

# ***Blinded Clinical Study of the LuCED<sup>®</sup> Test for Detection of Early Stage Lung Cancer***

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# VisionGate Produces the LuCED Test

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

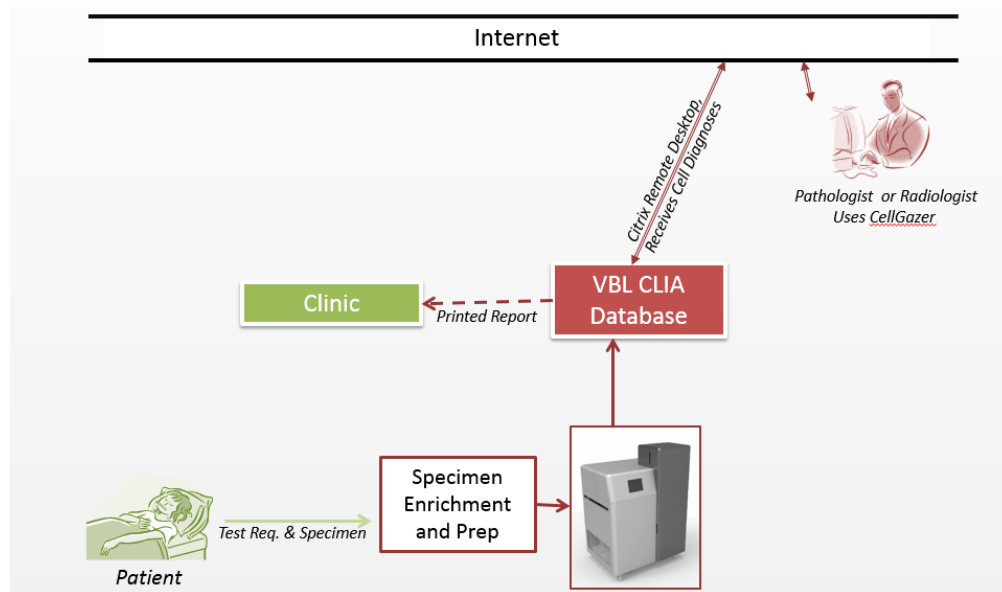
# The LuCED Test

## Overview

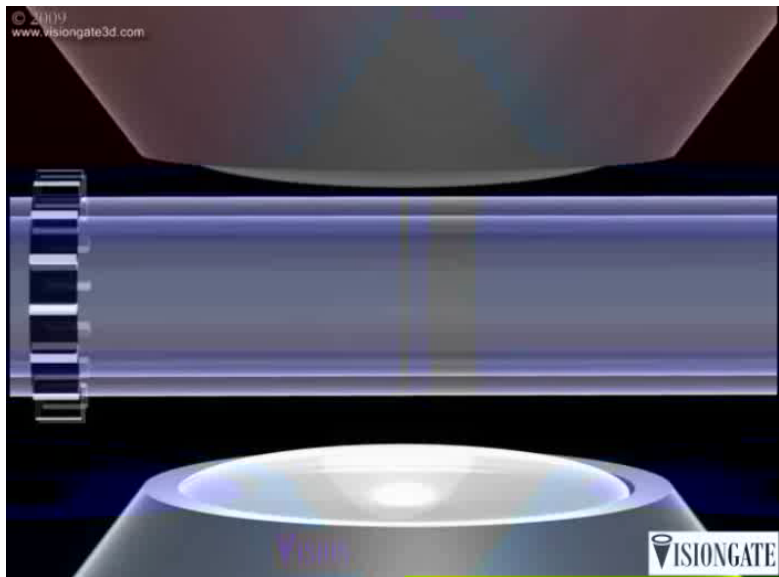
- Sample: non-Invasive 3-morning cough sputum
- Enrichment for normal bronchial epithelial cells
- Automated 3D cell imaging using the Cell-CT®
- Automated classification for high sensitivity and unrivaled specificity
- Remote, abnormal cell labeling using CellGazer

