient Guide. Patients should NOT drink the preservative liquid.

The risks related to using the Cologuard Collection Kit are low, with no serious adverse events reported among people in a clinical trial. Patients should be careful when opening and closing the lids to avoid the risk of hand strain.

Rx Only

Cologuard Indications and Important Risk Information

Cologuard Indications for Use

Cologuard 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. Cologuard is indicated to screen adults of either sex, 45 years or older, who are at typical average-risk for CRC. Cologuard is not a replacement for diagnostic colonoscopy or surveillance colonoscopy in high risk individuals.

The Mt-sDNA (Cologuard®) Collection Kit Overview

What's inside:


SHIPPING BOX


SAMPLE CONTAINER


PROBE + TUBE

PATIENT GUIDE INSTRUCTIONS

SAMPLE LABELS


BOTTLE OF LIQUID (PRESERVATIVE)

EASY STEPS FOR SAMPLE COLLECTION

Patients collect a single stool sample at home and send to Exact Sciences Labs via prepaid UPS shipping or pick-up

1 SIT

Cologuard is ready to use when you are ready to use it.

2 SCRAPE

Use the kit components to collect your sample.

3 SOAK

Fill the sample container with the liquid preservative.

4 SHIP

Ship your sample to complete the process.

The Cologuard Collection Kit is easy to use. If a patient has questions, a live Customer Support Specialist is available to assist via phone: 1-844-870-8870.

The Science Behind the Mt-sDNA (Cologuard®) Test[1,2]

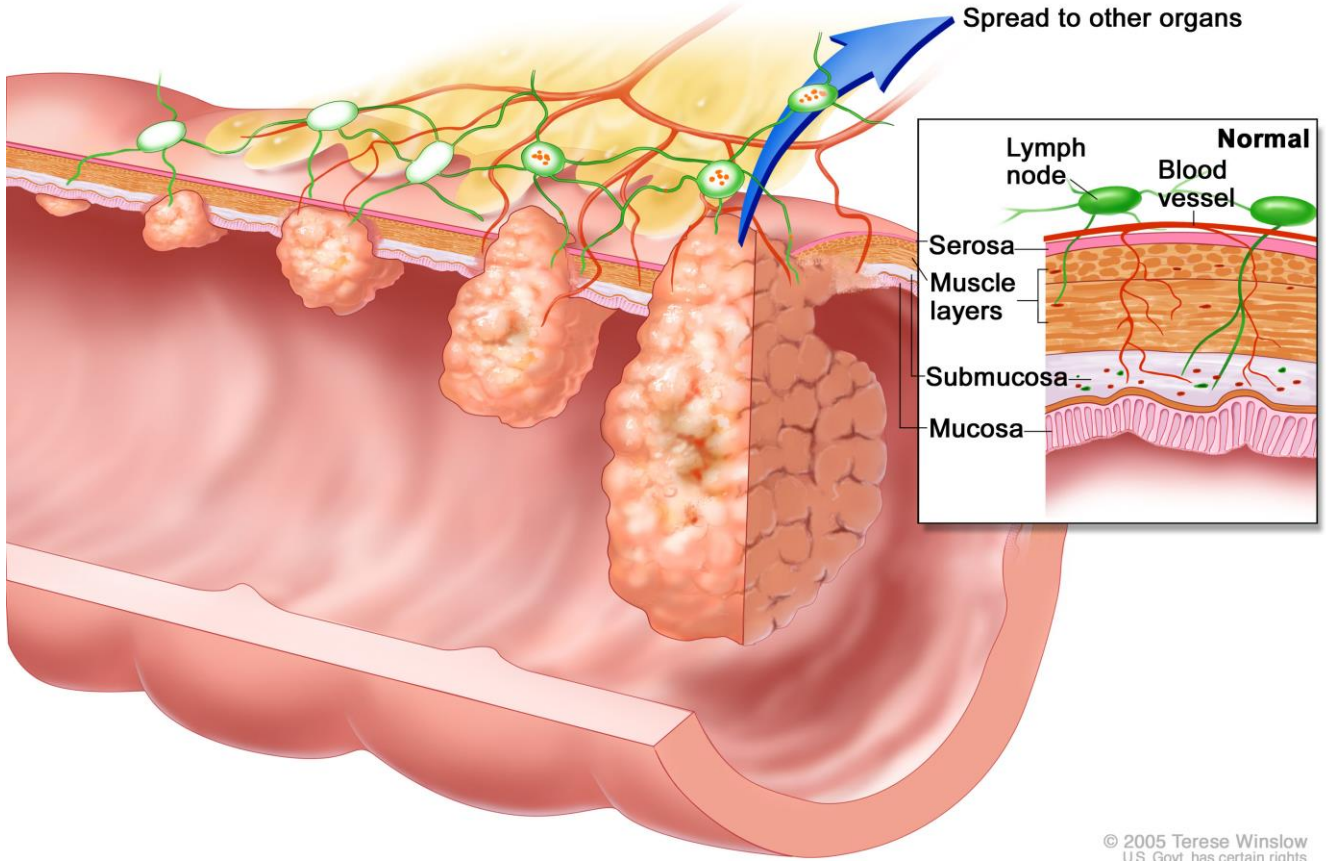
DNA biomarkers
are continuously shed
into the stool

Blood
is intermittently released
into the stool

mt-sDNA looks for the presence
of **10 DNA biomarkers**
plus hemoglobin in the
stool sample

Algorithm
calculates a single
qualitative result

- Negative result
- Positive result



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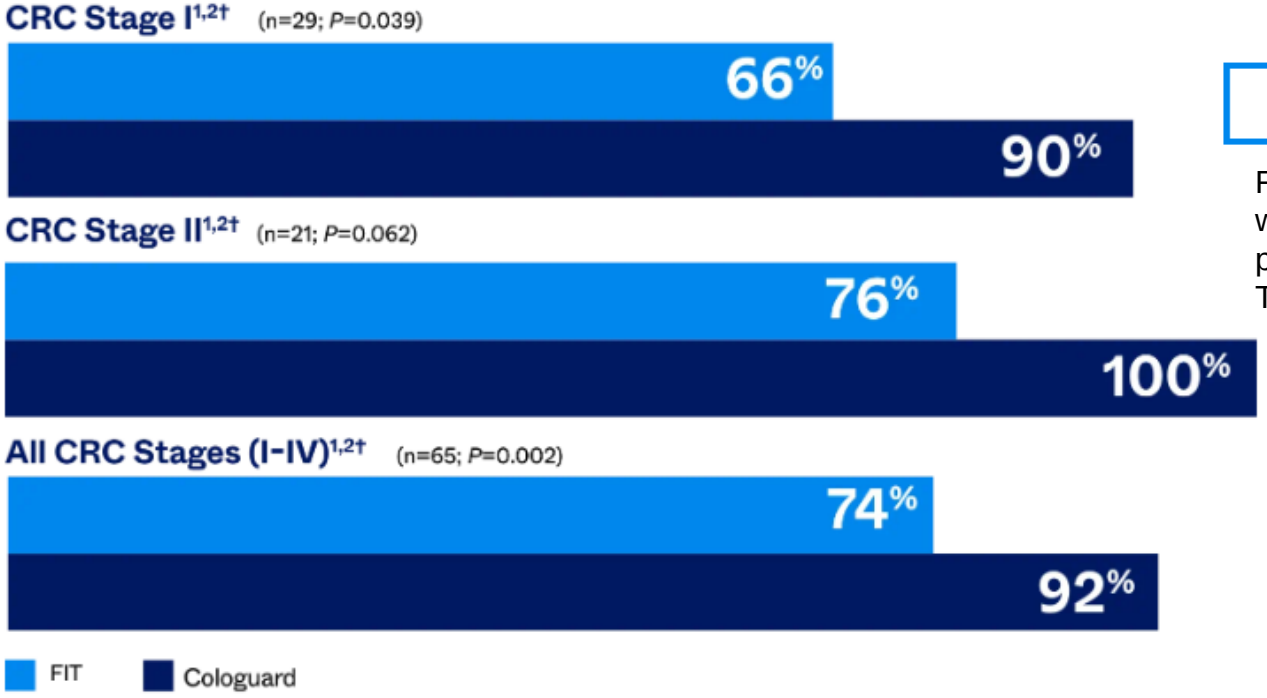
mt-sDNA: multi-target stool DNA.

