

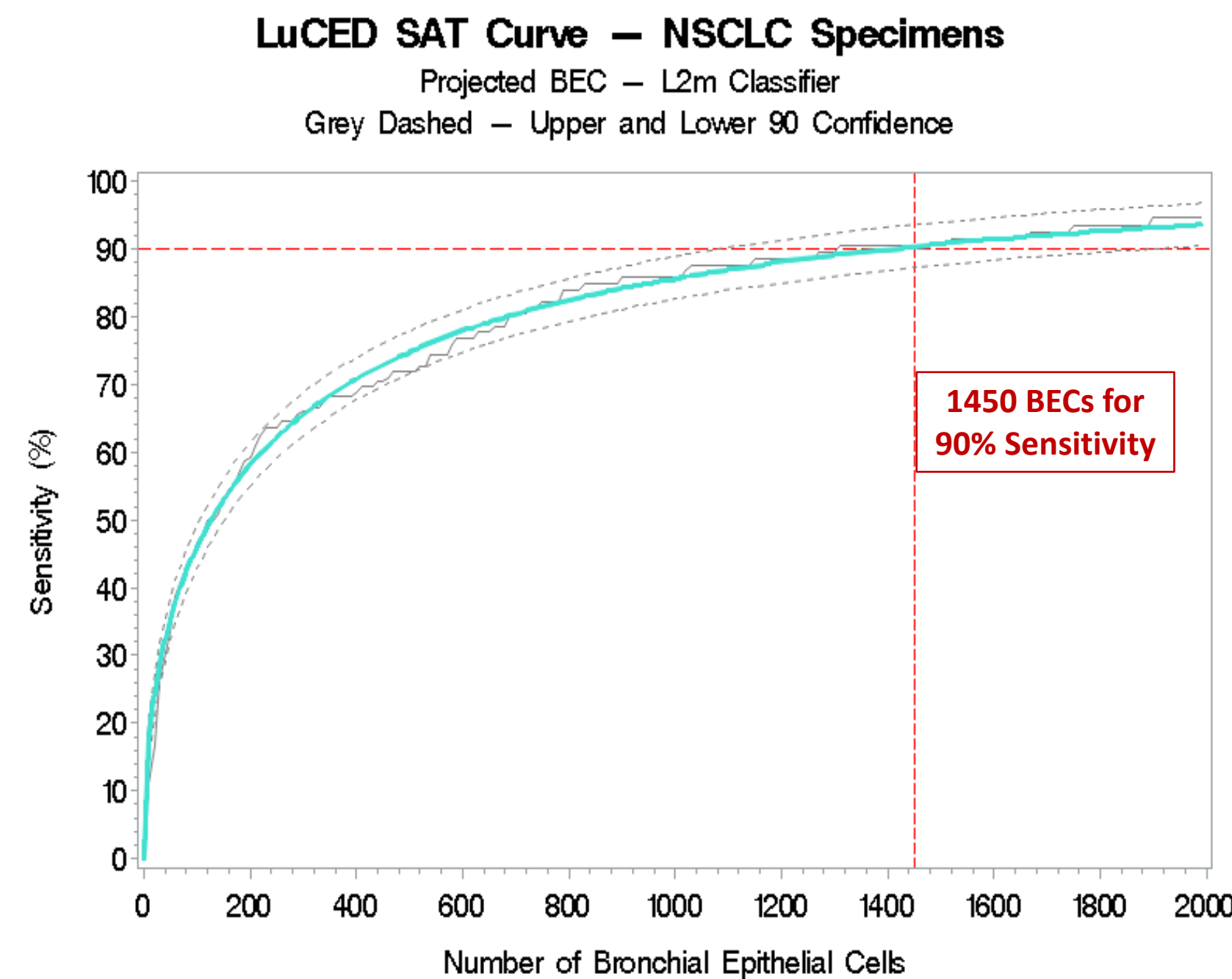
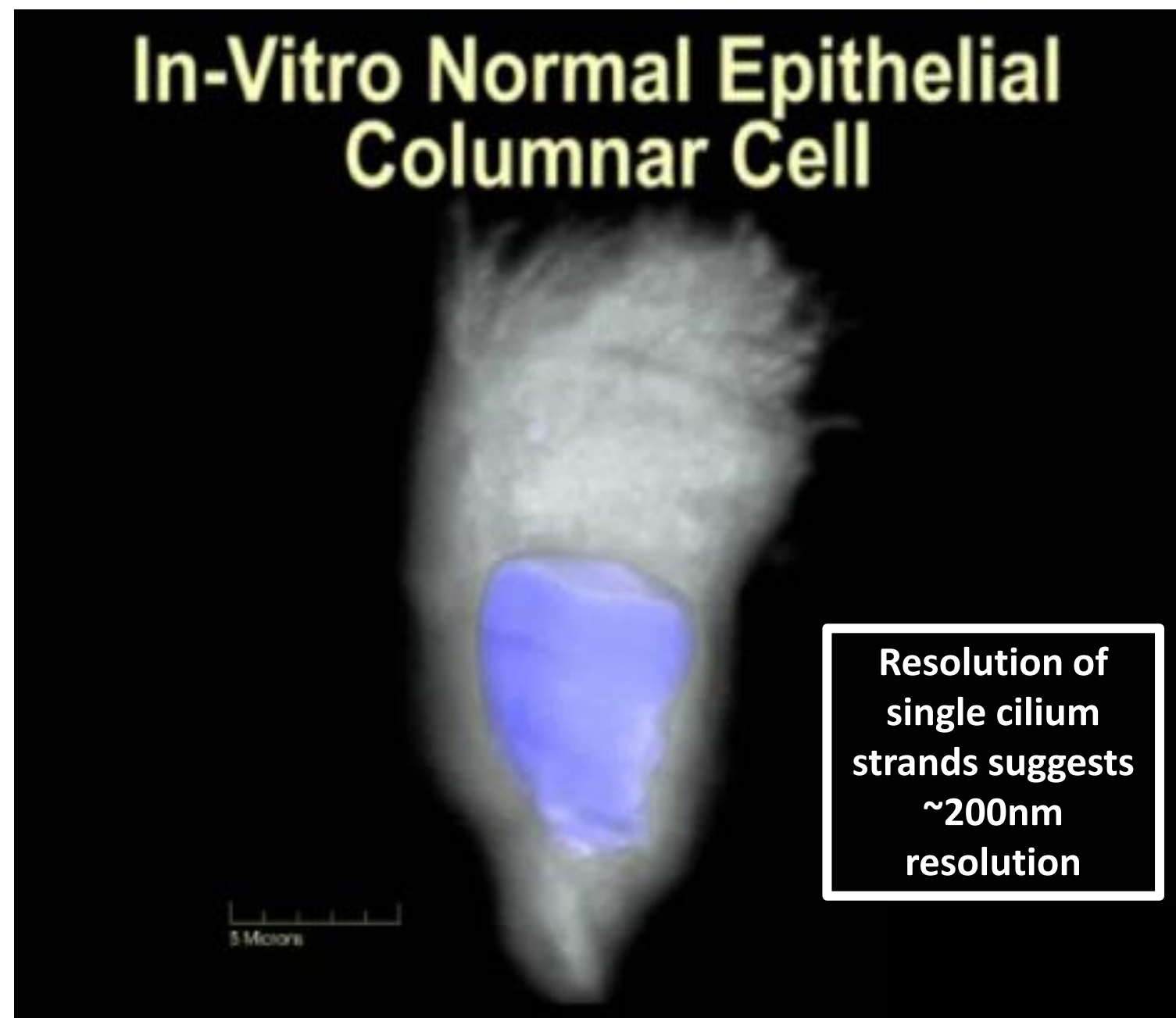
Non-Intrusive LuCED® Test for Detection of Early-Stage Lung Cancer: Subgroup Analysis for Patients with Chronic Obstructive Pulmonary Disease (COPD)

