

# Understanding Cologuard® Screening Results



**A positive test result** does not necessarily mean the patient has colorectal cancer. It means that Cologuard detected altered DNA and/or hemoglobin in the patient's stool. Patients with a positive result should have a follow-up colonoscopy.<sup>1</sup>



**A negative test result** means that Cologuard did not detect altered DNA and/or hemoglobin in the stool.<sup>1</sup> Patients with a negative result should continue in an appropriate screening program. The American Cancer Society-recommended screening interval for Cologuard is every 3 years after a negative result.<sup>2</sup>



**Sample Could Not Be Processed (SCNBP)** means that the sample received by the lab could not be processed for reasons such as required labeling information was missing, buffer addition could not be verified, stool sample exceeds allowable weight, collection kit was damaged, or an empty kit was received. For these, the patient will be contacted by Exact Sciences Laboratories and a fax sent to the provider.



**No Result Obtained (NRO)** means that a valid Cologuard result was not obtained for reasons such as insufficient DNA volume, fecal hemoglobin sample did not produce a valid result, technical issues, etc. For these, the patient will be contacted by Exact Sciences Laboratories and a fax sent to the provider.

**Reminder:** Results are delivered directly to the ordering provider so that you can communicate the results to your patients. Results are provided directly to patients only upon special request.

## Indications and Important Risk Information

Cologuard is intended for the qualitative detection of colorectal neoplasia associated DNA markers and for the presence of occult hemoglobin in human stool. A positive result may indicate the presence of colorectal cancer (CRC) or advanced adenoma (AA) and should be followed by diagnostic colonoscopy. Cologuard is indicated to screen adults of either sex, 45 years or older, who are at typical average risk for CRC. Cologuard is not a replacement for diagnostic colonoscopy or surveillance colonoscopy in high-risk individuals.

Cologuard is not for high-risk individuals, including patients with a personal history of colorectal cancer and adenomas; have had a positive result from another colorectal cancer screening method within the last 6 months; have been diagnosed with a condition associated with high risk for colorectal cancer such as IBD, chronic ulcerative colitis, Crohn's disease; or have a family history of colorectal cancer, or certain hereditary syndromes.

Positive Cologuard results should be referred to diagnostic colonoscopy. A negative Cologuard test result does not guarantee absence of cancer or advanced adenoma. Following a negative result, patients should continue participating in a screening program at an interval and with a method appropriate for the individual patient.

False positives and false negatives do occur. In a clinical study, 13% of patients without cancer received a positive result (false positive) and 8% of patients with cancer received a negative result (false negative). The clinical validation study was conducted in patients 50 years of age and older. Cologuard performance in patients ages 45 to 49 years was estimated by sub-group analysis of near-age groups.

Cologuard performance when used for repeat testing has not been evaluated or established. Rx only.

**REFERENCES:** 1. Cologuard Physician Brochure. Madison, WI: Exact Sciences Corporation. 2. Wolf AMD, Fonham ETH, Church TR, et al. Colorectal cancer screening for average-risk adults: 2018 guideline update from the American Cancer Society. *CA Cancer J Clin.* 2018;68(4):250-281.