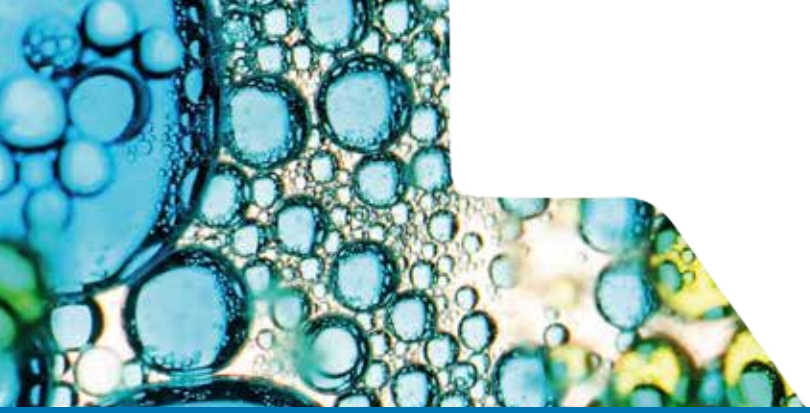
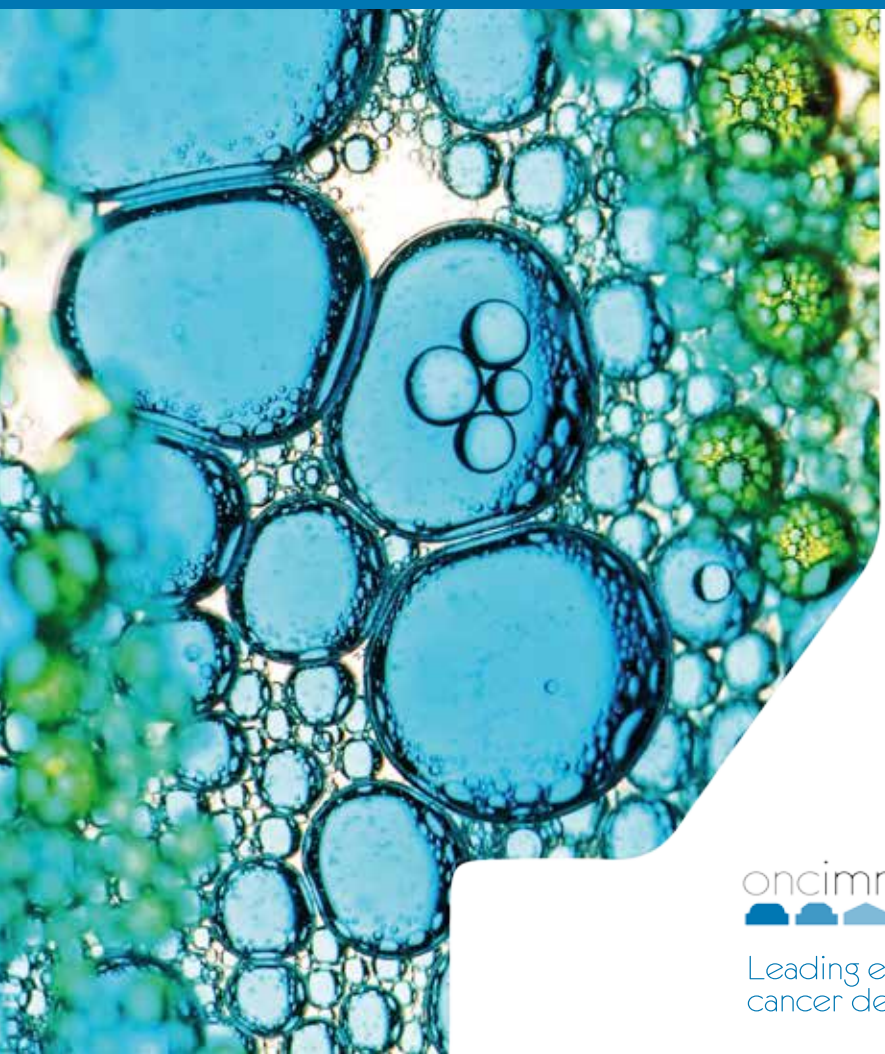


*Early*CDT®–Lung

Frequently Asked Questions (FAQs) for Patients



oncimmune®

Leading early cancer detection

1. What is *Early*CDT®-Lung?

- A simple **blood test** to aid in the risk assessment and early detection of lung cancer in **high-risk patients** and those with indeterminate pulmonary nodules.

