

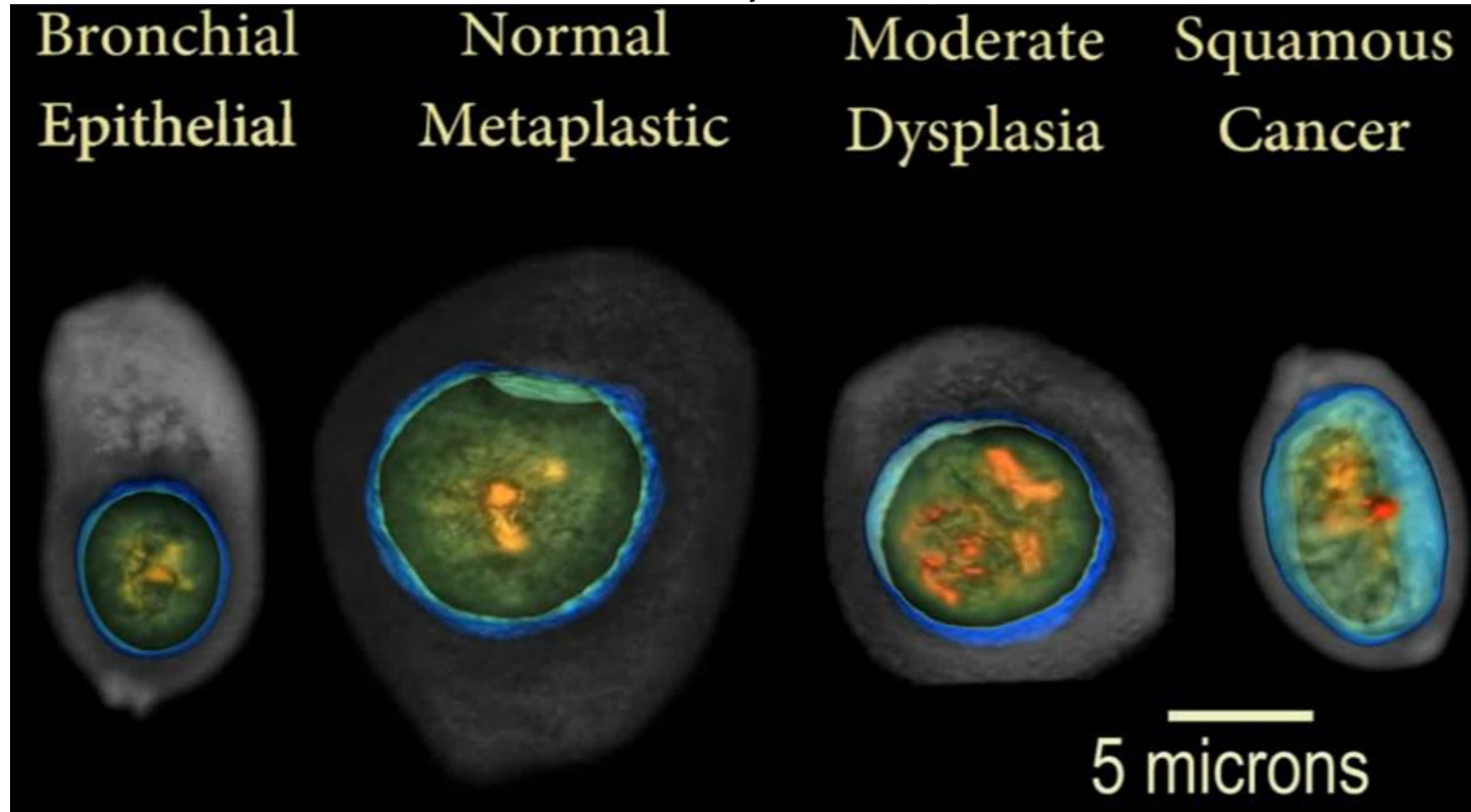
Non-invasive Detection of Lung Cancer from Cells in Sputum Using Cell-CT™

1. Demonstrate that abnormal cells are present in adequate sputum from lung cancer patients.
2. Show clinically that the Cell-CT detects lung cancer with high sensitivity and specificity.

