Oncimmune

Frequently Asked Questions for Patients
For screening of lung cancer in high-risk patients

What is *EarlyCDT®—Lung?*

EarlyCDT—Lung is a simple and affordable blood test that can detect early lung cancer in some people who are at high risk for the disease.

Who should take the *EarlyCDT—Lung* test?

EarlyCDT—Lung is designed for people at high-risk of lung cancer due to a combination of age, gender, smoking history and other risk factors such as environmental exposures, emphysema/COPD, and family history. You may be eligible to be tested with *EarlyCDT—Lung* if any of the following factors apply:
- You are over 50 years old and have a smoking history of 20 or more pack-years (20 pack-years is 1 pack (20 cigarettes) per day for 20 years, or 2 packs per day for 10 years).
- If you are over 40 years of age and have a 20 pack-year smoking history and at least one other risk factor such as a family history of the disease, or exposure to radon, dust, asbestos, or radioactive substances.

You are not eligible for *EarlyCDT—Lung* if you have had any type of cancer, with the exception of basal cell carcinoma. *EarlyCDT—Lung* is not recommended for patients younger than 40 years of age.

How does it work?

When a cancer is present, it produces abnormal proteins, known as antigens, which the body's immune system tries to fight off by producing autoantibodies. These autoantibodies, which can be produced in the earliest stages of cancer, have been shown to be present at all stages of the disease.

Oncimmune's proprietary *EarlyCDT* cancer detection platform was developed to measure the presence in the blood of autoantibodies against specific cancer proteins (tumour-associated antigens). These autoantibodies have the potential to signal the presence of cancer four years or more before cancer is diagnosed through standard care pathways, and can be applied to a wide range of solid tumour types.

EarlyCDT—Lung measures a panel of seven autoantibodies to detect the presence of lung cancer.

How is *EarlyCDT—Lung* different from other methods of lung cancer detection?

EarlyCDT—Lung is a simple blood test that detects cancer early. Currently, most lung cancer cases are only detected once symptoms appear, which usually occurs in the later stages of the disease when the chances of survival are much lower.

Measuring a panel of autoantibodies has the potential to detect lung cancer in its early stages of development, when there are more treatment options available and a greater potential for better outcomes.

Current methods of lung cancer detection, including x-ray, CT, and PET-CT scanning, are complimentary approaches to *EarlyCDT—Lung*. They each provide different information to the clinician and are important in making a definitive diagnosis.

Can you explain the possible test results?

EarlyCDT—Lung test results are reported as **No Significant Level of Autoantibodies Detected**, **Moderate Level**, or **High Level**, depending on the level of autoantibodies in the blood compared to low and high cut-off values for each autoantibody detected. These values have been set by studying thousands of patients with and without lung cancer.

Your clinician will recommend the best follow-up, which may include CT imaging, based upon your risk factors, any symptoms you may have, and previous radiological findings, if available.

How accurate is *EarlyCDT—Lung*?

- The overall accuracy of the test is 92%.[1]
- The test performs favourably when compared with other established cancer detection tests.
- *EarlyCDT—Lung* can detect lung cancer 4 years or more before standard clinical diagnosis.[2,3]

Why is *Early*CDT—Lung not recommended for those with a previous history of cancer? Why is basal cell carcinoma an exception?

Test performance may vary for patients with a previous history of cancer or cancer treatment. The panel of autoantibodies measured has been optimised to detect lung cancer, not other types of cancer, and the control population used to validate the test did not include any patients with a history of cancer. The exception to this recommendation is for patients with a history of basal cell carcinoma (BCC). Research data have suggested that BCC does not impact the *Early*CDT—Lung result.

Is *Early*CDT—Lung different from genetic testing? How?

*Early*CDT—Lung is designed to indicate the presence of lung cancer cells in the body (i.e., lung cancer is present), not your likelihood of developing cancer in the future, which is what genetic predisposition testing often looks for. Currently, there is no standardised genetic testing for lung cancer.

How does smoking cessation affect risk?

As the following graph illustrates, smoking cessation reduces your lung cancer risk. However, it is important to note that early cessation is key to limiting the damaging effects of smoking, which accumulate over time.
- The following graph compares the 1-year risk[4] of developing lung cancer in a current smoker, an ex-smoker who quit at the age of 40, and a non-smoker.
- The graph assumes that at age 40, both the current smoker and the ex-smoker had a 20-pack year smoking history, and that the current smoker continues to smoke at the same level.

Graph 1. Comparison of 1-year risk on male current, ex-smoker and non-smoker
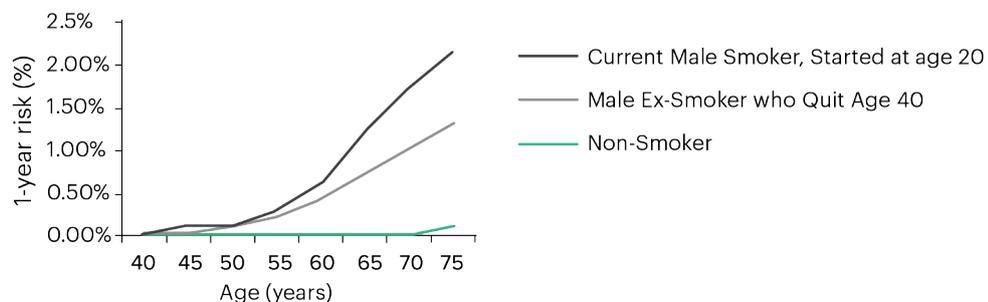
Where can I take the test?

Contact one of the test providers, which are listed on Oncimmune's website: *http://oncimmune.com/distributors/*

How are my results reported?

Your clinician will receive a test report and discuss the results with you.

How long does it take to get results?

Results are usually available reported to your clinician within 5–7 days from the blood sample being received by the laboratory.

How much does *Early*CDT—Lung cost and is it covered by medical insurance?

- The cost of the test is low relative to many other tests, particularly as it is not a genetic predisposition test.
- Patients with private insurance need to confirm coverage with their insurance provider.
- For information on the self-pay price for the test, please contact your test provider.

Who is Oncimmune?

Oncimmune is a leader in the development, manufacture and commercialisation of personalised immunodiagnostics for the screening, detection and care of cancer. Changing how clinicians, researchers and patients view, diagnose and treat cancer, our technology detects evidence of the body's natural response to cancer, enabling detection 4 years or more before standard clinical diagnosis. Our tests facilitate clinical decision-making and are complementary to diagnostic technologies, making them valuable additions to established and new care pathways. We partner with leading developers and distributors to make our technology available globally. Oncimmune was founded in 2002 and launched its platform technology in 2009, followed by its first commercial tests, *EarlyCDT—Lung* and *EarlyCDT—Liver*. Oncimmune is headquartered in Nottingham, UK with a CLIA lab in Kansas, US and offices in London, UK and Shanghai, China.

For additional information please call **+44 (0)115 823 1869** or email: *contact@oncimmune.co.uk*

References

1. Chapman CJ, Healey GF, Murray A, et al. *Early*CDT®–Lung test: improved clinical utility through additional autoantibody assays. *Tumor Biol.* 2012; 33(5):1319–1326.
2. Zhong L, Coe SP, Stromberg AJ, et al. Profiling tumour-associated antibodies for early detection of non-small cell lung cancer. *J Thorac Oncol.* 2006; 1:513–519.
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4. Spitz MR, Hong WK, Amos CI, et al. A risk model for prediction of lung cancer. *J Nat Cancer Inst.* 2007; 99:715–26.