2. What are the key benefits of *Early*CDT-Lung?

- The overall accuracy is **92%**[1].
- Can detect lung cancer up to **4 years earlier**[2] than other methods.
- Shows a **3x** to **16x risk increase** with a Moderate or High Level test result.
- *Early*CDT-Lung offers a **complementary approach to annual CT** screening.
- Can be billed to **Medicare Part B and most major private health insurances** in the US by your test provider.

3. How does it work?

- When a tumor is present it produces abnormal proteins (known as antigens).
- Cancer antigens are different than 'normal' antigens so the body reacts to these antigens by producing autoantibodies. These autoantibodies, which can arise in the earliest stages of cancer and have been shown to be present at all stages, are produced in sufficient quantities to be measured in an individual's blood using a simple blood test.
- Oncimmune's proprietary *Early*CDT® cancer detection platform was developed to measure the presence in the blood of autoantibodies against specific tumor associated antigens. These autoantibodies have the potential to signal the presence of cancer up to four years earlier than other methods[2] and can be applied to a wide range of solid tumor types.
- *Early*CDT-Lung measures a panel of seven autoantibodies to detect the presence of lung cancer.

4. Can you explain the possible test results?

- *Early*CDT-Lung test results are reported as Low Level, Moderate Level and High Level, depending on the level of autoantibodies in the blood compared to low and high cutoff values for each autoantibody. The interpretation of these results is discussed below (questions 7 to 9).

5. How accurate is *Early*CDT-Lung?

- The overall accuracy is 92%.
- The test performs favorably when compared with other established cancer detection tests.

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 Tumor-Associated Antibodies for Early Detection of Non-small Cell Lung Cancer. J Thor Oncol 2006;1:513-519.

6. How does *Early***CDT-Lung** performance compare to Annual CT Screening?

- *Early***CDT-Lung** offers a complementary approach to annual CT screening which is the gold standard in the USA for early lung cancer detection if an individual meets the high-risk criteria set by USPSTF[3].
- Annual CT screening has been shown to reduce mortality from lung cancer provided that:
  - The patient is high risk (as defined by the National Lung Screening Trial (NLST[4]) in the USA), that is, 55-74 years old with 30+ pack years smoking history or have quit within the last 15 years.
  - Testing is on an annual basis.
- As a simple blood test, *Early***CDT-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 *Early***CDT-Lung** result can be followed by CT scans at appropriate intervals in order to detect a lung cancer early, with the patient, physician and insurers better aware of the risk of cancer developing.

7. What if my test is High Level or Moderate Level?

- A **High Level or Moderate Level** test result is defined as one or more autoantibodies in the *Early***CDT-Lung** panel being above the relevant cutoff values.
- A High or Moderate Level test result indicates that your risk of having lung cancer is greater than that predicted by your gender, age, smoking history and other risk factors.
- Your physician 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.
- A High or Moderate Level test result does not definitely mean that lung cancer is present.

8. What if my test is Low Level?

- A **Low Level** test result is defined as all autoantibodies in the *Early***CDT-Lung** panel being below the low cutoff value.
- A Low Level test 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 in order to be eligible for the test you were already at an elevated risk of lung cancer as predicted by age, gender, smoking history and other risk factors. This has not changed appreciably.
- Regular monitoring and follow-up will be determined by your physician.

3 Final Update Summary: Lung Cancer: Screening. U.S. Preventive Services Task Force. July 2015. http://www.uspreventiveservicestaskforce.org/Page/Document/UpdateSummaryFinal/lung-cancer-screening

4 The National Lung Screening Trial Research Team. Reduced lung-cancer mortality with low-dose computed tomographic screening. N Engl J Med 2011;365:395-409.

