62nd Annual Scientific Meeting
American Society of Cytopathology

DALLAS

Lung Cancer Detection with LuCED®: A Non-Invasive Test Based on 3D Cell-CT® of Cells in Sputum

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Full Disclosure

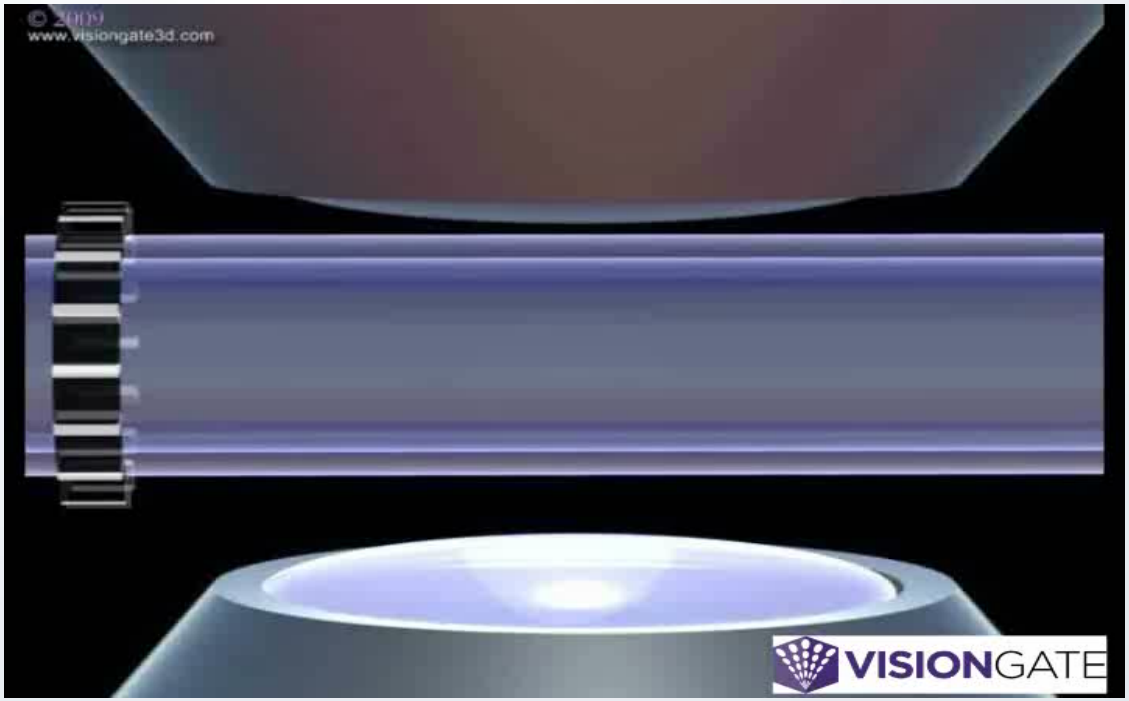
Employed as CTO at VisionGate, Inc.

Lung Cancer Dilemma

- 31 million US patients at high risk for lung cancer
- 160,000 die each year – largest cancer killer
- Potential methods of screening
  - Sputum cytology Meta-data analysis - Chest, 2003:
    - Average sensitivity = 60.4%, Average specificity = 98.1%
  - Low-Dose CT (LDCT) NLST study – NEJM, 2011:
    - 20% reduction in mortality
    - Recent CMS decision to reimburse LDCT
    - 94% false positive rate (specificity = 6%)

The LuCED® Test

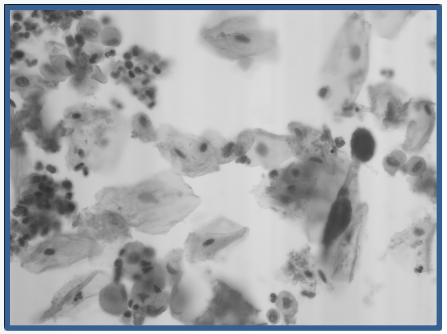
- Morning spontaneous or induced sputum
- Cell-CT: sub-micron resolution, isometric 3D cell imaging
- Highly accurate, automated, abnormal cell recognition
- Potentially resolves LDCT false positive issue



