EarlyCDT®–Lung

A Blood Test for Risk Stratification of Indeterminate Pulmonary Nodules
What is *EarlyCDT*-Lung?

*AIDS in RISK STRATIFICATION OF PULMONARY NODULES*

**EarlyCDT**-Lung

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%**

**PPV**
- **>77%**

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

**Specificity**
- **93%**

**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 <em>EarlyCDT-Lung</em> test results</th>
</tr>
</thead>
</table>
| <10% risk of lung cancer* | LOW RISK  
*High or Moderate *EarlyCDT-Lung* test result $\rightarrow$ risk raised to Intermediate risk |
| 10-65% risk of lung cancer* | INTERMEDIATE RISK  
*High* *EarlyCDT-Lung* test result raises risk to Intervention risk for all patients.  
*Moderate* *EarlyCDT-Lung* test result $>25\%$ increase in risk, so Intervention risk for some patients |
| >65% risk of lung cancer* | INTERVENTION RISK  
Occasional use of *EarlyCDT-Lung* following biopsy or bronchoscopy where it is deemed further risk evaluation is of value |

2. Take a sample of blood for the *EarlyCDT-Lung* and get patient’s revised malignancy risk via a detailed test report. Determine clinical follow up according to guidelines for that level of risk.

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*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)

“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
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%
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

**EarlyCDT®-Lung** now available with finger stick blood draw that the patient can use to give a specimen

It is:
- simple
- quick
- convenient

A simple finger stick blood test

**EarlyCDT®-Lung**

To aid in risk assessment of indeterminate pulmonary nodules

Easy to use for providers and patients

www.oncimmune.com  +1 913 583 9000
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 call 1-877-745-5342 or email info@legacyscientific.com
EarlyCDT®–Lung

For more information:

Call 1-877-745-5342

or email

info@legacyscientific.com