EarlyCDT®—Lung
and early lung cancer detection

I received my patient’s results... what should I do next?

Negative Result

What Steps Should I Consider?

A negative test result does not exclude the possibility of a patient having or developing cancer. The test should not be used in an attempt to exclude a cancer diagnosis.

Follow-up of these patients requires clinical judgment using published cancer screening guidelines and an assessment of their risk factors. They are still at increased risk for lung cancer due to their existing risk factors.

A negative test result means autoantibodies were not found to be above the cutoff for any of the 7 antibodies measured.

You likely will want to recommend that the patient continue regular schedule of testing and examination given their risk factors.

Patients with negative results should be re-tested with EarlyCDT-Lung bi-annually.

Positive Result

What Do I Do?

A positive test result means autoantibodies have been detected above a predetermined cutoff and does indicate that the patient is at significantly increased risk of having lung cancer. The first follow-up test is usually a chest CT scan. If the CT scan is abnormal, primary care physicians may consider referral to a pulmonary specialist or thoracic surgeon, as decisions about further work up or follow-up are aided by having a wealth of prior clinical experience. At a minimum, for those found to have indeterminate pulmonary nodules, follow-up CT scans using Fleischner guidelines is recommended.

What Steps Should I Take?

1. EarlyCDT-Lung is recommended for persons 40–75 years of age. Verify that the patient is age-appropriate and at risk with one or more of the following risk factors for lung cancer:
   - Long-term smoker or former smoker, especially of heavy-tar tobacco found in cigarettes and marijuana
   - Prolonged exposure to second-hand smoke
   - Immediate family members who had lung cancer
   - Extensive exposure to radon, asbestos, coal products and/or radioactive substances
   - Extensive exposure to chemicals such as arsenic, vinyl chloride and other carcinogens
   - Diagnosis of tuberculosis, silicosis and/or berylliosis with or without scarring on the lungs

2. EarlyCDT-Lung is not recommended for those with a current or prior diagnosis of cancer, since autoantibodies in the EarlyCDT-Lung panel occasionally can occur in other cancers of non-lung origin. Verify that the patient has no current or prior personal history of cancer of any type.

3. Validate the patient is current on all standardized screening modalities (i.e. mammography, colonoscopy) and that those are normal.

4. Order a CT scan once #1–3 have been checked.
**What Steps Should I Take if the CT is Normal?**

Please follow the suggested Patient Pathway located below, which is in line with the Fleishner Guidelines for following at risk patients.

### PATIENT PATHWAY

**FOLLOWING A POSITIVE EARLYCDT-LUNG:**

CT REGIME WITH ACTION POINT ON DETECTION OF LUNG NODULE*

<table>
<thead>
<tr>
<th>Initial CT</th>
<th>6 Months</th>
<th>12 Months</th>
<th>24 Months</th>
<th>36 Months</th>
<th>Action on CT result if nodule visible</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nodule &lt;4mm Nodule &gt;4mm</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>A</td>
</tr>
<tr>
<td>Negative - no nodule visible</td>
<td>Negative</td>
<td>Nodule &lt;4mm Nodule &gt;4mm</td>
<td></td>
<td></td>
<td>C</td>
</tr>
<tr>
<td>Negative</td>
<td>Negative</td>
<td>Negative</td>
<td>Nodule &lt;4mm Nodule &gt;4mm</td>
<td></td>
<td>C</td>
</tr>
<tr>
<td>Negative</td>
<td>Negative</td>
<td>Negative</td>
<td>Negative</td>
<td>Additional CT or Repeat EarlyCDT-Lung</td>
<td>D</td>
</tr>
</tbody>
</table>

**Key Summary**

A = Aggressive follow up within the time windows described in the Fleischner Guidelines. If patient develops increase in size of nodule then move to C.

B = Accelerated Fleischner as if 4-6mm. If patient develops increase in size of nodule then move to C.

C = Actively growing lesion detected. Clinician needs to consider actual size (eg still <4mm, change in size) and nature of the nodule as well as theoretical doubling time.

D = Repeat EarlyCDT-Lung at 36 months. If EarlyCDT-Lung positive repeat CT regime. (i.e. 12 months after 24 month scan).

*The patient Pathway was developed by Oncimmune® with input from its Lung Cancer Clinical Advisory Group.*

**REMEMBER**

Tests such as EarlyCDT-lung have been known to be positive as long as 2 to 3 years prior to cancer detection. If the CT scan is still negative after 36 months, meaning no pulmonary nodule was identified, then repeating the EarlyCDT-Lung is recommended.

For additional information, please contact Client Services by email at clientservices@oncimmune.com or call 1-888-583-9030.

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