1. Ahlquist DA, et al. *Clin Gastroenterol Hepatol*. 2012;10(3):272-277. 2. Cologuard Clinician Brochure. Exact Sciences Corporation. Madison, WI.

Mt-sDNA (Cologuard®) vs FIT

Mt-sDNA (Cologuard®) showed superior sensitivity compared with FIT* in detecting colorectal cancer (CRC) and advanced precancerous polyps[1,2]

In a prospective, head-to-head, point-in-time, 90-site, pivotal study of 10,000 patients aged 50-84 years at average risk for CRC, published in *The New England Journal of Medicine*, Cologuard demonstrated[1†]:



87% specificity overall with Cologuard§ vs 95% with FIT[1]

False positives and false negatives did occur in this pivotal study. 13% 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.

3X

FIT failed to detect 3 times more total CRC findings (stages I to IV)[1]

*OC FIT-CHEK, Polymedco, Inc.
†Statistic calculated using data from the pivotal study and reported within the Ahlquist review article. Cologuard sensitivity, per stage of cancer: I: 90% (n=29); II: 100% (n=21); III: 90% (n=10); IV: 75% (n=4).[2,4]
‡OC FIT-CHEK sensitivity, per stage of cancer: I: 66% (n=29); II: 76% (n=21); III: 90% (n=10); IV: 75% (n=4).[1,2]
§Cologuard specificity: 87% overall specificity, excluding CRC and advanced adenomas, and including all nonadvanced adenomas, nonneoplastic findings, and negative results on colonoscopy. There was 90% specificity in patients with no lesions biopsied on colonoscopy.[1]

References: 1. Imperiale TF, Ransohoff DF, Itzkowitz SH, et al. Multitarget stool DNA testing for colorectal-cancer screening. *N Engl J Med*. 2014;370(14):1287-1297. **2.** Cologuard® Clinician Brochure. Madison, WI: Exact Sciences Corporation.

Cologuard® Has Broad Payer Coverage Nationally

Coverage

Cologuard (mt-sDNA) is covered by **Medicare** and **Medicare Advantage** with no copay or deductible for eligible patients.[1,2]

Many national and regional payers have updated their medical policies to begin coverage of CRC screening at age 45.[2]

Billing

Exact Sciences encourages patients who receive a bill with out-of-pocket responsibilities after using Cologuard (mt-sDNA) to call the Customer Care Center at **1.844.870.8870** to discuss appeal support.

~94%

of Cologuard (mt-sDNA) patients have no out-of-pocket costs for screening nationally.[2,*]

~93% of Cologuard (mt-sDNA) patients aged 45-49 have no out-of-pocket costs.[2,*]

- Based on the Affordable Care Act, Cologuard (mt-sDNA) should be covered by most private insurers with no copay or deductible for eligible patients (ages 50-75 years; at average risk for colon cancer; without symptoms).[3†]
- In May 2021, the CMS Quality Measures Voting Members unanimously recommended the addition of CRC screening to the CMS Medicaid Adult Core Set of Quality Measures for adoption in 2022.[4]

*Exact Sciences estimate based on recent historical patient billing. Rate of coverage varies by state and region. Exceptions for coverage may apply, only the patient's insurer can confirm how Cologuard would be covered.
†Some exceptions may apply, so it is recommended that patients call their insurer to confirm.
mt-sDNA: multi-target stool DNA.
1. CMS. Screening for colorectal cancer – stool DNA testing. National Coverage Decision Summary CAG-00440N. October 9, 2014. Accessed July 12, 2022. https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=N&NCAId=277 2. Internal Data on File. Exact Sciences Corporation. Madison, WI. 3. Code of Federal Register. Rules and regulations for health plans. 29 CFR §2590.715-2713. (2015). Accessed July 12, 2022. https://www.govinfo.gov/content/pkg/CFR-2018-title29-vol9/pdf/CFR-2018-title29-vol9-sec2590-715-2713.pdf 4. CMS. 2022 updates to the child and adult core health care quality measurement sets. Updated December 10, 2021. Accessed July 12, 2022. https://www.medicaid.gov/federal-policy-guidance/downloads/cib121021.pdf

Inspiring and Motivating People to get Screened

Barriers to Colorectal Cancer Screening Adherence

Primary Barriers[1,2]

- Lack of access to health facilities
- Mistrust of Western healthcare systems
- Limited knowledge of colorectal cancer
- Embarrassment, particularly around the invasive nature of colonoscopy
- Privacy concerns
- Disgust associated with stool-based testing
- Fear of screening test
- Fear of test results
- Cost concerns and lack of insurance

Insurance Status[3]

- Lack of health insurance is 2.4x more common in this populations than in White individuals
- In 2019, 15% of American Indian/ Alaska Native people lacked health insurance.

1. Filippi MK, James AS, Brokenleg S, et al. Views, barriers, and suggestions for colorectal cancer screening among American Indian women older than 50 years in the Midwest. *J Prim Care Community Health*. 2013;4(3):160-166. 2. Redvers N, Wilkinson M, Fischer C. Colorectal cancer community engagement: a qualitative exploration of American Indian voices from North Dakota. *BMC Cancer*. 2022;22(1):158. 3. HHS Office of Minority Health. Profile: American Indian/Alaska Native. January 11, 2022. July 29, 2022. https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=3&lvlid=62.

Facilitators of Colorectal Cancer Screening Adherence

Primary Screening Motivators[1-4]

- Education and awareness via social support systems
- Leverage intergenerational relationships
- Culturally-relevant and tailored interventions
- Provider recommendation

Native populations feel connected to their community and culture

- ✓ Tailor messages to Native people[2,3]
- ✓ Leverage the power of intergenerational relationships[4]
- ✓ Build trust by embracing a culture of storytelling[1]
- ✓ Encourage conversations with family and friends[4]

1. Redvers N, Wilkinson M, Fischer C. Colorectal cancer community engagement: a qualitative exploration of American Indian voices from North Dakota. *BMC Cancer*. 2022;22(1):158. 2. James AS, Filippi MK, Pacheco CM, et al. Barriers to colorectal cancer screening among American Indian men aged 50 or older, Kansas and Missouri, 2006-2008. *Prev Chronic Dis*. 2013;10:E170. Published 2013 Oct 3. 3. Frerichs L, Beasley C, Pevia K, et al. Testing a Culturally Adapted Colorectal Cancer Screening Decision Aid Among American Indians: Results from a Pre-Post Trial. *Health Equity*. 2020;4(1):91-98. Published 2020 Apr 1. 4. Filippi MK, James AS, Brokenleg S, et al. Views, barriers, and suggestions for colorectal cancer screening among American Indian women older than 50 years in the Midwest. *J Prim Care Community Health*. 2013;4(3):160-166.

Exact Sciences is committed to providing solutions to overcome barriers for patients, providers and systems of care

How is Exact Sciences Addressing Health Equity?

- **FOCUS Grant Program**
- Implementation of **Evidence Based interventions**
- Improving **Patient Navigation**
- Addressing cost barriers through the **Exact Patient Assistance Program**
- Patient and provider resources that expand **language options** and enhance **health literacy.**
- Optimization of **EHR resulting and ordering of Cologuard**
- **Community engagement** through health fairs, events and sponsorships
- **Community Health Worker** training

Exact Sciences FOCUS Program

The Funding Opportunities for Colorectal Cancer Screening Uptake Strategies (FOCUS) program provides grant funding to initiatives aimed at **increasing colorectal cancer screening and access, particularly among vulnerable populations.**

In September 2022, Exact Sciences awarded

$525,000

to eight FQHCs and Community Clinics across the U.S.

