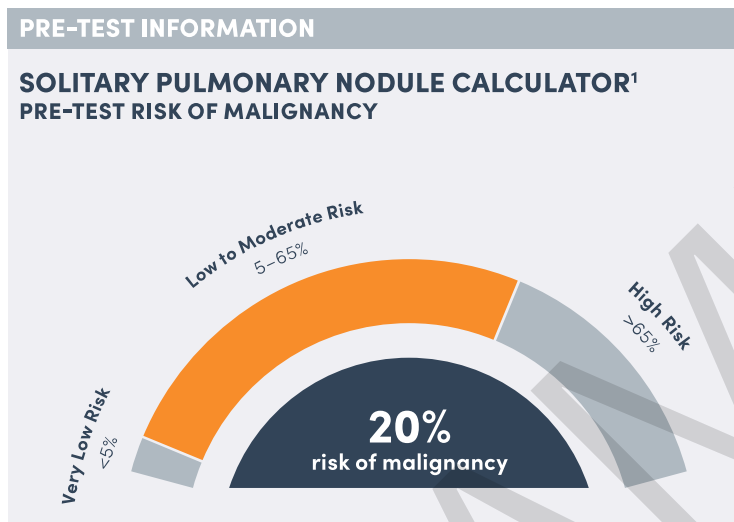
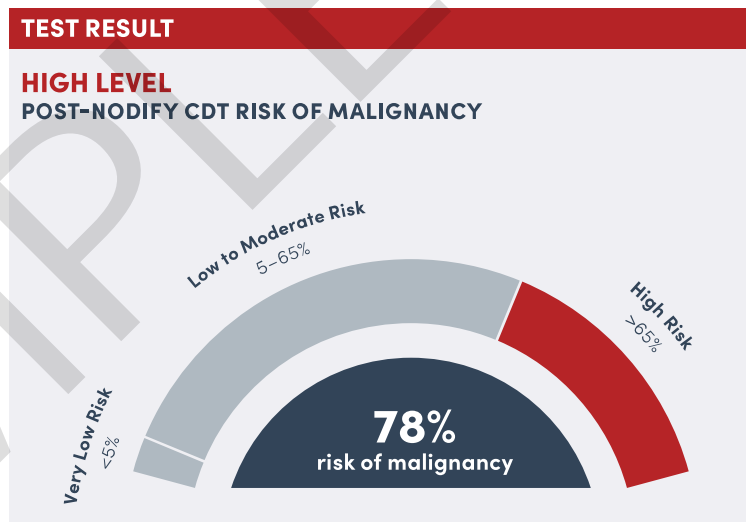


Test Result Report

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: CDTNYMMDD####	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>



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



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 nodules³.



Donald Joe Chaffin, M.D.
CAP Accredited CLIA Laboratory Director

Patient: <First and LastName>	Nodify CDT Accession No: CDTNYMMDD####	Date Performed Reported: <Mon DD, YYYY>
---	--	---

biodesix.com

8960 Commerce Drive, Building 6. De Soto, KS 66018

CLIA Number 17D1089651

©2021 Biodesix, Inc. All rights reserved. DOC-003653 v5.0

Test Result Report

NODIFY CDT TEST PERFORMANCE OVERVIEW²

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.

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.

Patient:
<First and LastName>

Nodify CDT Accession No:
CDTNYYMMDD####

Date Performed | Reported:
<Mon DD, YYYY>