

FREQUENTLY ASKED QUESTIONS



WHO SHOULD TAKE THE TEST?

The test is designed for high-risk patients aged 40 and over – those who are at risk for lung cancer due to a combination of age, gender, smoking history and other risk factors or family history. If you are diagnosed with an indeterminate pulmonary nodule then your doctor may also recommend you take the *EarlyCDT-Lung* test. You should not have any personal history of any type of cancer (exception: basal cell carcinoma*).

HOW DOES EARLYCDT-LUNG COMPARE TO ANNUAL CT SCANNING?

- *EarlyCDT-Lung* offers a complementary approach to annual CT screening, which is the gold standard in the USA for early lung cancer detection if the patient meets the high-risk criteria set by USPSTF⁴.
- *EarlyCDT-Lung* can be used when an individual is at increased risk but does not meet the criteria for annual CT screening. It can also be used when individuals are unwilling or unable to undergo lifelong annual CT screening.
- In either case, a Moderate or High Level *EarlyCDT-Lung* result can be followed by CTs at appropriate intervals in order to detect a lung cancer early, with the patient, physician and insurers better aware of any cancer that may be developing.

HOW ACCURATE IS THE TEST?

The overall accuracy of *EarlyCDT-Lung* is greater than 91%⁵.

IS THE TEST COVERED BY MEDICAL INSURANCE?

Claims are sent to Medicare and health insurers in the U.S., and will be submitted by the test provider. Oncimmune's Client Services Department at 1-888-583-9030 can advise on self-pay options.

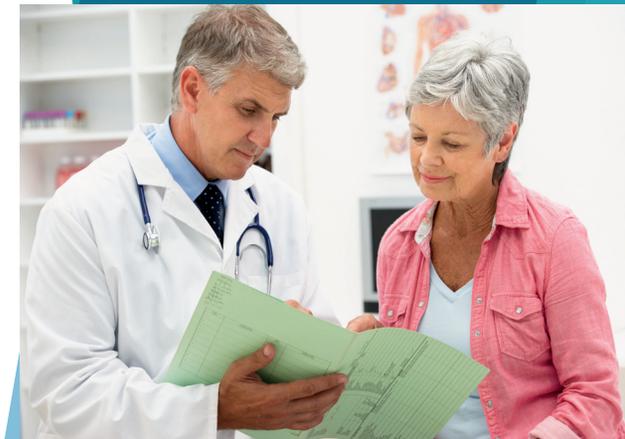
HOW CAN I TAKE THE TEST?

A physician must order the test through a test provider. Please contact a test provider directly for details on how to order, or call Oncimmune Client Services at 1-888-583-9030. Current test providers can be found on the website:

www.oncimmune.com/earlycdt-test/test_providers

EarlyCDT[®]-Lung

A simple blood test to aid
in the risk assessment & early
detection of
LUNG CANCER



¹ Howlader N, Noone AM, Krapcho M et al. SEER Cancer Statistics Review, 1975-2013, National Cancer Institute. Bethesda, MD, <http://seer.cancer.gov/statfacts/html/lungb.html> based on November 2015 SEER data submission, posted to the SEER web site, April 2016.

² The International Early Lung Cancer Action Program Investigators. Survival of Patients with Stage I Lung Cancer Detected on CT Screening. *N Engl J Med* 2006; 355(17): 1763-1771.

³ Zhong L, et al., Profiling Tumour-Associated Antibodies for Early Detection of Non-small Cell Lung Cancer. *J Thor Oncol* 2006; 1:513-519

⁴ <http://www.uspreventiveservicestaskforce.org/Page/Document/UpdateSummaryFinal/lung-cancer-screening>

⁵ Chapman CJ, Healey GF, Murray A, Boyle P, *EarlyCDT*[®]-Lung test: improved clinical utility through additional autoantibody assays.

* See *EarlyCDT-Lung* FAQs

oncimmune[®]

Leading early
cancer detection

EarlyCDT[®]-Lung

A simple blood test which is ordered by a physician to aid in the risk assessment and early detection of lung cancer in high-risk patients and those with indeterminate pulmonary nodules.

WHAT WILL THE RESULTS TELL ME?

EarlyCDT-Lung measures a panel of seven autoantibodies to detect the presence of lung cancer. Depending on the level of autoantibodies in the blood compared to cutoff values, the test results are reported as **High Level, Moderate Level** and **Low Level**.

A **High** or **Moderate Level** result means that you have an increased risk for lung cancer. Your physician will recommend the best follow up, which may include CT imaging, based upon your risk factors, any symptoms and previous radiological findings.

A **Low Level** test means that none of the autoantibodies were found above the cutoff level. A Low Level result indicates a lower likelihood of lung cancer than a Moderate or High Level result. However it does not mean that you do not have, or will not develop, lung cancer - because of your risk factors you are at high-risk of lung cancer and this has not changed. Regular monitoring and follow-up will be determined by your physician.

Using the example of a 65 year old male with a 45 pack year smoking history:

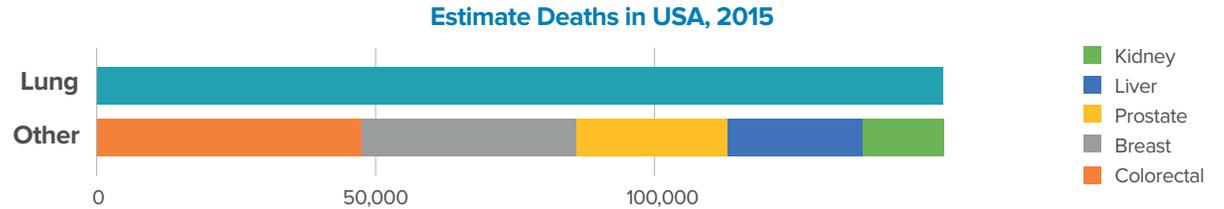
- If he has a **Low** Level test result, his estimated 1-year risk of lung cancer is essentially unchanged from the baseline risk of **1.2%**
- If he has a **Moderate** Level test result, his estimated 1 year risk of having lung cancer nearly triples to **3.5%**
- If he has a **High** Level test result, his estimated 1-year risk of having lung cancer is **19.3%**, an increased risk of over 16 times

HOW DEADLY IS LUNG CANCER?*

Lung cancer remains the number one killer in the USA of both men and women. Over 220,000 new cases of lung cancer in the USA and over 150,000 deaths.

In fact, **27% of all cancer deaths** are due to lung cancer.

Lung cancer kills more people than breast, prostate, liver, kidney and colorectal combined.



WHY IS LUNG CANCER SO DEADLY?

Lung cancer is generally detected late. Almost 80% of lung cancer is diagnosed after spread to other organs. **The 5 year survival rate is just 17.7%.**

EARLY DETECTION MAY BE YOUR BEST CHANCE FOR SURVIVING LUNG CANCER.

Lung cancer diagnosed in its early stage more than triples **the 5-year survival rate to 55%**². The **EarlyCDT-Lung** test measures a panel of seven autoantibodies to detect the presence of lung cancer. Autoantibodies may be detectable up to **4 years before**³ a tumor is visible.

