

<b>Patient:</b> Patient Name	<b>Date of Birth:</b> Aug 29, 1958	<b>MRN (if provided):</b> MRN-54321	<b>Date Reported:</b> Oct 13, 2025
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**NODIFY XL2<sup>®</sup> TEST RESULT AND INTERPRETATION**

**LIKELY BENIGN**

Patients with a **98% NPV Likely Benign Nodify XL2 test result (97% sensitivity, 44% specificity)<sup>1</sup>** have a high probability of having a benign nodule. This result does not definitively mean that the patient does not have lung cancer.

**POST-NODIFY XL2 RISK OF MALIGNANCY**



Post-Nodify XL2 risk of malignancy is calculated using a logistic regression model to convert the output of the test algorithm into a probability based on observed prevalence of lung cancer in multiple clinical studies.

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 surveillance with serial CT scans when the clinical probability of malignancy is very low (<5%).<sup>2</sup>

**PRE-TEST CLINICAL INFORMATION**

<b>Pre-test Risk of Malignancy per Solitary Pulmonary Nodule Calculator<sup>3</sup></b> (Mayo Clinic Model) 42%	<b>Nodule Size (mm):</b> 10.0  <b>Age (years):</b> 67	<b>Spiculation:</b> Yes  <b>Smoking History:</b> Current or Former	<b>Nodule Location:</b> Upper  <b>History of Cancer:</b> No History of Cancer
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**PATIENT INFORMATION**
**PHYSICIAN INFORMATION**

<b>Patient:</b> Patient Name	<b>MRN (if provided):</b> MRN-54321	<b>Physician:</b> Dr. Nod Jules
<b>Date of Birth:</b> Aug 29, 1958	<b>Gender:</b> Female	<b>Facility:</b> Lung Health Associates
<b>Specimen Type:</b> Whole Blood	<b>Date of Collection:</b> Oct 06, 2025	<b>Address:</b> 1234 Lungston Lane, Biop City, CO, 80001
<b>Nodify XL2 Accession No:</b> XL2N2510050003	<b>Date Received:</b> Oct 07, 2025	<b>Country:</b> United States
<b>Date Performed:</b> Oct 07, 2025	<b>Date Reported:</b> Oct 13, 2025	<b>Phone:</b> (555) 555-5555
		<b>Fax:</b> (555) 555-5555

**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 a 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 a lung nodule between 8 and 30mm and a pre-test risk of malignancy of 50% or less calculated using the solitary pulmonary nodule malignancy risk calculator.<sup>3</sup> The risk calculator and the Nodify XL2 test are 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 XL2 was developed and clinically validated in a population with a prevalence of cancer of 16%.<sup>1,4</sup> The Nodify XL2 test has not been evaluated outside of this population.

**REFERENCES:**

- 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.
- 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.
- 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 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 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 to aid in 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](http://www.biodesix.com).

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