PD-L1 and Tumor Mutation Burden Testing of Patients With Lung Cancer for Selection of Immune Checkpoint Inhibitor Therapies
Statements and Strengths of Recommendations

SUMMARY OF RECOMMENDATIONS

	Guideline Statement	Strength of Recommendation
1.	In patients with advanced non-small cell lung cancer (NSCLC), pathologists should use a validated program death ligand-1 (PD-L1) immunohistochemistry (IHC) expression assay, in conjunction with other targetable genomic biomarker assays where appropriate, to optimize selection for treatment with immune checkpoint inhibitors (ICI).	Strong Recommendation
2.	Pathologists should ensure appropriate validation has been performed on all specimen types and fixatives. *Note:* Specific validation requirements are out of scope with this guideline and laboratories should refer to the "Principles of Analytic Validation of Immunohistochemical Assays Guideline"[1] for details on how to validate IHC specimens.	Conditional Recommendation
3.	When feasible, pathologists should use clinically validated PD-L1 IHC assays as intended.	Conditional Recommendation
4.	Pathologists that choose to use laboratory developed tests for PD-L1 expression should validate according to the requirement of their accrediting body.	Strong Recommendation
5.	Pathologists should report PD-L1 IHC results using a percent expression score.	Conditional Recommendation
6.	Clinicians should not use tumor mutation burden alone to select patients with advanced NSCLC for ICI based on insufficient evidence in this population.	Conditional Recommendation

[1]Goldsmith JD, Troxell ML, Roy-Chowdhuri S, et al. Principles of analytic validation of immunohistochemical assays: guideline update. *Arch Pathol Lab Med.* Published online February 23, 2024. doi: 10.5858/arpa.2023-0483-CP

Sholl LM, Furtado LV, Awad M, et al. Programmed death ligand-1 and tumor mutation burden testing of patients with lung cancer for selection of immune checkpoint inhibitor therapies: guideline from the College of American Pathologists, the Association for Molecular Pathology, the International Association for the Study of Lung Cancer, the Pulmonary Pathology Society, and the LUNGevity Foundation. *Arch Pathol Lab Med*. Published online April 16, 2024. doi: 10.5858/arpa.2023-0536-CP