*Early*CDT™-Lung Test: Audit of the First 1000 Patients in Clinical Practice

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PURPOSE

*Early*CDT™-Lung is a blood test to aid physicians in the early detection of lung cancer in high risk patients. It measures autoantibodies (AABs) to a panel of six tumor-associated antigens (TAAs) (p53, NY-ESO-1, CAGE, GBU4-5, Annexin1 and SOX2) with a specificity of 90% and a sensitivity of 40% for lung cancer in clinical validation studies.[1] We report here on the first 1010 patients in clinical practice who have taken the *Early*CDT-Lung test.

METHODS

One thousand and ten (1010) patients at high risk for lung cancer (on the basis of age and smoking history) who were referred by their physician for testing by *Early*CDT-Lung (starting in May 2009) are included in this analysis. All patients considered here signed a HIPAA release agreeing to share their clinical information as part of this prospective audit. A total of 293 centers across 40 states in the USA participated (Figure 1).

As a means to evaluate performance of *Early*CDT-Lung in the clinic, physicians were contacted following patient testing by *Early*CDT-Lung to determine whether a cancer diagnosis had been made.

- For patients with a positive *Early*CDT-Lung test, the physician was contacted to establish what course of action had followed the test, and regular contact was maintained until a definitive decision had been made.
- For patients with a negative *Early*CDT-Lung test, the physician was contacted after 6 months and 18 months to ascertain if the patient had developed a cancer; in the interim, if a patient's physician proactively provided such information, this was recorded.

For patients submitting samples in the first 12 months, the 6 month follow up is 98%.

RESULTS

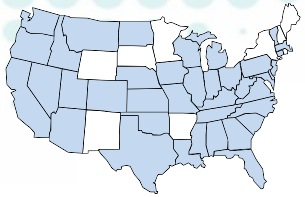

Figure 1. Regional coverage of physicians from 293 centers participating in this prospective audit of clinical data.

Table 1. Lung cancer diagnosis compared to *Early*CDT-Lung result.

	*Early*CDT-Lung		
	Positive	Negative	Total
Lung cancer confirmed	10	16	26
No cancer diagnosed at present	163	821	984
Total	173	837	1010

Table 2. Performance characteristics of *Early*CDT-Lung for this cohort of 1010 clinical patients, compared to previously published performance characteristics determined from clinical validation studies.

	Clinical Cohort of 1010 patients	Clinical Validation Studies[1] Group 2	Clinical Validation Studies[1] Group 3
Sensitivity	38.5% (10/26)	39% (33-45%) †	37% (31-43%) †
Specificity	83.4% (821/984)§	89% †	90% †
PPV*	5.8% - 1 in 17.3 (10/173)	7.2% ‡	7.0% ‡
NPV**	98.1% (821/837)	98.6% ‡	98.6% ‡

* PPV: positive predictive value
** NPV: negative predictive value
† Based on individually optimized cut-offs for each antigen
‡ Based on prevalence of lung cancer in an at-risk group of 2%
§ Specificity for first and second half of the cohort was 81.6% and 85.3%, respectively.

Evidence that *Early*CDT-Lung can detect early-stage lung cancer:

- 2 of the 10 *Early*CDT-Lung positives confirmed with lung cancer were Stage 1a.
- Both of the Stage 1a lung cancers were successfully resected.

CONCLUSIONS

- These are the first reported data of *Early*CDT-Lung being used in clinical practice. The results are consistent with the extensive validation datasets previously published on this test[1], with sensitivity for NSCLC at least as high as in the validation studies, including early stage disease.
- A positive test for *Early*CDT-Lung carried a three-fold difference in risk of lung cancer in this population.
- These figures take no account of occult lung cancers, which may present over the next few years as cancers have been shown to stimulate a cancer antigen-specific autoimmune response up to 5 years before detection by current imaging methods.[2] Any "yet to present" cancers will likely increase sensitivity and specificity for this cohort.
- This information can/could be used to help stratify high risk patients in diagnostic algorithms.

REFERENCES

1. Boyle P, et al. Clinical validation of an autoantibody test for lung cancer. *Ann Oncol* 2011; 22:383-389.
2. Zhong L, et al. Profiling tumor-associated antibodies for early detection of non-small cell lung cancer. *J Thorac Oncol* 2006; 1: 513–519.

14th World Conference on Lung Cancer (WCLC 2011); Amsterdam, The Netherlands; July 3-7, 2011