

What is ColoTest®?

ColoTest® is a FIT test, the preferred annual stool screening method for colon cancer according to Colorectal Cancer Alliance and Cleveland Clinic¹. ColoTest® detects blood in stool, which may be an early warning for:

Colorectal Cancer, Diverticulitis, Gastrointestinal Disorders, Colitis and Polyps.

ColoTest® advantages include:

- Fast Results as Soon as 1 Minute
- No Lab Testing Required
- No Prep or Diet Restrictions
- Self Test at Home
- Only 1 Stool Sample*
- 98.8% Accurate

If ColoTest® results are positive, the patient should consult their doctor for additional diagnostic procedures, likely including a colonoscopy.

¹ccalliance.org/screening-prevention/screening-methods, consultqd.clevelandclinic.org/colorectal-cancer-screening-choosing-the-right-test/

*Bleeding in the digestive system may be intermittent (not continuous). If concerned, it is recommended to perform the test on three different days with new feces samples each time to increase the chance of detecting fecal occult blood.



Colon Cancer Stats:



Colon Cancer is the 3rd most common cancer diagnosed in both men and women in the US, with an estimated 150,000 new cases diagnosed in 2023.¹



Colon Cancer is the 2nd most deadly cancer in the US with an estimated 52,000 expected to lose their battle in 2023.²



About 90% of CRC related deaths are thought to have been preventable if diagnosed early enough. That's 9 of every 10 individuals.³

Screening Saves Lives

- More than 29 million Americans are NOT screening for Colon Cancer⁴. Given the statistics above, we really want them to get screened.
- Screening is typically recommended from age 45 to 75, but earlier screening may be desired depending on family health history.
- Early onset colorectal cancer is a growing concern, with the proportion of cases among those younger than 55 years increased from 11% in 1995 to 20% in 2019.⁵

ColoTest® provides one of the easiest and least invasive screening options available to your patients, but there are many options available as outlined on the next page. Consider engaging with your patients to determine their screening status and encourage them to consider screening if they are out of compliance.

¹ <https://pubmed.ncbi.nlm.nih.gov/36856579/>

² <https://www.cancer.org/cancer/types/colon-rectal-cancer/about/key-statistics.html>

³ <https://www.ucsfhealth.org/education/colorectal-cancer-prevention-and-screening>

⁴ <https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/colorectal-cancer-facts-and-figures/colorectal-cancer-facts-and-figures-2020-2022.pdf>

⁵ <https://acsjournals.onlinelibrary.wiley.com/doi/full/10.3322/caac.21772>

Screening Saves Lives

There are several options available for colorectal cancer (CRC) screening. Screening methods recommended by the Colorectal Cancer Alliance are outlined below.*

METHOD	FREQUENCY	PROS	CONS	SENSITIVITY / SPECIFICITY FOR DETECTING CANCER	ESTIMATED COST ¹
Colonoscopy	Every 5-10 years depending on whether polyps are found	Views the entire colon. Polyps can be removed during the procedure if found.	Dietary restrictions 1-3 days prior to the procedure and prep to clean out the colon is needed.	Sensitivity 95% Specificity 86%	Typically covered by insurance for patients age 50+ Without insurance, the average cost is \$2,750 according to GoodRx.
Stool DNA	Every 3 years	No prep, dietary restrictions, or changes in medication necessary	More expensive than FIT if not covered by insurance. Follow-up colonoscopy necessary if test indicates precancer or cancer.	Sensitivity 92% Specificity 87%	Cologuard, a well-known Stool DNA test, is covered by some insurances. Without insurance, the cost is \$681 according to GoodRx.
Fecal Immunochemical Test (FIT)	Annually	No prep, needed. Performed at home. Relatively inexpensive.	Accuracy. Need a colonoscopy if blood is detected.	Sensitivity 73.8% Specificity 96.4%	Reese's ColoTest® 1ct recommended retail is \$19.99.
Fecal Occult Blood Test (FOBT)	Annually	No prep, needed. Performed at home. inexpensive.	Accuracy. Dietary restrictions. Need a colonoscopy if blood is detected Requires 2 separate samples.	Sensitivity 70% Specificity 92.5%	The Cleveland Clinic advises that FIT testing should replace FOBT. ²
Flexible Sigmoidoscopy	Every 5 years, may be combined with annual stool test	No sedation required. Can biopsy if small polyp detected.	Only views part of the colon. Need a colonoscopy if larger polyps or other issues are detected.	Sensitivity 95% Specificity 87% Only left sided cancers	Discuss with your gastroenterologist
Virtual Colonoscopy	Every 5 years	Quicker and less invasive than a colonoscopy. No sedation is needed.	Expensive and not covered by all insurance carriers. Dietary restrictions 1-3 days before the procedure. Full bowel prep is required. If a polyp is found, will need a colonoscopy	Sensitivity 95% Specificity 87% Only left sided cancers	Discuss with your gastroenterologist
Double Contrast Barium Enema	Every 5-10 years	Done without sedation. Less expensive than a colonoscopy.	Laxative prep is required. Polyps cannot be removed during the procedure. If polyps are found, a colonoscopy will be needed.	Very low sensitivity Very low specificity	Discuss with your gastroenterologist

