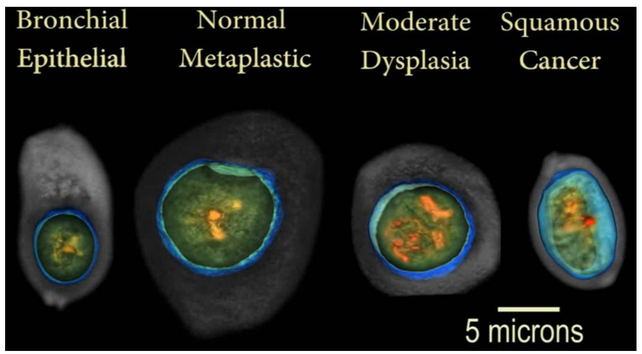
Effect of Tumor Size on the Sensitivity of the Non-Invasive LuCED® Test for Lung Cancer

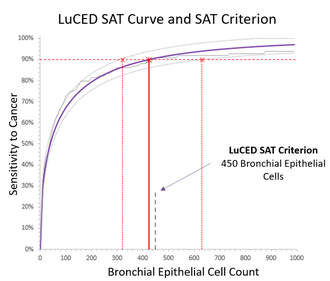
Abstract #9597: Meyer, Katdare, Presley, Wilbur, Zulueta, Nelson

Background – the LuCED Test

1. **Sputum Prep:** Dissolves mucous, stains chromatin, enriches for bronchial epithelial cells
2. **Cell-CT Processing:** Automatically analyzes cells in true 3D with isometric, sub-micron resolution



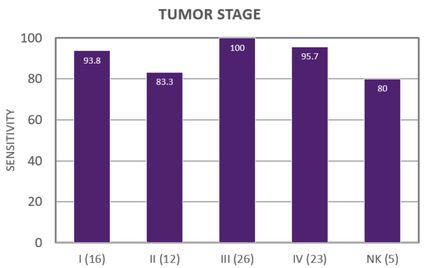
3. **Single-Cell Classification:** Morphometric classifier detects pre-cancer and malignant cells with high accuracy: Area Under ROC = 0.991
4. **Cytopathologist Review:** Detected cells suspicious for cancer are confirmed manually
5. **SAT Criterion:** Defines the number of bronchial epithelial cells require for safe termination of LuCED

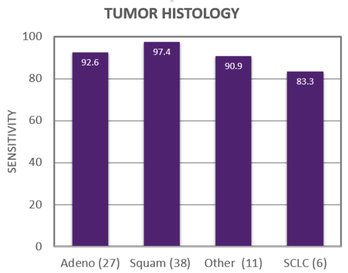


LuCED Clinical Performance

Case Sensitivity:

- 82 Biopsy confirmed NSCLC and SCLC
- 93.9% Overall sensitivity





Specificity:

- 54 Self declared normal cases including COPD, benign lesions
  - Patient selection does not rule out dysplasia or AAH
- 90.7% Overall specificity

Methods

Tumor Size:

- The largest dimension measured for the tumor in mm

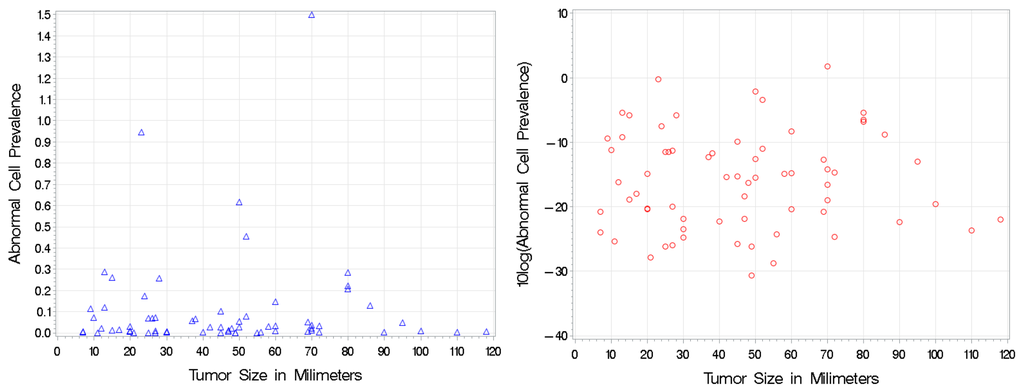
Abnormal Cell Prevalence:

- True positive cell count is normalized by an enumeration of the reference cells for LuCED (Bronchial Epithelial Cells)

LuCED Sensitivity to Tumor Size was Assessed by Examining Abnormal Cell Prevalence vs. Tumor Size

Results and Conclusions

Abnormal Cell Prevalence vs. Tumor Size in Millimeters



1.No trend observed in abnormal score prevalence vs tumor size

2. Potential explanations:

a) Tumor size does not correlate to tumor surface area
b) Exfoliation rate is not defined by tumor size
c) Sputum flow determines prevalence more than tumor size

3. This result implies that LuCED clinical results generalize to tumors in the indeterminant pulmonary nodule range (6 – 30 mm)

VISIONGATE
www.visiongate3d.com