

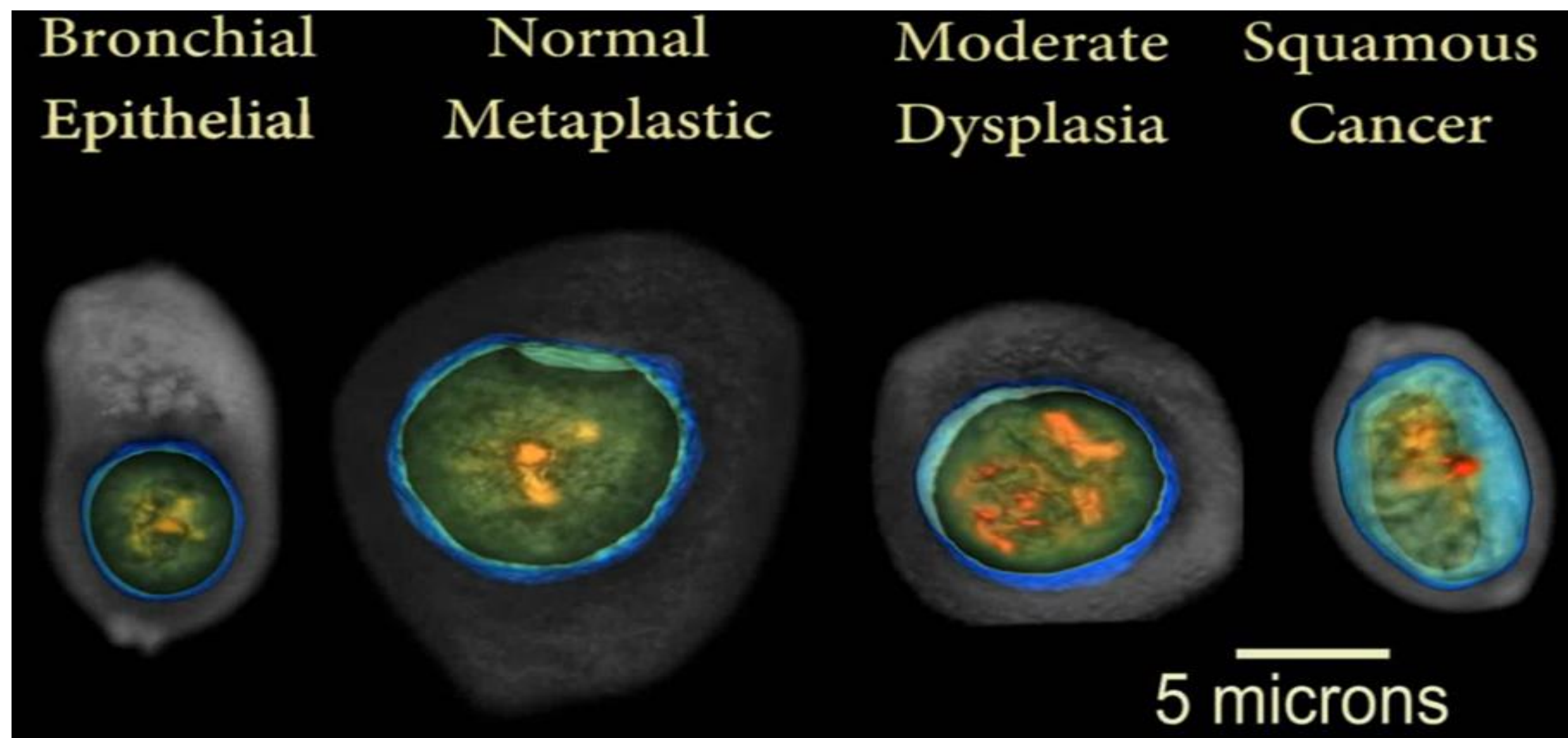
LuCED[®] Sputum Test for Assessment of Lung Cancer Risk in COPD Patients: Sensitivity and Specimen Satisfactory Rate

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Background

Sputum Prep: Dissolve mucous, stain chromatin, enrich bronchial epithelial cells

Cell-CT[®] Analysis: True 3D morphometry of cells with isometric, high resolution



Motivation:

VisionGate's LuCED[®] test measures 3D morphometry in cells from sputum using Cell-CT[™] 3D imaging. In published work, sensitivity and specificity have exceeded 90% in both categories as demonstrated in blinded studies. The accuracy of sputum analysis is governed by the number of normal bronchial epithelial cells (BECs) that are enumerated by the LuCED test. The chance of detecting abnormal cells increases when more BECs are analyzed so that a higher count of BECs is associated with a higher sensitivity. A normal result, defined as no abnormal cells detected, can be assigned for cases when a satisfactory number of BECs are enumerated. The sputum satisfactory rate (SAT Rate) is the percent of cases that have at least the required number of BECs. Patient sputum production increases with COPD, where lung cancer prevalence is also elevated. Here, we report the relationship of sensitivity and LuCED test SAT rate for patients who are current smokers with COPD.

