



Exact Sciences Laboratories, LLC | 145 East Badger Road, Suite 100 | Madison, WI 53713 USA
 Phone: 1-844-870-8879 | www.exactlabs.com

Test Name and Information

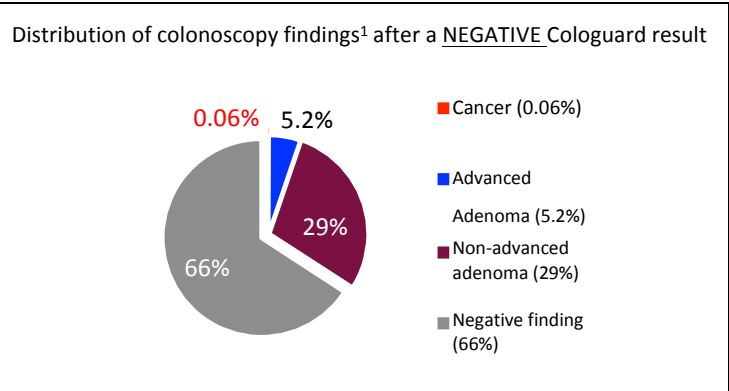
Name: Cologuard® colorectal cancer screening test

Description: Stool DNA-based test with hemoglobin immunoassay component, composite algorithmic analysis

Understanding Test Results¹

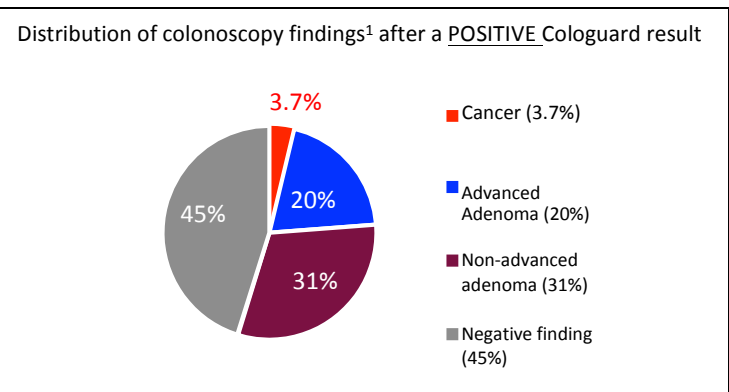
Negative

A negative result indicates a lower likelihood that colorectal cancer (CRC) or advanced adenoma (pre-cancer) is present. Periodic colorectal cancer screening is recommended in the future, at an interval, and with a method, appropriate for the patient.*



Positive

A positive result can indicate the presence of colorectal cancer (CRC) or advanced adenoma (pre-cancer). Correlate clinically and strongly consider a follow-up investigation with a structural examination of the colon such as with diagnostic colonoscopy.*



Cologuard Descriptive Information¹

Cancer Sensitivity		
Overall (Stage I-IV)	92%	(83% - 96%)
Screening relevant (Stage I-III)	93%	(84% - 98%)
Advanced Adenoma (Pre-cancer) Sensitivity		
Overall	42%	(39% - 46%)
High Grade Dysplasia	69%	(52% - 83%)
Specificity[^]	87%	(86% - 87%)
^Includes non-advanced adenomas and negative findings as true negatives and excludes colorectal cancer and advanced adenomas as true positives.		

¹Cologuard performance using colonoscopy as the reference method was evaluated in a pivotal prospective, 10,000 patient, cross-sectional, colorectal cancer screening study (Imperiale TF et al. *N Engl J Med* 2014; 370:1287-1297).



Additional Information

***Precautions and Limitations:** Cologuard may produce a false negative or false positive result. A negative Cologuard test result does not guarantee the absence of colorectal cancer 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 this follow-up has not been established. 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). Programmatic performance of Cologuard (i.e., benefits and risks with repeated testing over an established period of time) has not been studied. Performance has not been evaluated in adults who have been previously tested with Cologuard. Cologuard is intended for colorectal cancer screening of adults of either sex, 50 years or older, who are at typical average-risk for CRC. Cologuard test performance in patients less than 50 years of age has not been established. Cologuard has been approved for use by the U.S. FDA. Additional description of the Cologuard test process, warnings and precautions can be found at www.cologuardtest.com. Rx only.