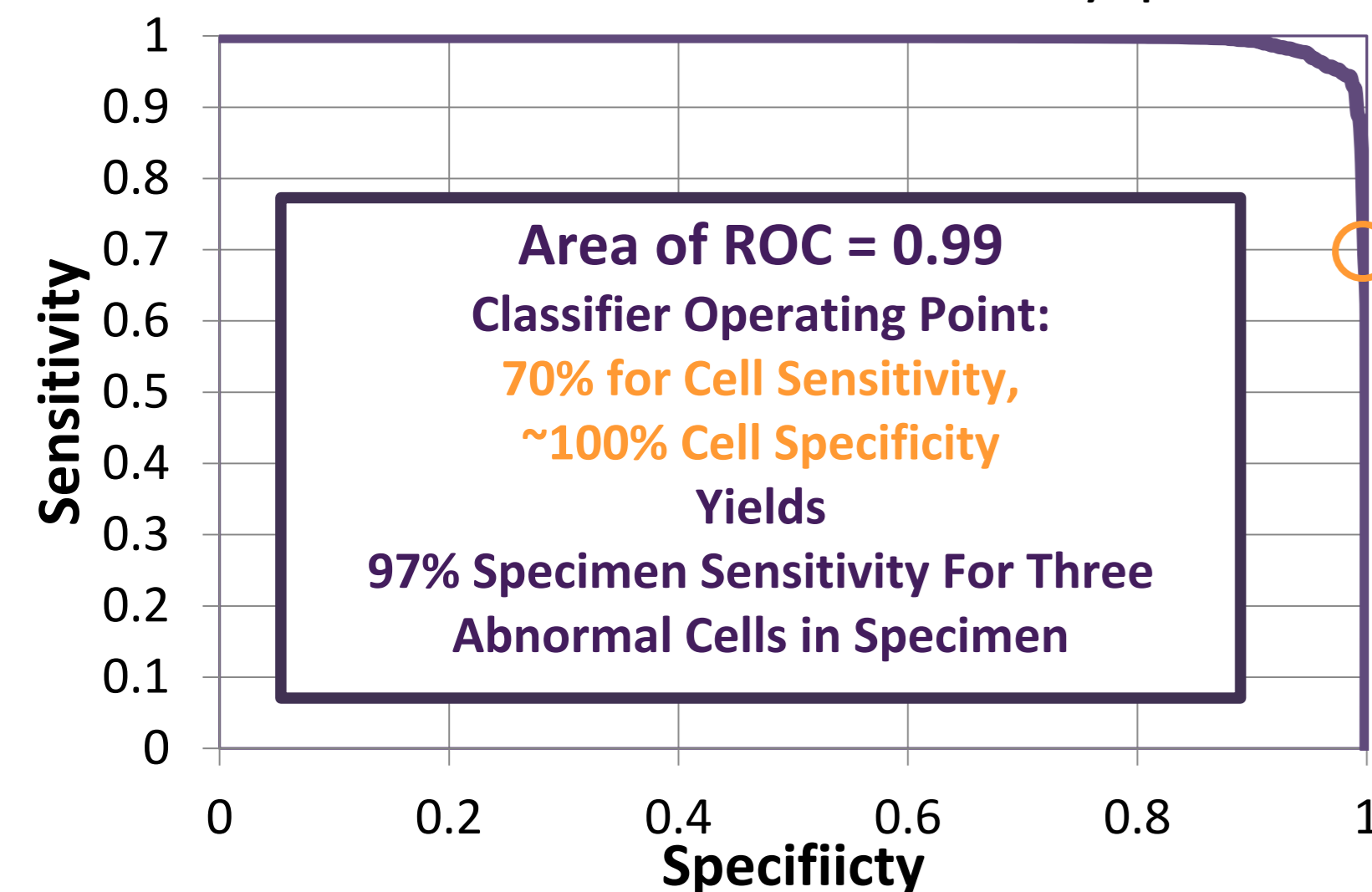
Background

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 cells of moderate dysplasia+.