Methods

LuCED AI Classifier Development:

- Over 800 morphometric biosignatures for each 3D cell image:
 - Nuclear, cell and cytoplasm segmentation
 - Texture – chromatin arrangement, distribution within nucleus
 - Nuclear/cytoplasm volume ratio
 - Nuclear grooves
- Ground truth defined by cytopathology
- Adaptively boosted logistic regression

Study Materials:

- Three-day morning cough sputum samples were home-collected from 11 current smokers with COPD for Cell-CT analysis.

Processing:

- Sputum samples were processed to LuCED classifiers was enumerated for each case.
- The SAT Rate was plotted as a function of the BEC count and fitted by an exponential.
- 400 BECs are required for 70% sensitivity, and 1,450 BECs are required for 90% sensitivity.
- The SAT Rate was determined for 70% and 90% LuCED sensitivity.

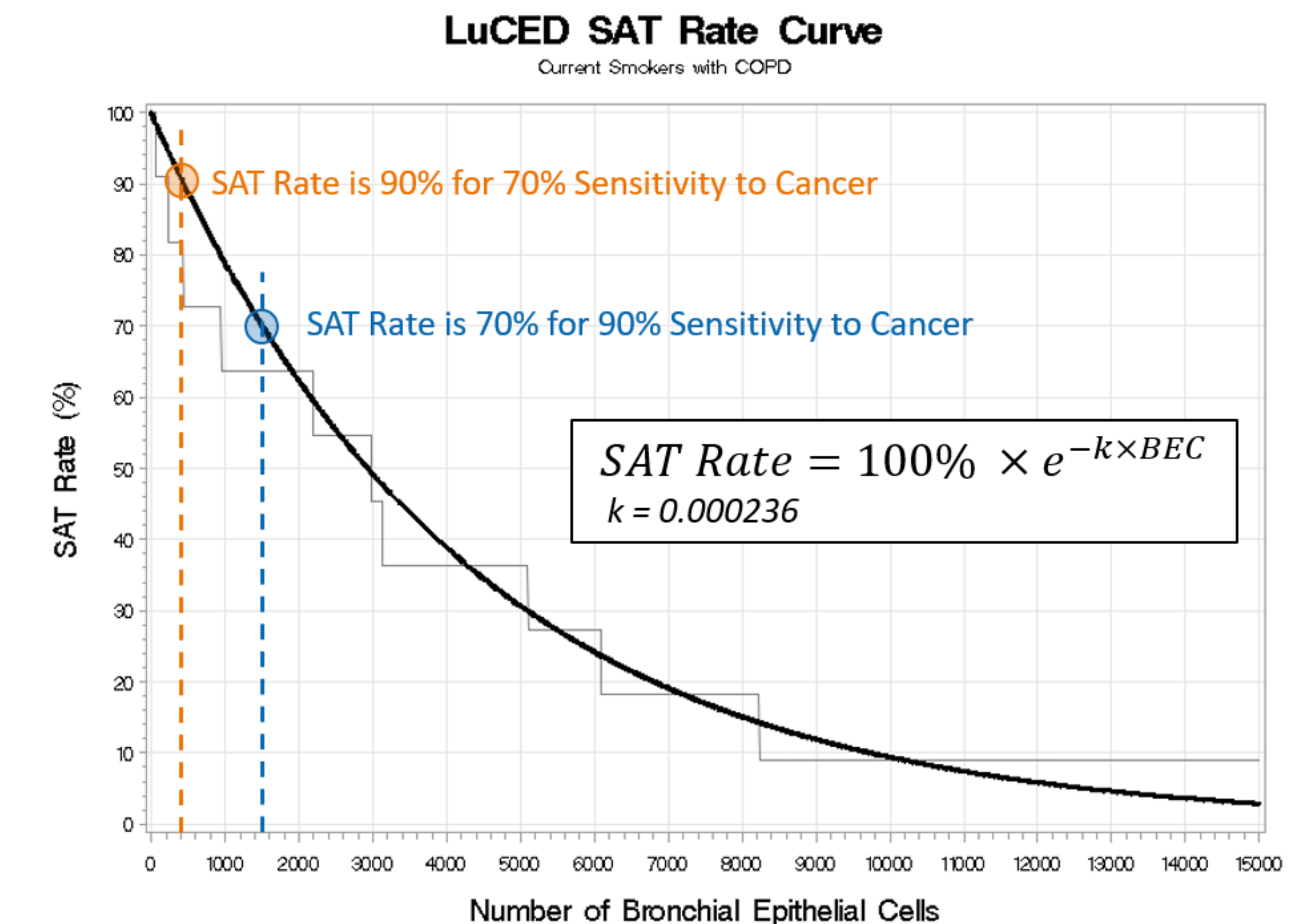
Outcome:

- The LuCED test may be tuned for optimal patient management strategies. For triage of patients to LDCT, when COPD patients would receive periodic or annual LuCED tests, one might prefer lower sensitivity to achieve higher SAT Rate, while a single LuCED test could deliver significantly higher sensitivity but with a lower SAT Rate. Physicians prefer this flexibility in managing patients at risk of lung cancer.

Results and Conclusions

Results:

- The SAT Rate curve with fitted exponential is shown below.
- For 90% sensitivity, a 70% SAT Rate was estimated.
- For 70% sensitivity a 90% SAT Rate was estimated.



For current smokers with COPD, a satisfactory LuCED analysis can be conducted based on a spontaneously collected sputum specimen.