

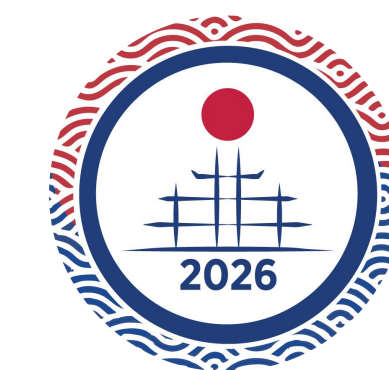


P2.116: A Real-World Comparative Study of Three Gene Testing Methods in Lung Adenocarcinoma: Driver Mutation Detection Rates and Economic Analysis

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IASLC 2026 World
Conference on Lung Cancer

SEPTEMBER 12 - 15, 2026
SEOUL, REPUBLIC OF KOREA

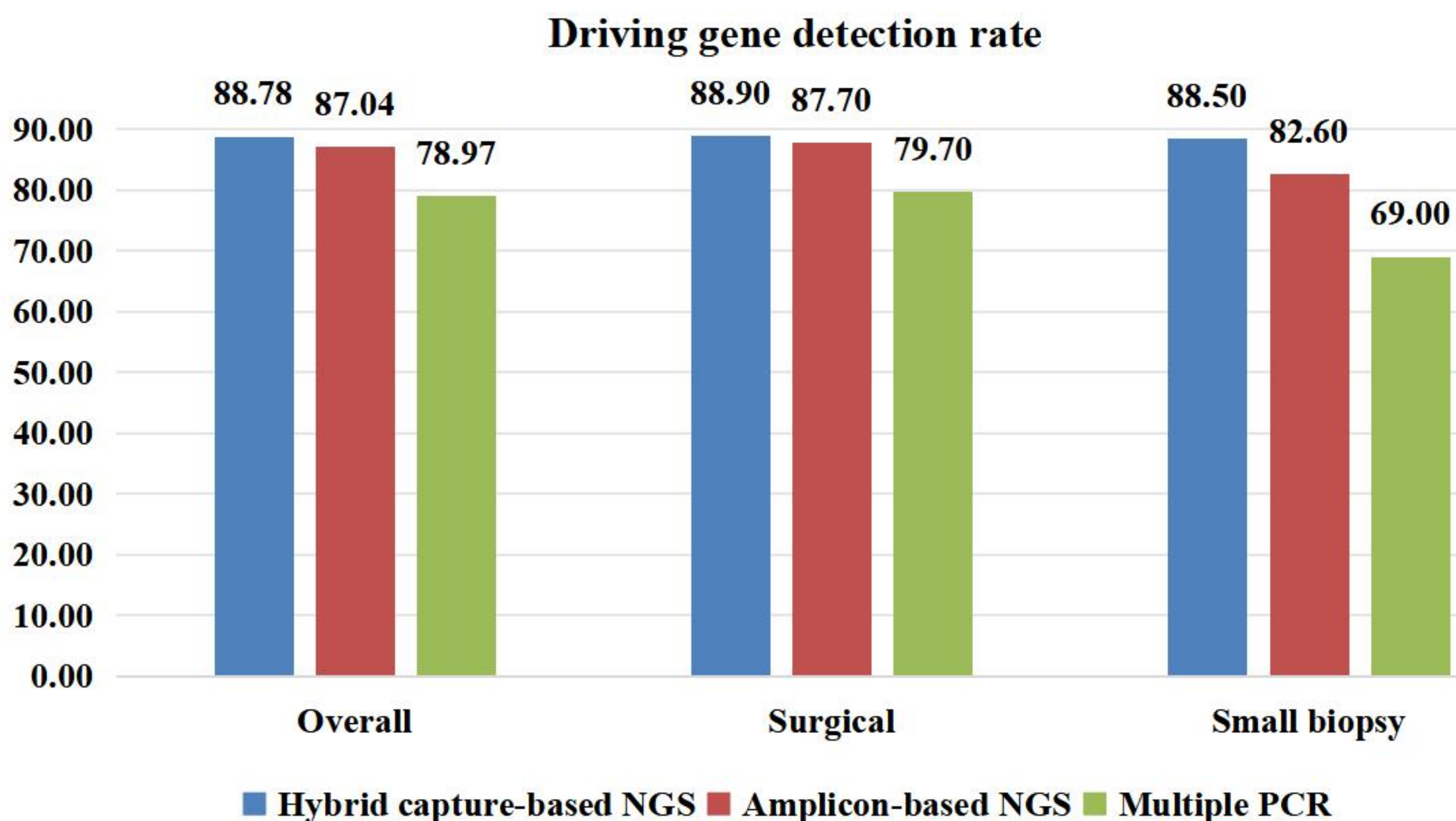
INTRODUCTION

Lung adenocarcinoma harbors a high frequency of actionable driver mutations. Multiplex PCR is rapid and low-cost but limited to predefined alterations, whereas NGS enable broad, parallel mutation detection at higher cost. Testing decisions are further complicated by the uncertain cost-effectiveness of sequential strategies (PCR first, with reflex NGS for negative cases). This study compared the real-world performance of three methods in lung adenocarcinoma, evaluated the impact of specimen type on detection rates, and developed an economic model to guide molecular testing strategy.

METHODS

Design:

We retrospectively analyzed data from routine gene testing of lung adenocarcinoma performed at our institution between 2023 and 2025, comprising 8,624 cases tested by hybrid capture-based NGS, 1,165 cases by amplicon-based NGS, and 2,154 cases by multiplex PCR. The overall detection rates of the core driver genes recommended by the NCCN guidelines (EGFR, KRAS, BRAF, ERBB2, MET, ALK, ROS1, RET, and NTRK1/2/3) were determined for each of the three methods, and detection rates were further stratified according to specimen type (surgical specimens versus small biopsy specimens). Based on the real-world testing data, an economic model was constructed under the assumption that patients testing positive by multiplex PCR discontinue further testing, whereas those testing negative proceed to NGS. The difference in mean patient cost between the sequential strategy and the direct-to-NGS strategy was calculated across a range of cost ratios. The cost of the sequential strategy is given by:



$C_{seq} = C_{PCR} + (1 - d) \times C_{NGS} = C_{NGS} + C_{PCR} - d \times C_{NGS}$
where C_{seq} denotes the cost of the sequential strategy, C_{PCR} the cost of multiplex PCR, C_{NGS} the cost of NGS, and d the driver gene detection rate of multiplex PCR. The real-world scenario of whether NGS-negative patients undergo subsequent testing was not considered in the present model.