- Sensitivity-true positives – this percentage indicates the number of people **WITH** colorectal cancer that are correctly identified
- Specificity-true negative – this percentage indicates the number of people **WITHOUT** colorectal cancer that are correctly identified

*ccalliance.org/screening-prevention/screening-methods

¹<https://www.goodrx.com/conditions/colon-cancer/colonoscopy-cost>, <https://www.goodrx.com/conditions/colon-cancer/at-home-colon-cancer-test>

²<https://consultqd.clevelandclinic.org/colorectal-cancer-screening-choosing-the-right-test/>

ColoTest[®] Kit Contents:



One Quick Guide



One Insert



One Test Cassette
in a Sealed Foil Pouch



One Sample
Collection Tube



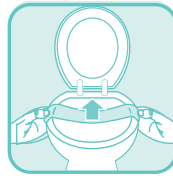
One Collection Paper

1. Prepare Stool Specimen:

1. Remove tape covers from back sides of collection paper.



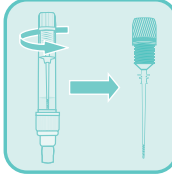
2. Loosely place paper at the back portion of the toilet bowl, affix tape, and then lower the seat.



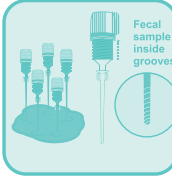
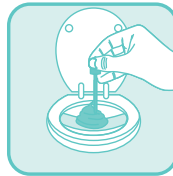
3. Deposit stool specimen on collection paper.



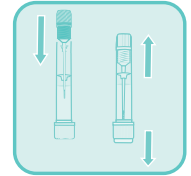
4. Unscrew and remove sampler from the collection tube.



5. Using the grooved tip of sampler, pierce the stool in at least 5 different sites.



6. Insert sampler back into collection tube, firmly tighten, and shake the tube to mix the liquid. Flush the remaining stool and paper.



2. Perform the Test:

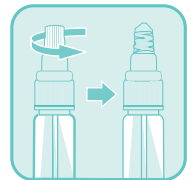
7. Open sealed foil pouch, remove test cassette, and place on a flat surface.



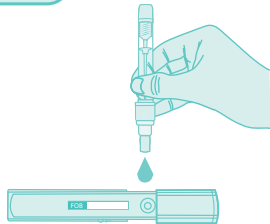
8. DO NOT remove cassette cap from device



9. Holding the collection tube upright, unscrew the clear cap.



10. Squeeze the collection tube to deliver one drop of the sample into the sample well as shown.



11. Close the cap with force until it stops to ensure reaction



12. Within 1-10 minutes, read the result window of the cassette. Follow the reading instructions below to identify whether your result is positive, negative or invalid. For positive results, consult a doctor.

POSITIVE (+)



Two lines in the result window:
The specimen contains a detectable level of blood.

NEGATIVE (-)



Only the C line appears:
The specimen does not contain a detectable level of blood.

INVALID



The test result is invalid. Review the procedure and repeat the test using a new cassette with the same specimen from collection tube.

Many conditions may cause blood in your stool. Contact your doctor right away.

How Does ColoTest® Work?

The test is a Driven Flow chromatic immunoassay. The device consists of one test strip in a plastic cassette. The test strip consists of:

- A conjugate pad treated with mouse anti-human hemoglobin antibodies conjugated with colloidal gold.
- A strip of nitrocellulose membrane with a Test line (T-line) and a Control line (C-line). The T-line is coated with anti-hHb antibodies, and the C-line is coated with goat anti-mouse IgG antibodies.

When an adequate volume of test specimen is dispensed into the sample well of the cassette, the test specimen migrates across the test strip. If the concentration of hHb in the specimen is at or above 50 ng/mL, the T-line visibly appears as a burgundy line. The intensity of the T-line may vary according to the concentration of the hHb in the sample. If the concentration of hHb in the sample is below 50 ng/mL, a T-line does not visibly appear. The C-line is coated with goat anti-mouse IgG antibody, which binds to the conjugated monoclonal antibody regardless of whether hHb is present in the sample. **Assay reading time is 1-10 minutes.**



ColoTest 1ct 4pc Display GTIN: 600-23513-13214-5 • ColoTest 1ct UPC: 0-23513-13214-3 • ColoTest 2ct UPC: 0-23513-13215-0

We often see patients gravitating to multiple count items to confirm their positive or negative results. We also love the idea of families monitoring their digestive health together. With this in mind, ColoTest® is available in both a 1ct and 2ct.

Where is ColoTest® Available?

ColoTest® can be ordered by the pharmacist through the following wholesalers:

