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

To:

Test, Reportone

From:

Exact Sciences Laboratories

Fax #: 844-870-8875

Sent: 3/3/2020 at: 1:45 PM

Subject: **Cologuard Results: Order #1070071**

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

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

Cologuard® PATIENT REPORT

ORDER INFORMATION

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

Client Order ID: 987654321
Cologuard Specimen ID: 20C063-000028
Specimen Collected: 3/2/2020
Specimen Received: 3/3/2020
Report Date: 3/3/2020

RESULT:

Positive

It is recommended that a positive Cologuard screen be clinically correlated and followed-up with a structural examination of the colon such as diagnostic colonoscopy. Colonoscopies performed for a positive Cologuard 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. (Table 3, Imperiale T. et al, N Engl J Med 2014;370(14):1286-1297.) The normal value (reference range) for this assay is negative.

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
145 E. Badger Rd., MADISON WI 53713
Director: LAFFIN, JENNIFER