- All awardees will utilize funds to **advance EBIs that are proven to increase CRC screening.**
- More information on the FOCUS program and a link to the application can be found here.

Evidence-Based/Informed Interventions (EBIs)

Who develops them?

- The Community Preventive Services Task Force (CPSTF) provides evidence-based findings and recommendations about community preventive services, programs, and other interventions aimed at improving population health. **These findings are listed on The Community Guide.**
- Advantages of Evidence-based Interventions include:
  - ❖ **Success**
  - ❖ **Resource Conservation**
  - ❖ **Value**
  - ❖ **Evaluation Focus**

The Community Guide: https://www.thecommunityguide.org/task-force/about-community-preventive-services-task-force

Recommended Evidence-Based Informed Interventions to Increase CRC Screening

Patient Targeted

- 1:1 education
- Navigation services (i.e. client reminders)
- CHW engagement
- Small media

Provider Targeted

- Provider assessment & feedback
- Provider reminder & recall systems

Community/System Targeted

- Reducing structural barriers
- Multi-component interventions

The Community Guide: chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/https://www.thecommunityguide.org/media/pdf/what-works-fact-sheets/what-works-fact-sheet-cancer-screening-p.pdf

Engaging patient early and often is foundational to the Cologuard Patient Navigation Program

Supporting nearly 10 million patients over 8 years[1]

When Cologuard is ordered, the Cologuard Patient Navigation Program provides **step-by-step guidance** to patients

Informing patients at all stages, from when to expect their Cologuard kit to arrive at their home through delivery of test results

Providing digital resources that explain the screening process, **how to complete the Cologuard kit**, what Cologuard results mean, and other support tools and videos

Reference: 1. Data on file. Exact Sciences Corporation. Madison, WI.

Cologuard® Patient Navigation Program: We're here for patients every step of the way

Through tailored outreach based on patient communication preferences, patients have our support

Outreach through the Cologuard Patient Navigation Program yielded a **22-percentage point increase** in Cologuard adherence vs. Cologuard patients who did not receive outreach*[1]

Submitting a patient's email address and phone number with the Cologuard order can help increase engagement and kit completion†

*The internal data on file yielded an increase from 37.4% to 59.5% in Cologuard Adherence vs. Cologuard patient who did not receive outreach.
†Internal data from orders between Sept 2022-Nov 2022.
Reference: 1. Data on file. Exact Sciences Corporation. Madison, WI.

Digital touchpoints aim to maximize adherence and the patient experience

Initial patient screening touchpoints

Cologuard **completion reminders** are sent soon after the order is placed and taper off through the year

3-year rescreen-eligible digital touchpoints

Digital patient engagement has helped yield an **80% Cologuard rescreen completion** rate for eligible patients[1]*

Patient satisfaction scores average 8.7 out of 10 across four Cologuard kit experience touchpoints in 2022†

The experience of individual patients may vary based on the visual shown here.

*Based on patients who completed screening within 90 days of receiving Cologuard kits for their second CRC screening from October 2020 to December 2021.[1]

†This score is equally weighted across four touchpoints, kit received, 45-day kit unreturned, kit returned, and result received.

Reference: 1. Internal data on file. Exact Sciences Corporation. Madison, WI.

Color Key: Operational Only if necessary

Cancer screening is a life-long journey

Our support doesn't stop after Cologuard is completed

If a **positive result is received**, the clinician is notified and should work with their patient to determine the next steps which likely include a follow-up colonoscopy (now covered as 'screening' with no out-of-pocket costs for most patients)

If a **negative result is received**, the clinician is notified and should communicate this result to their patient. In accordance with the American Cancer Society guidelines, the clinician can educate the patient that they can complete CRC screening again 3 years after receipt of a negative result

- **80% of patients screened chose to complete Cologuard again when they became eligible 3 years after a negative result[1]***
- For patients who receive a negative Cologuard result, Cologuard Patient Navigation Program continues routine outreach to ensure each patient is aware when they are due for CRC screening again at the **3-year interval** and encourages them to connect with their clinician about screening options

*Based on patients who completed screening within 90 days of receiving Cologuard kits for their second CRC screening from October 2020 to December 2021.[1]

Reference: 1. Data on file. Exact Sciences Corporation. Madison, WI.

Cologuard Patient Assistance Program

Available to all patients residing in the United States who have demonstrated household incomes at or below 400% of the Federal Poverty Guidelines for the 48 Contiguous States & District of Columbia

Household Size (2023)	Income Level (400% FPG)
1	$58,320 or less
2	$78,880 or less
3	$99,440 or less
4	$120,000 or less

- Applies to *any* amounts owed by the patient, except if their Medicaid plan assigns a small co-pay
- Patients remain qualified for 365 days and will incur no costs for subsequent services during that time

To apply or ask questions about our assistance program, call our Customer Care Center at 1-844-870-8870

Office Support Resources

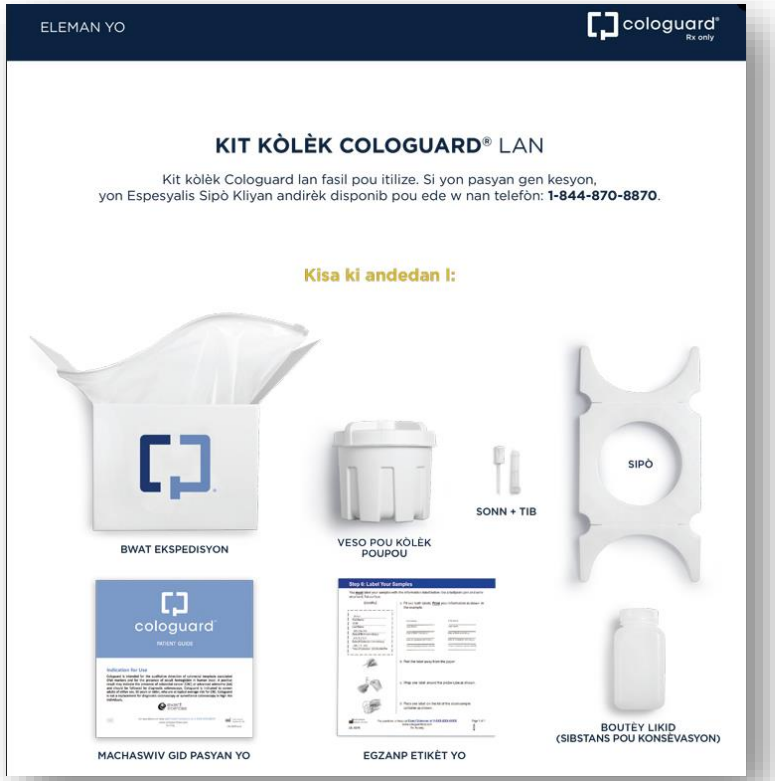
- Letter, text, and phone outreach templates
  - Evaluated from a health literacy perspective & available in English & Spanish

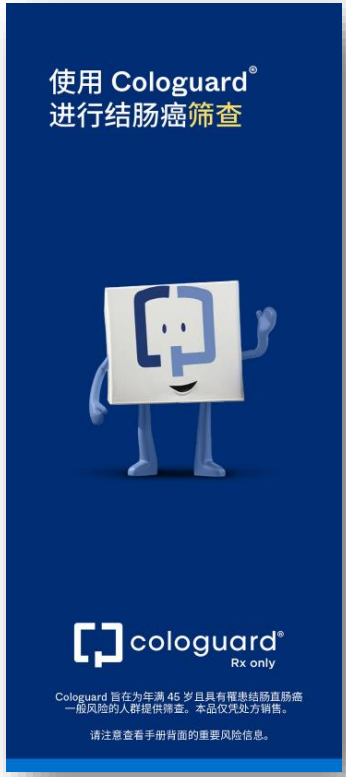
- Patient-facing materials (brochures, components flashcards) available in numerous languages including, but not limited to:
  - English
  - Spanish
  - Burmese
  - Korean
  - Chinese
  - Haitian Creole
  - Vietnamese
  - French
  - Russian
  - Arabic
  - Tagalong

Reminder to Schedule a Screening
Hi, <First Name>! Call <XXX-XXX-XXXX> today to schedule your colon cancer screening. Thank you.

