

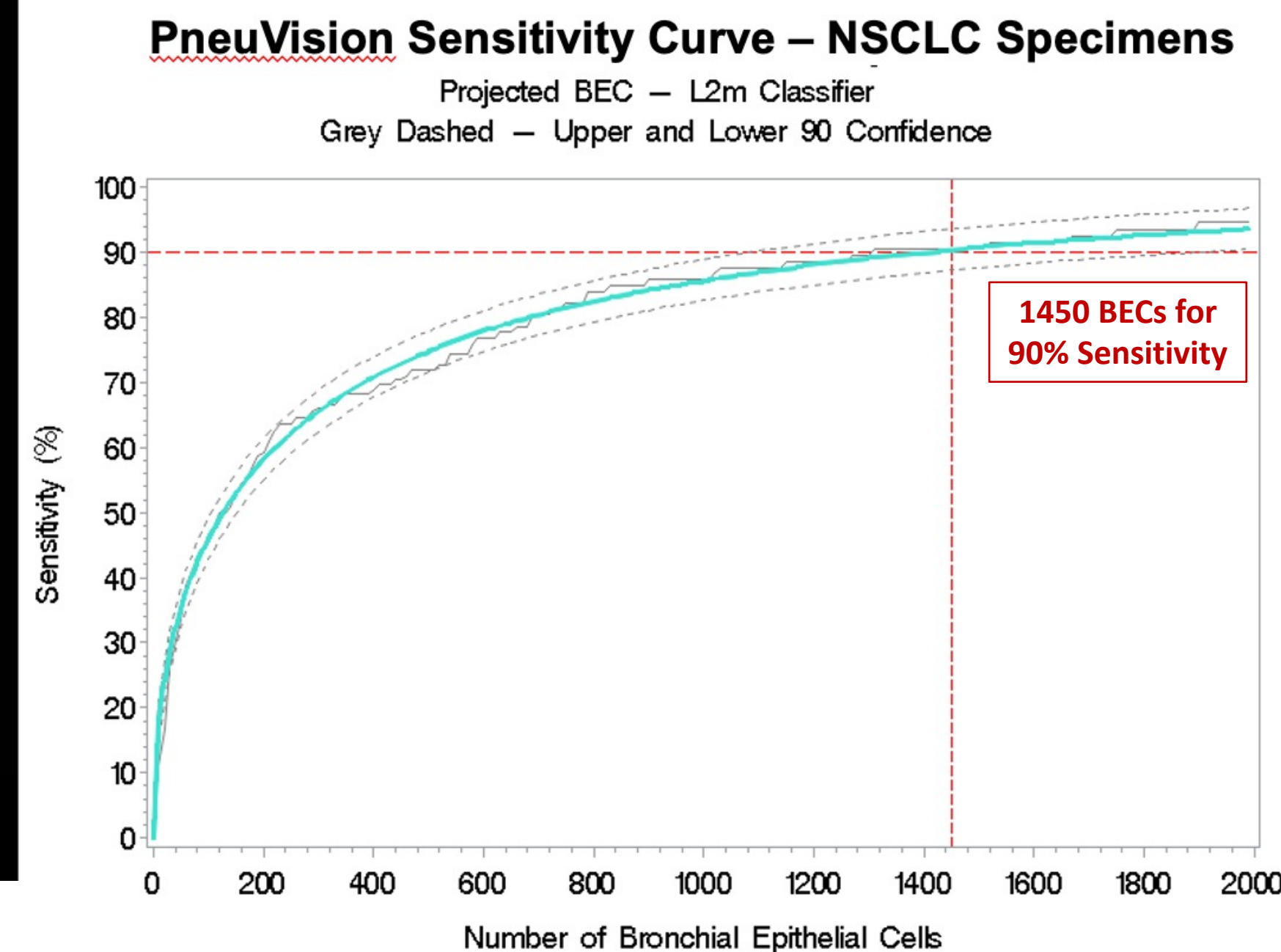
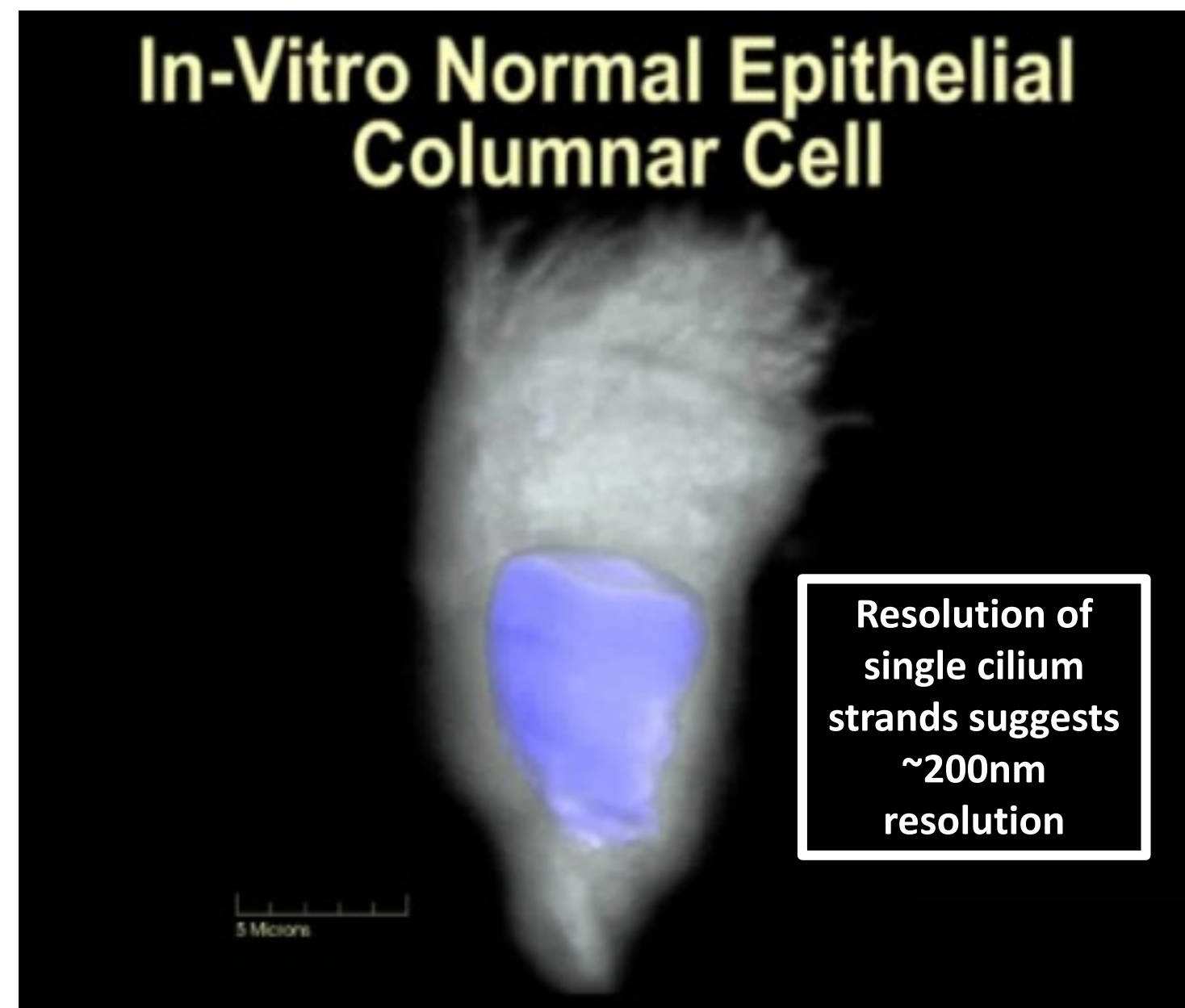
PneuVision® Sputum Test for Lung Cancer Achieves High Sensitivity in Detecting Both Squamous Cell Carcinoma and Adenocarcinoma

