

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		
				Value	Normal Value
Test Result				Negative	Negative

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

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

Guidelines recommend screening again 3 years after a negative Cologuard Plus result. Continued screening increases the chance of finding CRC early or preventing it entirely.

A clinical validation study showed the Cologuard Plus test is effective at ruling out CRC. Out of every 10,000 patients testing negative, approximately 2 will be falsely reassured that they do not have CRC, and out of every 100 patients testing negative, approximately 7 patients will be falsely reassured they do not have advanced 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.

Resulting Labs

CLIA 52D2162828	EXACT SCIENCES LABORATORIES (CLIA #:52D2162828), 650 Forward Dr., MADISON WI 53711 Director: Rajarao Kakuturu V, PhD	844-870-8870
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