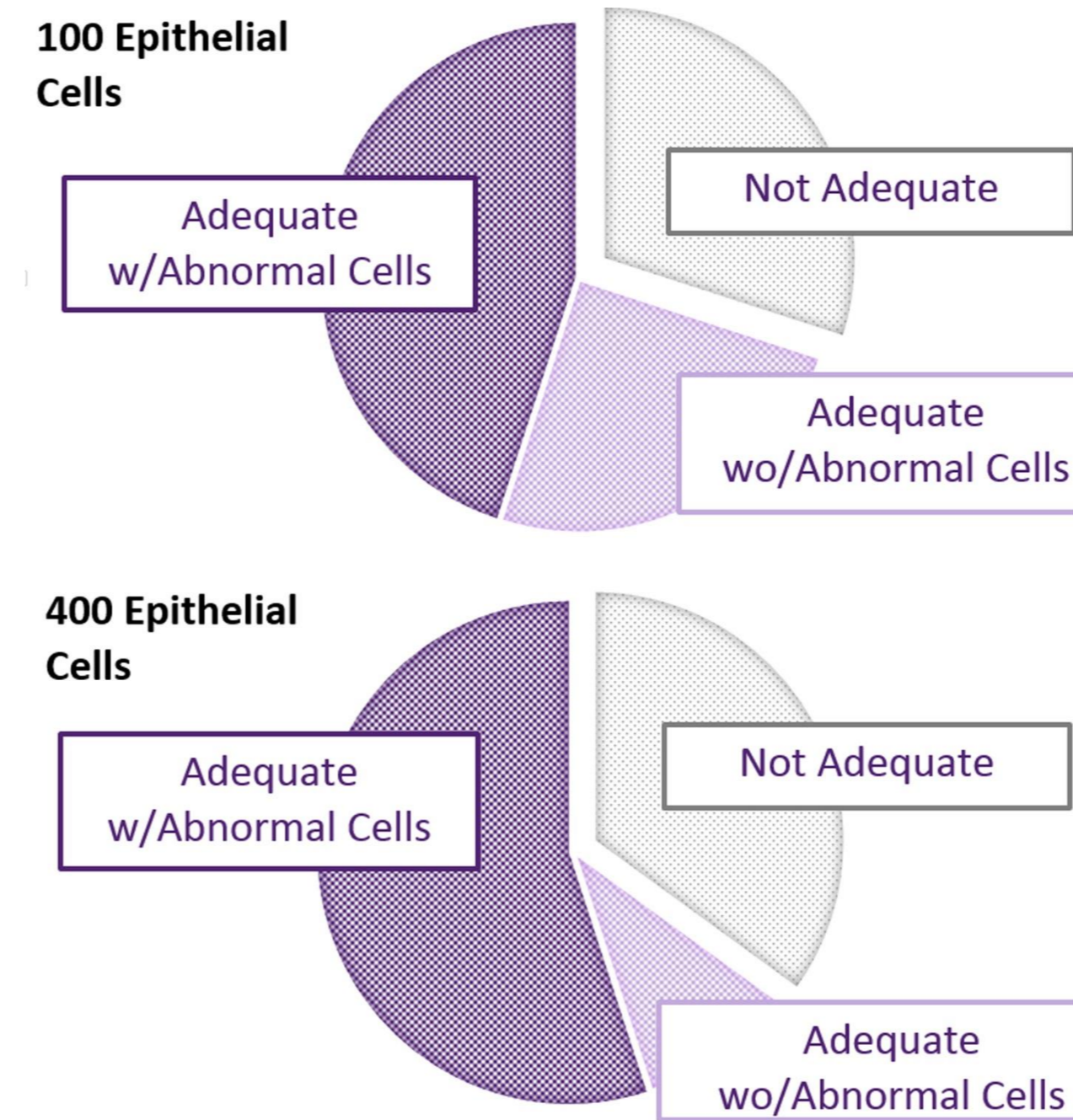
4. Cytopathologist Review: Detected cells suspicious for cancer are confirmed manually.

Methods

Ongoing clinical study now includes 53 normal and cancer patients.

Adequacy for Cell-CT Analysis:

- Pooled three-day spontaneous cough sputa from 36 patients with biopsy-confirmed cancer were analyzed by the Cell-CT.
- Cell diagnoses were assigned using Cell-CT image data.
- Numbers of normal bronchial epithelial cells and abnormal cells were enumerated.
- Adequate specimens have either abnormal cells or a count for bronchial epithelial cells exceeding a threshold.
- Different thresholds were tested. For each group of adequate specimens; the percent with abnormal cells was determined.
- Adequacy threshold defined when >90% of adequate cases had abnormal cells.



