EarlyCDT®-Lung

A Blood Test for Risk Stratification of Indeterminate Pulmonary Nodules
A simple blood test that complements CT scans

Measures a panel of 7 autoantibodies associated with all types/stages of lung cancer

Strong clinical data demonstrating high specificity and PPV

Determines malignancy risk of indeterminate nodules beyond current recommended risk calculators

May recategorize nodules to intervention risk allowing earlier intervention and better outcomes
Performance of EarlyCDT®-Lung For Pulmonary Nodule Population

**Specificity**
- 98% (High Level result)
  - A High Level result shifts the risk of intermediate risk nodules (10-65% risk) to intervention risk

**PPV**
- >77% (High Level result)

**Specificity**
- 93% (High Level and Moderate Level result)

**PPV**
- >59% (High Level and Moderate Level result)
  - A Moderate Level result will add >25% risk
  - A Moderate Level result will shift some nodules from Intermediate risk to Intervention risk

PPV based on 20% lung cancer prevalence.
Risk Stratification of Patients with Indeterminate Pulmonary Nodules

1. Apply the Swensen/ Mayo nodule risk calculator as recommended in ACCP guidelines

<table>
<thead>
<tr>
<th>Swensen/ Mayo risk level</th>
<th>Risk adjusted by EarlyCDT-Lung test results</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;10% risk of lung cancer*</td>
<td>Low Risk</td>
</tr>
<tr>
<td></td>
<td>High or Moderate EarlyCDT-Lung test result -&gt; risk raised to Intermediate risk</td>
</tr>
<tr>
<td>10-65% risk of lung cancer*</td>
<td>Intermediate Risk</td>
</tr>
<tr>
<td></td>
<td>High EarlyCDT-Lung test result raises risk to Intervention risk for all patients. Moderate EarlyCDT-Lung test result &gt;25% increase in risk, so Intervention risk for some patients</td>
</tr>
<tr>
<td>&gt;65% risk of lung cancer*</td>
<td>Intervention Risk</td>
</tr>
<tr>
<td></td>
<td>Occasional use of EarlyCDT-Lung following biopsy or bronchoscopy where it is deemed further risk evaluation is of value</td>
</tr>
</tbody>
</table>

*Risk categories according to the ACCP guidelines
EarlyCDT®-Lung fits in with ACCP guidelines by helping to assess the probability of malignancy of a nodule.

Difficult-to-assess nodules (i.e., 8-20mm)

High result (PPV)
Moderate result (PPV)
Initial risk = No Significant Level of Autoantibodies Detected result

“Moderate” or “High” Level

- Indicates that a patient’s risk of having lung cancer is significantly greater than that predicted by their gender, age, smoking history, nodule characteristics and other risk factors.

“No Significant Level of Autoantibodies Detected”

- Patient’s risk of lung cancer does not change from the calculated risk.
- Adds confidence in previously selected treatment pathway.
- Patient experiences less anxiety if next steps are watchful waiting.

Complete information at a glance:

<table>
<thead>
<tr>
<th>Test</th>
<th>Level</th>
<th>Moderate Level</th>
<th>High Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>CAGE autoantibody</td>
<td>0.63</td>
<td>0.16</td>
<td>0.01</td>
</tr>
<tr>
<td>GiBU4-5 autoantibody</td>
<td>2.88</td>
<td>0.16</td>
<td>0.01</td>
</tr>
<tr>
<td>Hid autoantibody</td>
<td>4.16</td>
<td>0.16</td>
<td>0.01</td>
</tr>
<tr>
<td>MAGE-A4 autoantibody</td>
<td>3.91</td>
<td>0.16</td>
<td>0.01</td>
</tr>
<tr>
<td>NY-ESO-1 autoantibody</td>
<td>0.21</td>
<td>0.16</td>
<td>0.01</td>
</tr>
<tr>
<td>P53 autoantibody</td>
<td>3.09</td>
<td>0.16</td>
<td>0.01</td>
</tr>
<tr>
<td>SK2 autoantibody</td>
<td>3.22</td>
<td>0.16</td>
<td>0.01</td>
</tr>
</tbody>
</table>

*This test is not intended for patients who have previously had cancer (exception: basal cell carcinoma).

