Frequently asked questions

What is the *Early*CDT—Lung test?

*Early*CDT—Lung is a simple and affordable blood test that measures seven proteins, known as autoantibodies, that are linked to the presence of lung cancer. These autoantibodies can be elevated very early in the formation of cancer and can therefore aid in its detection, even before symptoms appear.

Who should take the test?

The *Early*CDT—Lung test is designed for people at high risk of lung cancer. High risk means you should be:

- aged 50 or over with at least a 20 pack-year smoking history (equivalent to smoking 1 pack of cigarettes per day for 20 years, or 2 packs per day for 10 years); or
- aged 40–49 years with at least a 20 pack-year smoking history and at least one additional lung cancer risk factor such as family history, COPD or emphysema, or exposure to environmental risk factors including asbestos, radon, smoke, etc.

The *Early*CDT—Lung test is not suitable for you if you have ever had any type of cancer other than basal cell carcinoma.*

How accurate is the test?

The overall accuracy of *Early*CDT—Lung is 92%.[9]

What if the result is positive?

You should always discuss the result with your clinician who can advise on the right follow-up care for you. A **Moderate** or **High Level** *Early*CDT—Lung test result can be followed by CT scans at appropriate intervals to detect lung cancer earlier.

How can I take the test?

A clinician must order the *Early*CDT—Lung test through a clinical laboratory. Distributors of the test are listed at http://oncimmune.com/distributors

Contact your local test provider of *Early*CDT—Lung:

Early*CDT—Lung is a simple and affordable blood test to detect early signs of lung cancer and assess the risk of malignancy.

1. International Agency for Research on Cancer, World Health Organization. Fact sheet: Lung Cancer. Sept 2018. http://gco.iarc.fr/today/fact-sheets-cancers (accessed 23 Oct 2018).
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3. Noone AM, Howlader N, Krapcho M, et al. SEER Cancer Statistics Review, 1975-2015, National Cancer Institute. Bethesda, MD, https://seer.cancer.gov/csr/1975_2015/, based on November 2017 SEER data submission, posted to the SEER web site, April 2018.
4. Jett JR, Peek LJ, Fredericks L, et al. Audit of the autoantibody test, *Early*CDT—Lung, in 1,600 patients: an evaluation of its performance in routine clinical practice. *Lung Cancer* 2014;83(1):51–55.
5. National Lung Screening Trial Research Team. Reduced lung-cancer mortality with low-dose computed tomographic screening. *N Engl J Med.* 2011;365(5):395–409.
6. Zhong L, Coe SP, Stromberg AJ, et al. Profiling tumor-associated antibodies for early detection of non-small cell lung cancer. *J Thorac Oncol.* 2006;1(6):513–519.
7. Jett J, Healey G, MacDonald I, et al. Determination of the detection lead time for autoantibody biomarkers in early stage lung cancer using the UKCTOCS cohort. *J Thorac Oncol.* 2017;12(11):S2170.
8. Lung Cancer Alliance, Types of Lung Cancer, http://lungcanceralliance.org/get-information/types-of-lung-cancer.html.
9. 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.
* See *Early*CDT—Lung FAQs

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Oncimmune®

*Early*CDT®—Lung

A simple blood test to aid in the risk assessment and early detection of lung cancer

What will the results tell me?

The test results are reported as **High Level**, **Moderate Level** and **No Significant Level of Autoantibodies Detected**.

A **High** or **Moderate Level** result means that you have an increased risk of having lung cancer. Your clinician will recommend the best follow-up care, which may include CT imaging, based on your risk factors, symptoms, and radiological findings.

A **No Significant Level of Autoantibodies Detected** test result means that none of the autoantibodies were found above the cut-off values. This result simply indicates that you are at lower risk of having lung cancer than if you had a **Moderate** or **High Level** result. It does not rule out the possibility that you may have lung cancer now, or develop it in the future. Your clinician will determine your plan for follow-up and monitoring. If your clinician recommends continued monitoring (or "watchful waiting"), a **No Significant Level of Autoantibodies Detected** result should help you feel less anxious about your clinician's plans for follow-up.

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

If he has a **No Significant Level of Autoantibodies Detected** test result, his estimated risk of having lung cancer within 1 year is essentially unchanged from his baseline risk of **1.2%**.

If he has a **Moderate Level** test result, his estimated risk of having lung cancer within 1 year nearly triples to **3.5%**.

If he has a **High Level** test result, his estimated risk of having lung cancer within 1 year is **19.3%**, an increased risk of over 16 times.

How deadly is lung cancer?

Of all the cancers, lung cancer remains the number one killer globally. Every year the disease accounts for 2.09 million new diagnoses and 1.76 million deaths.[1]

Nearly one in five cancer deaths worldwide are due to lung cancer.[1]

Cancer	Percentage
Lung	19%
Liver	9.1%
Stomach	8.8%
Colorectum	8.5%
Breast	6.4%
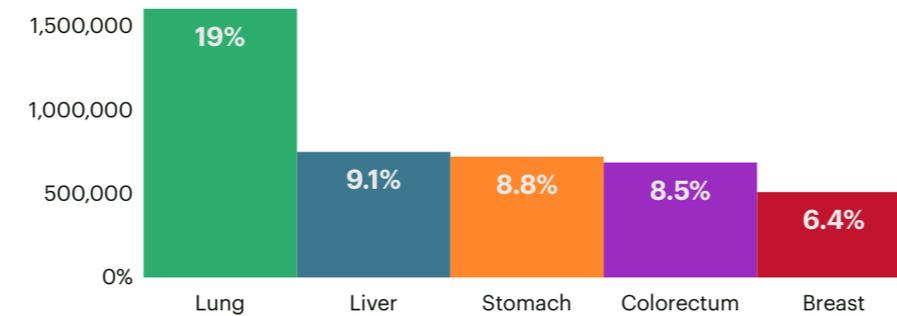
Why is lung cancer so deadly?

Lung cancer is generally detected late, and therefore the 5-year survival rate is less than 20% in most countries worldwide.[2]

Early detection may be your best chance for surviving lung cancer. Studies have shown that if lung cancer is diagnosed in its early stage, the 5-year survival rate triples to 56%.[3] *Early*CDT—Lung can help your clinician detect lung cancer early,[4] and early detection of lung cancer has been shown to save lives.[5]

Autoantibodies may be detectable four years or more before standard clinical diagnosis.[6,7]

*Early*CDT—Lung can detect lung cancer 4 years or more before diagnosis[6,7]

Detectable by CT (Pin head)

Clearly visible by CT (Pea)

Clinically apparent (Physical symptoms present) (Golf ball)

Death (Grapefruit)

Lung cancer usually detected at a late stage

Tumour size and detectability

| 0mm | 2mm | 8mm | 40mm | 100mm |

Fast growing tumours (as many as 30% of all lung cancers[8])

| 0 | 1.1yrs | 2.3yrs | 3.4yrs | 4.6yrs |

Examples: Large Cell Carcinoma, Small Cell Carcinoma

Intermediate growing tumours

| 0 | 4.2yrs | 8.4yrs | 12.6yrs | 16.8yrs |

Examples: Squamous Cell Carcinoma, Adenocarcinoma

Autoantibodies detectable by *Early*CDT—Lung