Case Sensitivity:

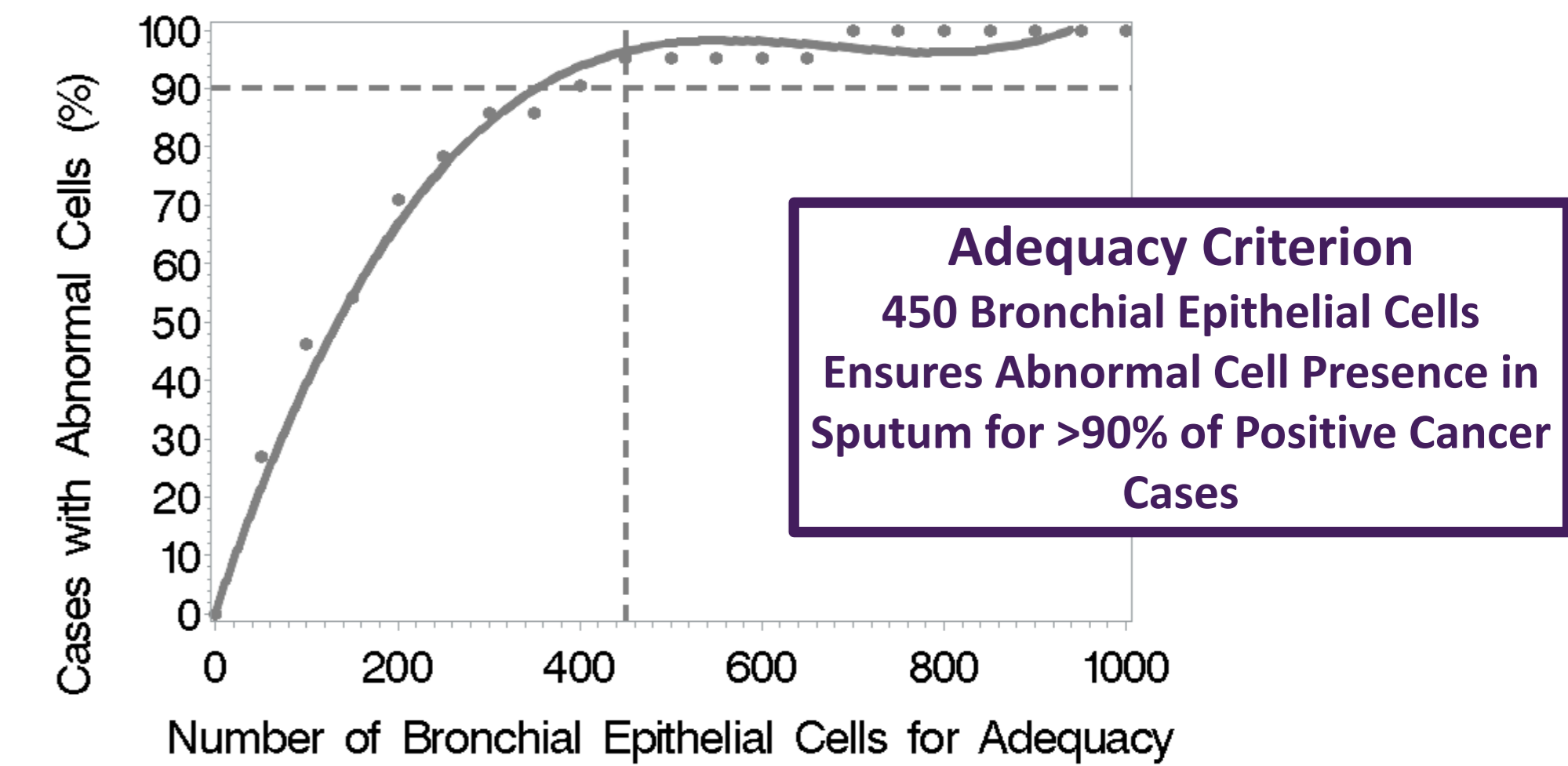
- Sensitivity is the rate of Cell-CT detected positive cases over the total number of adequate cases based on the above threshold.

Specificity:

- Sputa from 17 normal patients were analyzed by the Cell-CT.
- The number of normal cells analyzed was recorded (#NCells).
- Normal cell diagnoses were assigned using Cell-CT image data.
- Cell specificity = $100\% \times (1 - \text{FalsePositives}/\text{\#NCells})$.

Results and Conclusions

Adequacy



Case Sensitivity

Cancer Cases	Adequate Cases (Bronch. Ep. ≥ 450)	Cases w/ Abn. Cells	Cases detected by Cell-CT	Sensitivity (%)
36	21	20	20	95.2

Specificity

- 4,416 cells captured on 17 normal specimens.
- Zero false positive cells found.
- Lower 95% CI for specificity is 99.8%.

Cell-CT Sensitivity to Lung Cancer > 95%

Cell-CT Specificity = 99.8%

Cell-CT Analysis of Sputum Enables Non-Invasive Detection of Lung Cancer with High Sensitivity and Specificity