DISCUSSION AND CONCLUSION

Actionable Take Away Message

In lung adenocarcinoma, NGS achieves a higher driver gene detection rate than multiplex PCR and is therefore recommended as the preferred approach. When patient cost alone is considered, the sequential multiplex PCR-NGS strategy is recommended when the multiplex PCR cost is below 69.0% of the NGS cost; direct NGS testing is recommended when this proportion exceeds 79.7%; and within the 69.0%–79.7% range, direct NGS is recommended for small biopsy specimens, whereas the sequential strategy is recommended for surgical specimens.

RESULTS

Overall detection rates: The driver gene detection rate was 88.78% for hybrid capture-based NGS, 87.04% for amplicon-based NGS, and 78.97% for multiplex PCR. The detection rates of hybrid capture-based NGS and amplicon-based NGS were comparable, and both were significantly higher than that of multiplex PCR ($P < 0.01$).
Stratification by specimen type: For multiplex PCR, the detection rate was 79.7% in surgical specimens and 69.0% in small biopsy specimens, indicating that specimen type significantly affects the detection rate of multiplex PCR ($P < 0.01$). In both surgical and small biopsy specimens, detection rates ranked as hybrid capture-based NGS > amplicon-based NGS > multiplex PCR, with statistically significant differences ($P < 0.01$).

Economic analysis:

1. When the cost of multiplex PCR is less than 69.0% of the NGS cost, the sequential strategy (multiplex PCR followed by NGS) is recommended.
2. When the cost of multiplex PCR exceeds 79.7% of the NGS cost, direct-to-NGS testing is recommended.
3. When the cost of multiplex PCR lies between 69.0% and 79.7% of the NGS cost, direct-to-NGS is recommended for small biopsy specimens, whereas the sequential strategy is recommended for surgical specimens.

Furthermore, given that the cost of multiplex PCR is generally no less than 10% of the NGS cost, direct-to-NGS testing yields a lower mean patient cost for non-adenocarcinoma histologic subtypes with driver gene detection rates below 10%.

We have no conflicts of interest to disclose.
AI tools were not utilized in this research.