3-Year Rescreen Reminder
Hi, <First Name>! Call <XXX-XXX-XXXX> today to schedule your colon cancer screening. Thanks.

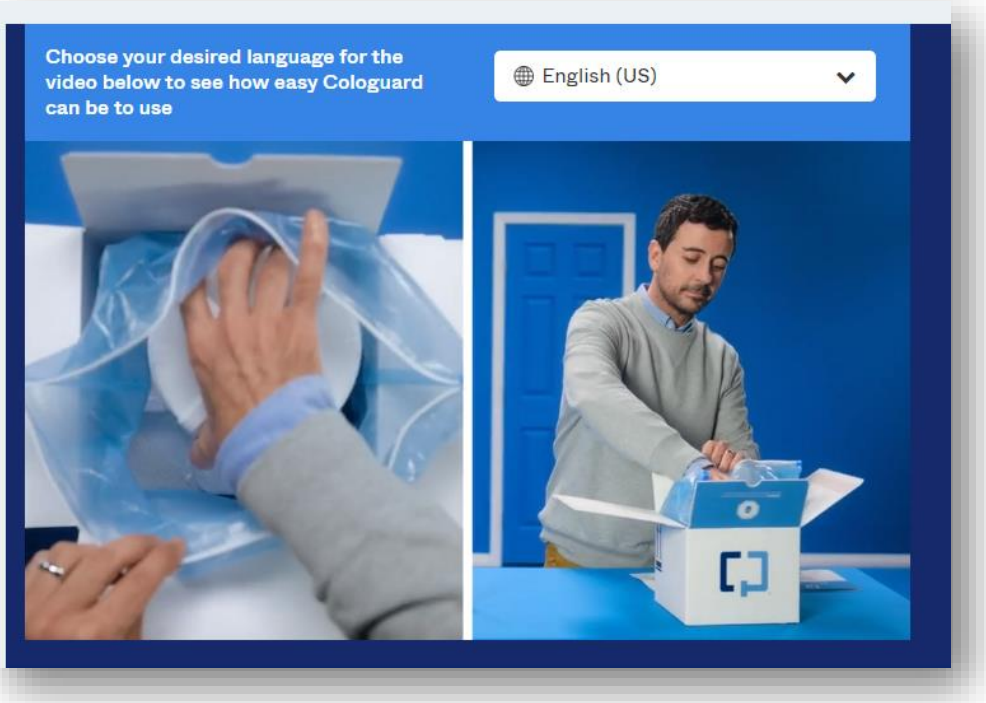
Post-Cologuard® Order 60-Day Outreach
Hi, <First Name>. We haven't received your Cologuard® kit yet. If you need a new kit, please call Exact Sciences at 1-844-870-8870. To talk to someone in your doctor's office, call <XXX-XXX-XXXX>. Thanks.

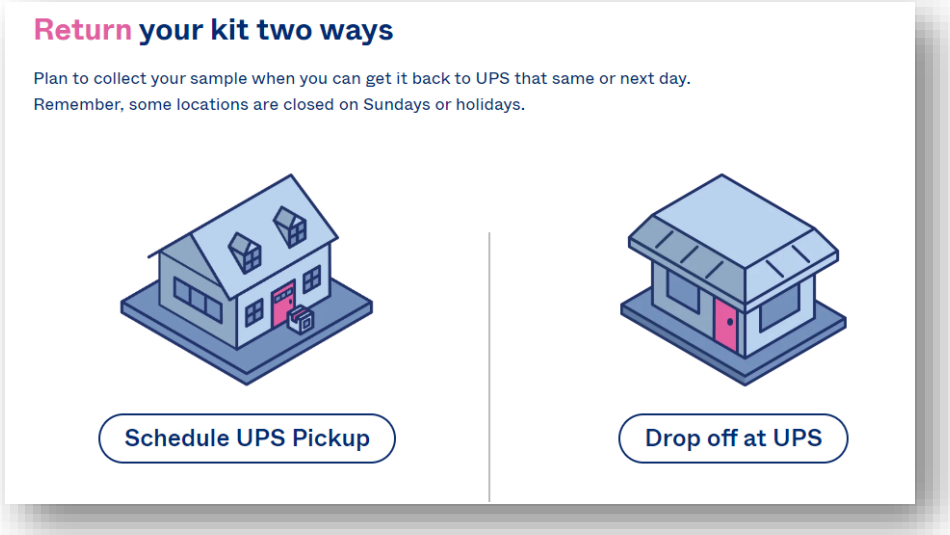




Office Support Resources

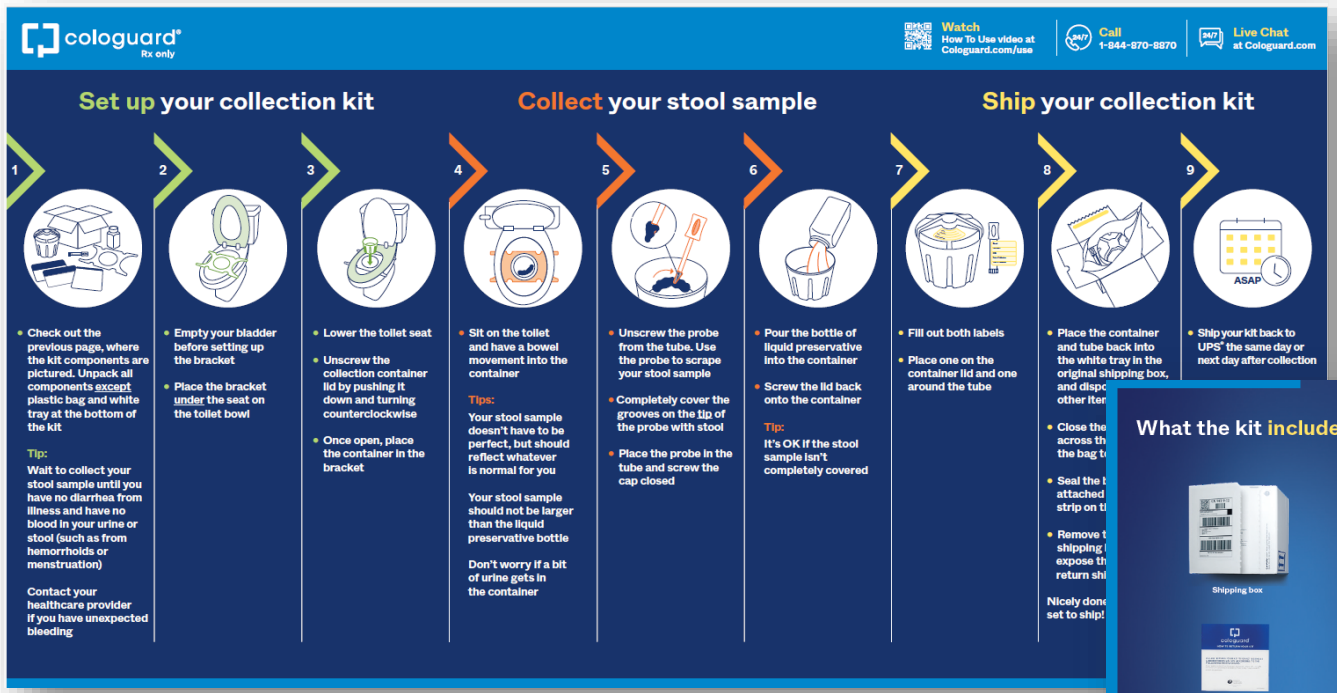
- Cologuard.com Resources:
  - How-To Video: Provides step by step instructions on how to complete the collection kit. **Available in nine languages.**
  - How-To Return Instructions: provides information on options for pick-up or drop-off following kit completion.





