biodesix®

NODIFY XL2® Test | Test Result Report

Patient:	Date of Birth:	MRN (if provided):	Date Reported:
Patient Name	Aug 29, 1958	MRN-54321	Oct 13, 2025

NODIFY XL2® TEST RESULT AND INTERPRETATION

LIKELY BENIGN

Patients with a **98% NPV Likely Benign Nodify XL2 test result (97% sensitivity, 44% specificity)**[1] 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

Very Low (<5%)	Low to Moderate (5-65%)	High (>65%)

3% 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%).[2]

PRE-TEST CLINICAL INFORMATION

Pre-test Risk of Malignancy per Solitary Pulmonary Nodule Calculator[3] (Mayo Clinic Model)	Nodule Size (mm):	Spiculation:	Nodule Location:
42%	10.0	Yes	Upper
	Age (years): 67	**Smoking History:** Current or Former	**History of Cancer:** No History of Cancer

PATIENT INFORMATION

Patient:	MRN (if provided):
Patient Name	MRN-54321
Date of Birth:	**Gender:**
Aug 29, 1958	Female
Specimen Type:	**Date of Collection:**
Whole Blood	Oct 06, 2025
Nodify XL2 Accession No:	**Date Received:**
XL2N2510050003	Oct 07, 2025
Date Performed:	**Date Reported:**
Oct 07, 2025	Oct 13, 2025

PHYSICIAN INFORMATION

Physician:	
Dr. Nod Jules	
Facility:	
Lung Health Associates	
Address:	
1234 Lungston Lane, Biop City, CO, 80001	
Country:	
United States	
Phone:	**Fax:**
(555) 555-5555	(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.[3] 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%.[1,4] The Nodify XL2 test has not been evaluated outside of this population.

REFERENCES:

1. 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.
2. 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.
3. 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.
4. Kearney P, Hunsucker S, Li X, et al. An integrated risk predictor for pulmonary nodules. ***PLOS ONE.*** 2017; 12(5): e0177635.

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