

Patient: Patient, Sample
Date of Birth: MMDD/YYYY
Medical Record#: 000000
Sex: Male

Report Date: MM/DD/YYYY
Client Order ID: 000000

Cancerguard (Final result)

ID:	00X000-000000	Order ID:	000000
Collected:	MMDD/YYYY HH:MM	Authorized by:	Sample Physician, MD
Received:	MMDD/YYYY HH:MM	Type:	Blood
Resulting Lab:	CUA 52D2162828	Source:	Blood, Venous
			Normal Value
			Value

CANCERGUARD INTERPRETATION

Negative

Negative

NEGATIVE TEST RESULT (NO CANCER SIGNAL DETECTED): A negative Cancerguard result means that the blood test did not identify a cancer signal. The patient should continue with recommended cancer screening procedures as directed by their healthcare provider.

For additional education, information, and frequently asked questions for patients, please visit:
<https://exactsciences.com/cancerguardneginfo>

TEST DESCRIPTION: The Cancerguard test is a multi-biomarker assay that combines detection of methylated DNA and protein biomarkers in blood. Data from both assays are processed by an algorithm to generate a positive (cancer signal detected) or negative result (cancer signal not detected).

A test development study for the Cancerguard test including 590 participants with one of 19 cancer types (excluding breast and prostate cancer) and 2,434 participants with no cancer revealed a sensitivity of 64.1% (95% CI: 60.1%, 67.8%) with an overall specificity of 97.4% (95% CI: 96.7%, 97.9%). In this development study, individual cancer type sensitivities ranged from 23.1% to 80.0% for cancer types that had at least 10 cases. An independent, case control clinical validation study that included samples from 223 participants with one of 17 cancer types (excluding breast and prostate cancer) and 800 participants with no cancer revealed an overall sensitivity of 55.6% (95% CI: 49.0%, 62.0%) with an overall specificity of 97.4% (95% CI: 96.0%, 98.3%). In the clinical validation study, individual cancer type sensitivities ranged from 16.7% to 91.7% for cancer types that had at least 10 cases. (Cancerguard Test Information for Healthcare Providers July 2025, Exact Sciences, Madison WI).

All data presented here was generated from case-control studies of patients who were already known to have cancer or to be healthy (no active cancer or suspicion of cancer). These performance characteristics may not accurately reflect the test performance in a clinical setting.

For more details about the Cancerguard test, including additional performance data, visit:
<https://exactsciences.com/cancerguardtestinfo>

DISCLAIMER: The Cancerguard test was developed, and the performance characteristics validated by Exact Sciences Laboratories following College of American Pathologists (CAP) and Clinical Laboratory Improvement Amendments (CLIA) regulations. This test has not been cleared or approved by the US Food and Drug Administration. The test is performed at Exact Sciences Laboratories. Exact Sciences Laboratories is accredited by CAP, certified under CLIA regulations, and qualified to perform high-complexity clinical laboratory testing.

The Cancerguard test is intended for use in adults ages 50-84 with no known cancer diagnosis in the last three years. It

Value	Normal Value
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detects alterations in circulating tumor DNA and tumor-associated protein levels that are commonly associated with cancer. The test does not detect all cancers and is not a replacement for existing recommended cancer screening or diagnostic modalities for cancer. The test is not indicated for screening breast and prostate cancer. The test was not evaluated for the detection of pre-cancerous lesions.

Results should be interpreted in the context of a patient's medical history, clinical signs, and symptoms. Results of the Cancerguard test should be interpreted in the context of a patient's medical history, clinical signs, and symptoms. A negative result does not rule out the presence of cancer of any type. A positive result alone does not confirm the presence of any cancer. False positive and false negative test results can occur. Albumin concentration of ≥ 6 g/dl may interfere with detection of methylated DNA strands which can result in a false negative.

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Classifier semantic version: CEX-Classifier-1.0.0

Resulting Labs

CLIA 52D2162828	EXACT SCIENCES LABORATORIES (CUA #52D2162828), 650 Forward Dr., MADISON WI 53711 Director: Rajarao Kakuturu V, PhD	844-870-8870
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