Office Support Resources

- *New* Cologuard Quick Start Guide

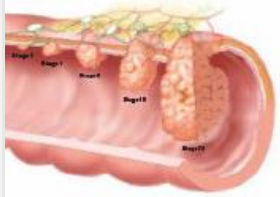


Office Support Resources

- **Screening Options Tear Pad (English & Spanish)**

Screening for colorectal cancer (CRC) on time matters[1]

Regular screening can help find CRC in early stages, which is why it's important to screen on time.[1]
See how CRC develops below:



- CRC typically starts as a polyp on the wall of the colon or rectum which may **develop** into cancer[1]
- Many people with early-stage CRC have **no symptoms**, but screening can detect signs of cancer[1]
- **Black Americans** are most likely to develop and die from colon cancer[2]
- **Hispanic Americans** have the second-highest death rate due to colon cancer[2]

Focus on the CRC facts

- Colon cancer affects all races, genders, and ethnicities[2]
- 3rd — It's the 3rd most common cancer among men and women[3]
- 75% — About 75% of people have no family history[3]
- It's on the rise in people 45-49[4]

See your choices for CRC screening on the other side

When caught in early stages, CRC is more treatable in about 90% of people[5]*

There are many screening options, but whichever you choose, the American Cancer Society recommends regular screening starting at age 45. Even if you've screened before, you'll need to screen again when your healthcare provider recommends.[1,4]

*Based on 5-year survival

There are choices when it comes to CRC screening[1,4,6-10]

Use this chart to help you decide which option might work best for you

	Colonoscopy (visual exam)	Multitarget stool DNA test* (Cologuard®)	FIT/FOBT* (fecal immunochemical test/fecal occult blood test)
How does it work?	Uses a scope to look for and remove abnormal growths in the colon/rectum[1]	Finds altered DNA and blood in the stool sample[1]	Detects blood in the stool sample[1]
Who is it for?	Adults at high or average risk[1,6]	Adults 45+ at average risk[4]	Adults at average risk[4]
How often?	Every 10 years[1†]	Every 3 years[4]	Once a year[4]
Non-invasive?	No[1,7]	Yes, used at home[4]	Yes, used at home[1]
Prep required?	Yes, full bowel prep including fasting and laxatives[1,7]	No[8]	No/Yes[1‡]
Time it takes?	1-2 days for bowel prep and procedure[7]	The time it takes to collect a sample[6]	The time it takes to collect a sample[6]
Covered?[§]	Covered by most insurers[4]	Covered by most insurers[9]	Covered by most insurers[10]
After a positive result?	Polyps removed and examined (biopsy)[1]	A colonoscopy is needed[1]	A colonoscopy is needed[1]

*All positive results on non-colonoscopy screening tests should be followed up with timely colonoscopy.[4]

†For adults at high risk, testing may be more frequent and should be discussed with your healthcare provider.[1]

‡FIT does not require changes to diet or medication. FOBT requires changes to diet or medication.[1]

§Insurance coverage can vary; only your insurer can confirm how CRC screening is covered under your insurance policy.

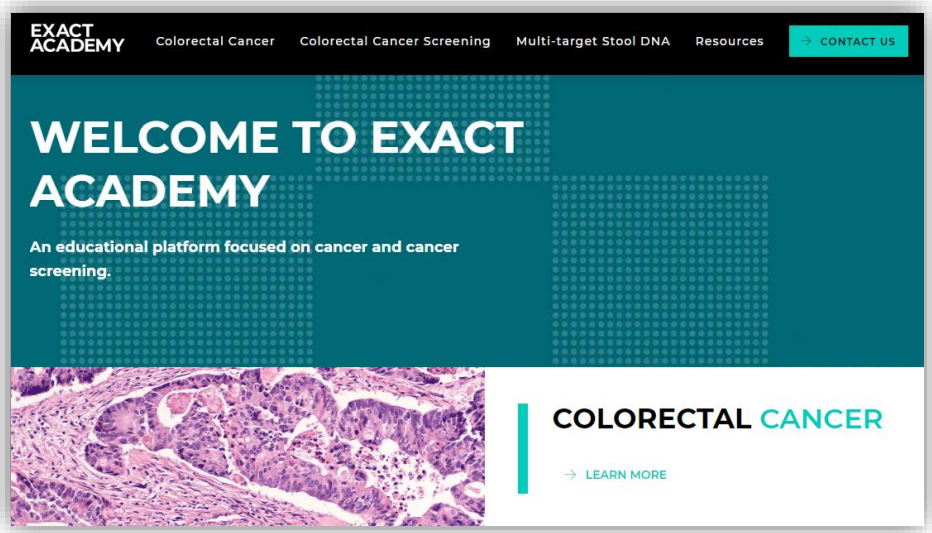
Choose the screening option(s) below to discuss with your prescriber today:

☐ Colonoscopy ☐ Multitarget stool DNA test* ☐ FIT/FOBT*

Office Support Resources

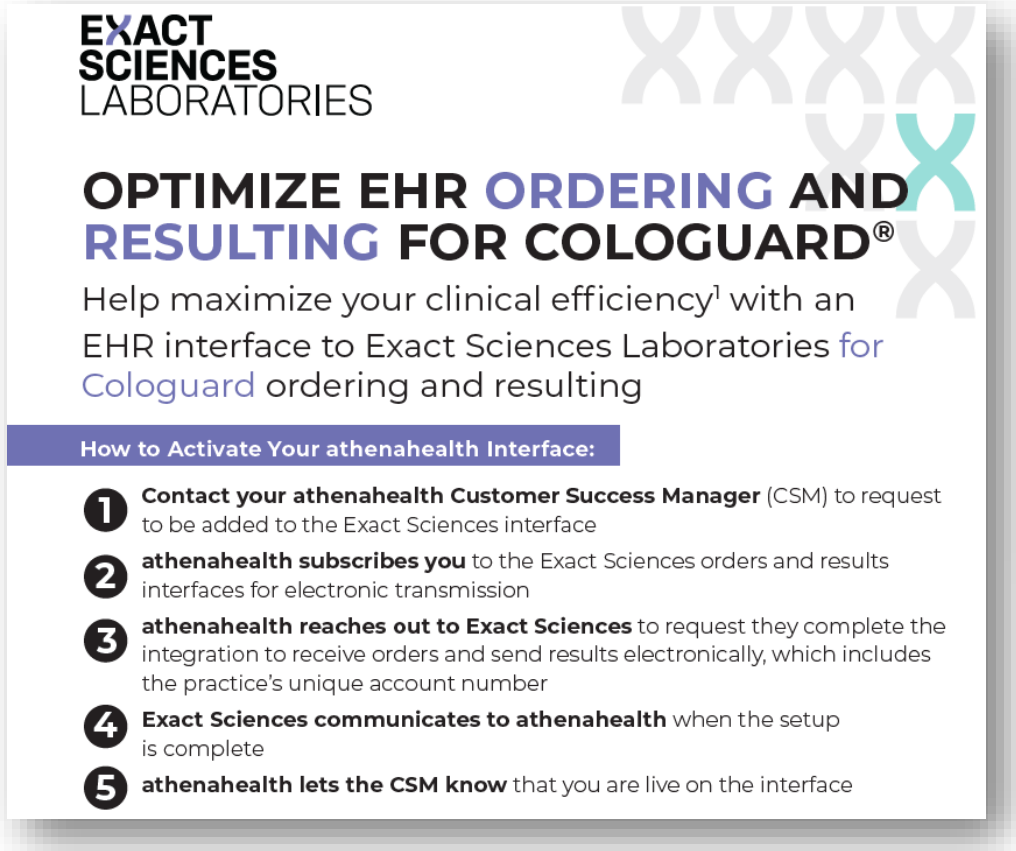
- Exact Academy: An Educational platform focused on cancer and cancer screening

- Screening Has Meaning: A website and resources specifically built to raise awareness of the need for CRC screening among Spanish-speaking (LatinX/Hispanic) and Black/African American patients.



