*Early*CDT®–Lung

A simple blood test to aid in the risk assessment and early detection of lung cancer in high-risk patients and to stratify indeterminate pulmonary nodules for the risk of malignancy.

The Facts

80%
almost 80% of lung cancer is diagnosed after spread to other organs[i]

18%
5-year survival rate is only 17.7%[i]

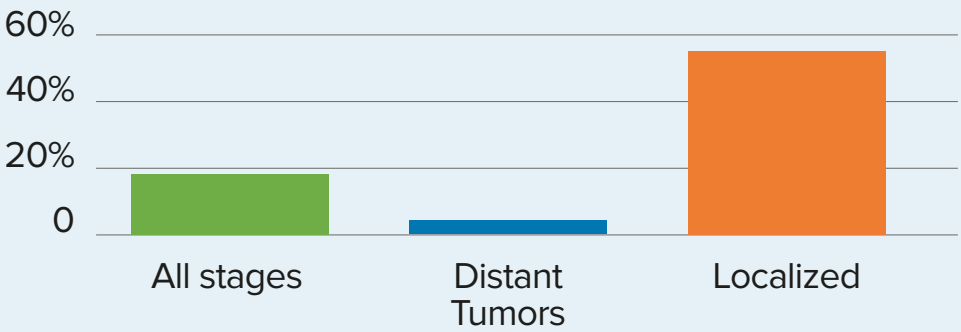
56%
of patients perish in the 1st year after diagnosis[ii]

With over 120,000 tests completed during development and 150,000 tests performed commercially in the US from over 2,000 physicians, *Early***CDT-Lung** benefits high-risk patients by aiding in the risk assessment and detection of any type of lung cancer at the earliest possible stages, when treatment can be most successful.

The Impact

As NIH data show, when found early, while still localized, the 5-year survival rate for lung cancer more than triples to 55%.

Lung Cancer 5-Year Survival Rates[i]



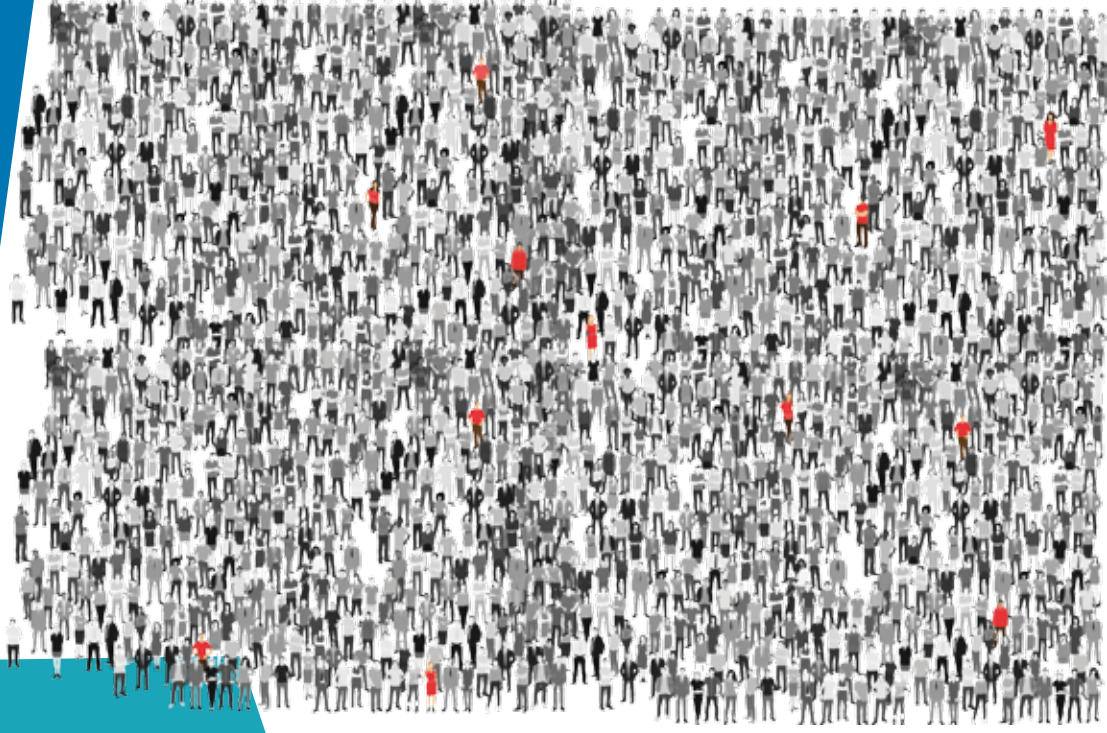
oncimmune®

Leading early cancer detection

The Challenge

The challenge is how to find the **12** lung cancers in a population of **1,000 high-risk patients** early, ***before*** symptoms appear

