EXACT SCIENCES LABORATORIES

EXACT SCIENCES LABORATORIES, LLC
145 E. Badger Rd, STE 100, Madison, WI 53713

Patient: Result, Testing
Date of Birth: 1/2/1969
Medical Record #: 12345
Sex: Female

Report Date: 1/2/2024
Client Order ID: 54321

COLOGUARD (Final result)

ID:	24C002-000006	Order ID:	37192
Collected:	1/2/2024 1250	Authorized by:	David M Deci, MD
Received:	1/2/2024 1250	Type:	Stool
Resulting Lab:	CLIA 52D2162828	Source:	Per Rectum

	Value	Normal Value
Test Result	Negative	Negative

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 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

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