



EarlyCDT[®]-Lung

Addressing the Diagnostic Gaps in Lung Cancer Screening

The Problem:

- Only 3% of patients at risk for Lung Cancer are compliant with Lung Cancer screening with low dose CT (LDCT) ¹
- When nodules are found on LDCT, 95% are FALSE positives for lung cancer.²

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:

- Test performance has been optimized for “rule in” use in conjunction with LDCT scanning.³⁻⁴
- EarlyCDT-Lung can detect lung cancer up to 4 years earlier than other methods.⁸

The Science Behind the Test:

- EarlyCDT-Lung is an advanced, molecular diagnostic that measures seven autoantibodies (CAGE, GBU4-5 , p53, NY-ESO- 1, SOX-2 , MAGE A4, HuD) in blood that identify elevated risk of 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.³⁻⁴

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%.⁹
 - When Lung Cancer is found late, the five-year survival rate drops to 4%.⁹

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.



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

- Gopal M, Abdullah SE, Grady JJ, Goodwin JS. Screening for Lung Cancer with Low-Dose Computed Tomography: A Systematic Review and Meta-Analysis of the Baseline Findings of Randomized Controlled Trials. *J Thorac Oncol*. 2010 Aug;5(8):1233-9.
- Croswell JM, Kramer BS, Kreimer AR, et al. Cumulative Incidence of False-Positive Results in Repeated, Multimodal Cancer Screening. *Annals of Family Medicine*. 2009;7(3):212-222.
- 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.
- 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
- Howlander N, et al. SEER Cancer Statistics Review, 1975-2014, National Cancer Institute, Bethesda, MD, https://seer.cancer.gov/csr/1975_2014/.
- <http://www.eclstudy.org/home>
- Moyer VA, on behalf of the U.S. Preventive Services Task Force. Screening for Lung Cancer: U.S. Preventive Services Task Force Recommendation Statement. *Ann Intern Med*. 2014;160:330–338.
- Zhong L, et al. Profiling Tumour-Associated Antibodies for detection of Non-small Cell Lung Cancer. *J Thor Oncol* 2006; 1:513-519.
- 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> and <http://onlinelibrary.wiley.com/doi/10.3322/caac.21172/full>
- Jett JR, Peek LJ, Fredericks L, Jewell W, Pingleton WW, Robertson JF. Audit of the autoantibody test, EarlyCDT-Lung, in 1600 patients: an evaluation of its performance in routine clinical practice. *Lung Cancer*. 2014 Jan;83(1):51-5. doi: 10.1016/j.lungcan.2013.10.008. Epub 2013 Oct 22)

1 All patient, sampling and physician demographics appear at the top of each page.

2 Autoantibody levels are noted numerically and color coded red, orange or green based upon results. Levels above the 'high' cut-off are color coded red. Levels above the 'Moderate' cut-off are color coded orange. Levels below both cut-offs are color coded green.

EarlyCDT-Lung	Results	Cutoff Moderate	Cutoff High	Prev. Results	Physician's Notes
CAGE autoantibody* (RU)	3.39	4.25	5.27		
GBU4-5 autoantibody* (RU)	4.32	4.36	5.92		
HuD autoantibody* (RU)	5.58	7.31	8.15		
MAGE A4 autoantibody* (RU)	5.96	6.19	7.94		
NY ESO-1 autoantibody* (RU)	4.34	3.02	4.27		
p53 autoantibody* (RU)	4.04	5.79	6.47		
SOX-2 autoantibody* (RU)	<3.22	5.48	5.58		

3 Test Results are calculated using gender, age and smoking history alone and together with EarlyCDT-Lung autoantibody levels. Both results are provided as the patients current percent risk of having lung cancer.

4 Interpretation of results: Depicts the increase in the patient's individual risk after EarlyCDT-Lung.

Test Results
The patient's risk of lung cancer based ONLY on gender, age and smoking history is 1.9%, and including the High Risk Result, is now 28.0% **

Risk Stratification Results

UNCHANGED (1X) → MODERATE (3X) → HIGH (15X) → RELATIVE RISK + RISK

Relative risk identified by EarlyCDT-Lung at this time is high. The level of one or more of the autoantibodies in the EarlyCDT-Lung panel is higher than the high cutoff. This result indicates an increased risk that the patient has lung cancer. Additional monitoring for lung cancer, including imaging with low dose CT (LDCT), is recommended, consistent with the patient's history, risk profile and the increased risk identified by EarlyCDT-Lung. This test result does not definitively mean that lung cancer is present.

High specificity means a low false positive rate for high risk patients.

90% SPECIFICITY

96% SPECIFICITY

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