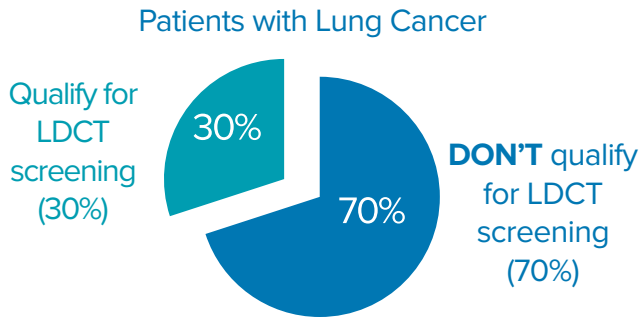
(1.2% prevalence = 12 cancers in 1,000)



The Good News

Annual low-dose CT scanning (LDCT) is now an approved method of lung cancer screening in the US with associated reimbursement. **BUT** only if you meet the strict criteria published by the USPSTF guidelines[iii], derived from the National Lung Screening Trial (NLST): age 55-80, current or ex smoker (cessation within 15 years) and ≥30 pack year history.

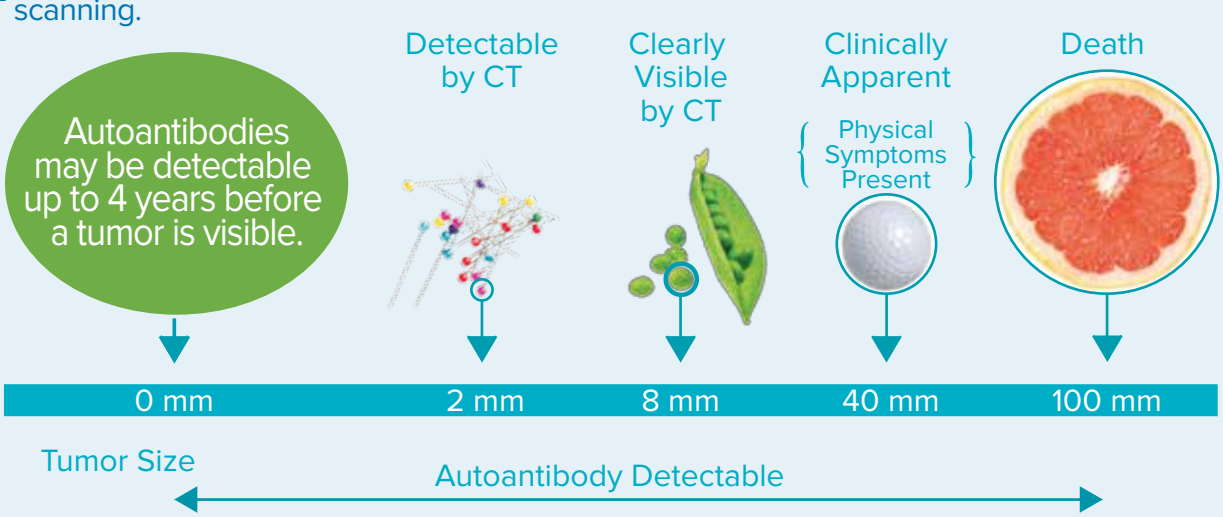
SO, what do you do with the 70% of patients with lung cancer who don't meet the strict criteria for LDCT screening[iv]?



What Else Is There For Early Detection?

*Early*CDT®–Lung

As a simple blood test, *Early***CDT-Lung** can be used when a patient is at increased risk of lung cancer but does not meet the criteria for annual CT screening. In addition, some patients are unwilling or unable to commit to annual CT scanning.



