



### THE CHALLENGE

- 57% of Lung Cancers are found in the late stage, when the 5-year Survival Rate is 5% or lower. (1)
- 96% of nodules found on Low Dose CT are false positives and can lead to unnecessary procedures. (2)
- Compliance with lung cancer screening is 2-4%. (3)

### THE EARLYCDT<sup>®</sup>-LUNG SOLUTION

- *EarlyCDT-Lung* is a blood test that can detect all types of lung cancer at all stages of disease (I-IV) with high accuracy.
- *EarlyCDT-Lung* can be used in conjunction with Low Dose CT Scans to rule in and assess the risk of lung cancer in patients with indeterminate pulmonary nodules and those at increased risk for lung cancer.

### 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)
- Over 25 peer-reviewed clinical publications
- More than 60 peer-reviewed oral and poster presentations at key conferences

### WHY USE THIS TEST IN MY PRACTICE?

- *EarlyCDT-Lung* can detect lung cancer up to 4 years earlier than other methods. (7,8)
- The *EarlyCDT-Lung* test significantly aids in the further risk assessment of lung nodules. (5,6)
- Test performance has been optimized for rule in use in conjunction with LDCT scanning.(7,8)

### PATIENT SELECTION CRITERIA

- *EarlyCDT-Lung* can be used in conjunction with Low Dose CT Scans to rule in and assess the risk of lung cancer in patients with indeterminate pulmonary nodules and those at increased risk for lung cancer.

**Contact Us Today to Get Started!**

**1-855-420-7140**

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### EarlyCDT®-Lung LABORATORY RESULTS

<b>Patient</b>	Name:	Phone #:	Patient ID #:	<b>Specimen</b>	Collection Time:	Specimen ID:	<b>Provider</b>	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: 2014-08-26

#### 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 guidelines<sup>3</sup> recommend assessing the risk of malignancy of a pulmonary nodule, e.g., with the Swensen/Mayo nodule malignancy risk calculator,<sup>2</sup> available at [oncimmune.com/module-calculator](http://oncimmune.com/module-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.<sup>4,5</sup>

<5% risk of lung cancer*	<b>VERY LOW RISK</b>	<b>High EarlyCDT-Lung test result:</b> risk raised from very low risk to moderate risk. <b>Moderate EarlyCDT-Lung test result:</b> risk raised from very low risk to low risk.
5%-65% risk of lung cancer*	<b>LOW to MODERATE RISK</b>	<b>High EarlyCDT-Lung test result:</b> risk raised to high risk if pre-test risk >10%; <b>Moderate EarlyCDT-Lung test result:</b> risk raised to high risk if pre-test risk >45%; <b>Otherwise,</b> consider patient at increased moderate risk.
>65% risk of lung cancer*	<b>HIGH RISK</b>	<b>Occasional use of EarlyCDT-Lung test</b> following biopsy or bronchoscopy where further risk evaluation is deemed of value.

\* Risk categories according to the ACCP guidelines.<sup>3</sup>

## TEST INTERPRETATION

- 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 until you rule in or rule out lung cancer.
- *EarlyCDT-Lung* positive results may reclassify clinicians' assessment of cancer risk in pulmonary nodules

## Contact Us Today to Learn More

# 1-855-420-7140

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2. National Cancer Institute Lung Cancer Screening: May 27, 2019 ([https://www.cancer.gov/types/lung/hp/lung-screening-pdq#\\_69\\_toc](https://www.cancer.gov/types/lung/hp/lung-screening-pdq#_69_toc))
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