2021 WCLC – Abstract #635, P63 - Screening and Early Detection: M. Meyer, A. Nelson

Background

LuCED® Test using Cell-CT® Analysis:

The Cell-CT instrument analyzes cells in 3D, measuring true 3D morphometry with isometric 200nm resolution. The image below is of a columnar cell from the lung epithelium. LuCED® AI identifies cells with abnormal features that are then cytologically diagnosed using VisionGate's digital pathology workstation, CellGazer™. Cells that are in neoplastic categories of atypia through cancer trigger a LuCED report of abnormality. In published work, sensitivity and specificity both exceed 90%. Sensitivity is selectable as it is governed by the number of normal bronchial epithelial cells (BECs) that are counted, following the SAT curve shown below. False positive case reports may occur when normal cells are diagnosed incorrectly as abnormal through the digital pathology process.



Motivation:

Pre-cancer abnormal cells may trigger an abnormal LuCED case report. Therefore, LuCED specificity should be measured on cases understood to be free of cancer and, moreover, should be free of certain non-cancer diseases, such as COPD, that are often associated with pre-cancer conditions such as dysplasia and atypical adenomatous hyperplasia. Here, we measure the abnormal cell detection rate of the LuCED test as a function of lung cancer sensitivity for two control (non-cancer) populations: ostensibly normal – without known disease, and with diseases such as COPD, emphysema, and bronchitis with likely undiagnosed pre-cancer.

Methods

Specimens:

- Three-day spontaneous morning cough sputum samples were collected from non-cancer cases as shown in the table below (n = 99):

Non-Cancer Case Count	
With Non-Cancer Diseases (e.g. COPD)	No Non-Cancer Diseases
62	37

Processing:

- Sputum samples were prepped using standard fixation and staining methods and processed by the Cell-CT
- LuCED classifier outputs were enumerated for each case
- Cell images were evaluated cytologically using CellGazer
- LuCED data was re-evaluated at different BEC thresholds for 10-to-95% sensitivity, in 5% increments
- The sensitivity to lung cancer, known from previous published studies through the SAT curve, was plotted against the positive rate for the two control subgroups (with and without non-cancer disease).
- LuCED specificity – the percentage of cases without abnormal cells, was assessed for the non-disease group

Outcome:

- Trendlines demonstrate strong differences in response by the LuCED test in the two control groups: With and without non-cancer diseases.

