*Early*CDT®–Lung

A Blood Test for Risk Stratification of Indeterminate Pulmonary Nodules

oncimmune®

LEGACY SCIENTIFIC

2018

What is *Early*CDT®-Lung?

*Early*CDT®-Lung

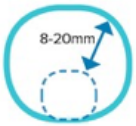
Aids in risk stratification of pulmonary nodules

A simple blood test that *complements CT scans*

Measures a panel of 7 autoantibodies associated with *all types/stages of lung cancer*

Strong clinical data demonstrating *high specificity and PPV*

Determines malignancy risk of indeterminate nodules beyond current recommended risk calculators

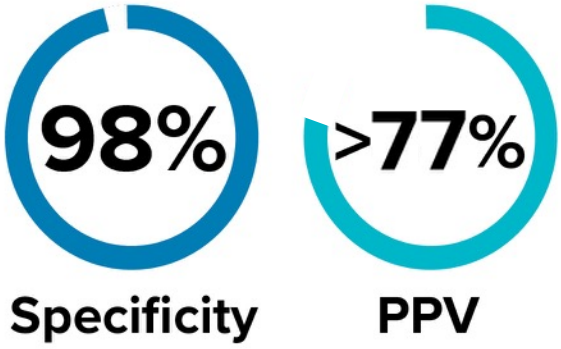


May recategorize nodules to intervention risk allowing *earlier intervention and better outcomes*

Healey GF, et al. *J Cancer Ther.* 2017; 8:506-517.
Massion PP, et al. *J Thorac Oncol.* 2017; 12(3):578-584.
Healey GF, et al. *J Thorac Dis*. 2013;5(5):618-625.

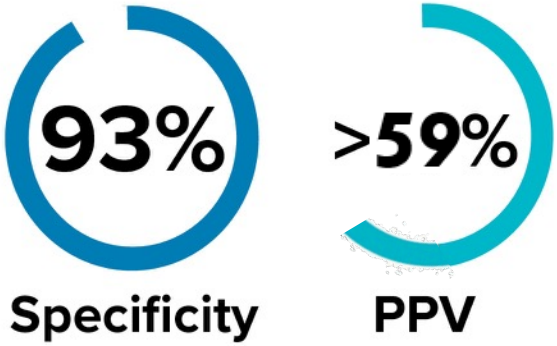
Performance of *Early*CDT®-Lung For Pulmonary Nodule Population

*Early*CDT®–Lung



"High Level" result

- A High Level result shifts the risk of intermediate risk nodules (10-65% risk) to intervention risk



"High Level" and "Moderate Level" result

- A Moderate Level result will add >25% risk
- A Moderate Level result will shift some nodules from Intermediate risk to Intervention risk

PPV based on 20% lung cancer prevalence.

Healey GF, et al. *J Cancer Ther.* 2017; 8:506-517.
Massion PP, et al. *J Thorac Oncol.* 2017; 12(3):578-584.
Healey GF, et al. *J Thorac Dis*. 2013;5(5):618-625.
National Lung Screening Trial Research Team, et al., *N Engl J Med.* 2013;368(21):1980-91.

Risk Stratification of Patients with Indeterminate Pulmonary Nodules

*Early*CDT®–Lung

1. Apply the Swensen/Mayo nodule risk calculator as recommended in ACCP guidelines

2. Take a sample of blood for the *Early***CDT-Lung** and get patient's revised malignancy risk via a detailed test report. Determine clinical follow up according to guidelines for that level of risk.