Cell-CT®

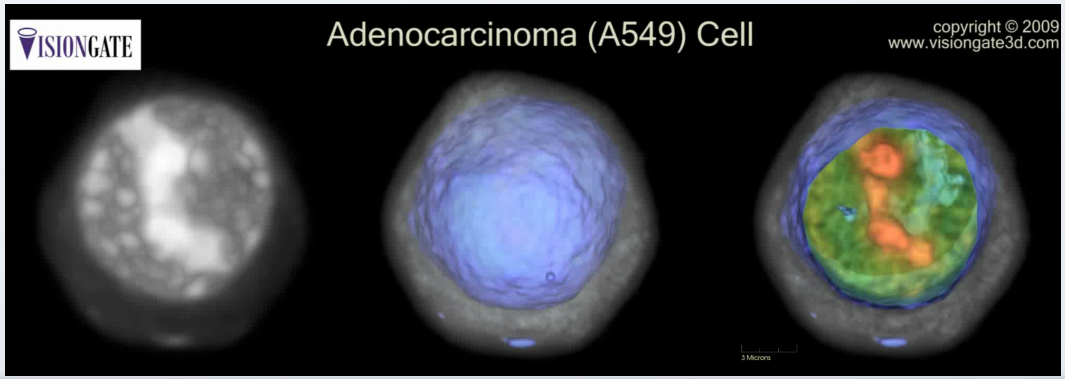
3D vs. 2D Cell Imaging

Critical for ***Machine*** recognition of abnormal cells



2D: Objects are overlapped and often out of focus
3D: Each cell is analyzed separately

2D: Image may not contain critical morphology
3D: Cell is represented comprehensively



3D: Critically important morphology "seen" ***only*** in 3D

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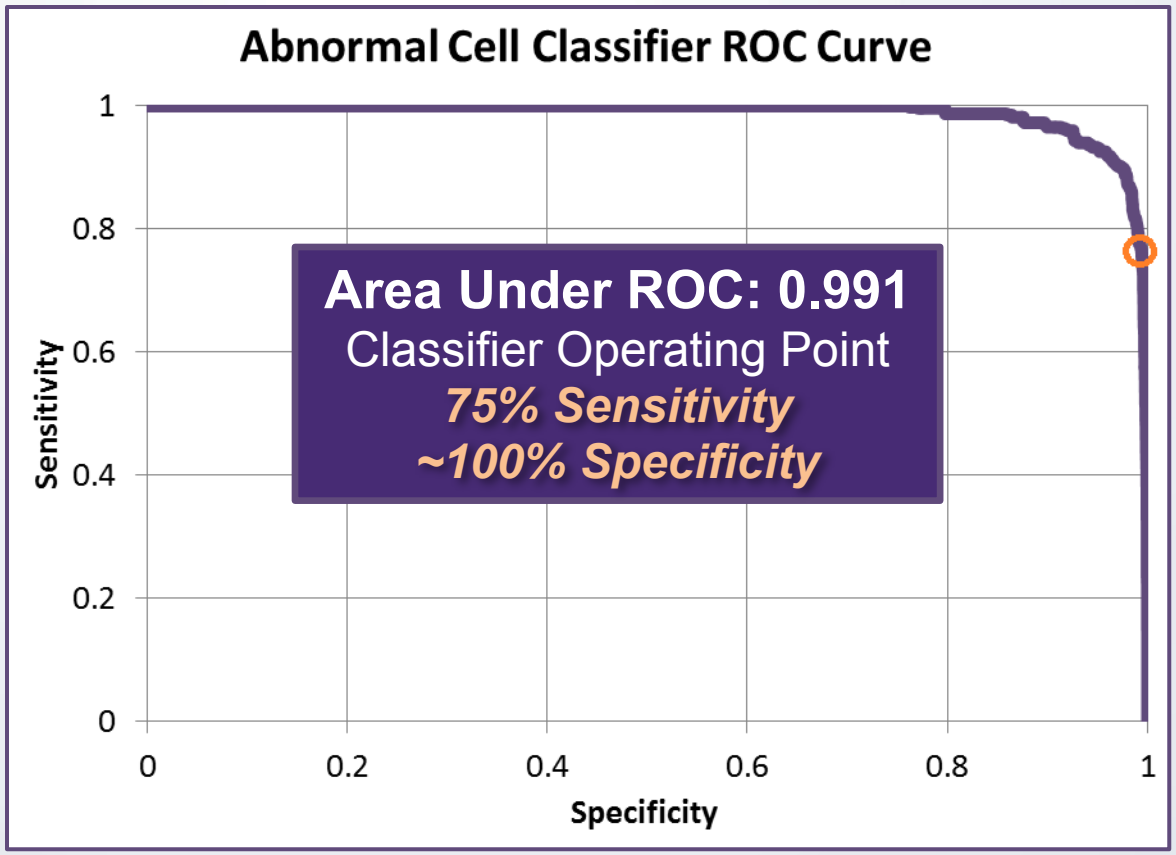
Abnormal Cell Detection

