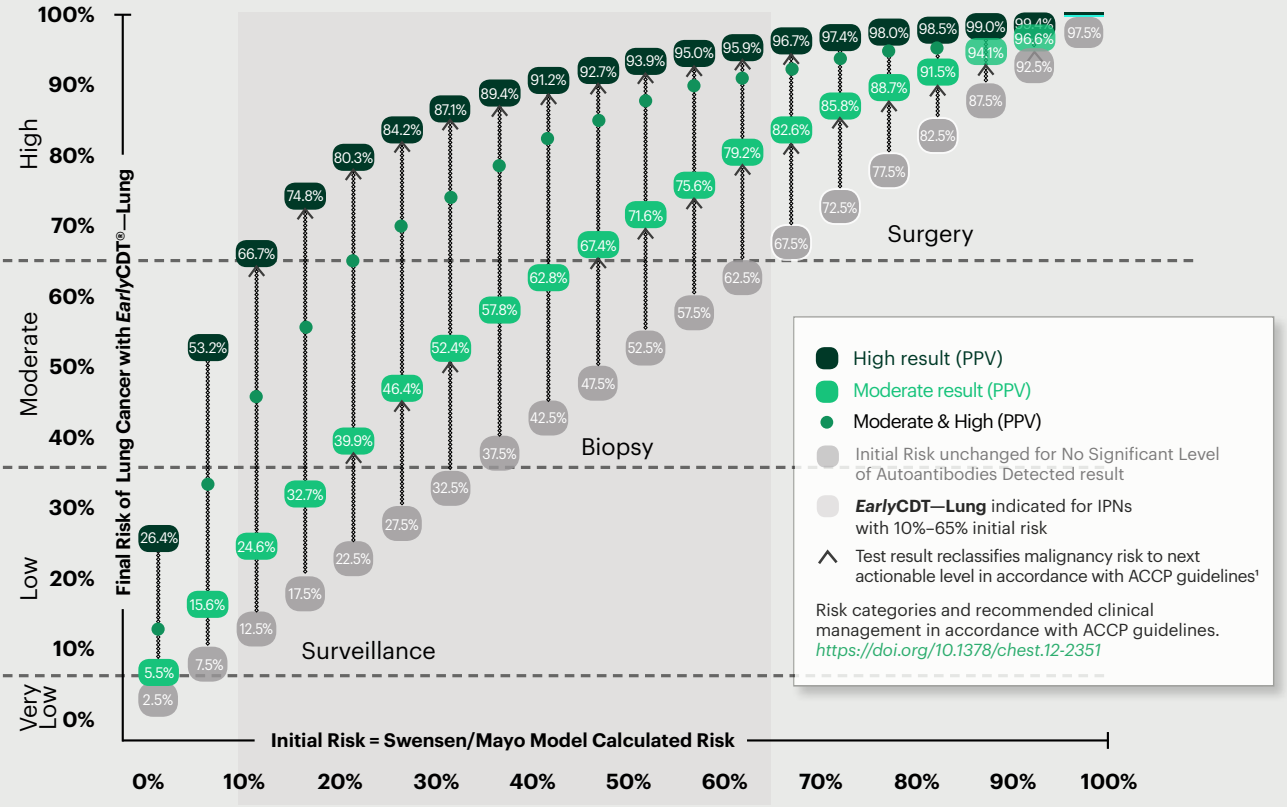
*Early*CDT®—Lung

A simple blood test to aid in indeterminate pulmonary nodule risk assessment.

- **Complement to CT scans**
- **Measures a panel of autoantibodies**
- **Characterizes risk of indeterminate nodules**
- **May recategorize nodule to intervention risk**
- **Earlier intervention and better outcomes**

***Early*CDT—Lung** Reclassifies Malignancy Risk in Nodules with 10%–65% Initial Risk



A nodule risk calculator combining the Swensen/Mayo model with ***Early*CDT—Lung** is available at *http://oncimmune.com/nodule-calculator*
Risk calculations: Healey GF, Macdonald IK, Reynolds C, et al. Tumor-Associated Autoantibodies: Re-Optimization of ***Early*CDT—Lung** Diagnostic Performance and its Application to Indeterminate Pulmonary Nodules. *J Cancer Ther.* 2017; 8:506–517.

- Strong clinical data demonstrating high specificity and high PPV (Rule-in Test)
- Highly cost-effective and may be billed to Medicare and commerical insurance companies

1. Massion PP, Healey GF, Peek LJ, et al. *J Thorac Oncol.* 2017; 12(3):578–584.

Test reports show complete information at a glance

*Early*CDT®—Lung

Nodule Risk Assessment
Patient Report

Note: This test is not intended for patients who have a previous diagnosis of cancer (except basal cell carcinoma).

