

Non-Invasive LuCED[®] Test to Detect Early Stage Lung Cancer

Meyer, Bell, Sussman, Wilbur, Presley, Hayenga, Lakers, Reyna,
Davies, Field, Yang, Lancaster, Zulueta, Nelson



VisionGate Produces the LuCED Test

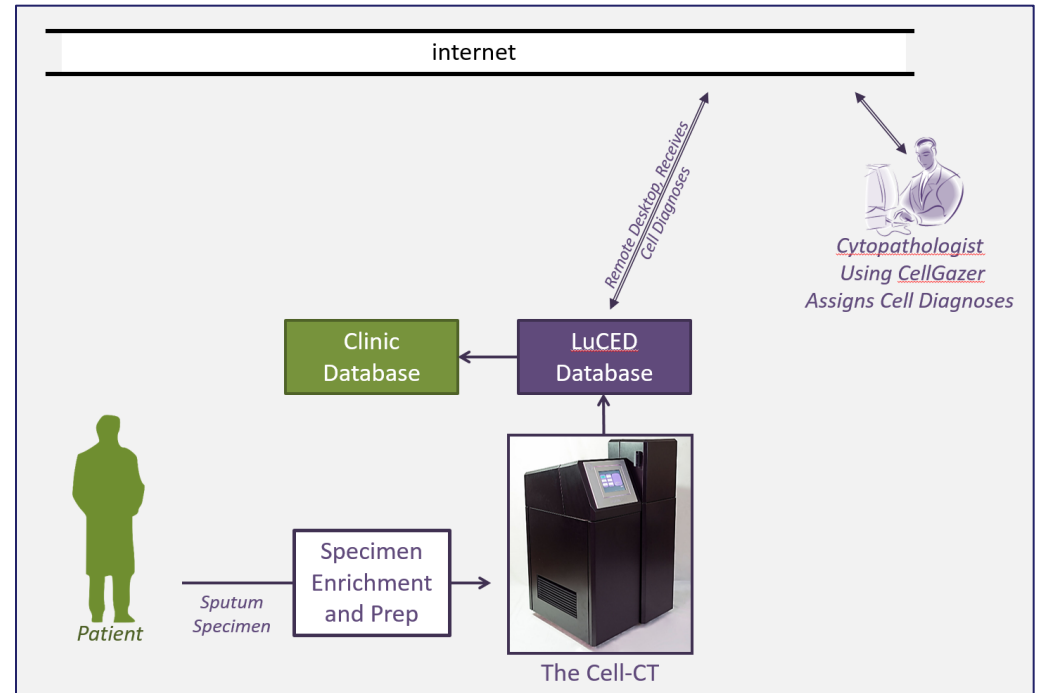
The presenter is the CEO of VisionGate who receives compensation and owns stock

Overview

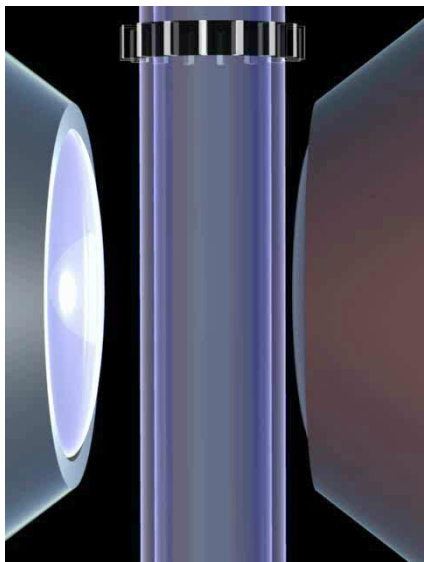
- Sample: Non-invasive 3-morning cough sputum
- Enrichment for normal bronchial epithelial cells
- Automated 3D cell imaging using the Cell-CT®
- Automated classification for high sensitivity and unrivaled specificity
- Remote, abnormal cell labeling using CellGazer®

