

EP04.03: LuCED® Assay for Detection of Early-Stage Lung Cancer from Home-Collected Sputum

VisionGateAI

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IASLC 2026 World
Conference on Lung Cancer

SEPTEMBER 12 - 15, 2026
SEOUL, REPUBLIC OF KOREA

INTRODUCTION

VisionGateAI has developed the Cell-CT™ which produces 3D isotropic high-resolution cell images. Cells from spontaneously collected sputum were imaged by the Cell-CT. A supervised learning/AI process was employed to train a set of extremely accurate classifiers between cell image features and cell normal/abnormal ground truth produced by gold standard cytopathology. The result is the LuCED assay to detect stage 1 surgically curable lung cancer.

METHODS

Design:

This poster summarizes the clinical performance of the next-gen LuCED assay that includes a new set of enhanced single-cell classifiers and introduces new methods that further improve processing efficiency of the Cell-CT.

In this clinical study analysis, there are Nc = 107 biopsy-confirmed cancer cases plus Nn = 27 normal controls that were processed by the Cell-CT and next-gen LuCED classifiers to produce the results of this study.

DISCUSSION AND CONCLUSION

Actionable Take-Away Messages

- The LuCED assay detects early-stage NSCLC consistently with >90% sensitivity to stage 1 lung cancer and also detects SCLC.
- Detection and surgical resection of stage 1a lung cancer provides 95% confidence in 20-year survival¹ from lung cancer.
- The LuCED assay therefore can essentially promote the cure of lung cancer.
- The LuCED assay specificity is nearly perfect. Abnormal reports on control cases indicates detection of precancer.

Future Directions for Research

- Clinical studies are now ongoing to further confirm LuCED performance.
- A future version of the LuCED assay is being developed to streamline commercialization.

REFERENCES & ACKNOWLEDGEMENTS

References

More information on VisionGateAI can be found on our website:
www.visiongate3d.com

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Acknowledgements

We gratefully acknowledge the clinics supplying specimens for this effort, most notably, Vrije University, Amsterdam – PI: Dr. Eric Thunnissen

