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Control/Tracking Number: 2023-RA-814-WCLC

Activity: Regular Abstract

Current Date/Time: 3/23/2023 3:42:44 PM

The PneuVision Test Detects Both Lung Squamous Cell Carcinoma and Adenocarcinoma from Cells in Sputum

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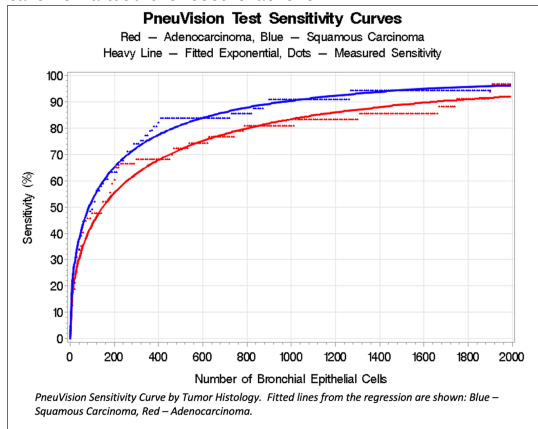
Abstract:

Introduction: The PneuVision test for early detection of NSCLC begins by collecting a patient's sputum from home. The Cell-CT platform analyzes the cells in 3D with sub-micron, isometric resolution. 3D imaging represents cells comprehensively, eliminating perspective bias inherent in 2D imaging. Accordingly, a set of highly accurate (aROC=0.991) cell classifiers were trained through a machine-learning process to detect abnormal cells in sputum. The result is highly accurate NSCLC detection: Test sensitivity exceeds 90% for biopsy-confirmed, early-stage cancer, while specificity is near perfect. In this study, we examine the sensitivity of the PneuVision test for squamous cell carcinoma and adenocarcinoma.

Methods: The Cell-CT analyzes cells in sputum from patients with biopsy-confirmed squamous cell carcinoma (N=94) and adenocarcinoma (N=94) for a total sample size of 188. Because sputum has a high intra- and inter-patient variability, the analysis was normalized by the enumeration of normal bronchial epithelial cells (BECs) automatically detected by classifiers in the Cell-CT. Abnormal cells are detected by the Cell-CT and confirmed by 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 and the regression lines were examined vs. BEC count by histology as shown in the figure.

Results: Trends in sensitivity vs. BEC count by cancer type show that, for a given sensitivity, more cells from the specimen would need to be processed for adenocarcinoma vs. squamous carcinoma. For example, if 90% sensitivity for squamous carcinoma is desired, the test should be set up to process at least 1000 BECs. With this optimization, the detection sensitivity for adenocarcinoma would be approximately 83%.

Conclusions: Sensitivity increases as more 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 level, then the sensitivity to squamous cell carcinoma would exceed that level.



Track (Complete): 04. Screening and Early Detection

Funding Source (Complete):

* Is your study funded in any way by a Pharmaceutical/Biotech Company?: Yes

If yes, enter the specific Pharmaceutical/Biotech Company names: : VisionGate

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Keywords (Complete): NSCLC ; Detection ; Sensitivity

Status: Finalized

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