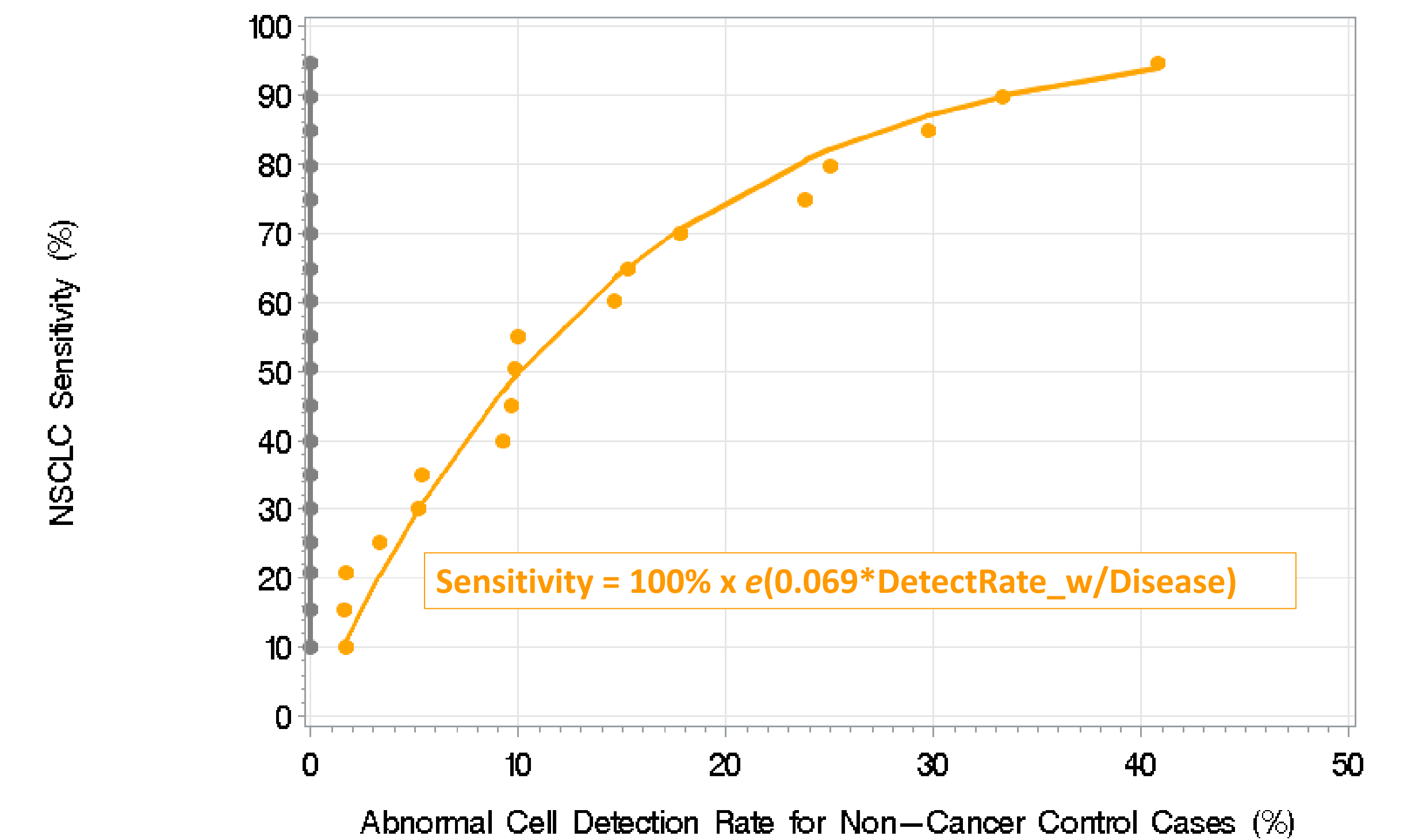
Results and Conclusions

Results:

- No false positive indications were found for the cases without disease
- The positive rate for non-cancer patients with COPD increases exponentially with increased lung cancer sensitivity
- The LuCED test detects pre-cancerous cells and accordingly, indicates presence of pre-cancerous lesions which are often associated with non-cancer diseases such as COPD.

LuCED Sensitivity vs. Abnormal Cell Detection Rate for Non-Cancer Control Cases

Grey – No known lung diseases, Orange – COPD, Emphysema, etc.
Lines fit the measured values (Dots)



LuCED Offers High Sensitivity and Specificity Detection of Lung Cancer While Also Indicating Cases with Likely Pre-Cancer