Office Support Resources – EHR Optimization

- Low literacy AVS templates available in English and Spanish
- Health system-specific interface optimization guides



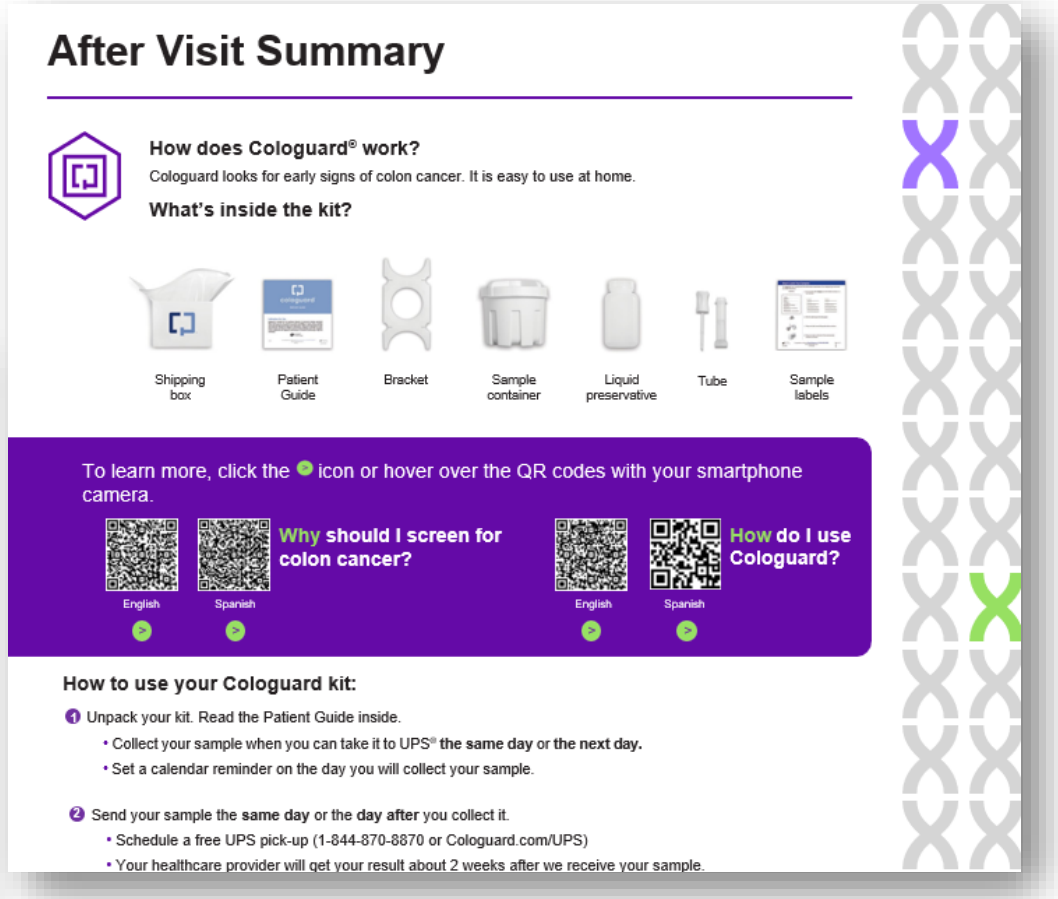
EXACT SCIENCES LABORATORIES

OPTIMIZE EHR ORDERING AND RESULTING FOR COLOGUARD®

Help maximize your clinical efficiency[1] with an EHR interface to Exact Sciences Laboratories for Cologuard ordering and resulting

How to Activate Your athenahealth Interface:

1. **Contact your athenahealth Customer Success Manager** (CSM) to request to be added to the Exact Sciences interface
2. **athenahealth subscribes you** to the Exact Sciences orders and results interfaces for electronic transmission
3. **athenahealth reaches out to Exact Sciences** to request they complete the integration to receive orders and send results electronically, which includes the practice's unique account number
4. **Exact Sciences communicates to athenahealth** when the setup is complete
5. **athenahealth lets the CSM know** that you are live on the interface



After Visit Summary

How does Cologuard® work?

Cologuard looks for early signs of colon cancer. It is easy to use at home.

What's inside the kit?

Shipping box | Patient Guide | Bracket | Sample container | Liquid preservative | Tube | Sample labels

To learn more, click the icon or hover over the QR codes with your smartphone camera.

Why should I screen for colon cancer? English | Spanish

How do I use Cologuard? English | Spanish

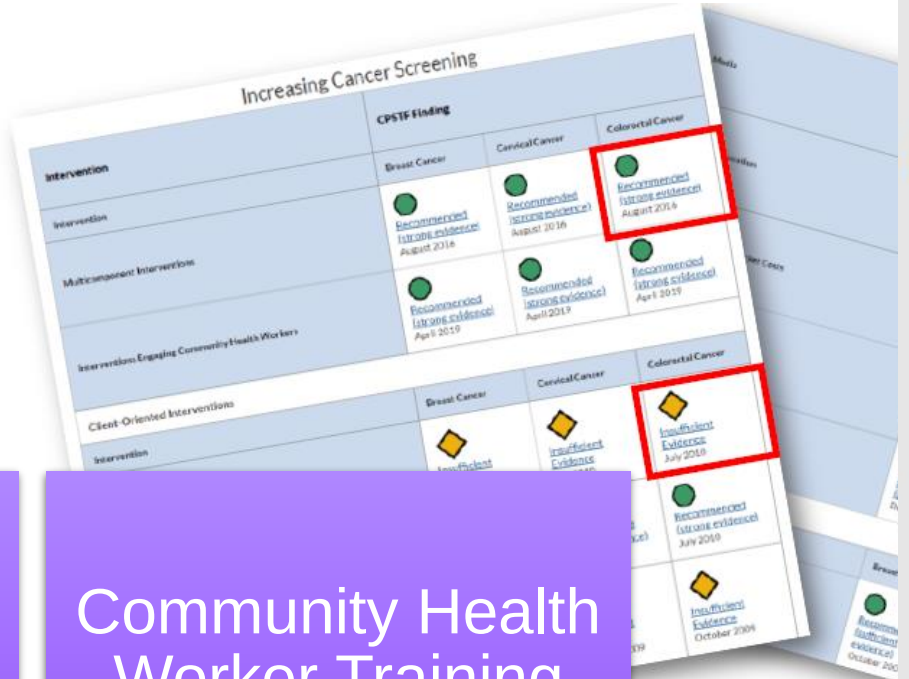
How to use your Cologuard kit:

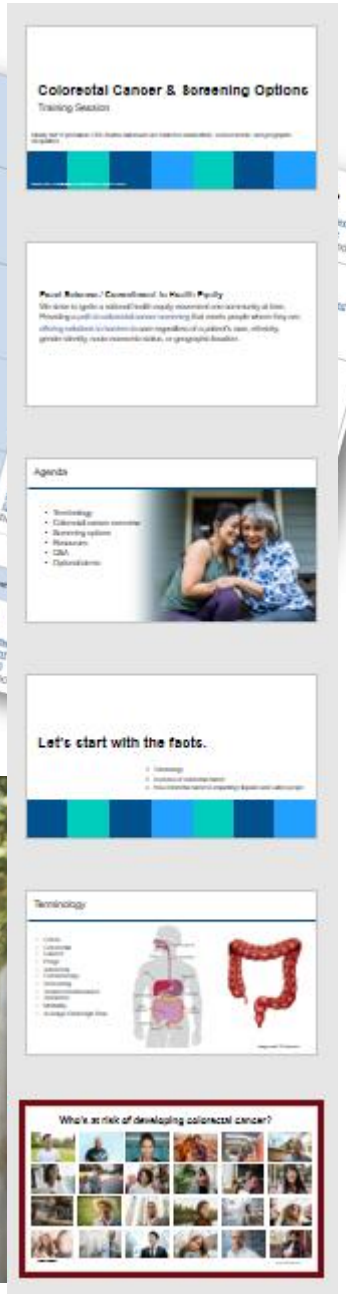
1. Unpack your kit. Read the Patient Guide inside.
   - Collect your sample when you can take it to UPS® **the same day** or **the next day.**
   - Set a calendar reminder on the day you will collect your sample.
2. Send your sample the **same day** or the **day after** you collect it.
   - Schedule a free UPS pick-up (1-844-870-8870 or Cologuard.com/UPS)
   - Your healthcare provider will get your result about 2 weeks after we receive your sample.