## Clinical Deployment

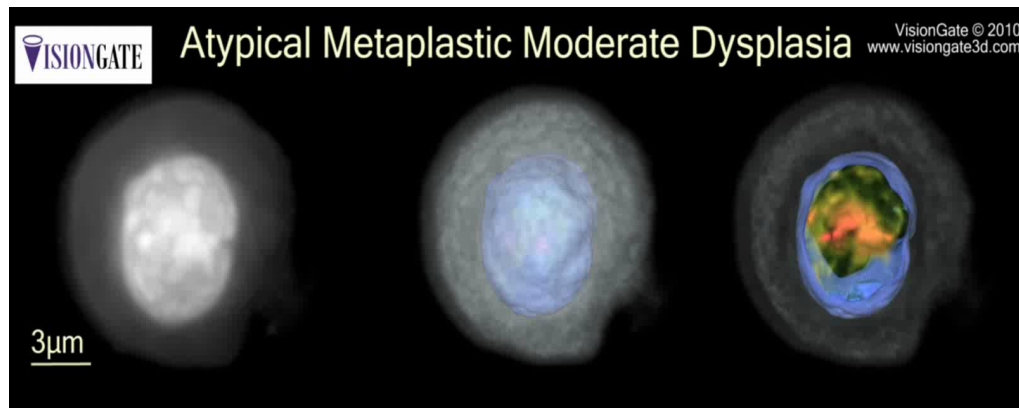
- LuCED adjunct to LDCT to reduce false positives
- Primary screening ahead of LDCT



# Cell-CT<sup>®</sup> Processing



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



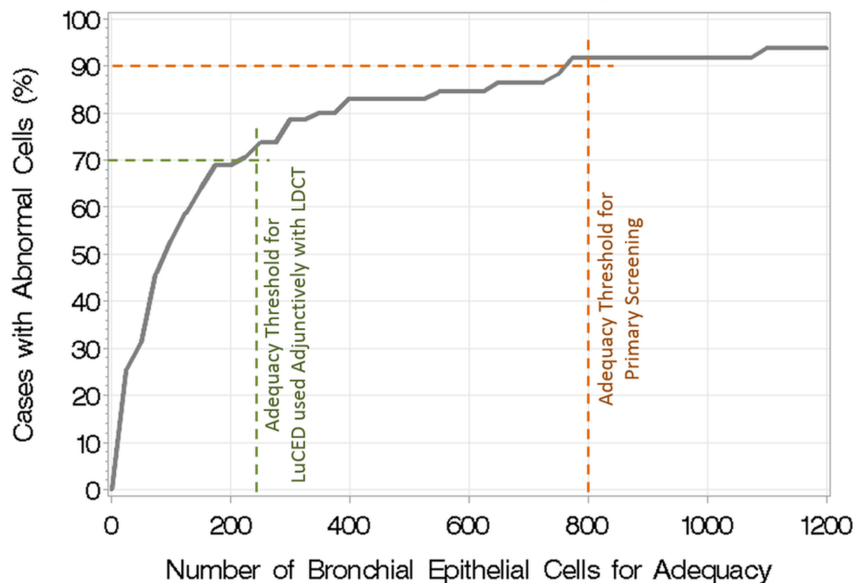
## Automated Cell Recognition

- 594 morphometric features
- Pathologists supplies ground truth for cell diagnosis
- 25,000 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 Adequacy Criteria

Percent Cancer Cases with Abnormal Cells vs.  
Threshold for Adequacy



## Why Adequacy?

- Sputum is highly variable
- Adequacy criterion defines the stopping rule for processing
- LuCED enumerates normal bronchial epithelial cells (BEC)
- Primary Screener: 800 normal BECs: > 90% sensitivity
- Adjunct to LDCT: 250 normal BECs: > 70% sensitivity