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Background

PneuVision Sputum Test using Cell-CT® Analysis:

The Cell-CT device analyzes cells in true 3D, measuring 3D morphometry with unprecedented isometric 200nm resolution. For example, the image below is a columnar epithelial cell from the lung. PneuVision 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 PneuVision report of abnormality. In published work, sensitivity and specificity both exceed 90%. The aROC is 0.99 for the detection of a single abnormal cell. Sensitivity is selectable as it is governed by the number of normal bronchial epithelial cells (BECs) that are counted, following the Sensitivity Curve shown below:



Motivation:

The PneuVision Sensitivity Curve shows the relationship between normal bronchial epithelial cell counts and sensitivity to non-small cell lung cancer. In this analysis, squamous carcinoma and adenocarcinoma are analyzed independently to define trends in sensitivity vs BECs independently for both histology types.

Methods and Results

Methods:

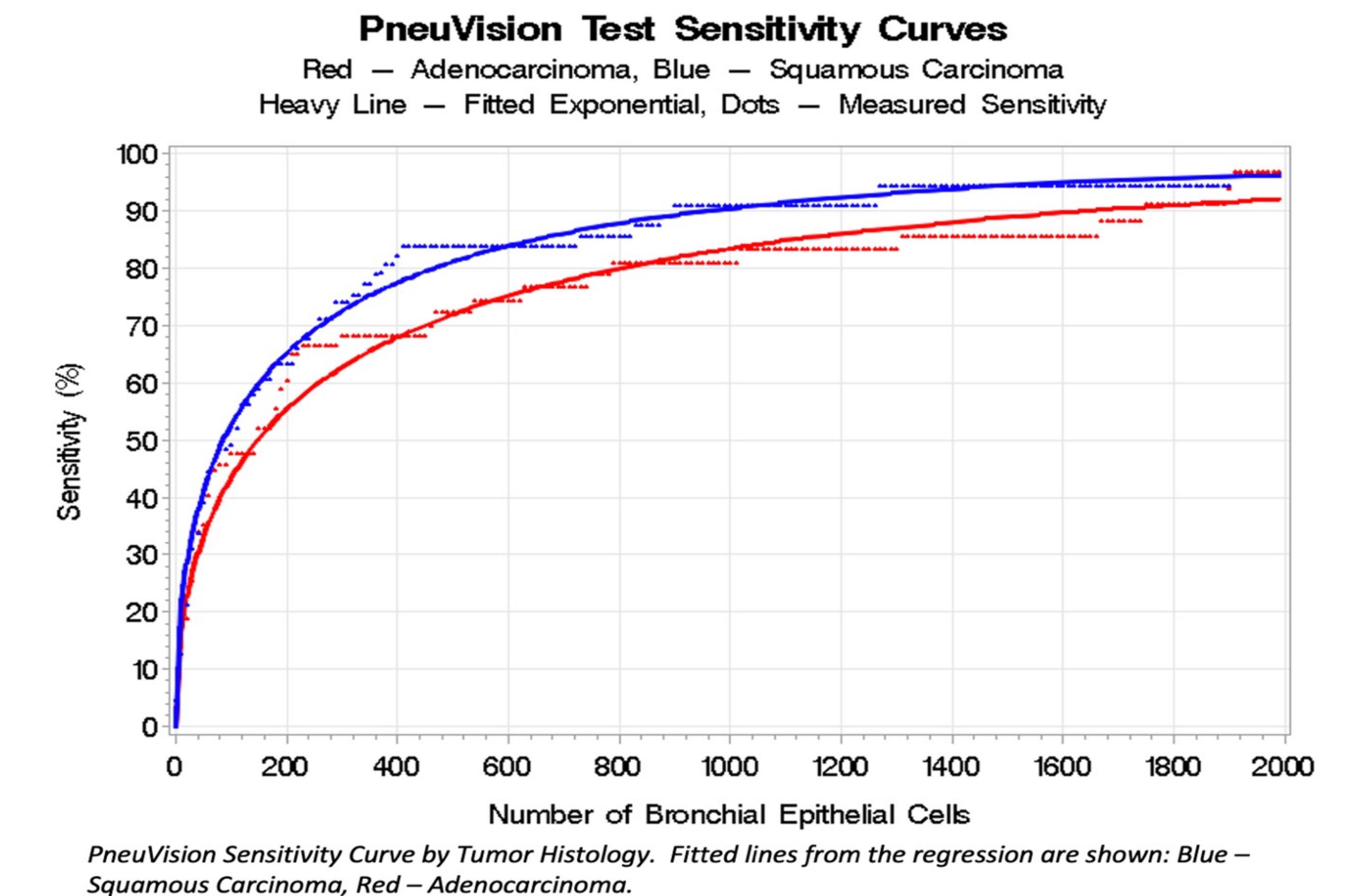
Spontaneous deep cough sputum is collected from patients with biopsy-confirmed squamous cell carcinoma (N=94) and adenocarcinoma (N=94) for a total sample size of 188. Because sputum has high intra- and inter-patient variability, the Cell-CT analysis was normalized by the enumeration of normal bronchial epithelial cells (BECs) automatically detected by classifiers in the Cell-CT. The abnormal cells detected by the Cell-CT were confirmed by expert cytologists. The sensitivity vs. BEC count data was fitted by histologically confirmed cancer type using least squares regression to an exponential with zero intercept and variable exponential constant. The percentage of cancer cases with abnormal cells (sensitivity) and the regression lines were examined vs. BEC count by histology as shown in the figure.

Results:

Sensitivity vs. BEC count by cancer type shows that, for a given sensitivity, more cells from the specimen would need to be processed for adenocarcinoma vs. squamous cell carcinoma. For example, if 90% sensitivity for squamous cell carcinoma is selected, the test should be set up to process at least 1000 BECs. With this same BEC count, the detection sensitivity for adenocarcinoma would be 83%.

Conclusions

Sensitivity increases as more normal cells from the bronchial epithelium are processed, and sensitivity increases more rapidly for squamous cell carcinoma than for adenocarcinoma. In practice, if the sensitivity for adenocarcinoma were set at an acceptable clinical level, then the sensitivity to squamous cell carcinoma would exceed that level.



PneuVision Test Detects both Squamous Cell Carcinoma and Adenocarcinoma with High Sensitivity