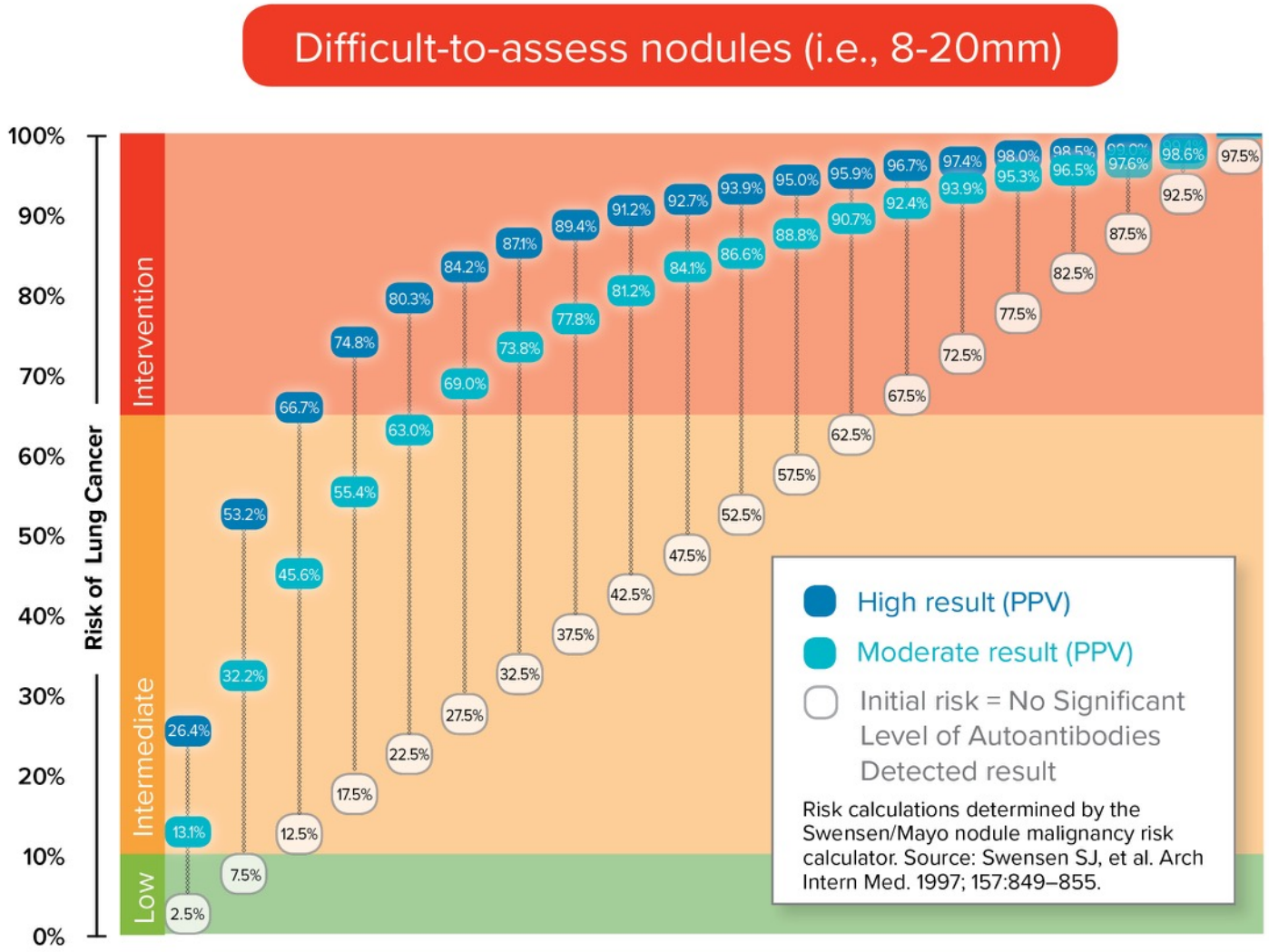
Swensen/Mayo risk level		**Risk adjusted by *Early*CDT-Lung test results**
<10% risk of lung cancer*	LOW RISK	**High or Moderate** *Early*CDT-Lung test result -> **risk raised to Intermediate risk**
10-65% risk of lung cancer*	INTERMEDIATE RISK	**High** *Early*CDT-Lung test result **raises risk to Intervention risk for all patients**. **Moderate** *Early*CDT-Lung test result **>25% increase in risk**, so **Intervention risk for some patients**.
>65% risk of lung cancer*	INTERVENTION RISK	Occasional use of *Early***CDT-Lung** following biopsy or bronchoscopy where it is deemed further risk evaluation is of value.

Swensen SJ, et al. *Arch Intern Med.* 1997; 157:849-855.
Healey GF, et al. *J Cancer Ther.* 2017; 8:506-517.
Massion PP, et al. *J Thorac Oncol.* 2017; 12(3):578-584.