1. 594 features are computed on every cell:
   - e.g. N/C ratio, chromatin distribution, nuclear pleomorphism, etc.
2. Final normal/abnormal cell diagnosis by a cytopathologist



#Abn. Cells	Cell Sens.	Case Sens.
1	75%	75.0%
2	75%	93.8%
3	75%	>98.0%

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LuCED Workflow

Cytology for the 21st Century

Internet

Encrypted Data for Download

Encrypted Remote Viewing

Clinic Database

LuCED Report

VisionGate Database

CellGazer: review of "positive" cells (0.5%) for ~100% case specificity

Sputum Specimen

Cell-CT: Sputum Prep, enrichment and 3D cell imaging

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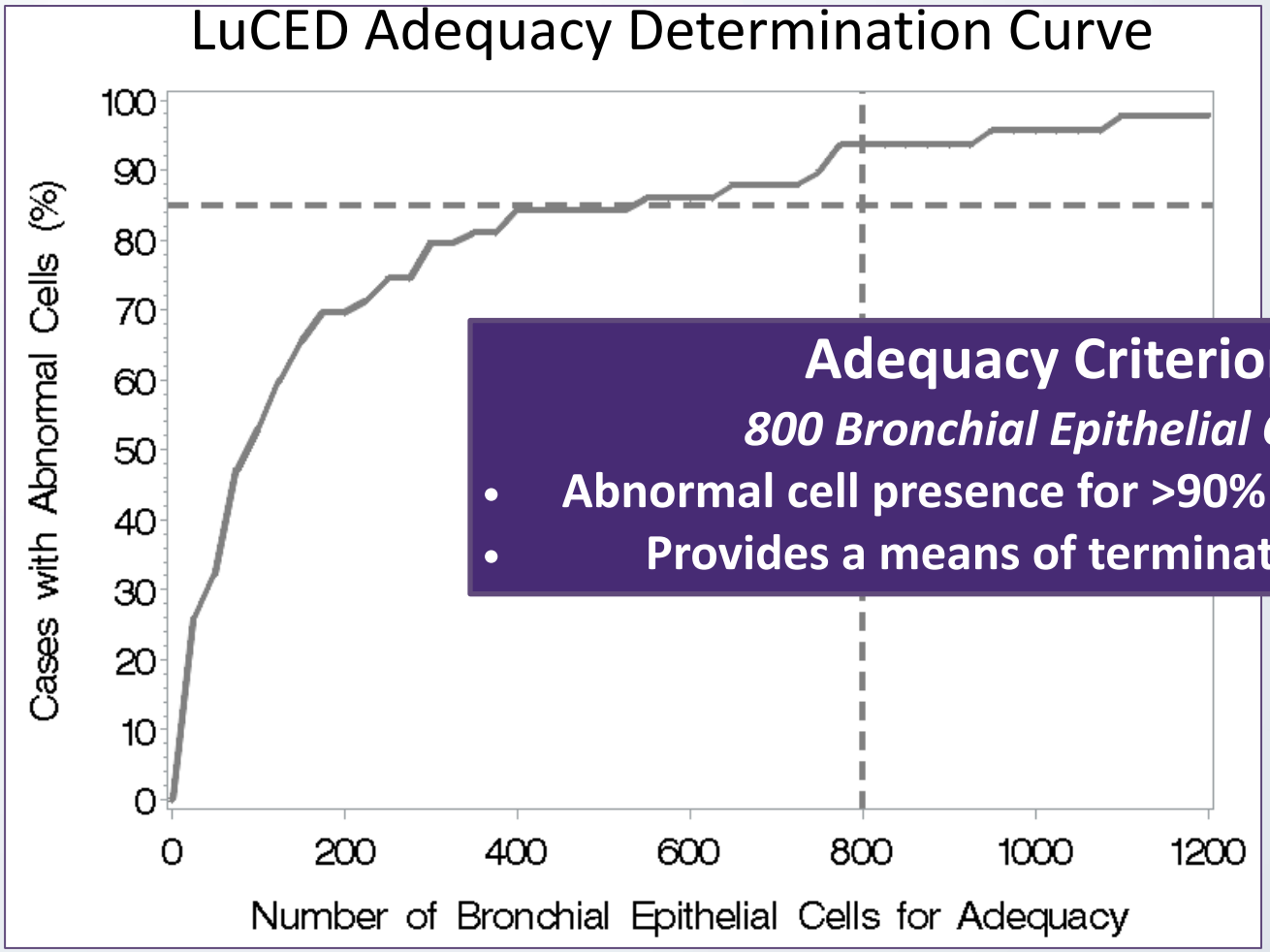
Sputum Adequacy