Clinical Utility:
The ACP guidelines recommend assessing the risk of malignancy of a pulmonary nodule, e.g., with the Swenson/Mayo nodule malignancy risk calculator, available at http://onimmune.com/nodule-risk-calculator. The calculated risk can be divided into three categories and the patient managed accordingly. EarlyCDT™-Lung provides further risk characterization to assist with triaging difficult to assess nodules.

Detailed breakdown of cutoff levels and further education on results for patients.
Autoantibody Cut-offs

- Each Autoantibody (Aab) has 2 cut-offs: a moderate and a high cut-off

- Positive results:
  - If 1 or more AAb is above the High cut-off → High Level result
  - If 1 or more AAb is above the Moderate cut-off and none are above the high cut-off → Moderate Level result

- If all AAbs are below the Moderate cut-off → No Significant Level of Autoantibodies Detected result

- Cut-offs were optimized for each AAb to maximize specificity of the 7-AAb panel in case-control studies using high risk subjects
  - Specificity @ High Level = 98%
  - Specificity @ Moderate Level = 93%
EarlyCDT®-Lung Publications for Risk Assessment of Pulmonary Nodules

**Tumor-Associated Autoantibodies: Re-Optimization of EarlyCDT-Lung Diagnostic Performance and Its Application to Indeterminate Pulmonary Nodules**


- Receiver-operating characteristic (ROC) curve to predict EarlyCDT-Lung performance from 0-100% specificity; optimum at high specificity.
- Area under the curve (AUC) = 0.743
- Theoretical evaluation of a cohort with indeterminate pulmonary nodules.

<table>
<thead>
<tr>
<th>Specificity</th>
<th>PPV</th>
<th>Relative Risk</th>
<th>DLRp</th>
</tr>
</thead>
<tbody>
<tr>
<td>90%</td>
<td>54%</td>
<td>3.7</td>
<td>4.2</td>
</tr>
<tr>
<td>98%</td>
<td>78%</td>
<td>5.0</td>
<td>14.0</td>
</tr>
</tbody>
</table>

- EarlyCDT-Lung enables risk re-classification of intermediate risk nodules to facilitate more appropriate intervention.
- Describes how EarlyCDT-Lung can help in assessing the risk of malignancy of a pulmonary nodule, as recommended by the ACCP guidelines*

**Autoantibody Signature Enhances the Positive Predictive Power of Computed Tomography and Nodule-Based Risk Models for Detection of Lung Cancer**


- High specificity of EarlyCDT-Lung complements the low specificity of CT.
- A positive (Moderate or High) EarlyCDT-Lung result represented a more than 2-fold increased risk of lung cancer versus a negative (No Significant Level of Autoantibodies Detected).
- EarlyCDT-Lung provides additional evidence of lung cancer thereby improving the PPV over nodule-based risk models alone.

**EXAMPLE**

With a risk threshold of 30% using the Mayo risk calculator, the PPV increased from 48% to 91% with a positive EarlyCDT-Lung result.

EarlyCDT-Lung significantly increases the PPV of CT scanning and of nodule-based risk calculators\(^1\).

- EarlyCDT-Lung used in combination with the initial assessment of nodule probability of malignancy provides invaluable additional data:
  - May lead to earlier intervention, and
  - Better patient outcomes

- The Swensen/Mayo risk calculator to calculate the malignancy risk of a nodule with the added value of EarlyCDT-Lung is available via our website, or our mobile App.
Our easy to use Risk Calculator App is available for Android and iOS and on our web site

EarlyCDT-Lung for Nodules App

- For the App simply search for EarlyCDT or Oncimmune
- For Apple: https://itunes.apple.com/gb/app/earlycdt-lung-for-nodules/id1310399708?mt=8
- Web: www.oncimmune.com/
EarlyCDT®-Lung now available with a simple finger stick blood draw

It is:
- simple
- quick
- convenient
The specimen collection kit makes *EarlyCDT®-Lung* simple to order

- *EarlyCDT®-Lung* specimen collection kit contains everything needed to order the test for both finger stick and traditional blood draw

- Choose the draw option that works best for you and your patient.

- Order specimen collection kits here or call 1-888-583-9030

- Download specimen collection instructions here

- Download Test Requisition Form here
EarlyCDT®–Lung

Order specimen collection kits [here](#)

For more information:

Call 1-888-583-9030

or [email](mailto:clientservices@oncimmune.com)