*Early***CDT-Lung** measures 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 **4 years earlier**[v] than other methods of cancer detection.

Who Do I Test?

*Early***CDT-Lung** is recommended for high-risk patients[vi]– those who are at risk of lung cancer due to a combination of age, gender, smoking history and other risk factors such as those with a history of emphysema/COPD, first degree relative family history, or environmental exposures (radon, dust, asbestos, radioactive substances). The patient should be ≥50 years old with ≥20 pack-years smoking history, or 40-49 years old with ≥20 pack-years smoking history, plus at least 1 additional risk factor(s) (as above) and have no previous history of any type of cancer (exception: basal cell carcinoma*).

But Is *Early*CDT-Lung Accurate?

YES. The overall accuracy is 92%[vii].
*Early***CDT-Lung** performs favorably when compared with other established cancer detection tests:

	Accuracy	Performance (PPV)[viii]
***Early*CDT-Lung (High)**[ix]	**97%**	**1 in 5**
***Early*CDT-Lung (Moderate & High)**[ix]	**92%**	**1 in 10**
CT Screening (Annual)[x]	73%	1 in 25
Mammography[xi]	92%	1 in 26
Cologuard® [xii]	84%	1 in 27

Assumed cancer rates: ***Early*CDT-Lung** & CT Screening = 1.2%, Mammography = 0.8%, Cologuard® = 0.6%
True Positive = cancer False Positive = no 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**. Approximately ⅔ of the combined Moderate and High test results are High Level.

How Will *Early*CDT-Lung Benefit My Patients?

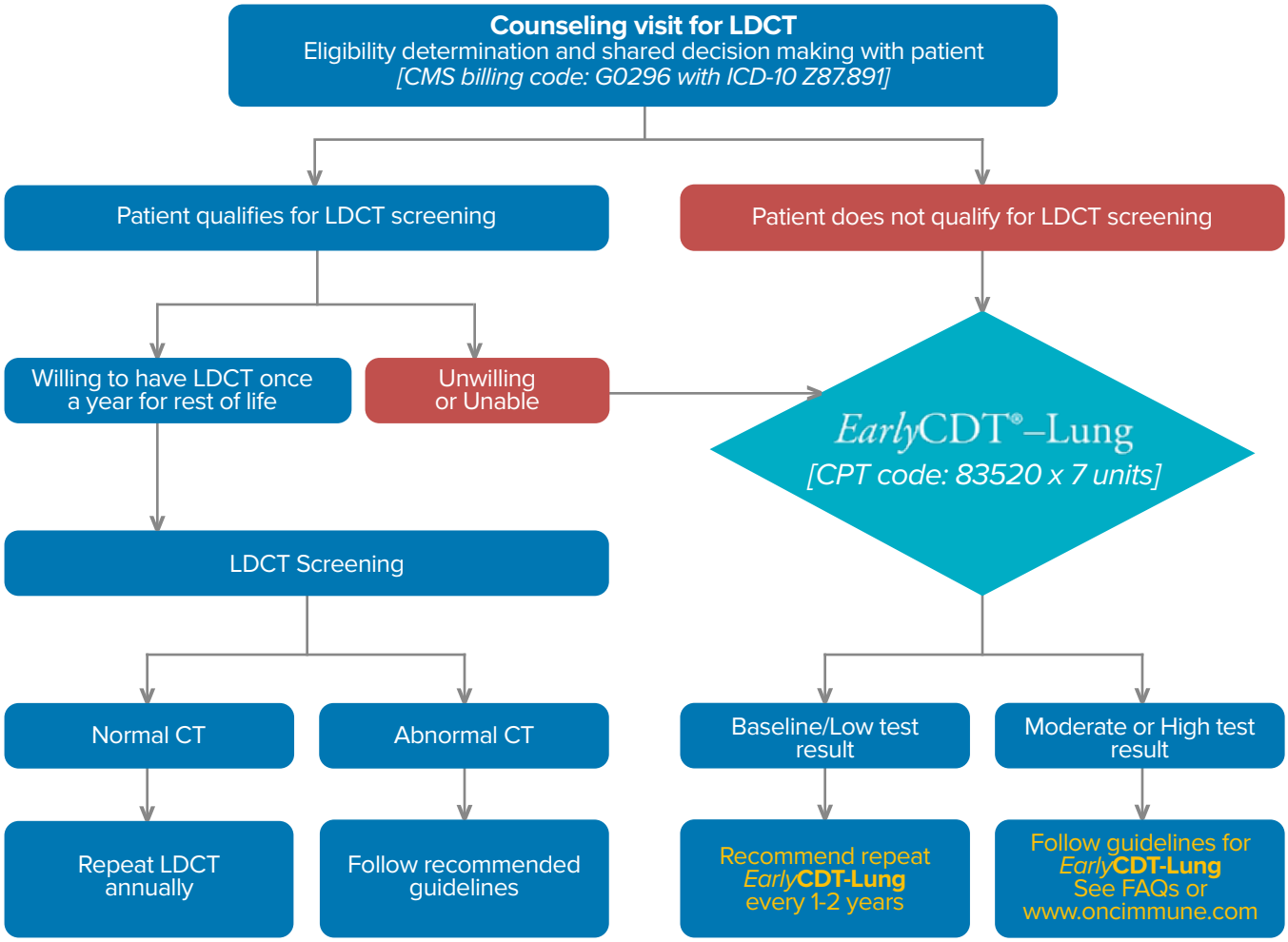
A Typical High-Risk Patient:
65 year old male
45 pack year smoking history

