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

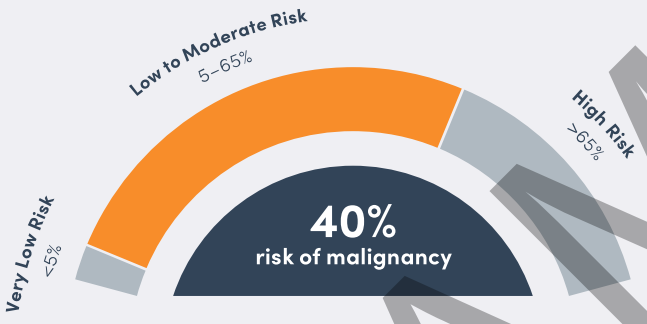
nodify xl2 PROTEOMIC TEST

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 XL2 Accession No: XL2NYYMMDD####	**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

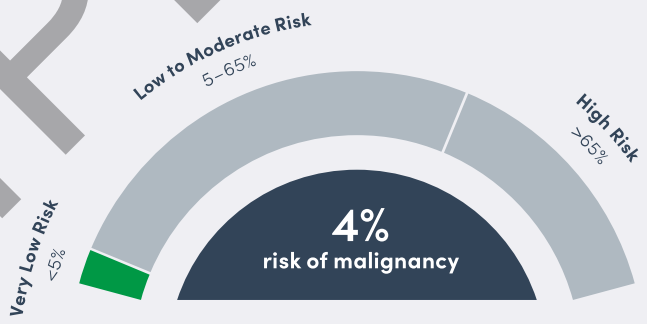
SOLITARY PULMONARY NODULE CALCULATOR[1]
PRE-TEST RISK OF MALIGNANCY



Nodule Size (mm): **16**	Nodule Location: **Upper**
Spiculation: **No**	Smoking History: **Current/Former**
Age (years): **72**	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 nodules[3].

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nodify xl2 PROTEOMIC TEST

Test Result Report

NODIFY XL2 TEST PERFORMANCE OVERVIEW[2]

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 calculator[1]. 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:

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

Patient:
<First and LastName>

Nodify XL2 Accession No:
XL2NYYMMDD####

Date Performed | Reported:
<Mon DD, YYYY>

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