Criterion for sufficient sampling of the lung



Adequacy Criterion

800 Bronchial Epithelial Cells

- **Abnormal cell presence for >90% of cancer cases**
- **Provides a means of terminating the test**

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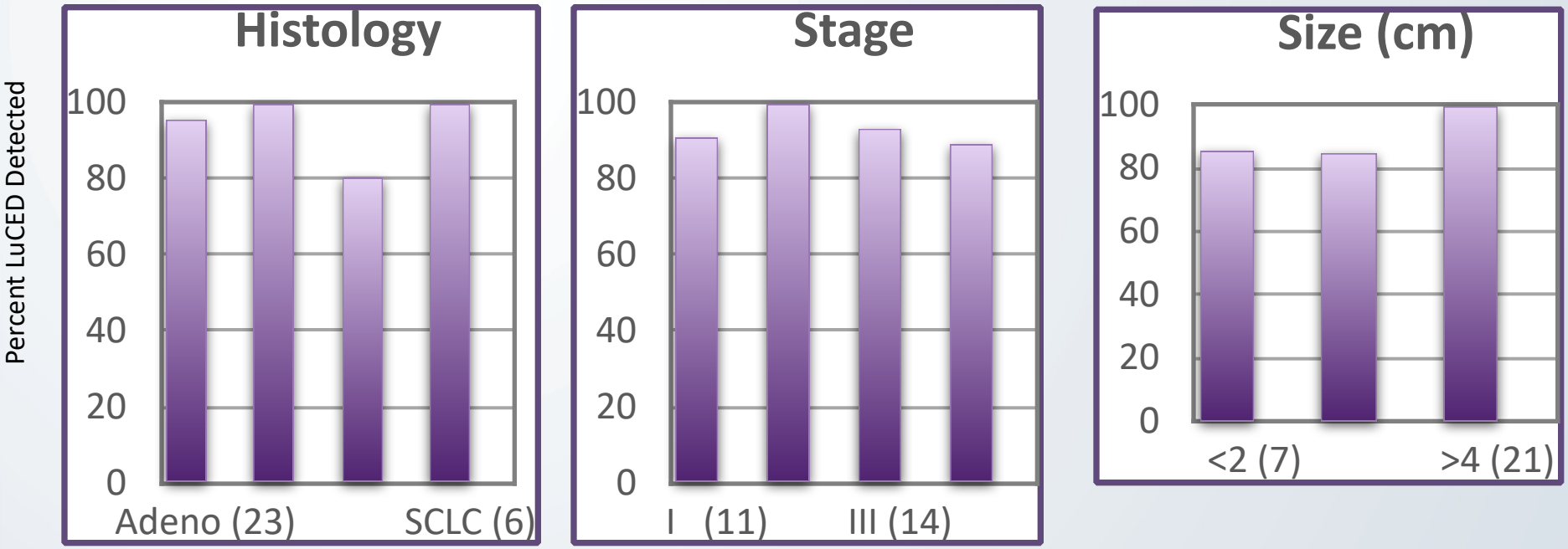
LuCED Case Sensitivity

