

Patient: Patient Name	Date of Birth: Jul 28, 1949	MRN (if provided): MR-12354	Date Reported: Oct 08, 2025
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NODIFY CDT[®] TEST RESULT AND INTERPRETATION

HIGH LEVEL

Patients with a **High Level Nodify CDT test result (78% PPV, 98% specificity, 28% sensitivity)¹** have a higher risk of malignancy than predicted by clinical factors alone. This result does not definitively mean that the patient has lung cancer.

POST-NODIFY CDT RISK OF MALIGNANCY



The post-Nodify CDT risk of malignancy was calculated based on the performance of the Nodify CDT test result in the clinical validation study.^{1,2} See the Nodify CDT Test Result and Interpretation for additional information about this result.

Risk categories are according to the American College of Chest Physicians (ACCP) guidelines for lung nodules. These guidelines suggest patients with a new, solid, indeterminate nodule that measures >8 mm in diameter receive surgical diagnosis when the clinical probability of malignancy is high (>65%).³

PRE-TEST CLINICAL INFORMATION

Pre-test Risk of Malignancy per Solitary Pulmonary Nodule Calculator⁴ (Mayo Clinic Model) 13%	Nodule Size (mm): 9.0 Age (years): 76	Spiculation: No Smoking History: Never	Nodule Location: Upper History of Cancer: No History of Cancer
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PATIENT INFORMATION
 PHYSICIAN INFORMATION

Patient: Patient Name	MRN (if provided): MR-12354	Physician: Dr. Nod Jules
Date of Birth: Jul 28, 1949	Gender: Male	Facility: Lung Health Associates
Specimen Type: Whole Blood	Date of Collection: Oct 06, 2025	Address: 1234 Lungston Lane, Biop City, CO, 80001
Nodify CDT Accession No: CDTN2510070004	Date Received: Oct 07, 2025	Country: United States
Date Performed: Oct 07, 2025	Date Reported: Oct 08, 2025	Phone: (555) 555-5555
		Fax: (555) 555-5555

NODIFY CDT ANALYSIS DESCRIPTION

The Nodify CDT test is a blood-based lung nodule test designed to help identify low to moderate risk patients with a nodule that is likely malignant. The test utilizes a proprietary multi-analyte immunoassay technology to measure blood levels of a panel of seven autoantibodies to tumor-associated antigens that have been shown to be elevated for all types of lung cancer and from the earliest stage of the disease.^{2,5} The measurements of these seven autoantibodies are incorporated into an algorithm that generates a test result.

The Nodify CDT test is intended for patients at least 40 years of age with a lung nodule between 8 and 30mm, no history of cancer (except basal cell carcinoma) and a pre-test risk of malignancy of 65% or less calculated using the solitary pulmonary nodule malignancy risk calculator.⁴ The risk calculator is not validated for patients with a prior lung cancer diagnosis or with a history of extrathoracic cancer diagnosed within 5 years of nodule presentation. Nodify CDT positive predictive value was estimated based on a 20% prevalence of lung cancer.^{1, 4, 6, 7, 8, 9}

REFERENCES:

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Nodify CDT was developed and its performance characteristics determined by Biodesix, Inc. It has not been cleared or approved by the US Food and Drug Administration. The FDA does not require this test to go through premarket FDA review. This test is used for clinical purposes, it should not be regarded as investigational or for research. This laboratory is certified under the Clinical Laboratory Improvement Amendments (CLIA) as qualified to perform high complexity clinical laboratory testing.

By accepting receipt of the Nodify CDT Test Result Report or any content derived from it ("Nodify CDT TRR"), the ordering physician, institution of ordering physician, or any third parties to whom the Nodify CDT TRR is transferred, agree the Nodify CDT TRR may only be used to aid in the clinical management of the patient identified in the Nodify CDT TRR by the physician. Any other use of the Nodify CDT TRR including, without limitation, correlative studies, diagnostic development, derivative works or other analyses is expressly prohibited. The results of any unauthorized use of the Nodify CDT TRR shall belong solely and exclusively to Biodesix, Inc. Additional terms and conditions related to this Nodify CDT TRR can be found at www.biodesix.com.