9. How often do you recommend I have a repeat *Early***CDT-Lung** test given a Low Level test result?
   - We do not recommend a definitive repeat period as your physician will have to take into account your on-going risk. Our general advice for repeat testing is between 1 and 2 years.

10. Who should take the test?[5]
   - The test is designed for high-risk patients – those who are at risk for lung cancer due to a combination of age, gender, smoking history and other risk factors such as environmental exposures (radon, dust, asbestos, radioactive substances), emphysema/COPD, and first-degree relative family history.
   - If you are over 40 years of age with a specific risk profile then your doctor may recommend you take the *Early***CDT-Lung** test.
   - If you are diagnosed with an indeterminate pulmonary nodule then your doctor may recommend you take the *Early***CDT-Lung** test[6].
   - You should not have any personal history of any type of cancer (exception: basal cell carcinoma).

11. Why is *Early***CDT-Lung** not recommended for those with a previous history of cancer and 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 optimized 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). A study was conducted, and the data suggested that BCC does not impact the *Early***CDT-Lung** result.

12. How is *Early***CDT-Lung** different from other methods of lung cancer detection?
   - *Early***CDT-Lung** is a simple blood test.
   - The goal of this test is early cancer detection. Currently most lung cancer cases are only detected once symptoms appear and usually in later stages of the disease.
   - Measuring a panel of autoantibodies has the potential to detect lung cancer in its early stages of development, giving the patient more treatment options with subsequent improved prognosis.
   - Current methods of lung cancer detection, including x-ray and CT scanning, involve levels of radiation exposure.

13. 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 at any stage, not your likelihood of developing cancer in the future, which is what genetic testing is often looking for.
     Note: Currently there is no standardized genetic testing for lung cancer.

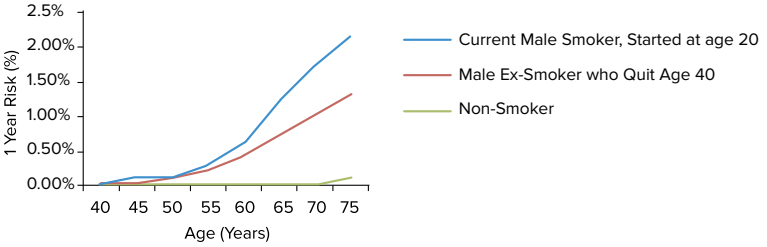
5 *Early***CDT-Lung** is not recommended for use in patients <40 yrs of age.

6 Massion P, Healey GF, Peek LJ, et al. Autoantibody Signature Enhances the Positive Predictive Power of Computed Tomography and Nodule-Based Risk Models for Detection of Lung Cancer. J Thor Oncol 2017; 12(3):578-584.

14. 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 as the effects of smoking accrue over time.
- The graph compares the 1 year risk[7] 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 had a 20 pack year smoking history and that the current smoker continues to smoke at the same level.

Comparison of 1 Year Risk on Male Current, Ex-Smoker and Non-Smoker



15. What is a pack year?

- It is a way to quantify the amount a person has smoked over a long period of time. It is calculated by multiplying the number of packs of cigarettes smoked per day by the number of years the person has smoked. For example, 1 pack year is equal to smoking 20 cigarettes (1 pack) per day for 1 year.

16. Where can I take the test?

- Contact client services at 1-888-583-9030 for a local test provider in the US. Current test providers in the UK and in other regions of the world are listed on our website: http://www.oncimmune.com/earlycdt-test/test_providers

17. How are my results reported?

- We will provide the test results to your chosen test provider. They will then inform your physician of the results who will discuss these with you, the patient.

18. Where is the sample for *Early***CDT-Lung** sent?

- The sample is sent to Oncimmune's CLIA[8]-certified laboratory in De Soto, Kansas, USA for testing, analysis and reporting.

19. How long does it take to get results?

- Results are usually available for release within 5-7 days from the blood sample being received by the laboratory, however this will depend upon your choice of provider.
- Results will only be released to patients by their physician.

