



EarlyCDT[®]-Lung

Addressing the Diagnostic Gaps in Lung Cancer Screening

The Problem:

- When nodules are found on Low Dose CT (LDCT), 95% are FALSE positives for lung cancer.¹

Why Should I Use This Test in My Practice?

- EarlyCDT-Lung can be used in conjunction with LDCT to ‘rule-in’ and assess the risk of lung cancer in asymptomatic patients at increased risk for cancer. It is not a ‘rule-out’ test.

The EarlyCDT-Lung Solution:

- The EarlyCDT-Lung test significantly aids in the further risk assessment of lung nodules.²⁻³
- Test performance has been optimized for “rule in” use in conjunction with LDCT scanning.²⁻³
- EarlyCDT-Lung can detect lung cancer up to 4 years earlier than other methods.^{4,5}

The Science Behind the Test:

- EarlyCDT-Lung is an enzyme-linked immunosorbent assay (ELISA) that measures blood levels of seven autoantibodies (CAGE, GBU4-5, p53, NY-ESO-1, SOX-2, MAGE A4, HuD) to tumor-associated antigens that are linked to lung cancer.
- Over 120,000 patient samples examined, and 12 million data points analyzed to validate the technical and clinical performance of EarlyCDT-Lung in early lung cancer diagnosis.
- EarlyCDT-Lung is being evaluated in the largest randomized trial for the early detection of lung cancer through the National Health Service (NHS) Scotland ECLS study of 12,000 high-risk smokers.⁶
- More than 150,000 commercial tests have been run in the US laboratory.
- EarlyCDT-Lung has been validated for the management of indeterminate pulmonary nodules found on LDCT.²⁻³

EarlyCDT-Lung Patient Profile:


- EarlyCDT-Lung should be considered in patients who have:
 - No personal history of cancer
 - Patients with indeterminate pulmonary nodules detected by LDCT
 - 20+ pack-year history of smoking or vaping
 - Environmental Exposures


The Patient Benefit:

- Finding Lung Cancer early saves lives.
 - When Lung Cancer is found early, the five-year survival rate is 54%.⁷
 - When Lung Cancer is found late, the five-year survival rate drops to 4%.⁷

How Do I Get Started?

- Fill out a new account form and submit it to client relations clientrelations@myinnovativelab.com.
- Upon completion of new account form, a starter kit(s) will be shipped based upon your testing needs.
- Schedule training of your staff through an onboarding call with Innovative Diagnostic Laboratory.





EarlyCDT®-Lung
LABORATORY RESULTS

Patient	Name:		Phone #:		Patient ID #:		Specimen	Collection Time:		Specimen ID:		Provider	Requesting Provider			
	Fasting Status:		Gender:		Birthdate:			Age:		Collection Date:			Report Type:		Client ID:	
	Height:		Weight:		BMI:			Prev. BMI:		Received Date:			Report Date:			
	Pack-Year† :		Packs/Day Smoked† :		Smoking Status† :			† patient self-reported smoking history								

EarlyCDT-Lung	Results	Cutoff		Prev. Results	Physician's Notes
		Moderate	High		
CAGE autoantibody* (RU)	2.82	4.25	4.52	3.75	
GBU4-5 autoantibody* (RU)	2.87	4.36	4.53	2.26	
HuD autoantibody* (RU)	<4.81	7.31	7.69	3.67	
MAGE A4 autoantibody* (RU)	7.99	6.19	7.17	4.98	
NY-ESO-1 autoantibody* (RU)	3.45	3.02	3.39	<0.70	
p53 autoantibody* (RU)	<3.89	5.79	5.99	<3.09	
SOX-2 autoantibody* (RU)	<4.02	5.48	6.98	<2.67	

Tested on: 2014-08-26

Clinical Utility		
<small>The ACCP guidelines* recommend assessing the risk of malignancy of a pulmonary nodule, e.g., with the Swensen/Mayo nodule malignancy risk calculator,⁶ available at oncimmune.com/nodule-calculator. The calculated risk can be divided into three categories and the patient managed accordingly. EarlyCDT-Lung facilitates further risk characterization to assist with triaging difficult to assess nodules.⁶</small>		
<5% risk of lung cancer*	VERY LOW RISK	High or Moderate EarlyCDT-Lung test result: risk raised from very low risk to low to moderate risk.
5%-65% risk of lung cancer*	LOW to MODERATE RISK	High EarlyCDT-Lung test result: risk raised to high risk if pre-test risk >10%. Moderate EarlyCDT-Lung test result: risk raised to high risk if pre-test risk >45%; otherwise, consider patient at increased moderate risk.
>65% risk of lung cancer*	HIGH RISK	Occasional use of EarlyCDT-Lung test following biopsy or bronchoscopy where further risk evaluation is deemed of value.

* Risk categories according to the ACCP guidelines.*

Interpretive Comments

A **High Level** result is reported when any one or more autoantibodies in the EarlyCDT-Lung panel are above the high cut-off value. For a nodule with a pre-test risk of >10%, a High Level EarlyCDT-Lung result will move the nodule to high risk (>65%). Consider changing the patient's treatment pathway to that recommended by guidelines for a nodule at high risk of malignancy.

What Do I Do with the Results?

- If you have a patient screened with LDCT who has an indeterminate nodules, use EarlyCDT-Lung as a rule-in test.
- If you have a patient with an elevated EarlyCDT-Lung score and negative LDCT – continue monitoring patient until you rule in or rule out lung cancer.

References

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- American Cancer Society Lung Cancer Prevention and Early Detection Last Medical Review: April 1, 2018 Last Revised: April 14, 2018 <https://www.cancer.org/health-care-professionals/american-cancer-society-prevention-early-detection-guidelines/lung-cancer-screening-guidelines.html>