***Risk categories according to the ACCP guidelines**

*Early*CDT®-Lung fits in with ACCP guidelines by helping to assess the probability of malignancy of a nodule

*Early*CDT®–Lung



Massion PP, Healey GF, Peek LJ, et al. J Thorac Oncol. 2017; 12(3):578-584
Healey GF, Macdonald IK, Reynolds C, et al. J Cancer Ther. 2017; 8:506-517.

*Early*CDT®-Lung Easy-To-Read Test Results

*Early*CDT®–Lung

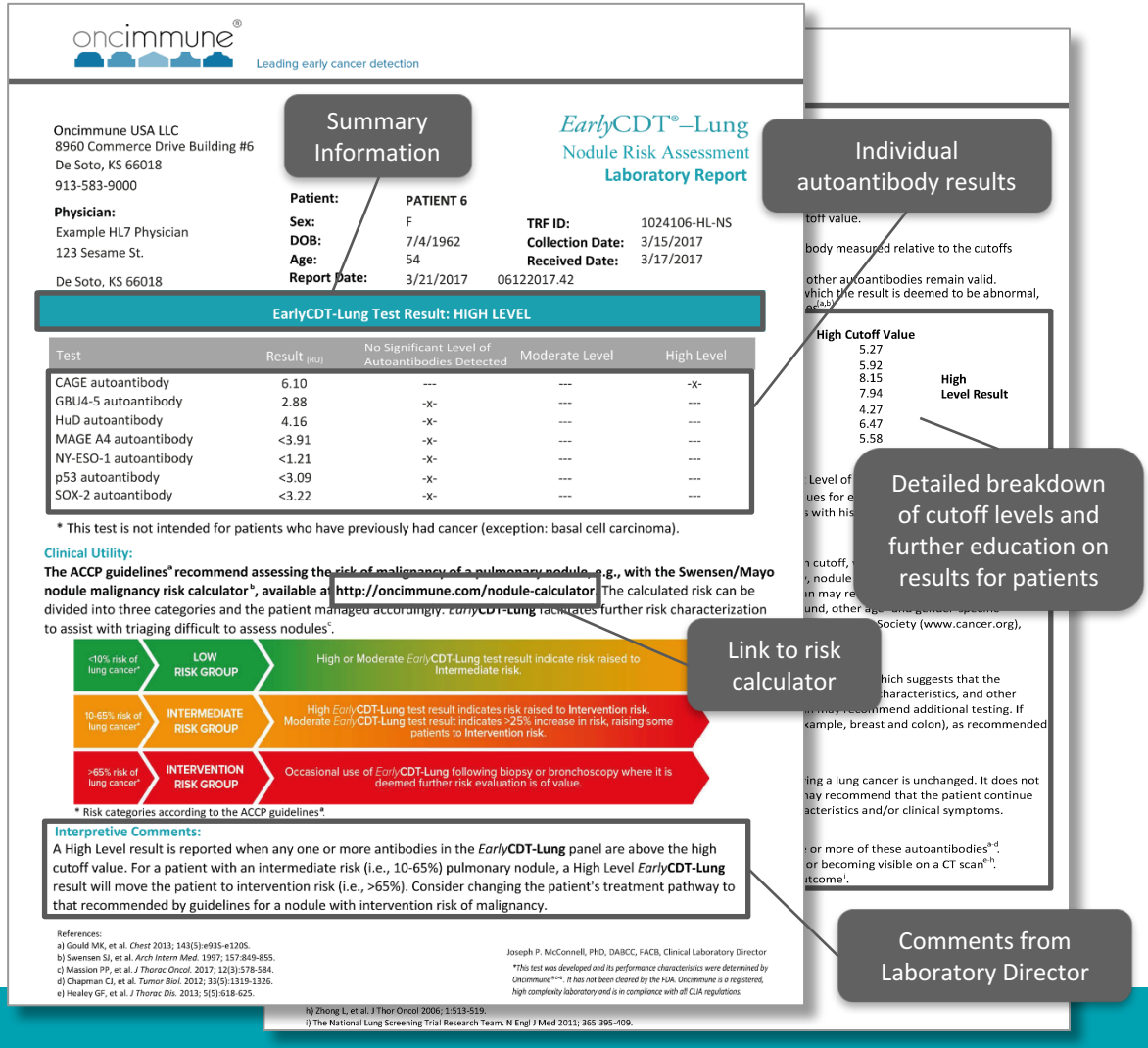
“Moderate” or “High” Level

- Indicates that a patient’s risk of having lung cancer is significantly greater than that predicted by their gender, age, smoking history, nodule characteristics and other risk factors