Patient	Specimen Information	Clinician
PATIENT 5	T	mple HL7 Physician
Sex: F	C	mple HL7 Clinic
D.O.B: 7/4/1962	R	Sesame St.
Age: 55	Report date: 8/31/2017	De Soto, KS 66018

Summary information

EarlyCDT-Lung Test Result: HIGH LEVEL

Test	Result (RU)	No Significant Level of Autoantibodies Detected	Moderate Level	High Level
CAGE autoantibody	<2.76	-x-	---	---
GBU4-5 autoantibody	1.06	-x-	---	---
NY-ESO-1 autoantibody	<1.01	-x-	---	---
p53 autoantibody	<3.09	-x-	---	---
SOX-2 autoantibody	5.62	---	---	-x-
MAGE A4 autoantibody	<3.91	-x-	---	---
HuD autoantibody	<3.99	-x-	---	---

Individual antibody results

Clinical Utility
The ACCP guidelines[a] recommend assessing the risk of malignancy of a pulmonary nodule, e.g., with the Swensen/Mayo nodule malignancy risk calculator[b], available at oncimmune.com/nodule-calculator
The calculated risk can be divided into three categories and the patient managed accordingly.
***Early*CDT—Lung** facilitates further risk characterization to assist with triaging difficult to assess nodules.[c,d]

Link to risk calculator

<5% risk of lung cancer*	**VERY LOW RISK**	**High or Moderate *Early*CDT—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 *Early*CDT—Lung test result:** risk raised to high risk if pre-test risk >10%. **Moderate *Early*CDT—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 *Early*CDT—Lung** following biopsy or bronchoscopy where further risk evaluation is deemed of value.

* Risk categories according to the ACCP guidelines.[1]

Interpretive Comments
A **High Level** result is reported when any one or more autoantibodies in the ***Early*CDT—Lung** panel are above the high cut-off value. For a nodule with a pre-test risk of >10%, a High Level ***Early*CDT—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.

Joseph P. McConnell, PhD, DABCC, FACB, Clinical Laboratory Director

Comments from laboratory director

References
a) Gould MK, et al. *Chest* 2013; 143(5):e93S-e120S.
b) Swensen SJ, et al. *Arch Intern Med.* 1997; 157:849–
c) Massion pp, et al. *J Thorac Oncol.* 2017; 12(3):578–
d) Healey GF, et al. *J Cancer Ther.* 2017; 8(5):506–517.
Biol. 2012; 33(5):1319–1326.
Dis. 2013; 5(5):618–625.

This test was developed and its performance charact… been cleared by the FDA. Oncimmune is a COLA accredited, high complexity laboratory and is …

Oncimmune www.oncimmune.com **Questions?** Call 1-888-583-9030

Detailed breakdown of cutoff levels and further education on results for patients

…n Relative Units (RU) for autoantibodies or ng/mL for alpha-

…result is below the low cut-off value.
…the high cut-off value.

…measured relative to the cut-off for each biomarker.
…arkers remain valid.
…result is deemed to be abnormal, as established

Cut-off alue		High Cut-off alue	
8.696		9.033	
6.865		9.696	
6.574	**Moderate Level** result	6.774	**High Level** result
7.972		8.172	
6.286		6.606	
6.515		6.715	
7.826		8.026	
00 ng/mL		221 ng/mL	

…ndard cut-off applied when AFP is used as a single biomarker test to …k of recurrence after liver transplant.

…e)
…oderate Level or No Significant Level of Biomarkers Detected, …ared to the high and low cut-off values for each biomarker. …w. The patient should discuss the results with his/her clinician … steps.

…arkers were detected above the high cut-off, which suggests …ly increased; however, this result does not definitively mean …additional testing. If liver cancer is not found, other age- and … breast and colon), as recommended by the American Cancer …

… biomarkers were detected between the low and high cut-off, …n is increased; however, this result does not definitively mean …additional testing. If liver cancer is not found, other age- and …mended by the American Cancer Society (*www.cancer.org*),

…arkers Detected"?
…ggests the risk of having a liver cancer is unchanged. It does …ure. A clinician may recommend that you continue a schedule …y and/or clinical symptoms.

What do these biomarker levels have to do with liver cancer?
Some individuals with liver cancer have been found to have elevated levels of one or more of these biomarkers.[a–f] Autoantibodies have been shown to be present in the blood up to four years prior to cancer diagnosis by imaging.[g–i] Early detection of liver cancer has been shown to increase the potential for an improved outcome.[k]

References
a) Middleton CH, et al. PLoS ONE 2014; 9(8):e103867.
b) Hong Y, et al. *World J Hepatol.* 2015; 7(11):1581–1585.
c) Chen Y, et al. *Cancer Letters* 2010; 289:32–39.
d) Liu H, et al. *Cancer Epidemiol.* 2012; 36(1):82–88.
e) Tatarinov IS. *Vopr Med Khim.* 1964; 10:90–91.
f) Hu B, et al. *Int J Mol Sci.* 2013; 14(12):23559–23580.
g) Trivers GE, et al. *Clin Cancer Res.* 1996; 2:1767–1775.
j) Li Y, et al. *Int J Cancer.* 2005; 114:157–160.
i) Zhong L, et al. *J Thor Oncol.* 2006; 1:513–519.
j) Jett J, et al. *J Thorac Oncol.* 2017; 12(11):S2170.
k) Zhang BH, et al. *J Cancer Res Clin Oncol.* 2004; 130(7):417–422.

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