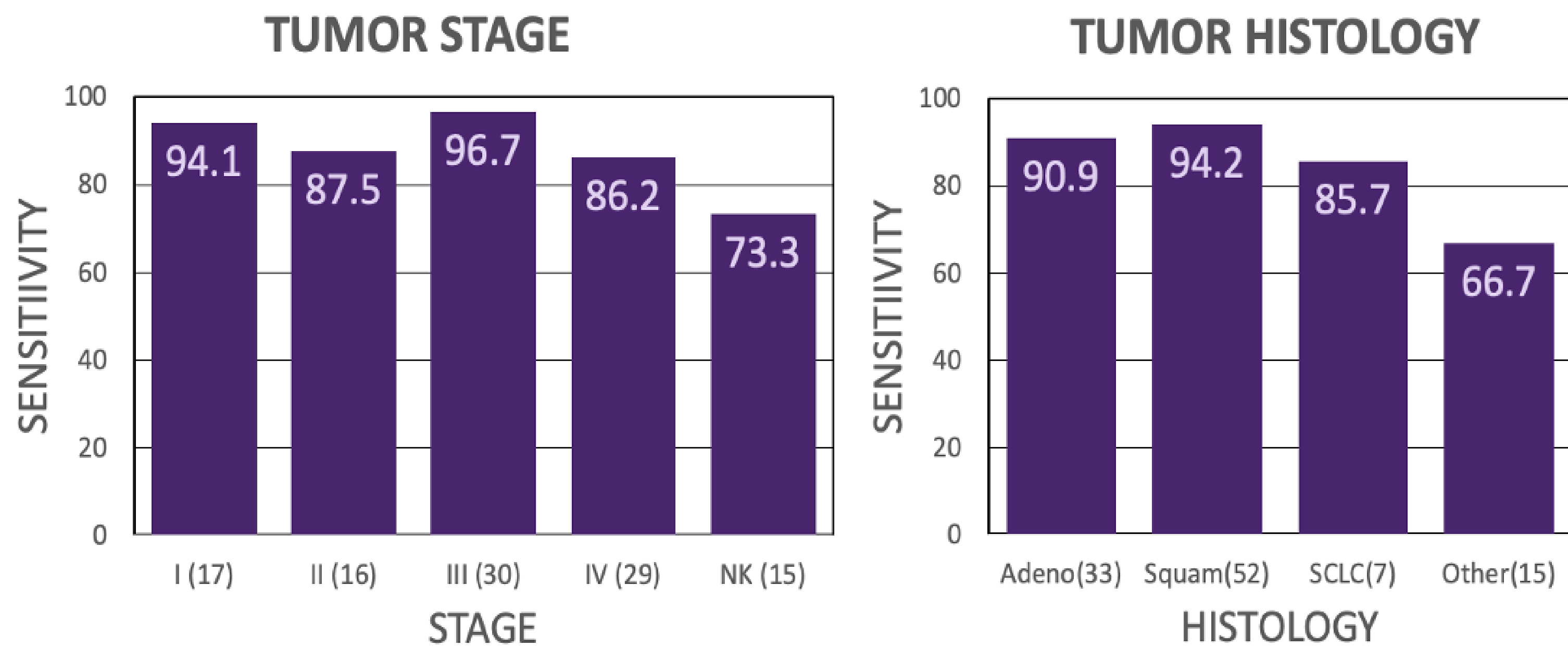
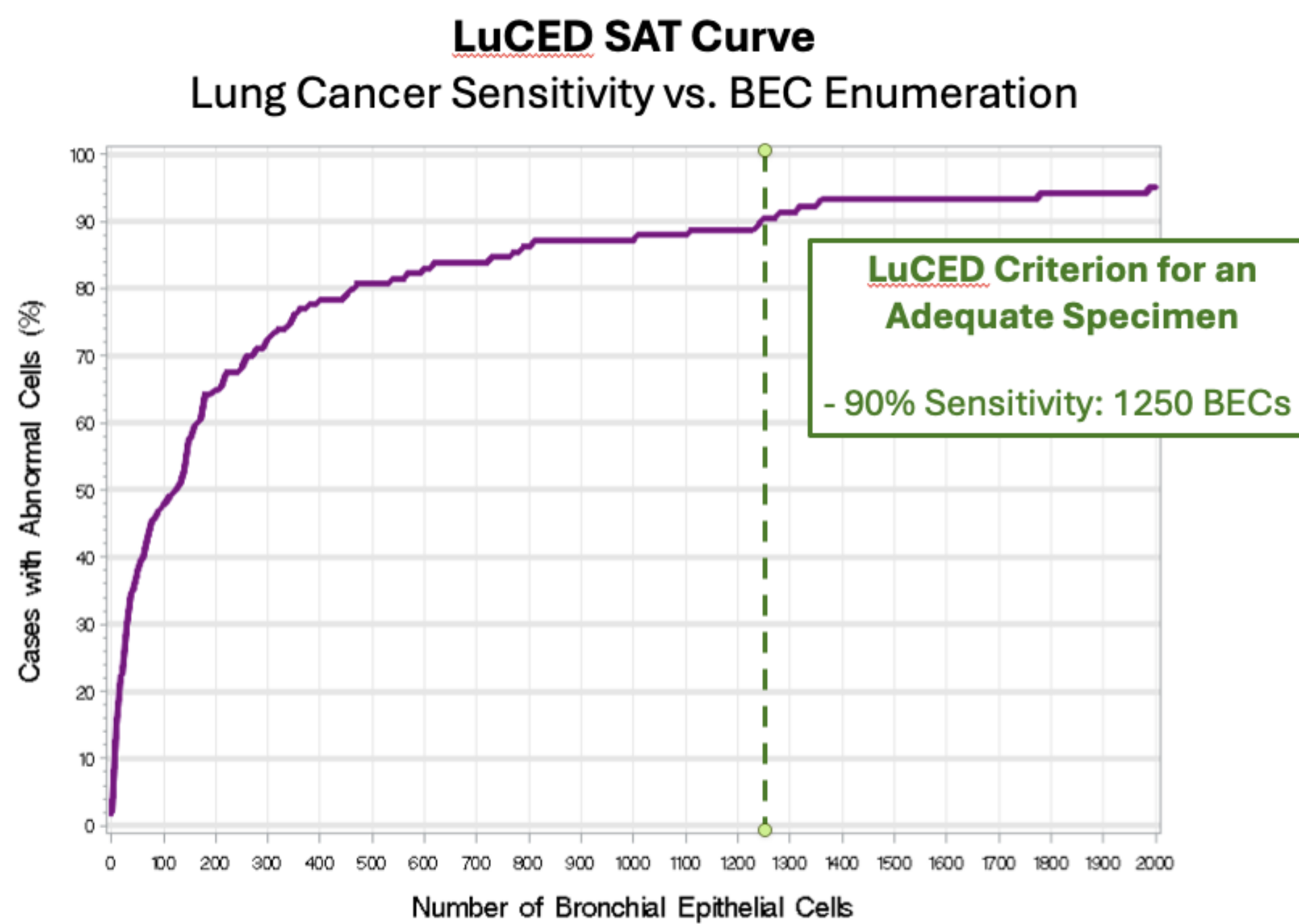
Artificial Intelligence (AI) Use Disclaimer

Grammarly was used when creating content. Otherwise, AI tools were not used to write this poster.

RESULTS

The more cells that are processed by LuCED, the more likely it is to discover an abnormal cell. A classifier that detects normal bronchial epithelial cells (BECs) is used to index the progress of LuCED case processing and to set the criterion for case adequacy. The SAT curve demonstrates an exponential relationship between the cancer detection rate and the BEC enumeration. The chart shows that 90% sensitivity may be expected after 1250 BECs have been processed by the Cell-CT.

The 107 cancer cases were analyzed. Bar charts show LuCED sensitivity by cancer stage and histology. While some sampling-induced variance is evident, the charts show no trend toward lower sensitivity with early-stage cancer or adenocarcinoma.



The 27 normal cases were analyzed. Classifier positives are cytologically confirmed so there are no false positive cells. LuCED detects abnormal cells, and as lung diseases such as COPD are associated with lung dysplasia^{2,3}, the assay may produce abnormal reports on such cases to increase vigilance in monitoring for cancer.

Control (Normal) Cases

Non-Cancer Lung Diseases (e.g. COPD)	Case Count	Cases with Abnormal Cells Detected
Y	19	3
N	8	0