“No Significant Level of Autoantibodies Detected”

- Patient’s risk of lung cancer does not change from the calculated risk
- Adds confidence in previously selected treatment pathway
- Patient experiences less anxiety if next steps are watchful waiting

Complete information at a glance:



Autoantibody Cut-offs

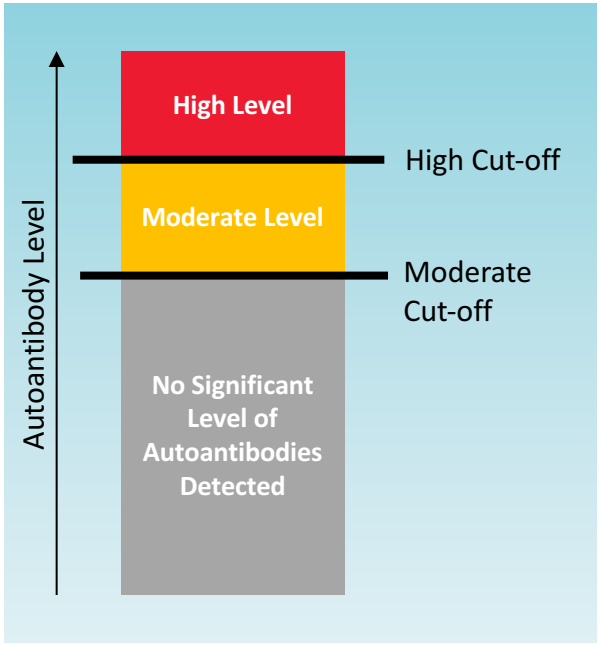
EarlyCDT®–Lung

- Each Autoantibody (Aab) has 2 cut-offs: a moderate and a high cut-off

- Positive results:
  - If 1 or more AAb is above the High cut-off → High Level result
  - If 1 or more AAb is above the Moderate cut-off and none are above the high cut-off → Moderate Level result

- If all AAbs are below the Moderate cut-off → No Significant Level of Autoantibodies Detected result

- Cut-offs were optimized for each AAb to maximize specificity of the 7-AAb panel in case-control studies using high risk subjects
  - Specificity @ High Level = 98%
  - Specificity @ Moderate Level = 93%



*Early*CDT®-Lung Publications for Risk Assessment of Pulmonary Nodules

*Early*CDT®–Lung

Tumor-Associated Autoantibodies: Re-Optimization of EarlyCDT-Lung Diagnostic Performance and Its Application to Indeterminate Pulmonary Nodules

Graham F. Healey, Isabel K. Macdonald, Chris Reynolds, et al.

Journal of Cancer Therapy 2017; 8:506-517.

- Receiver-operating characteristic (ROC) curve to predict *Early***CDT-Lung** performance from 0-100% specificity; optimum at high specificity.
- Area under the curve (AUC) = 0.743
- Theoretical evaluation of a cohort with indeterminate pulmonary nodules.

Specificity	PPV	Relative Risk	DLRp
90%	54%	3.7	4.2
98%	78%	5.0	14.0

- *Early***CDT-Lung** enables risk re-classification of intermediate risk nodules to facilitate more appropriate intervention.
- Describes how *Early***CDT-Lung** can help in assessing the risk of malignancy of a pulmonary nodule, as recommended by the ACCP guidelines*

Autoantibody Signature Enhances the Positive Predictive Power of Computed Tomography and Nodule-Based Risk Models for Detection of Lung Cancer

Pierre P. Massion, Graham F. Healey, Laura J. Peek, et al.

Journal of Thoracic Oncology 2017; 12(3):578-584.

- High specificity of *Early***CDT-Lung** complements the low specificity of CT.
- A positive (Moderate or High) *Early***CDT-Lung** result represented a more than 2-fold increased risk of lung cancer versus a negative (No Significant Level of Autoantibodies Detected).
- *Early***CDT-Lung** provides additional evidence of lung cancer thereby improving the PPV over nodule-based risk models alone.

