Instructions for Ordering Nodify Lung™ Testing with Biodesix Mobile Phlebotomy Services

1) Complete all required information on the enclosed Test Request Form (TRF)

2) Select "Coordinate Home Phlebotomy" in the BLOOD DRAW INSTRUCTIONS section

3a) FAX INSTRUCTIONS

- Print the form, then sign and date the AUTHORIZATION AND CERTIFICATION OF MEDICAL NECESSITY section

- Fax the signed and dated form to (866) 432-3338.

3b) EMAIL INSTRUCTIONS

- Email the completed form to homephlebotomy@biodesix.com

- Include a request in the email to complete the order with a digital signature

If this is your first time ordering a test from Biodesix, a Customer Care representative will contact you to confirm details about your practice.

If you would like to order Nodify Lung testing and coordinate a blood draw independently, order a test kit or contact us for more information.

nodify lung™ NODULE RISK ASSESSMENT

Test Request Form

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

ATTACH PATIENT ID LABEL HERE
(With Name, Date of Birth, and Draw Date)

PATIENT INFORMATION (REQUIRED)

Patient Last Name:	Patient First Name:	
Address:		
City:	State:	Zip Code:
Date of Birth: Date (MM|DD|YYYY):	Gender:	Phone:

PATIENT CHARACTERISTICS (REQUIRED)

Nodule Diagnosis (ICD-10 Code):
- ☐ R91.1 Solitary pulmonary nodule
- ☐ R91.8 Abnormal findings of lung (multiple pulmonary nodules)
- ☐ Other:

For your convenience, the ICD-10 codes that are used to identify patients with single or multiple nodules are listed. Please report the code(s) that best describe the reason the test is being ordered, whether listed or not.

Nodule Diameter (mm):

Smoking Status:
☐ Current ☐ Former ☐ Non-Smoker

Nodule located in upper lobe?
☐ Yes ☐ No

Nodule Spiculated?
☐ Yes ☐ No

Does the patient have a history of cancer?
- ☐ Lung Cancer
- ☐ Non-Lung Cancer (diagnosed within 5 years)
- ☐ Non-Lung Cancer (diagnosed more than 5 years ago)
- ☐ No History of Cancer

BILLING INFORMATION (REQUIRED)

Check Only One Box
- ☐ Patient insurance information is ATTACHED (Please attach a copy of the patient's insurance card and/or Face Sheet if possible)
- ☐ Patient does not have insurance (please complete the financial assistance application included in test kit and attach a copy)

Biodesix will bill for the Nodify XL2 test using CPT code 0080U and for the Nodify CDT test using CPT code 81599.

TEST MENU (REQUIRED)

Select the box next to Nodify Lung™ Nodule Risk Assessment to order full test offering, or check the individual options below to order tests individually

☐ **Nodify Lung™ Nodule Risk Assessment Testing**

The Nodify CDT test (CDT) will be performed before the Nodify XL2 test (XL2) **unless**:

the CDT result is positive **OR** the pre-test risk is 50%-65%, then the CDT result is delivered and XL2 is not performed **OR** the pre-test risk is >65%, then the primary contact will be notified that neither test will be performed

☐ **Nodify XL2™ Proteomic Test Only**

☐ **Nodify CDT™ Proteomic Test Only**

The pre-test risk of malignancy according to the Solitary Pulmonary Nodule (SPN) Calculator. The SPN Calculator was not validated for patients with a previous diagnosis of lung cancer or non-lung cancer within 5 years.[1]

Nodify Testing is intended for patients who are at least 40 years of age with an incidental nodule between 8-30mm.

The Nodify XL2 test is intended for patients with a pre-test risk of malignancy of 50% or less.

The Nodify CDT test is intended for patients with a pre-test risk of malignancy of 65% or less and no previous diagnosis of cancer (except basal cell carcinoma).

DIAGNOSTIC PLAN (IF APPLICABLE)

Prior to receiving test results, which procedures are you considering for this patient (check all that apply)

- ☐ Follow-up CT or LDCT
- ☐ PET
- ☐ Bronchoscopy (type of Bronchoscopy):
- ☐ Needle Biopsy (type of Needle Biopsy):
- ☐ Surgery
- ☐ Other (please specify):

Date of Procedure (if scheduled):	Physician Assessed Risk (%):

PHYSICIAN INFORMATION (REQUIRED)

Office | Practice:		
Ordering Physician:		
Address:		
City:	State:	Zip Code:
Office | Practice Primary Contact:	Phone:	Fax:
Office | Practice Secondary Contact:	Phone:	Fax:

Test Result Delivery: ☐ Encrypted Email ☐ Fax ☐ Copy Secondary Contact ☐ Physician Portal

Email:

By checking any of these test delivery options, you are authorizing the electronic delivery of test results by Biodesix in accordance with the Health Insurance Portability and Accountability Act and the rules reflected in the HITECH Act.

BLOOD DRAW INSTRUCTIONS (REQUIRED)

Select the location of blood draw
- ☐ Ambulatory Surgery Center
- ☐ In Office (non-hospital)
- ☐ Independent Lab (enter name):
- ☐ Hospital (inpatient)
- ☐ Hospital (outpatient)
- ☐ Independent Phlebotomist (enter name):

☐ Coordinate Home Phlebotomy (**Please fax this form to 1.866.432.3338**)

For Phlebotomist Use Only

☐ I, the phlebotomist, verify that the enclosed specimen was collected and processed according to the protocol provided by Biodesix. I verify that this specimen is the specimen taken from the patient named on this form.

Initial: Date (MM|DD|YYYY):

AUTHORIZATION AND CERTIFICATION OF MEDICAL NECESSITY (REQUIRED)

Your signature constitutes a certification of medical necessity and intent to consider and use the results of the test(s) ordered. All of the information on this form is true and correct. You have obtained patient consent and authorize Biodesix to use and release the results and patient information for reimbursement purposes and as may be appropriate for additional clinical testing services.

Signature of treating physician or authorized representative. Date (MM|DD|YYYY):

Medicare Signature Requirements for providers define a valid signature as "handwritten or electronic." Please provide a wet ink or electronic signature on this form. If you are unable to do so, please contact Biodesix Customer Care at 1.866.432.5930.

INTERESTED IN ONLINE ORDERING AND TEST DELIVERY?

Contact Customer Care at 1.866.432.5930 to learn more about the Biodesix Physician Portal.

CALCULATE RISK OF MALIGNANCY AT NODULERISK.BIODESIX.COM

1. Swensen SJ, Silverstein MD, Ilstrup DM, et al. The probability of malignancy in solitary pulmonary nodules. Application to small radiologically indeterminate nodules. *Arch Intern Med.* 1997; 157(8): 849-55.

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