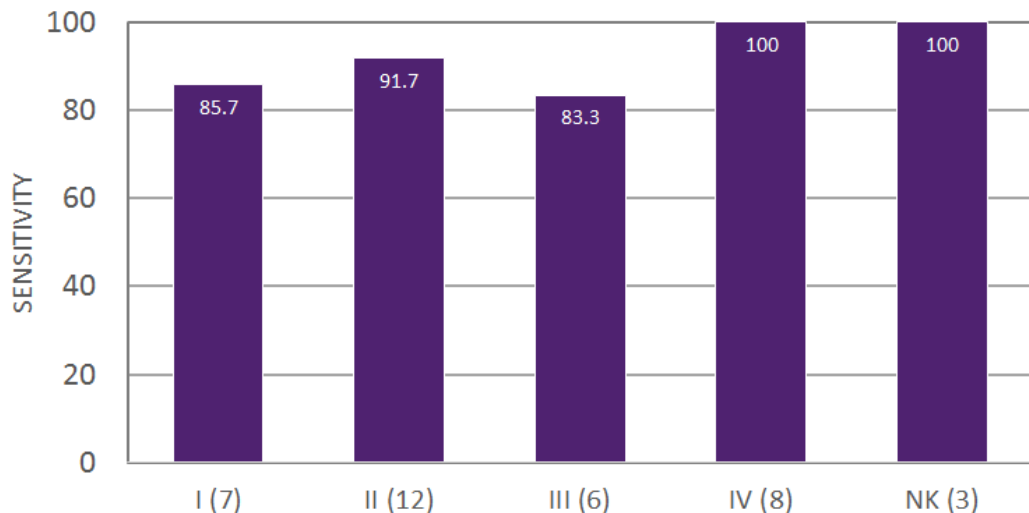
# Blinded Clinical Study Results

- Sputum from 36 confirmed lung cancer cases and 48 cancer free patients were collected, N = 84
- Specimens were processed by the LuCED algorithm using the Cell-CT
- Blinded, hierarchical cytology review using CellGazer of LuCED positive cells:
  - Cytotechnologist and then a cytopathologist
  - Blinded so review was done without the case diagnosis
- Clinical performance, assuming 1% cancer incidence:
  - Sensitivity = 92%                      PPV = 31.8%
  - **Specificity = 98%**                      **NPV = 99.9%**

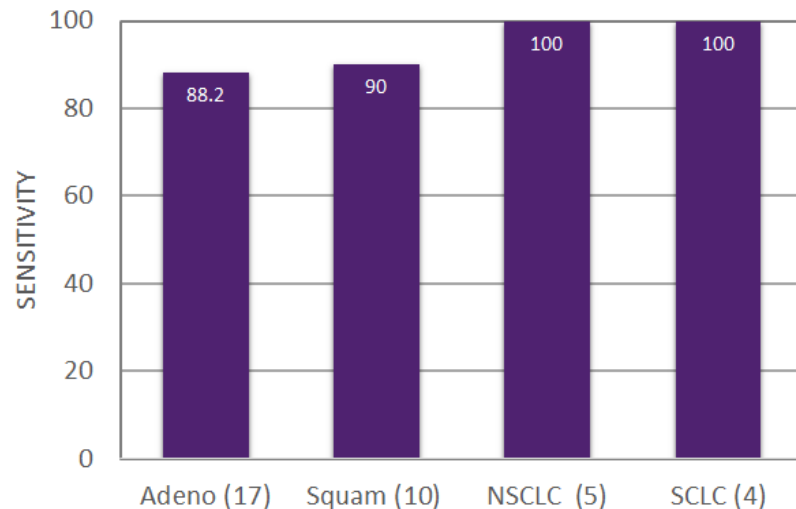


# Blinded Clinical Study Results

TUMOR STAGE



TUMOR HISTOLOGY



# Patient Management Scenarios

## Scenario 1: LDCT followed by LuCED on LDCT suspicious cases

Helps resolve LDCT false positives

May improve overall cost effectiveness

## Scenario 2: LuCED followed by LDCT on LuCED positive cases

92% sensitivity and >98% specificity lung cancer screening

Highly cost effective





# Summary

**The LuCED Test Detects Lung Cancer with  
92% Sensitivity and 98% Specificity (NPV = 99.9%)**

## **LuCED Uses**

1. Adjunctive with LDCT
2. Primary screener for lung cancer