EXAMPLE

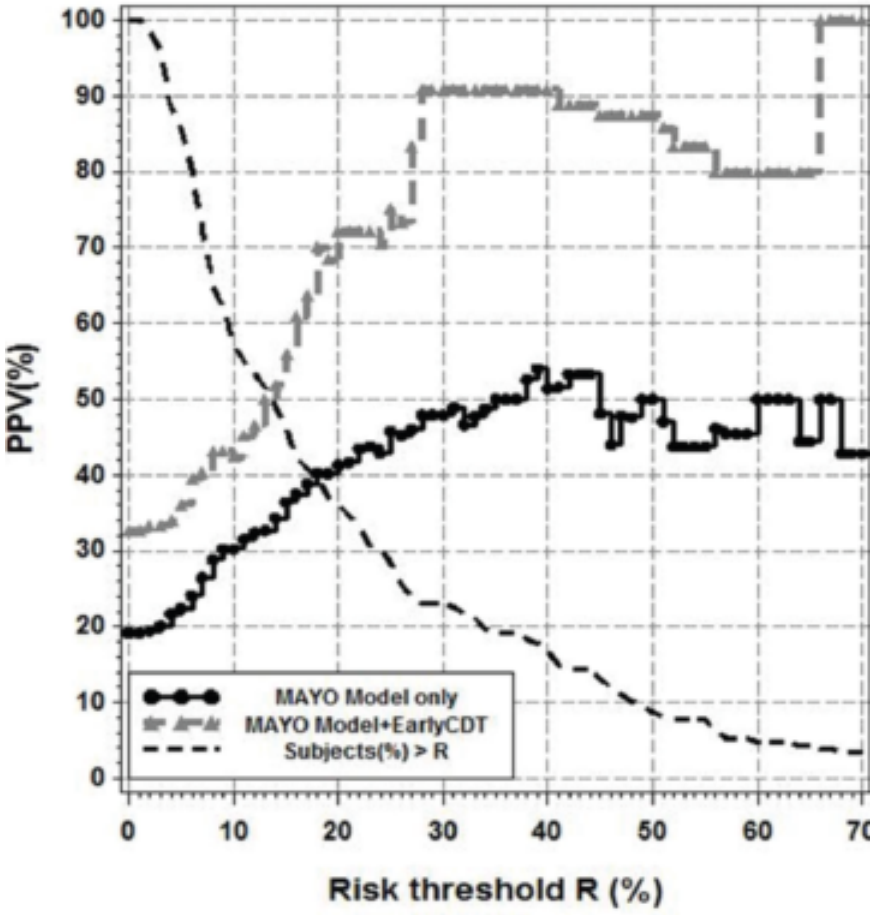
With a risk threshold of 30% using the Mayo risk calculator, the PPV increased from 48% to 91% with a positive *Early***CDT-Lung** result.

*Gould MK, et al. Chest 2013; 143(5):e93S-e120S.

EarlyCDT-Lung significantly increases the PPV of CT scanning and of nodule-based risk calculators[1]

EarlyCDT®–Lung

- EarlyCDT-Lung used in combination with the initial assessment of nodule probability of malignancy provides invaluable additional data:
  - May lead to earlier intervention, and
  - Better patient outcomes
- The Swensen/Mayo risk calculator to calculate the malignancy risk of a nodule with the added value of EarlyCDT-Lung is available via our website, or our mobile App