Community Engagement

Community Health Events & Sponsorships

Community Health Worker Training

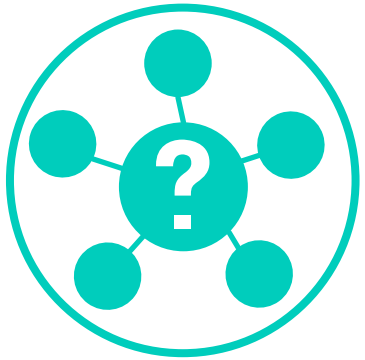




In Summary

CRC is the second most common cause of cancer-related mortality,[1] but it can be prevented through early detection[2-3]

Currently, 43% of eligible adults, aged 45-75, is nonadherent with CRC screening guidelines[4]



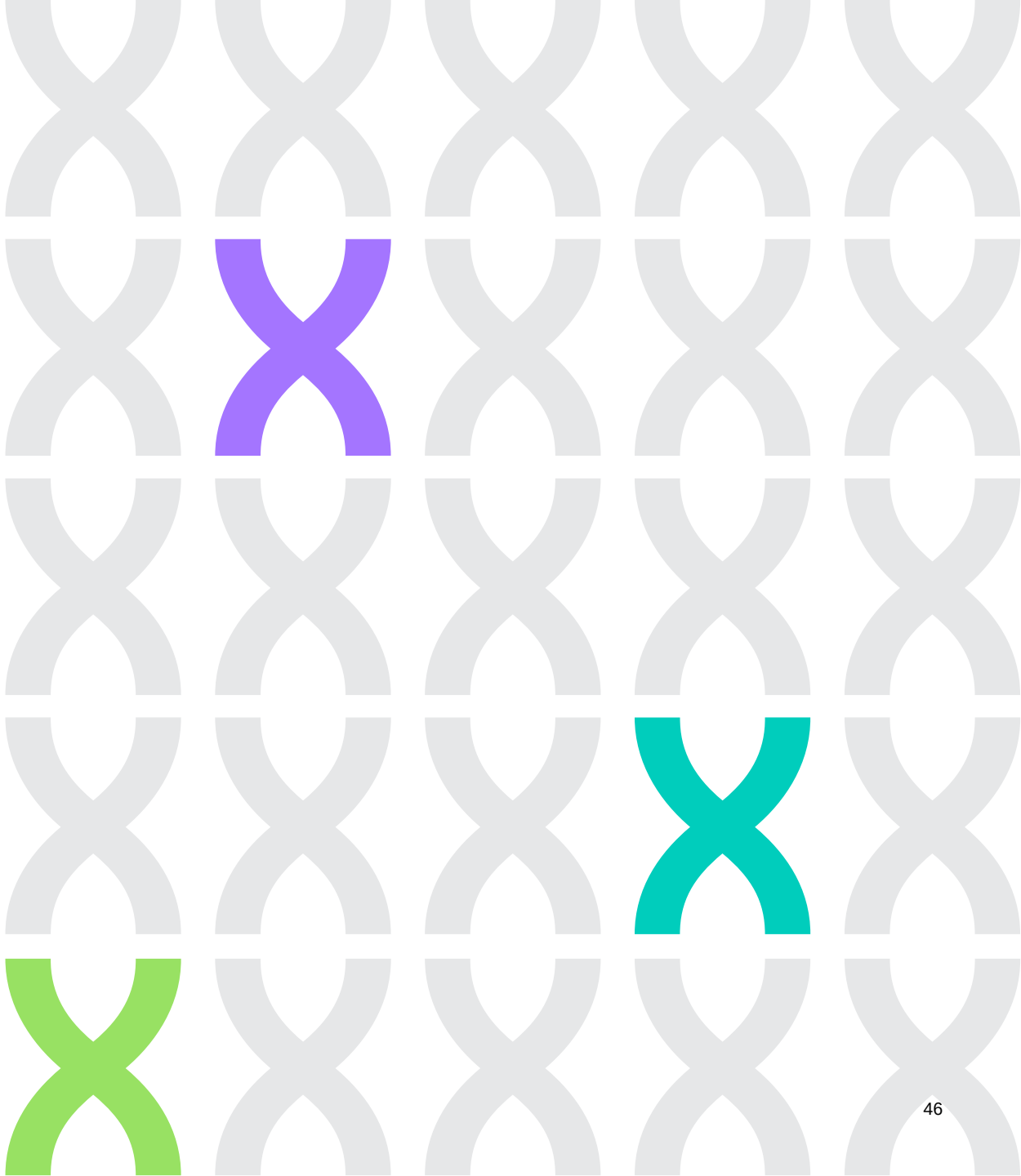
National guidelines recommend shared decision making and offering screening choices to improve screening adherence[2-5]

Cologuard provides a wide array of patient and provider support options including navigation, patient assistance, and educational resources.

- CRC: colorectal cancer; mt-sDNA: multi-target stool DNA.
- 1. Siegel RL, et al. *CA Cancer J Clin*. 2023;73(1):17-48. 2. Wolf AMD, et al. *CA Cancer J Clin*. 2018;68(4):250-281.3. Davidson KW, et al. *JAMA*. 2021;325(19):1965-1977. 4. American Cancer Society. Colorectal cancer facts and figures 2023-2025, https://acsjournals.onlinelibrary.wiley.com/doi/full/10.3322/caac.21772 . Shaukat A, et al. *Am J Gastroenterol.* 2021;116:458-479. 6. Cologuard Clinician Brochure. Exact Sciences Corporation. Madison, WI.

EXACT SCIENCES

Questions?



Thank you.

Contact us at:
HeathEquity@exactsciences.com

Appendix

Follow-Up Colonoscopy After a Positive Stool-Based Test

New Coverage Requirements for Colonoscopies After Positive Stool-Based Tests

Federal guidance requires commercial health plans under the Affordable Care Act (ACA) to cover follow-up colonoscopy after a positive, noninvasive CRC screening test ***without patient cost share***[1]

Effective January 1, 2023, Medicare will now cover as a preventive service, a screening colonoscopy after a positive non-invasive stool test, ***with no out-of-pocket costs***[2]

