



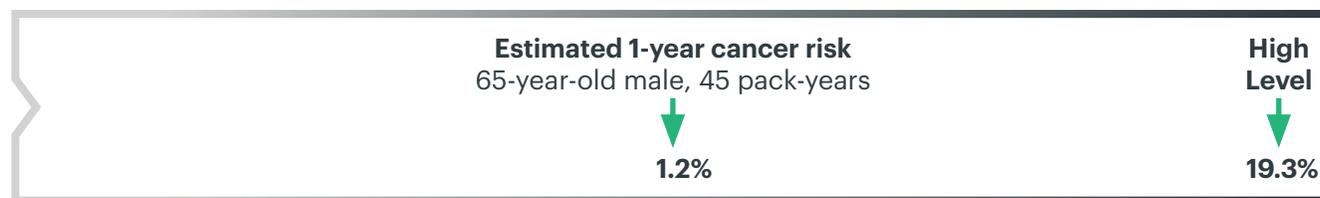
Note: This test is not intended for patients who have a previous diagnosis of cancer (except basal cell carcinoma).

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	7.12	---	---	-x-
MAGE A4 autoantibody	<3.91	-x-	---	---
HuD autoantibody	<3.99	-x-	---	---

A personalized assessment of the estimated risk of lung cancer as calculated based upon gender, age, smoking history. This test result can be obtained online at [oncimmune.com/smoking-calculator](http://oncimmune.com/smoking-calculator)



#### 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. This result suggests a greater likelihood of lung cancer than predicted by gender, age, smoking history, and other clinical factors.<sup>a-b</sup> Additional monitoring for lung cancer is recommended, including imaging with CT, consistent with the patient's history and other clinical findings. The graph below shows the impact of the test result for a 65-year-old male with a 45 pack-year smoking history.<sup>c</sup>

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

#### 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) Spitz MR, et al. *J Natl Cancer Inst.* 2007;99:715–726.

This test was developed and its performance characteristics were determined by Oncimmune.<sup>a-b</sup> 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.<sup>a,b</sup>

Autoantibody		Low Cut-off Value		High Cut-off Value	
CAGE	<b>No Significant Level of Autoantibodies Detected</b>	4.25	<b>Moderate Level result</b>	4.52	<b>High Level result</b>
GBU4-5		4.36		4.53	
NY-ESO-1		3.02		3.39	
p53		5.79		5.99	
SOX-2		5.48		6.98	
MAGE A4		6.19		7.17	
HuD		7.31		7.69	

## 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, and other clinical factors. This result does not definitively mean that lung cancer is present. A clinician may recommend additional testing, including a chest CT scan. 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](http://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 patients’s gender, age, smoking history, 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](http://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 a 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 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.<sup>a-d</sup> Autoantibodies have been shown to be present in the blood up to four years prior to a tumor becoming visible on a CT scan.<sup>e-i</sup> Early detection of lung cancer has been shown to increase the potential for an improved outcome.<sup>j</sup>

## 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.