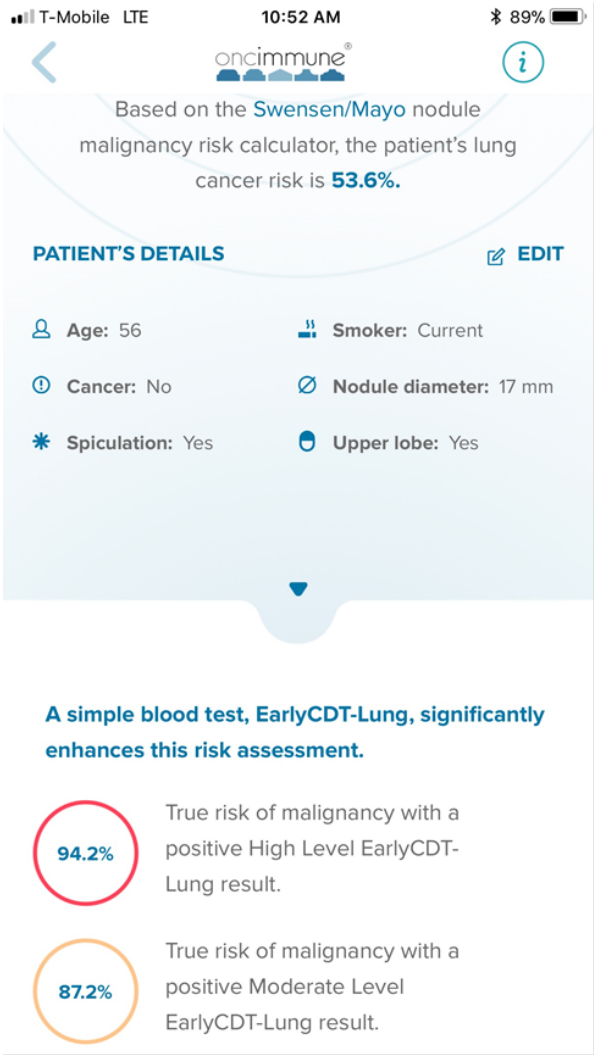
Massion P., Healey G., et al: Autoantibody Signature Enhances the Positive Predictive Power of Computed Tomography and Nodule-based Risk Models for Detection of Lung Cancer J Thorac Oncol. 2017 March; 12(3):578-584/j.tho.2016.08.143

Our easy to use Risk Calculator App is available for Android and iOS and on our web site

EarlyCDT®–Lung

EarlyCDT-Lung for Nodules App

- For the App simply search for EarlyCDT or Oncimmune
- For Android: https://play.google.com/store/apps/details?id=com.oncimmune
- For Apple: https://itunes.apple.com/gb/app/earlycdt-lung-for-nodules/id1310399708?mt=8
- Web:
- www.oncimmune.com/



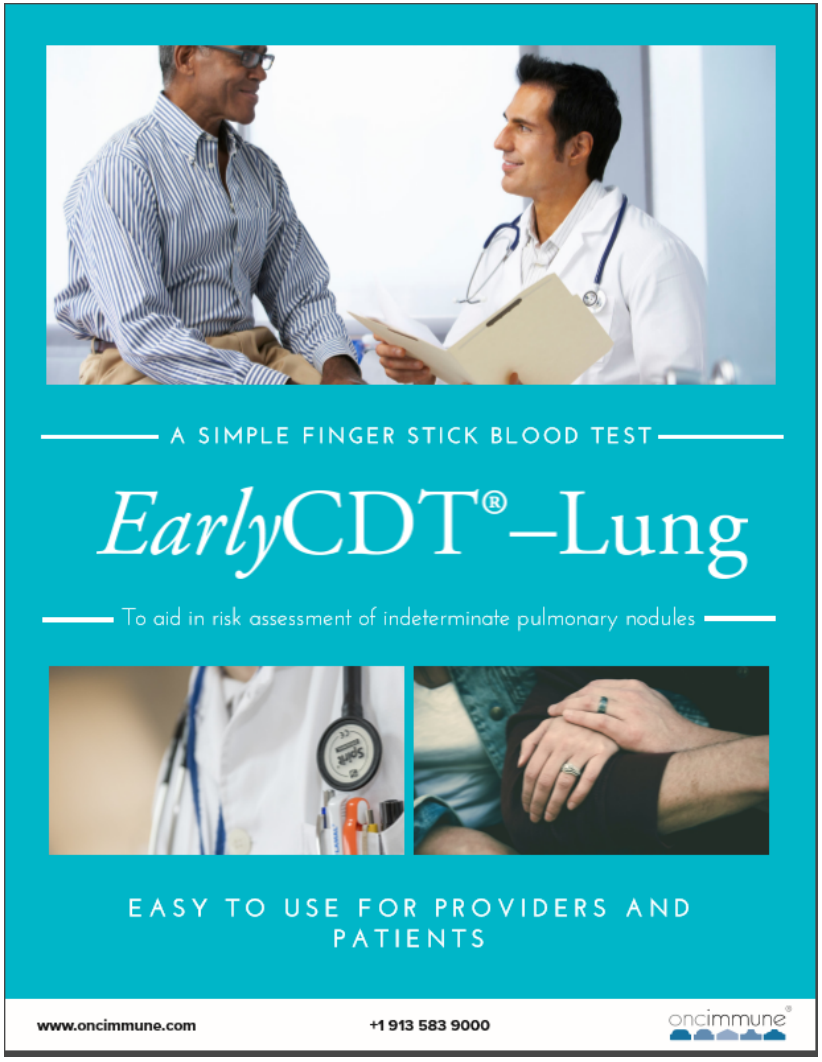
*Early*CDT®-Lung now available with a simple finger stick blood draw

