Clinical Statistics

Understanding How the Cologuard Plus™ Test Detects Colorectal Cancer

A **positive Cologuard Plus test** may indicate the presence of colorectal cancer (CRC) or advanced precancerous lesions (APLs) and **should be followed by a colonoscopy**.[1,*]

True positive result (sensitivity) describes how well a test can correctly identify people **with CRC or advanced colorectal precancer** when compared to colonoscopy as the reference method

True negative result (specificity) describes how well a test can correctly identify people **without CRC or advanced colorectal precancer** when compared to colonoscopy as the reference method

In 100 individuals with CRC

1 person icon represents 10 people

CRC sensitivity†:
95.3%
(95% CI, 88.4-98.7)

95.3% true positive test

~95 persons with CRC were identified

4.7% false negative test

~5 persons with CRC **were missed**

Category 3-6 specificity†
(no CRC or APLs):
90.7%
(95% CI, 90.3-91.1)‡

90.7% true negative test

~91 persons without CRC or advanced colorectal precancer were identified

9.3% false positive test

~9 persons were incorrectly identified as having CRC or advanced colorectal precancer

A **false positive** result occurs when the test produces a positive result even though a colonoscopy will not find CRC or APLs.

A **false negative** result occurs when the test does not detect an APL or CRC even when a colonoscopy identifies either of these findings.

True positive:
"I have CRC and the test accurately indicates it."

False positive:
"I don't have CRC but the test incorrectly indicates that I do."

True negative:
"I don't have CRC and the test accurately indicates that I am CRC-free."

False negative:
"I have CRC but the test incorrectly indicates that I don't have it."

Disclaimer: The Cologuard Plus test is intended to screen adults 45 and older at average risk for colorectal cancer. Rx only. This document is not for promotional use.

*Effective January 1, 2023, Medicare now covers a screening colonoscopy after a positive noninvasive stool test as a preventive service, with no out-of-pocket costs.[2,3]
†Based on a large clinical study (NCT04144738) on adults 45 years and older who are at average risk for CRC.
‡No colorectal neoplasia (Category 6) specificity: 92.7% (95% CI, 92.2-93.2).
APL: advanced precancerous lesion; **CI:** confidence interval; **CRC:** colorectal cancer.

1. Cologuard Plus Clinician Brochure. Exact Sciences Corporation. Madison, WI. 2. CMS. HHS finalizes physician payment rule strengthening access to behavioral health services and whole-person care. Accessed March 5, 2025. https://www.cms.gov/newsroom/press-releases/hhs-finalizes-physician-payment-rule-strengthening-access-behavioral-health-services-and-whole 3. CMS. Colorectal cancer screening tests. Accessed March 5, 2025. https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=281&ncdver=7&keyword-type=starts&keyword=colorectal&bc=0

Learn more about colorectal cancer, colorectal cancer screening, and the Cologuard Plus test at Exact Academy.

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