

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 (TM) test was performed on this specimen.

NEGATIVE TEST RESULT. A negative Cologuard result indicates a low likelihood that a colorectal cancer (CRC) or advanced adenoma (adenomatous polyps with more advanced pre-malignant features) is present. The chance that a person with a negative Cologuard test has a colorectal cancer is less than 1 in 1500 (negative predictive value >99.9%) or has an advanced adenoma is less than 5.3% (negative predictive value 94.7%). These data are based on a prospective cross-sectional study of 10,000 individuals at average risk for colorectal cancer who were screened with both Cologuard and colonoscopy. (Imperiale T. et al, N Engl J Med 2014;370(14):1286-1297) The normal value (reference range) for this assay is negative.

COLOGUARD RE-SCREENING RECOMMENDATION: Periodic colorectal cancer screening is an important part of preventive healthcare for asymptomatic individuals at average risk for colorectal cancer. Following a negative Cologuard result, the American Cancer Society and U.S. Multi-Society Task Force screening guidelines recommend a Cologuard re-screening interval of 3 years.

References: American Cancer Society Guideline for Colorectal Cancer Screening: <https://www.cancer.org/cancer/colon-rectal-cancer/detection-diagnosis-staging/acs-recommendations.html>; Rex DK, Boland CR, Dominitz JK, Colorectal Cancer Screening: Recommendations for Physicians and Patients from the U.S. Multi-Society Task Force on Colorectal Cancer Screening, Am J Gastroenterology 2017; 112:1016-1030.

TEST DESCRIPTION: Composite algorithmic analysis of stool DNA-biomarkers with hemoglobin immunoassay. Quantitative values of individual biomarkers are not reportable and are not associated with individual biomarker result reference ranges. Cologuard is intended for colorectal cancer screening of adults of either sex, 45 years or older, who are at average-risk for colorectal cancer (CRC). Cologuard has been approved for use by the U.S. FDA. The performance of Cologuard was established in a cross sectional study of average-risk adults aged 50-84. Cologuard performance in patients ages 45 to 49 years was estimated by sub-group analysis of near-age groups. Colonoscopies performed for a positive result may find as the most clinically significant lesion: colorectal cancer [4.0%], advanced adenoma (including sessile serrated polyps greater than or equal to 1cm diameter) [20%] or non- advanced adenoma [31%]; or no colorectal neoplasia [45%]. These estimates are derived from a prospective cross-sectional screening study of 10,000 individuals at average risk for colorectal cancer who were screened with both Cologuard and colonoscopy. (Imperiale T. et al, N Engl J Med 2014;370(14):1286-1297.) Cologuard may produce a false negative or false positive result (no colorectal cancer or precancerous polyp present at colonoscopy follow up). A negative Cologuard test result does not guarantee the absence of CRC or advanced adenoma (pre-cancer). The current Cologuard screening interval is every 3 years. (American Cancer Society and U.S. Multi-Society Task Force). Cologuard performance data in a 10,000 patient pivotal study using colonoscopy as the reference method can be

Value **Normal Value**

accessed at the following location: www.exactlabs.com/results. Additional description of the Cologuard test process, warnings and precautions can be found at www.cologuard.com.

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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