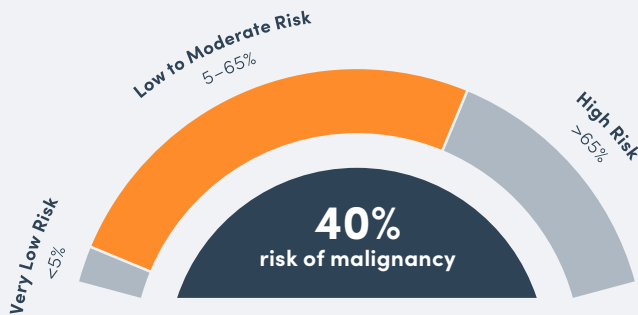


Test Result Report

PATIENT INFORMATION		PHYSICIAN INFORMATION	
Patient: <First and LastName>		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 XL2 Accession No: XL2YYMMDD####	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

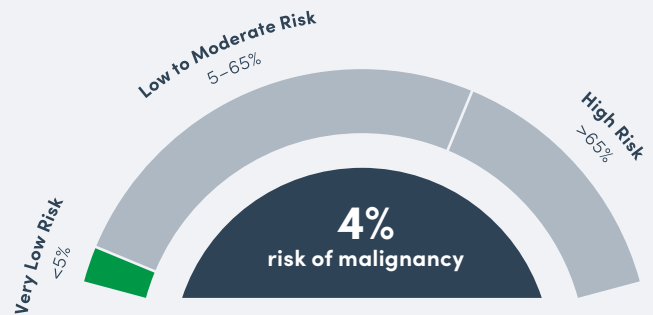
SOLITARY PULMONARY NODULE CALCULATOR¹ PRE-TEST RISK OF MALIGNANCY



Nodule Size (mm): 14	Nodule Location: Upper
Spiculation: Yes	Smoking History: Current/Former
Age (years): 52	History of Cancer: No History of Cancer

TEST RESULT

LIKELY BENIGN POST-NODIFY XL2 RISK OF MALIGNANCY



INTERPRETATION OF RESULTS

Patients with a Likely Benign Nodify XL2™ test result have a high probability of having a benign nodule. This result does not definitively mean that the patient does not have lung cancer.

The post-Nodify XL2 risk of malignancy was calculated based on the performance of the 98% NPV Likely Benign Nodify XL2 test result in the PANOPTIC clinical validation study.²

See the highlighted row in the Nodify XL2 Test Performance Overview for additional information about this test result.

Risk categories are according to the American College of Chest Physicians (ACCP) guidelines for incidental lung nodules³.

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

Patient: <First and LastName>	Nodify XL2 Accession No: XL2YYMMDD####	Date Performed Reported: <Mon DD, YYYY>
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Test Result Report

NODIFY XL2 TEST PERFORMANCE OVERVIEW²

Test Report	Negative Predictive Value (NPV) (95% CI)	Sensitivity (95% CI)	Specificity (95% CI)
Likely Benign	98% (92% - 100%)	97% (82% - 100%)	44% (36% - 52%)
Reduced Risk	97% (91% - 100%)	93% (77% - 99%)	49% (41% - 57%)
Reduced Risk	96% (90% - 99%)	90% (73% - 98%)	54% (45% - 62%)
Reduced Risk	95% (89% - 99%)	86% (68% - 96%)	55% (47% - 63%)
Reduced Risk	94% (87% - 98%)	83% (64% - 94%)	56% (47% - 64%)
Reduced Risk	93% (86% - 98%)	79% (60% - 92%)	57% (44% - 65%)
Reduced Risk	92% (85% - 96%)	76% (56% - 90%)	58% (49% - 66%)
Reduced Risk	91% (84% - 96%)	69% (49% - 85%)	64% (56% - 72%)
Reduced Risk	90% (84% - 95%)	55% (36% - 74%)	83% (75% - 88%)
Indeterminate	<90%	-	-

NODIFY XL2 ANALYSIS DESCRIPTION

The Nodify XL2 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 benign. The test integrates two circulating proteins measured by mass spectrometry with clinical risk factors associated with lung cancer into a proprietary algorithm that generates a test result.

The Nodify XL2 test is intended for patients at least 40 years of age with an incidental lung nodule between 8 and 30mm and a pre-test risk of malignancy of 50% or less calculated using the solitary pulmonary nodule calculator¹. Nodify XL2 was developed and clinically validated in a population with a prevalence of cancer of 16%^{2,4}. The Nodify XL2 test has not been evaluated outside of this population.

REFERENCES:

- 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.
 - Silvestri G, Tanner N, Kearney P, et al. Assessment of plasma proteomics biomarkers ability to distinguish benign from malignant lung nodules. *CHEST*. 2018; 154(3): 491-500.
 - Gould M, Donington J, Lynch W, et al. Evaluation of Individuals with Pulmonary Nodules: When is it Lung Cancer? *CHEST*. 2013; 143(5): e93S-e120S.
 - Kearney P, Hunsucker S, Li X, et al. An integrated risk predictor for pulmonary nodules. *PLoS One*. 2017; 12(5): e0177635.
- Nodify XL2 was developed and its performance characteristics were determined by Biodesix, Inc. The laboratory meets the requirements for high complexity tests under the Clinical Laboratory Improvement Amendments of 1988, as amended, and its implementing regulations.
- By accepting receipt of the Nodify XL2 Test Result Report or any content derived from it ("Nodify XL2 TRR"), the ordering physician, institution of ordering physician, or any third parties to whom the Nodify XL2 TRR is transferred, agree the Nodify XL2 TRR may only be used for the clinical management of the patient identified in the Nodify XL2 TRR by the physician. Any other use of the Nodify XL2 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 XL2 TRR shall belong solely and exclusively to Biodesix, Inc. Additional terms and conditions related to this Nodify XL2 TRR can be found at www.biodesix.com.

Patient:
<First and LastName>

Nodify XL2 Accession No:
XL2YYMMDD####

Date Performed | Reported:
<Mon DD, YYYY>