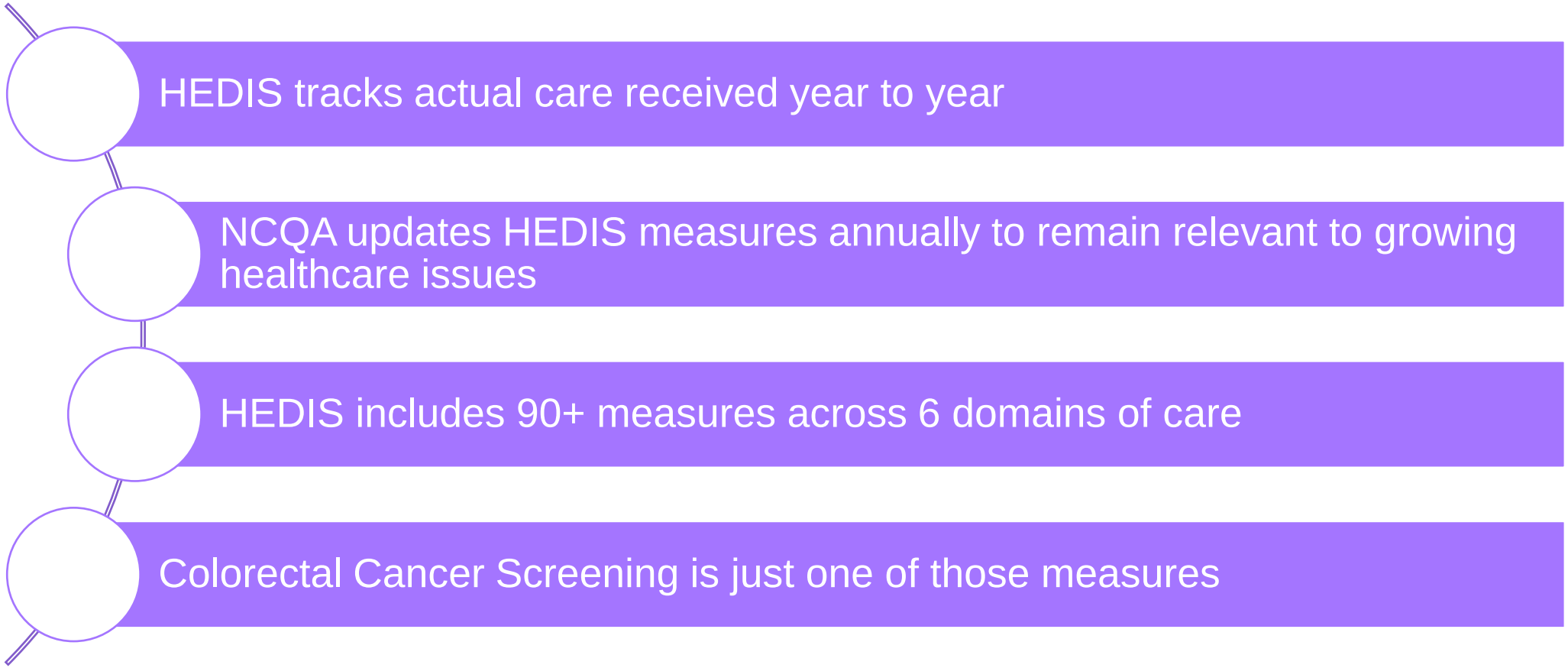
Patients and providers are encouraged to ask their individual insurers about coverage[3]

- Some commercial plans may have exceptions[3]
- Polyp removal or other services may be subject to separate charges, regardless of a positive stool-based test[3]
- Plan and benefit designs are different, and the rules may differ if a provider is out-of-network[3]

ACA: Affordable Care Act; **CRC:** colorectal cancer.

1. DOL. FAQs About Affordable Care Act Implementation Part 51, Families First Coronavirus Response Act and Coronavirus Aid, Relief, and Economic Security Act Implementation. Published January 10, 2022. Accessed December 14, 2022. https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-51.pdf 2. Centers for Medicare & Medicaid Services. HHS Finalizes Physician Payment Rule Strengthening Access to Behavioral Health Services and Whole-Person Care. [Press Release]. Published November 1, 2022. Accessed December 14, 2022. https://www.cms.gov/newsroom/press-releases/hhs-finalizes-physician-payment-rule-strengthening-access-behavioral-health-services-and-whole 3. American Cancer Society. Insurance Coverage for Colorectal Cancer Screening. Published May 19, 2021. Accessed January 12, 2023. https://www.cancer.org/cancer/colon-rectal-cancer/detection-diagnosis-staging/screening-coverage-laws.html

Healthcare Effectiveness Data & Information Set (HEDIS)



https://www.ncqa.org/hedis/

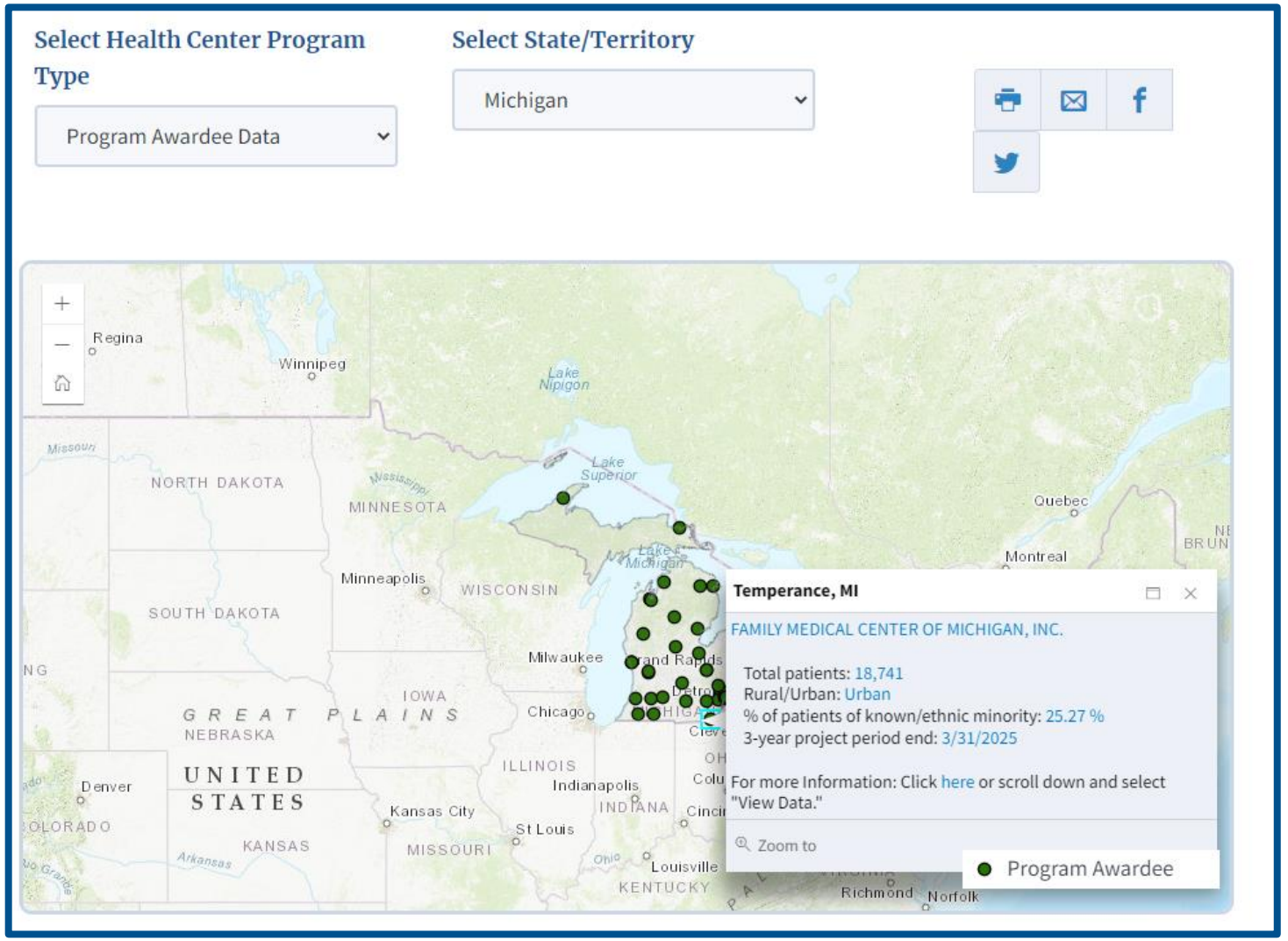
Health Center Program Uniform Data System (UDS)

Each calendar year, HRSA Health Center Program awardees and look-alikes are required to report a core set of information as part of a standardized reporting system known as the UDS.

The information UDS collects includes:

- Data on patient characteristics
- Services provided
- Clinical processes and health outcomes
- Patients' use of services
- Staffing, costs, and revenues

This data is available on the UDS website on a state/territory level



https://data.hrsa.gov/tools/data-reporting/program-data?type=AWARDEE&state=MI