If this patient has a **Low Level** test result, his estimated 1-year risk of lung cancer is essentially unchanged from his pre-test high-risk status 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 his test result is **High Level,** his estimated 1-year risk of having lung cancer is **19.3%**, an increased risk of over 16 times

Suggested Pathway In Combination With Low Dose CT



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Claims for *Early***CDT-Lung** are sent to Medicare and health insurers in the US and will be submitted by the test provider. More than **150,000 tests** have already been performed by **more than 2,000 physicians** in the US. *Early***CDT-Lung** detects all types and stages of lung cancer and has led to the detection of numerous early stage lung cancers.

It is simple to become a Provider of *Early***CDT-Lung** with no cost or commitment for your practice. Just contact your laboratory services provider and ask for *Early***CDT-Lung** or contact Oncimmune at clientservices@oncimmune.com or call +1 888 583 9030.

Learn more at: **www.oncimmune.com**

[i] 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.
[ii] American Cancer Society, Cancer Facts & Figures 2015. Atlanta: American Cancer Society; 2015.
[iii] http://www.uspreventiveservicestaskforce.org/Page/Document/UpdateSummaryFinal/lung-cancer-screening.
[iv] Pinsky PF and Berg CD, J Med Screen. 2012;19(3):154-156.
[v] Zhong L, Coe SP, Stromberg AJ et al., J Thor Oncol 2006; 1:513-519.
[vi] *Early***CDT-Lung** is not recommended for use in patients <40 yrs of age
[vii] Chapman CJ, Healey GF, Murray A et al., Tumor Biol; 201;33(5):1319-26. doi: 10.1007/s13277-012-0379-2.
[viii] Positive Predictive Value - the number of positive test results required to detect a cancer.
[ix] Boyle P, Chapman CJ, Holdenrieder S et al., Ann Oncol 2001; 22(2):383-389.
Chapman CJ, Healey GF, Murray A et al.,Tumor Biol; 2012; 33(5):1319-26.
Healey GF, Lam S, Boyle P et al., J Thoracic Diseases 2013; 5(5): 618-625.
[x] The National Lung Screening Trial Research Team, N Engl J Med 2011; 365:395-409.
Aberle DR, DeMello S, Berg CD et al., N Engl J Med 2013; 369:920-931.
[xi] National Cancer Institute, Breast Cancer Surveillance Consortium: Evaluating Screening Performance in Practice, NIH Publication 2004 No. 04-5490. Bethesda, MD: National Cancer Institute, National Institutes of Health, U.S. Department of Health and Human Services, April 2004.
[xii] Imperiale TF, Ransohoff DF, Itzkowitz SH et al., N Engl J Med 2014; 370(14):1287-1297.

* See *Early***CDT-Lung** FAQs