*Early*CDT®–Lung

*Early*CDT®-Lung now available with finger stick blood draw that the patient can use to give a specimen

It is:

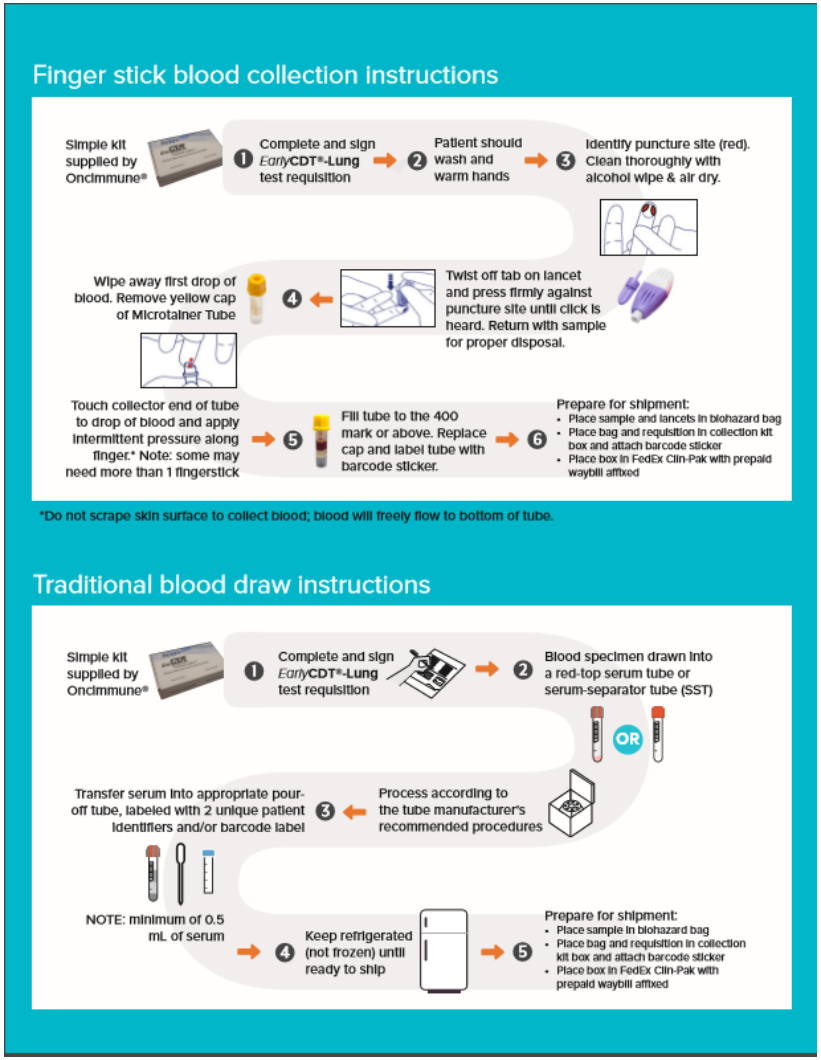
- simple
- quick
- convenient



The specimen collection kit makes *Early*CDT®-Lung simple to order

*Early*CDT®–Lung

- *Early*CDT®-Lung specimen collection kit contains everything needed to order the test for both finger stick and traditional blood draw
- Choose the draw option that works best for you and your patient.
- Order specimen collection kits call 1-877-745-5342 or email info@legacyscientific.com



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For more information:

Call 1-877-745-5342

or **email**

info@legacyscientific.com

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