

Patient: Patient, Sample
Date of Birth: MM/DD/YYYY
Medical Record #: 000000
Sex: Female

Report Date: MM/DD/YYYY
Client Order ID: 000000

COLOGUARD (Final result)

ID:	00C000-000000	Order ID:	000000
Collected:	MM/DD/YYYY HH:MM	Authorized by:	Sample Physician, MD
Received:	MM/DD/YYYY HH:MM	Type:	Stool
Resulting Lab:	CLIA 52D2162828	Source:	Per Rectum

Test Result	Value	Normal Value
	Positive (A)	Negative

The Cologuard Plus (TM) test was performed on this specimen.

POSITIVE TEST RESULT. A positive (abnormal) Cologuard Plus result means the patient has a higher-than-average chance of having colorectal cancer (CRC) or precancer (polyps or lesions that could become cancer). The normal value (reference range) for this assay is negative.

A positive result should be followed by a colonoscopy to locate and confirm the presence of cancer or precancer. A positive Cologuard Plus result is not a cancer diagnosis. The federal government now considers the colonoscopy following a positive Cologuard Plus test result a covered preventive service. Call 1-844-870-8870 for more information.

A clinical validation study measured the effectiveness of the Cologuard Plus test. Out of 100 patients testing positive: approximately 3 patients will have CRC; 34 patients will have advanced precancer; 33 will have a non-advanced precancer; and 30 will have no cancer or precancer.

TEST DESCRIPTION: The Cologuard Plus test is a multi-target stool DNA (mt-sDNA) test that analyzes DNA and hemoglobin biomarkers in stool. It uses a proprietary algorithm to qualitatively detect CRC and advanced precancer. It is FDA-approved and indicated for use in adults 45 years or older at average risk for CRC.

A positive (abnormal) result should be followed by a colonoscopy. Patients with a negative (normal) result should screen again in 3 years. False positive and false negative results may occur. The USPSTF recommends the Cologuard test as a CRC screening option. Their modeling estimates that screening with the test every 3 years from ages 45-85 could prevent up to 73% of CRC and avoid up to 85% of CRC deaths.

A 18,911-patient clinical trial found the Cologuard Plus test effectively detects CRC and precancer. The study found the test was 95% sensitive for CRC, 43% sensitive for advanced precancer, and had a 91% specificity (Cologuard Plus Clinician Brochure. Exact Sciences Corporation. Madison, WI.). Visit <https://www.exactsciences.com/references/cologuard-plus> for more test information, references, warnings, and precautions.

Legend

A - Abnormal

Resulting Labs

CLIA 52D2162828

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