Phone: **1.866.432.5930** | Fax: **1.866.432.3338**
Email: **CustomerSupport@biodesix.com**

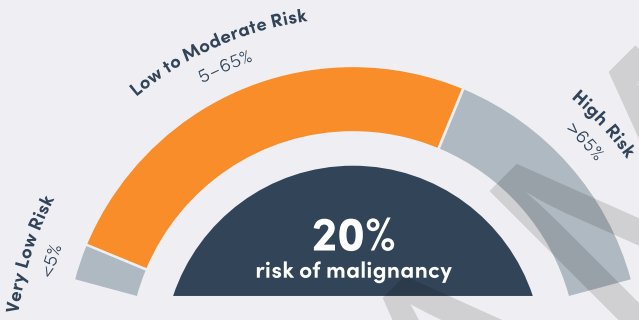
nodify cdt PROTEOMIC TEST

Test Result Report

PATIENT INFORMATION		PHYSICIAN INFORMATION	
Patient: <First and LastName>	**MRN** (if provided)**:** <########>	**Physician:** Dr. <First and LastName>	
Date of Birth: <Mon DD, YYYY>	**Gender:** <Gender>	**Facility:** <Ordering Facility Name>	
Specimen Type: <Sample Format>		**Address:** <Street Address, City, State, Postal Code>	
Nodify CDT Accession No: CDTNYYMMDD####	**Date of Collection:** <Mon DD, YYYY>	**Country:** <Country Code>	
Date Received: <Mon DD, YYYY>	**Date Performed | Reported:** <Mon DD, YYYY>	**Phone:** <Phone Number>	**Fax:** <Fax Number>

PRE-TEST INFORMATION

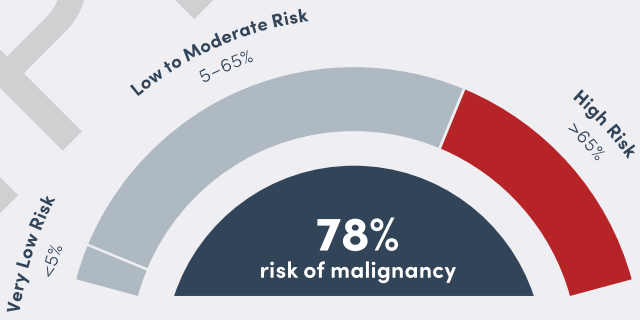
SOLITARY PULMONARY NODULE CALCULATOR[1]
PRE-TEST RISK OF MALIGNANCY



Nodule Size (mm): 10	Nodule Location: Upper
Spiculation: No	Smoking History: Current/Former
Age (years): 67	History of Cancer: No History of Cancer

TEST RESULT

HIGH LEVEL
POST-NODIFY CDT RISK OF MALIGNANCY



INTERPRETATION OF RESULTS

Patients with a High Level Nodify CDT® test result have a higher risk of malignancy than predicted by clinical factors alone. This result does not definitively mean that the patient has lung cancer.

The post-Nodify CDT risk of malignancy was calculated based on the performance of the High Level Nodify CDT test result in the clinical validation study.[2]

See the highlighted row in the Nodify CDT Test Performance Overview for additional information about this result.

Risk categories are according to the American College of Chest Physicians (ACCP) guidelines for incidental lung nodules[3].

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PROTEOMIC TEST

Test Result Report

NODIFY CDT TEST PERFORMANCE OVERVIEW[2]

Test Report	Positive Predictive Value (PPV)	Specificity	Sensitivity
High Level	78%	98%	28%
Moderate Level	59%	93%	41%
No Significant Level of Autoantibodies Detected	–	–	–

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 an incidental lung 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.[4,5] The measurement 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 an incidental 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 calculator.[1] Nodify CDT test performance was calculated based on a 20% prevalence of cancer expected in a nodule cohort.[2]

REFERENCES:

1. Swensen SJ, Silverstein MD, Ilstrup DM, et al. The probability of malignancy in solitary pulmonary nodules. Application of small radiologically indeterminate nodules. *Archives of Internal Medicine*. 1997; 157(8): 849-55.

2. Healey G, Macdonald I, Murray A, et al. Tumor-Associated Autoantibodies: Re-Optimization of EarlyCDT-Lung Diagnostic Performance and Its Application to Indeterminate Pulmonary Nodules." *Journal of Cancer Therapy*. 2017; 8(5): 506-517.

3. Gould M, et al. Evaluation of Individuals with Pulmonary Nodules: When is it Lung Cancer? *CHEST*. 2013; 143(5): e93S-e120S.

4. Jett J, Healey G, Macdonald I, et al. Determination of the detection lead time for autoantibody biomarkers in early stage lung cancer using the UKCTOCS cohort. *Journal of Thoracic Oncology*. 2017; 12(11): S2170.

5. Chapman C, Healey G, Murray A, et al. EarlyCDT—Lung test: improved clinical utility through additional autoantibody assays. *Tumor Biology*. 2012; 33(5):1319–1326.

Patient:
<First and LastName>

Nodify CDT Accession No:
CDTNYYMMDD####

Date Performed | Reported:
<Mon DD, YYYY>

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