



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	TRF ID: 08312017-HL	Example HL7 Physician
Sex: F	Collection date: 11/13/2018	Example HL7 Clinic
D.O.B: 7/4/1962	Received date: 11/14/2018	123 Sesame St.
Age: 56	Report date: 11/16/2018	De Soto, KS 66018

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-	---	---

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.

EarlyCDT—Lung facilitates further risk characterization to assist with triaging difficult to assess nodules.^{c,d}

<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 following biopsy or bronchoscopy where further risk evaluation is deemed of value.

* Risk categories according to the ACCP guidelines.^a

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.

References

- a) Gould MK, et al. *Chest* 2013; 143(5):e93S-e120S.
 b) Swensen SJ, et al. *Arch Intern Med*. 1997; 157:849–855.
 c) Massion pp, et al. *J Thorac Oncol*. 2017; 12(3):578–584.

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

- d) Healey GF, et al. *J Cancer Ther*. 2017; 8(5):506–517.
 e) Chapman CJ, et al. *Tumor Biol*. 2012; 33(5):1319–1326.
 f) Healey GF, et al. *J Thorac Dis*. 2013; 5(5):618–625.

This test was developed and its performance characteristics were determined by Oncimmune.^{e-f} It has not been cleared by the FDA. Oncimmune is a COLA accredited, high complexity laboratory and is in compliance with all CLIA regulations.



Definitions

Test: Indicates the autoantibody analyzed for testing.

Result: Calculated reportable value of a given autoantibody in Relative Units (RU).

No Significant Level of Autoantibodies Detected: Reportable result is below the low cut-off value.

Moderate Level: Reportable result is between the low and the high cut-off value.

High Level: Reportable result is above the high cut-off value.

Test Result: Determined based upon the highest level of autoantibody measured relative to the cut-offs for each autoantibody.

Invalid: Unable to determine result for this autoantibody. All other autoantibodies remain valid.

Cut-off: Threshold value for each autoantibody assay above which the result is deemed to be abnormal, as established from results of clinical validation studies.^{a,b}

Autoantibody		Low Cut-off Value		High Cut-off Value	
CAGE	No Significant Level of Autoantibodies Detected	4.25	Moderate Level result	5.27	High Level result
GBU4-5		4.36		5.92	
NY-ESO-1		3.02		4.27	
p53		5.79		6.47	
SOX-2		5.48		5.58	
MAGE A4		6.19		7.94	
HuD		7.31		8.15	

Understanding your results (for patient use)

EarlyCDT—Lung test results are reported as High Level, Moderate Level, and No Significant Level of Autoantibodies Detected, depending on the level of autoantibodies in the blood compared to high and low cut-off values for each autoantibody. Answers to some frequently asked questions are given below. The patient should discuss the results with his/her clinician for a clinical interpretation and recommendations for next steps.

What do I do if the result is “High Level”?

A “High Level” result means that one or more autoantibodies were detected above the high cut-off, which suggests that the likelihood of lung cancer is much greater than predicted by the patient’s gender, age, smoking history, nodule characteristics and other clinical factors. This result does not definitively mean that lung cancer is present. A clinician may recommend additional testing, including a PET scan, bronchoscopy, needle biopsy, or other testing. If lung cancer is not found, other age- and gender-specific screenings for other cancers (for example, breast and colon), as recommended by the American Cancer Society (www.cancer.org), should also be considered.

What do I do if the result is “Moderate Level”?

A “Moderate Level” result means that one or more autoantibodies were detected at an elevated level, which suggests that the likelihood of lung cancer is greater than predicted by the patient’s gender, age, smoking history, nodule characteristics, and other clinical factors. This result does not definitively mean that lung cancer is present. A clinician may recommend additional testing. If lung cancer is not found, other age- and gender-specific screenings for other cancers (for example, breast and colon), as recommended by the American Cancer Society (www.cancer.org), should also be considered.

What do I do if the result is “No Significant Level of Autoantibodies Detected”?

A “No Significant Level of Autoantibodies Detected” result suggests the patient’s risk of having lung cancer is unchanged. It does not rule out the possibility of the patient having lung cancer now or in the future. A clinician may recommend that the patient continue a schedule of testing and examination based on the patient’s personal history, nodule characteristics and/or clinical symptoms.

What do these autoantibody levels have to do with lung cancer?

In all types of lung cancer, some individuals have been found to have elevated levels of one or more of these autoantibodies.^{a-d} Autoantibodies have been shown to be present in the blood up to four years prior to a tumor becoming visible on a CT scan.^{e-i} Early detection of lung cancer has been shown to increase the potential for an improved outcome.^j

References

- a) Chapman CJ, et al. *Tumor Biol.* 2012; 33(5):1319–1326.
- b) Healey GF, et al. *J Thorac Dis.* 2013; 5(5):618–625.
- c) Massion PP, et al. *J Thorac Oncol.* 2017; 12(3):578–584.
- d) Lam S, et al. *Cancer Prev Res.* 2011; 4(7):1126–1134.
- e) Chapman C, et al. *Chest* 2010; 138:s775A.

- f) Trivers GE, et al. *Clinical Cancer Res.* 1996; 2:1767–1775.
- g) Li Y, et al. *Int J Cancer.* 2005; 114:157–160.
- h) Zhong L, et al. *J Thor Oncol.* 2006; 1:513–519.
- i) Jett J, et al. *J Thorac Oncol.* 2017; 12(11):S2170.
- j) The National Lung Screening Trial Research Team. *N Engl J Med.* 2011; 365:395–409.