LuCED Clinical Deployment

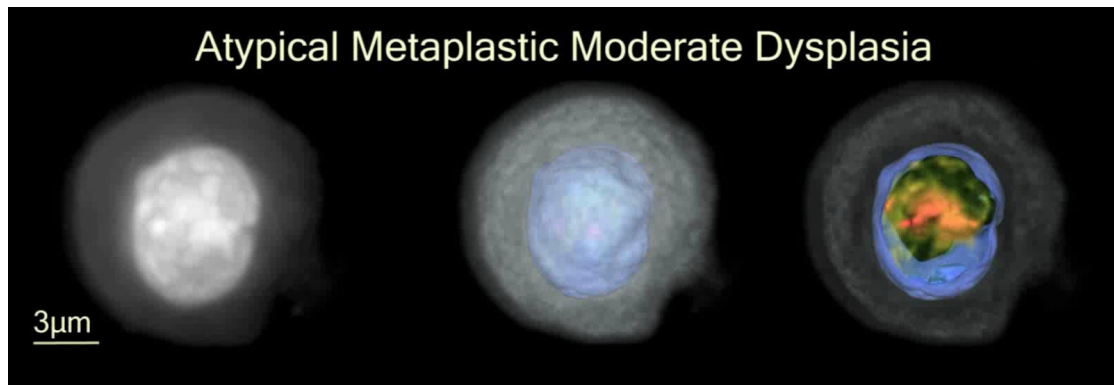
- Process incidentally discovered nodules
- Adjunct to LDCT to reduce false positives
- Primary screening ahead of LDCT



Cell-CT Processing



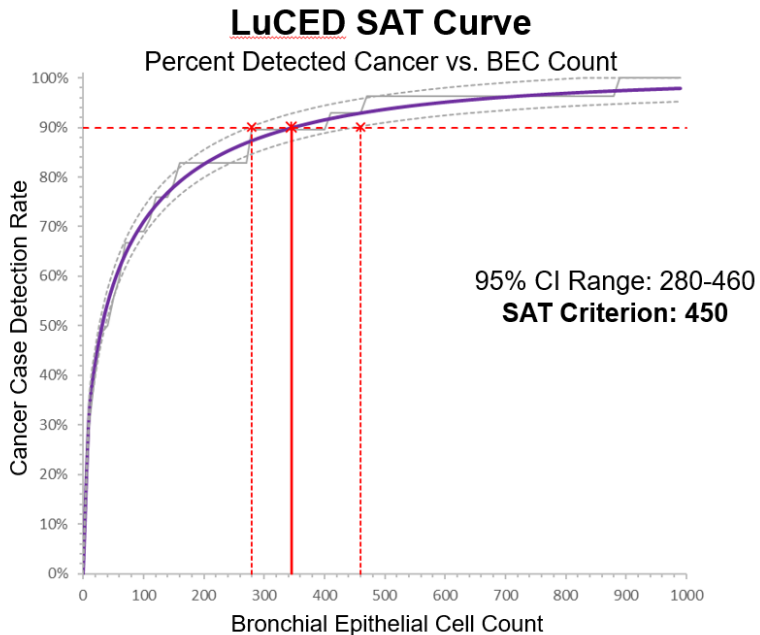
Sub-micron *isometric* resolution,
quantitative 3D single cell imaging



Automated Cell Recognition

- 704 structural biomarkers
- Pathologist supplies cell diagnosis to guide training
- 88,000 cells used in training & 72,000 cells used in testing
- Classification to identify abnormal cells:
 - AROC = 0.991 – 95% CI (0.988 – 0.992)

LuCED Criterion for a Satisfactory (SAT) Specimen



Why Use an SAT Criterion?

- Sputum is highly variable
- SAT criterion defines the stopping rule for processing
- LuCED enumerates normal bronchial epithelial cells (BECs)
- 450 BECs for >90% sensitivity with 95% confidence

