

COLORECTAL CANCER TEST COMPARISON

Colorectal Cancer is the third most commonly diagnosed cancer among men and women in the United States.¹ Current guidelines emphasize routine screening beginning at age 45.²

Screening is an important tool in earlier detection of colorectal and other cancers. A recent study shows that a multitarget stool DNA test is less effective and considerably more expensive screening modality when compared to other screening tests, such as FIT, making it a less efficient screening option.³

LabCorp's FIT test offers physicians a cost effective, easy to interpret, highly accurate option for colorectal cancer screening.

	iFOBT / FIT	Cologuard / FIT-DNA
Sensitivity	86% ⁴	92.3% ⁵
Specificity	94.9% ⁶	86.6% ⁵
False Positive Rate	3.6-5.1% ⁶	10.2-13.4% ⁶
Patient Cost/Coverage	Insurance coverage should have no out of pocket cost to patient. ^{7,8,9}	Insurance coverage varies by payor; list price \$649 ^{10,11}
Sample Requirements	1 sample-0.01g ¹²	2 samples (from one BM) approx. 300g. ¹² BM to be collected and placed into large bucket-like container AND in a sample collection bottle. ¹³
Patient Collection Process	12* activities ¹⁴	38* activities ¹³
DRE Collection	Yes ¹⁵	No ⁵
Storage/Stability	stable at room temp for 15 days or 30 days if refrigerated ¹⁵	lab must receive with in 72 hours ¹⁰
Result Type	Qualitative (neg-pos) ¹⁵	Qualitative (neg-pos) ¹⁶
Result Interpretation	Positive-detection of Hgb in stool-lower GI specific ¹⁷ Negative-no detection of Hgb in stool	Positive- detection of abnormal DNA and/or Hgb in stool Negative-did not detect abnormal DNA and/or Hgb in stool ¹⁶
Kit Distribution Process	Option 1: Inreach (mailer given to patient from physician in office or PSC) Option 2: Outreach (mailed to patient) Option 3: In office physician collected sample via DRE	Option 1: Physicians fills out and sends in a completed order to Exact Sciences and kit is mailed to patient ¹⁰
Kit Return Options	Option 1: Direct to lab via prepaid mailing envelope Option 2: Bring back to physician office Option 3: Bring to patient service center	Option 1: Samples returned via UPS ⁸
USMSTF ratings	Tier 1 ¹⁸	Tier 2 ¹⁸
USTFPPF Screening Frequency Recommendation	1 year ¹⁹	1-3 years ¹⁹

*Number of ways the patient has to engage with kit, materials, and specimen



iFOBT / FIT

“
Colonoscopy and FIT are recommended as the cornerstones of screening regardless of how screening is offered.¹⁸
”

“
At this time, the brand of FIT that has been most extensively tested and is available in the United States is OC FIT-CHEK® (OC-Auto) (Polymedco).²⁰
”

“
Among the FITs that are cleared by the US Food and Drug Administration (FDA) and available for use in the United States OC FIT-CHECK family of FITs (Polymedco)-which include the OC Light and the OC Auto-have the best test performance characteristics (i.e. high sensitivity and specificity).¹⁹
”

Cologuard / FIT-DNA

“
Screening with FIT-DNA is less specific than screening with FIT, resulting in more false-positive results per screening test.¹⁹
”

“
Because of the genetic component of these tests, there is some thought that utilization may lead to increased follow-up invasive testing in persons who may not be at risk.¹⁹
”

References

1. American Cancer Society. Colorectal Cancer Facts & Figures 2014-2016. Atlanta, Ga: American Cancer Society; 2014.
2. American Cancer Society Guideline for Colorectal Cancer Screening, <https://www.cancer.org/cancer/colon-rectal-cancer/detection-diagnosis-staging/acs-recommendations.html>. Accessed February 2, 2020.
3. Naber SK, Knudsen AB, Zauber AG, Rutter CM, Fischer SE, Pabiniak CJ, et al. (2019) Cost-effectiveness of a multitarget stool DNA test for colorectal cancer screening of Medicare beneficiaries. *PLoS ONE* 14(9): e0220234. <https://doi.org/10.1371/journal.pone.0220234>
4. Lee JK, Liles EG, Bent S, Levin TR, Corley DA. Accuracy of fecal immunochemical tests for colorectal cancer: systematic review and meta-analysis. *Ann Intern Med*. 2014;160(3):171. doi:10.7326/M13-1484
5. Summary of Safety and Effectiveness Data-Cologuard. https://www.accessdata.fda.gov/cdrh_docs/pdf13/P130017b.pdf. Accessed November 26th, 2019.
6. Imperiale, TF et al. Multitarget Stool DNA Testing for Colorectal-Cancer Screening. *N Engl J Med* 2014; 370:1287-1297.
7. Insurance Coverage for Colorectal Cancer Screening. American Cancer Society. <https://www.cancer.org/cancer/colon-rectal-cancer/detection-diagnosis-staging/screening-coverage-laws.html>. Accessed November 26th, 2019.
8. Preventative Care Benefits for Adults. *Healthcare.gov*. <https://www.healthcare.gov/preventive-care-adults/>. Accessed March 11th, 2020.
9. Preventive Services Covered by Private Health Plans under the Affordable Care Act. Kaiser Family Foundation. <https://www.kff.org/health-reform/fact-sheet/preventive-services-covered-by-private-health-plans/>. Accessed March 11th, 2020.
10. Frequently Asked Questions. *Cologuard*. <https://www.cologuardtest.com/faq>. Accessed November 26, 2019.
11. Insurance and Patient Support. *Cologuard*. <https://www.cologuardtest.com/insurance>. Accessed November 26th, 2019.
12. Colorectal Cancer Screening. https://www.rmlonline.com/site/sections/686?section_id=686. Accessed November 26th, 2019.
13. Cologuard Patient Guide. *Exact Sciences*. https://www.accessdata.fda.gov/cdrh_docs/pdf13/P130017c.pdf. Accessed November 26th, 2019.
14. 21001 LabCorp iFOBT patient Instructions
15. OC-Auto Micro iFOB Test package insert. PN-51357-09
16. Cologuard Physician Brochure. *Exact Sciences*. <https://cdn2.hubspot.net/hubfs/377740/LBL-0260%20Rev%202%20FINAL.pdf>. Accessed November 26th, 2019.
17. Occult Blood, Fecal, Immunoassay. LabCorp Test Menu. <https://www.labcorp.com/test-menu/32161/occult-blood-fecal-immunoassay>. Accessed November 26th, 2019.
18. Rex, DK et al. Colorectal Cancer Screening: Recommendations for Physicians and Patients from the U.S. Multi-Society Task Force on Colorectal Cancer *American Journal of Gastroenterology*. 112(7):1016-1030, JULY 2017
19. US Preventive Services Task Force. Screening for Colorectal Cancer: US Preventive Services Task Force Recommendation Statement. *JAMA*. 2016;315(23):2564-2575.
20. Wender, R. Screening for Colorectal Cancer: Optimizing Quality. https://www.cdc.gov/cancer/colorectal/quality/crc_screening_optimizing_quality_primary_care2.pdf. Accessed November 26th, 2019.



For more information, contact your Labcorp sales representative, or visit **Labcorp.com**.

