EXACT SCIENCES LABORATORIES
145 E. Badger Rd, STE 100, Madison, WI 53713
PH: 844-870-8870 | ExactLabs.com

To:

Test, Reporttwo

From:

Exact Sciences Laboratories

Fax #: 844-870-8875

Sent: 3/3/2020 at: 1:28 PM

Subject: **Cologuard Results: Order #1070062**

If you have any questions about this communication, please call our Customer Care Center at 1-844-870-8870. Our specialists are available 24 hours a day, seven days a week.

Thank you,

Exact Sciences Laboratories

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Cologuard® PATIENT REPORT

ORDER INFORMATION

Patient: Test, Reporttwo
Date of Birth: 10/9/1954
Medical Record #: 123456789
Sex: Male
Authorizing Provider: OSCOPY, COLIN

Client Order ID: 987654321
Cologuard Specimen ID: 20C063-000018
Specimen Collected: 3/2/2020
Specimen Received: 3/3/2020
Report Date: 3/3/2020

RESULT:
Negative

A negative result indicates a low likelihood that a colorectal cancer (CRC) or an 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 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) The normal value (reference range) for this assay is negative.

COLOGUARD RE-SCREENING RECOMMENDATION: Periodic routine colorectal cancer screening is an important part of preventive healthcare for asymptomatic persons 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 (ACS). Colorectal cancer prevention and early detection. Atlanta, GA: American Cancer Society; [updated 2016 Apr 24]. https://www.cancer.org/cancer/colon-rectal-cancer/detection-diagnosis-staging/acs-recommendations.html.
Accessed August 31, 2018; 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.

COLOGUARD DESCRIPTIVE INFORMATION

TEST TYPE: 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.

Reference Range: <Not Applicable> **Specimen Type:** Stool
PRECAUTIONS AND LIMITATIONS: 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. Cologuard may produce a false negative or false positive result. A negative Cologuard test result does not guarantee the absence of CRC or advanced adenoma (pre-cancer). Patients with a negative Cologuard test result should be advised to continue participating in a colorectal cancer screening program. The screening interval for Cologuard is currently recommended at an interval of every 3 years by the American Cancer Society and U.S. Multi-Society Task Force. A false positive result occurs when Cologuard produces a positive result, even though a colonoscopy may not find colorectal cancer or precancerous polyps. The performance of Cologuard has been established in a cross sectional study (i.e., single point in time) 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. 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.cologuardtest.com. Rx only.

Resulting Labs

EXACT SCIENCES LABORATORIES (CLIA #:52D2072838), 844-870-8870
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Director: LAFFIN, JENNIFER