Test Result Report

PATIENT INFORMATION

Patient: <First and LastName>
Date of Birth: <Mon DD, YYYY>
Gender: <Gender>
Specimen Type: <Sample Format>

MRN (if provided): <########>

PHYSICIAN INFORMATION

Physician: Dr. <First and LastName>
Facility: <Ordering Facility Name>
Address: <Street Address, City, State, Postal Code>

Notify CDT Accession No: CDTNYYMMDD####
Date of Collection: <Mon DD, YYYY>

Physician Information:
Address:

Date Received: <Mon DD, YYYY>
Date Performed | Reported: <Mon DD, YYYY>

Pre-Test Information

SOLITARY PULMONARY NODULE CALCULATOR®
PRE-TEST RISK OF MALIGNANCY

LOW TO MODERATE RISK

HIGH RISK

20% risk of malignancy

Nodule Size (mm): 10
Nodule Location: Upper
Spiculation: No
Smoking History: Current/Former
Age (years): 67
History of Cancer: No History of Cancer

Test Result

HIGH LEVEL
POST-SELECTED CDT RISK OF MALIGNANCY

LOW TO MODERATE RISK

HIGH RISK

78% risk of malignancy

INTERPRETATION OF RESULTS

Patients with a High Level Notify CDT® test result have a higher risk of malignancy than predicted by clinical factors alone. This result does not definitively mean that the patient has lung cancer.

The post-Notify CDT risk of malignancy was calculated based on the performance of the High Level Notify CDT test result in the clinical validation study.2

See the highlighted row in the Notify CDT Test Performance Overview for additional information about this result.

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

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

Date Performed | Reported: <Mon DD, YYYY>

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CLIA Number 17D1089651
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Test Result Report

NODIFY CDT TEST PERFORMANCE OVERVIEW^2

<table>
<thead>
<tr>
<th>Test Report</th>
<th>Positive Predictive Value (PPV)</th>
<th>Specificity</th>
<th>Sensitivity</th>
</tr>
</thead>
<tbody>
<tr>
<td>High Level</td>
<td>78%</td>
<td>98%</td>
<td>28%</td>
</tr>
<tr>
<td>Moderate Level</td>
<td>59%</td>
<td>93%</td>
<td>41%</td>
</tr>
<tr>
<td>No Significant Level of Autoantibodies Detected</td>
<td>-</td>
<td>-</td>
<td>-</td>
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</tbody>
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NODIFY CDT ANALYSIS DESCRIPTION

The Nodify CDT 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 malignant. The test utilizes a proprietary multi-analyte immunoassay technology to measure blood levels of a panel of seven autoantibodies to tumor-associated antigens that have been shown to be elevated for all types of lung cancer and from the earliest stage of the disease.4,5 The measurement of these seven autoantibodies is incorporated into an algorithm that generates a test result.

The Nodify CDT test is intended for patients at least 40 years of age with an incidental lung nodule between 8 and 30mm, no history of cancer (except basal cell carcinoma) and a pre-test risk of malignancy of 65% or less calculated using the solitary pulmonary nodule calculator.4 Nodify CDT test performance was calculated based on a 20% prevalence of cancer expected in a nodule cohort.6

REFERENCES:


Nodify CDT was developed and its performance characteristics determined by Bodesix, 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 intended for clinical purposes, it should not be used 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 CDT Test Result Report or any content derived from it (“Nodify CDT TRR”), the ordering physician, institution of ordering physician, or any third parties to whom the Nodify CDT TRR is transmitted, agree the Nodify CDT TRR may only be used for in the clinical management of the patient identified in the Nodify CDT TRR by the physician. Any other use of the Nodify CDT 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 CDT TRR shall belong solely and exclusively to Bodesix, Inc. Additional terms and conditions related to the Nodify CDT TRR can be found at www.bodesix.com.