7 Spitz MR, Hong WK, Amos CI, et al. A Risk Model for Prediction of Lung Cancer. J Nat Cancer Inst 2007;99:715-26.

8 CLIA (Clinical Laboratory Improvement Amendments) is a lab testing quality standard that was first established in 1988 in the US, and became part of the Federal Register in 1992. CLIA certification is required for any laboratory that performs tests on "materials derived from the human body" for diagnostic, treatment, health assessment or prevention purposes.

20. Can I have a copy of my results?

- At this time, we can only provide results to your test provider. Your physician may provide you with additional information at the time of your follow up appointment.

21. How much does the test cost and is it covered by medical insurance in the US or by the NHS or medical insurance in the UK?

- In the US, *Early***CDT-Lung** may be billed to Medicare Part B and most major private insurances by the test provider. You should contact your chosen test provider for insurance billing questions.
- In the US, if you choose to pay out-of-pocket, the self-pay price is comparable to many US insurance plans' co-pays or deductibles for other cancer detection tests. Oncimmune's Client Services Department at 1-888-583-9030 can advise on self-pay options.
- The cost of *Early***CDT-Lung** is not currently covered by the NHS or medical insurance in the UK. You will pay for the cost of the test yourself. The cost varies according to the test provider.

22. Who is Oncimmune®?

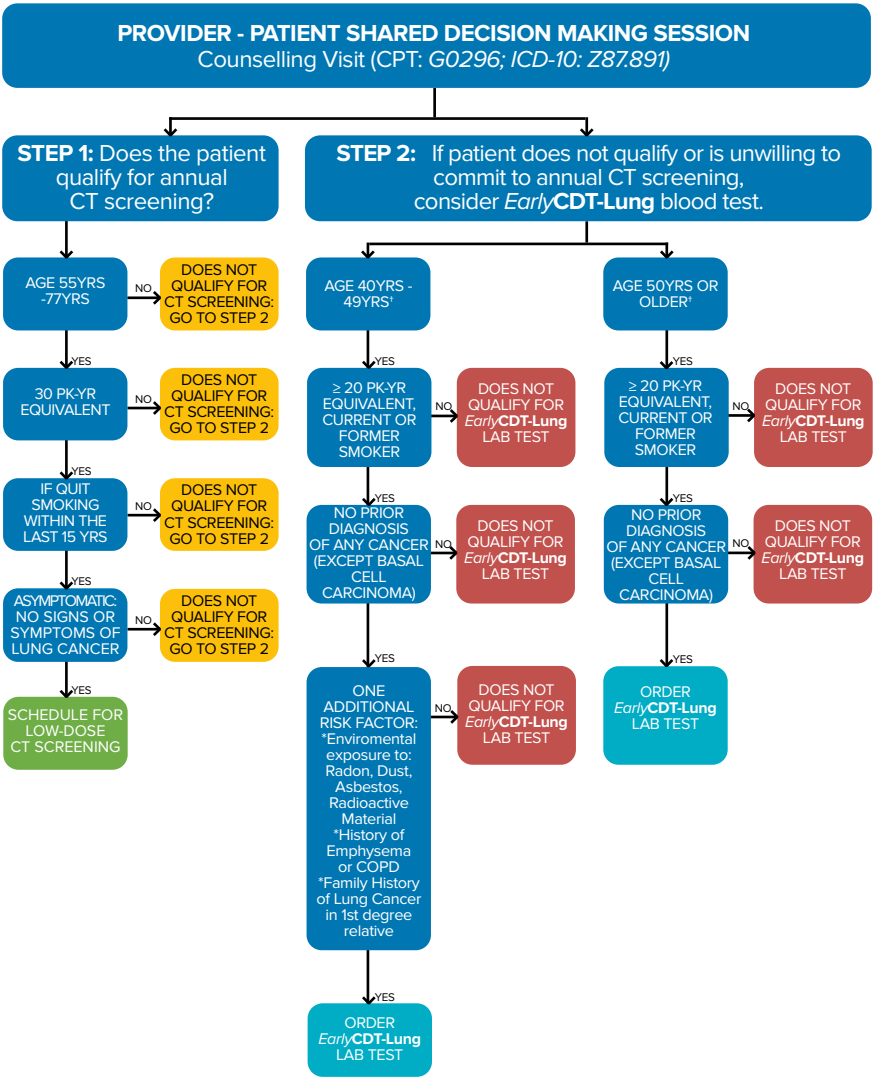
- Oncimmune is a leading early cancer detection company. It has pioneered the development of autoantibody assay technologies that have the potential to allow cancer detection up to four years earlier than other methods and be applied to a wide range of solid tumor types.
- Oncimmune Ltd is headquartered in Nottingham, UK, and testing is conducted in our CLIA-certified laboratory, based in De Soto, Kansas, USA.
- In 2009, the company launched its proprietary platform technology for early cancer detection, called *Early***CDT**®.
- For additional information please call Client Services 1-888-583-9030 or email clientservices@oncimmune.com in the US, and elsewhere please call +44 (0)115 8231869 or email contact@oncimmune.co.uk.