Adequate Cases	Abnormal Cells Present	Abnormal Cells Detected	Sensitivity
47	45	44	**93.6%**



Consistent sensitivity across tumor histology, stage and size

Early stage (I & II) detection rate = 94.1%

LuCED Case Specificity

- Sputum from 47 patients without NSCLC or SCLC
  - 4 clinics worldwide
  - 11 COPD, chondroma, lymphoma, inflammation, emphysema, 9 benign lesions, 26 normal
- 609 FP/122,005 cells or 99.5% cell specificity by the LuCED classifier before cytologist adjudication
- No significant variation by disease state

Positive Cells are Resolved by the Cytologist for *Essentially 100% Case Specificity*

Conclusions

LuCED case sensitivity:

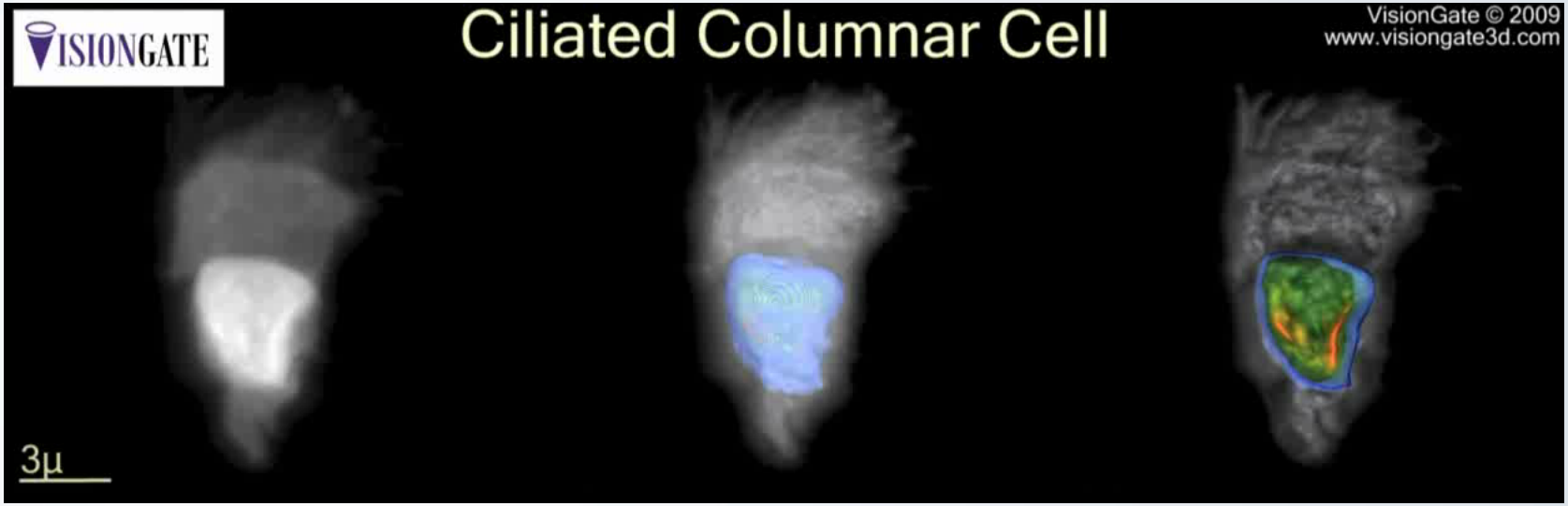
- >94% for early stage lung cancer
- Independent of tumor histology, stage and size

LuCED case specificity:

- ~100% case specificity following cytologist review

LuCED addresses LDCT false positive indications and confirms positive diagnoses for cost-effective lung cancer screening

Questions



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