



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?

1. Fill out a new account form and submit it to client relations clientrelations@myinnovativelab.com.
2. Upon completion of new account form, a starter kit(s) will be shipped based upon your testing needs.
3. 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: _____				

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: 2014-08-28

Test Result and Interpretive Comments

Test Result: HIGH LEVEL

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.

Clinical Utility

The ACCP guidelines³ recommend assessing the risk of malignancy of a pulmonary nodule, e.g., with the Swensen/Mayo nodule malignancy risk calculator,² 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.^{3,4}

<5% risk of lung cancer*	VERY LOW RISK	High <i>EarlyCDT-Lung</i> test result: risk raised from very low risk to moderate risk. Moderate <i>EarlyCDT-Lung</i> test result: risk raised from very low risk to low risk.
5%-65% risk of lung cancer*	LOW to MODERATE RISK	High <i>EarlyCDT-Lung</i> test result: risk raised to high risk if pre-test risk >10%; Moderate <i>EarlyCDT-Lung</i> 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 <i>EarlyCDT-Lung</i> test following biopsy or bronchoscopy where further risk evaluation is deemed of value.

* Risk categories according to the ACCP guidelines.³

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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2. Gould MK, et al. Evaluation of individuals with pulmonary nodules: when is it lung cancer? Diagnosis and management of lung cancer, 3rd ed: American College of Chest Physicians evidence-based clinical practice guidelines. *Chest* 2013; 143(5):e93S-e120S.
3. Massion PP, 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 Thorac Oncol*. 2017 Mar;12(3):578-584 7.
4. Zhong L, et al. Profiling Tumour-Associated Antibodies for detection of Non-small Cell Lung Cancer. *J Thor Oncol* 2006; 1:513-519.
5. Jett J, et al. Determination of the detection lead time for autoantibody biomarkers in early stage lung cancer using the UKCTOCS cohort. *J Thor Oncol* 2017; 12(11):S2170
6. Sullivan FM, et al. Detection in blood of autoantibodies to tumour antigens as a case-finding method in lung cancer using the *EarlyCDT®-Lung* Test (ECLS): study protocol for a randomized controlled trial. *BMC Cancer* 2017 17:187
7. 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-careprofessionals/american-cancer-society-prevention-earlydetection-guidelines/lung-cancer-screening-guidelines.html>