Appendix 1
How do I determine whether I, the patient, qualify for CT screening or *Early***CDT-Lung**?

US Preventive Services Task Force (USPSTF) Guidelines recommend annual screening for lung cancer with low-dose computed tomography (LDCT) for patients who meet the eligibility criteria.

The Problem

More than 70% of all patients diagnosed with lung cancer fall outside the defined high risk group who are eligible for low-dose CT screening.[§]



§ Pinsky PF and Berg CD. J Med Screen. 2012;19(3):154-156

† *Early***CDT-Lung** is not recommended for patients <40 years of age

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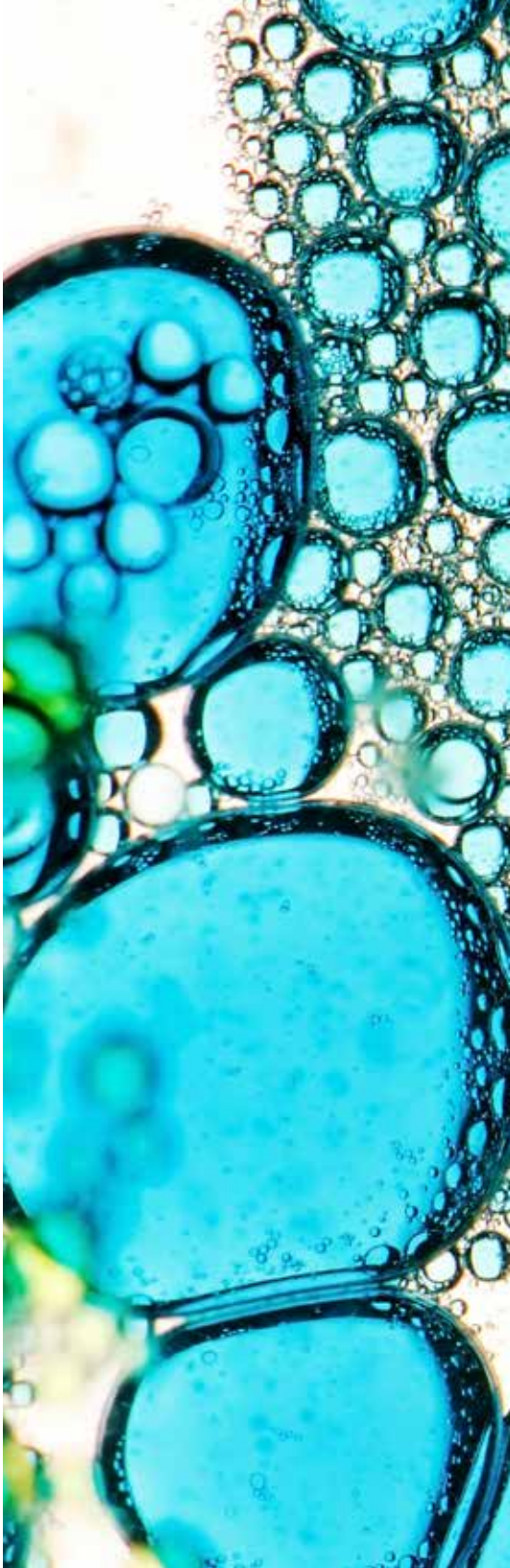
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