Note: BEC = Bronchial Epithelial Cell

Blinded Cytopathologist Clinical Results

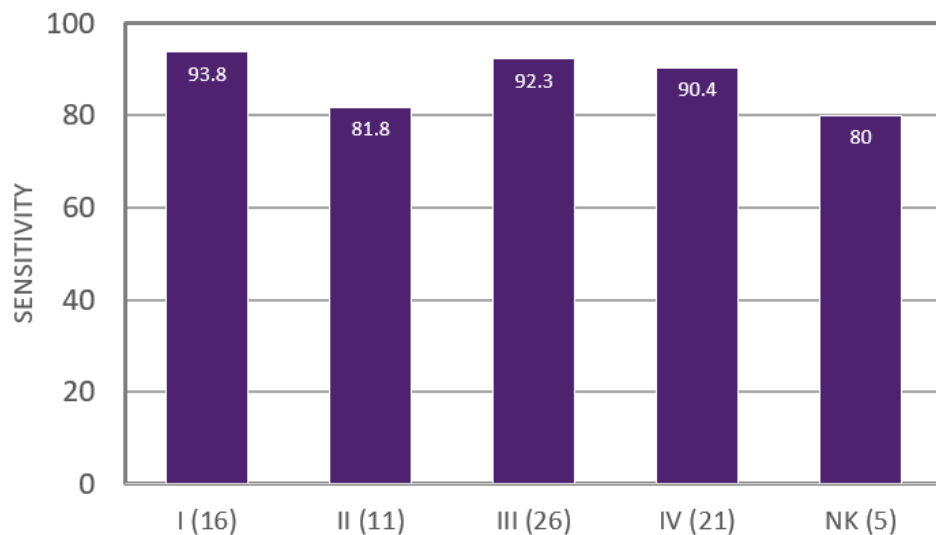
- 139 Specimens processed by LuCED:
 - 60 Cancer-free cases – high risk, COPD
 - 79 Biopsy confirmed cancers
 - 9 International sources – England, Greece, Israel, Netherlands, Spain, 4 clinics in U.S.
 - U. Colorado, Florida Baptist, Yuma Regional Medical, Swedish Hospital
- Hierarchical cytology review of LuCED positive cells using CellGazer:
 - Cytotechnologist initial review followed by case-dx blinded cytopathologist review

		Cancer Prevalence for Incidental nodules = 35% ¹		Cancer Prevalence for Primary Screening = 1% ²	
Sensitivity	Specificity	NPV	PPV	NPV	PPV
90%	97%	94.7	94.2	99.9	23.3

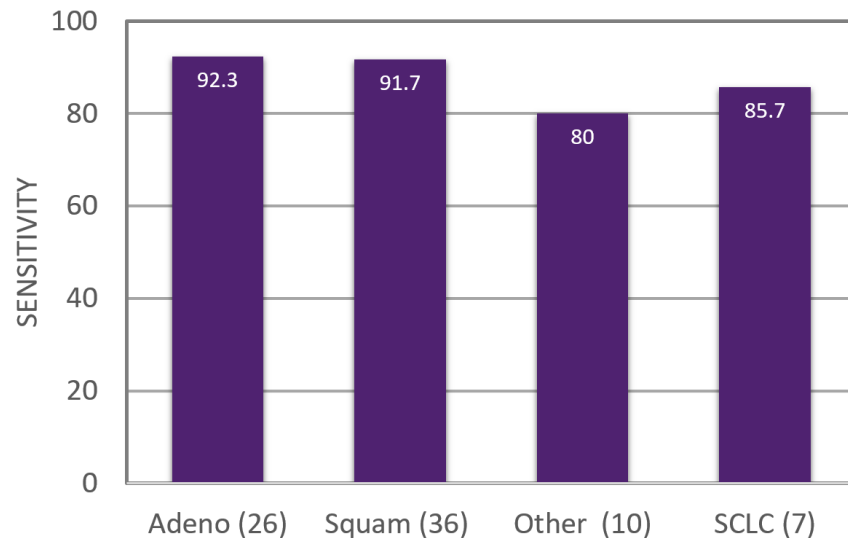
1 – Unpublished Data, 2 – NLST Team, Reduced lung-cancer mortality with LDCT screening. *N Engl J Med.* 2011;365:395-409.

Detailed Clinical Results

TUMOR STAGE



TUMOR HISTOLOGY



Summary

The Non-Invasive LuCED Test Detects Lung Cancer with 90% Overall Sensitivity and 97% Specificity

LuCED Uses

1. Resolution of incidental nodule findings
2. Adjunctive with LDCT
3. Primary screener for lung cancer