

INTRODUCTION

- PD-L1 is an established biomarker in NSCLC.
- Analytical consistency across assays remains important.
- Leica Biosystems is developing a new PD-L1 assay using the CAL10 clone to identify PD-L1 protein in immunohistochemically stained tissue.
- This feasibility study evaluated concordance with SP263 and 22C3.

METHODS

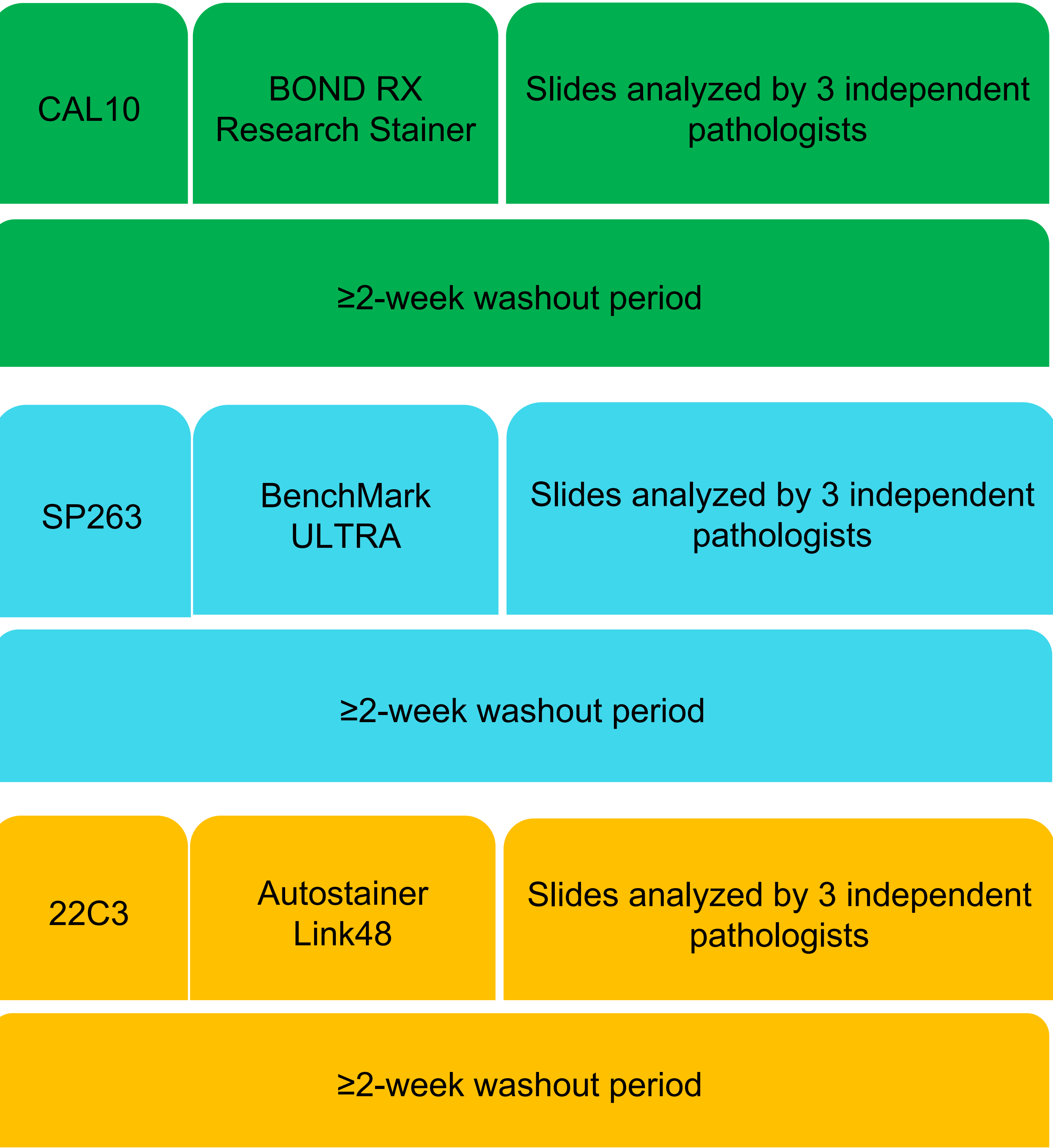


Figure 1. Study Design

- 100 unique resected NSCLC FFPE specimens (4 µm sections) were randomly selected.
- In this feasibility study, we compared PD-L1 CAL10 with SP263 and 22C3 at ≥1% and ≥50% tumor proportion score (TPS) cutoffs and also assessed inter-observer (inter-pathologist) agreement for each assay at ≥1% and ≥50% TPS cutoffs.

RESULTS

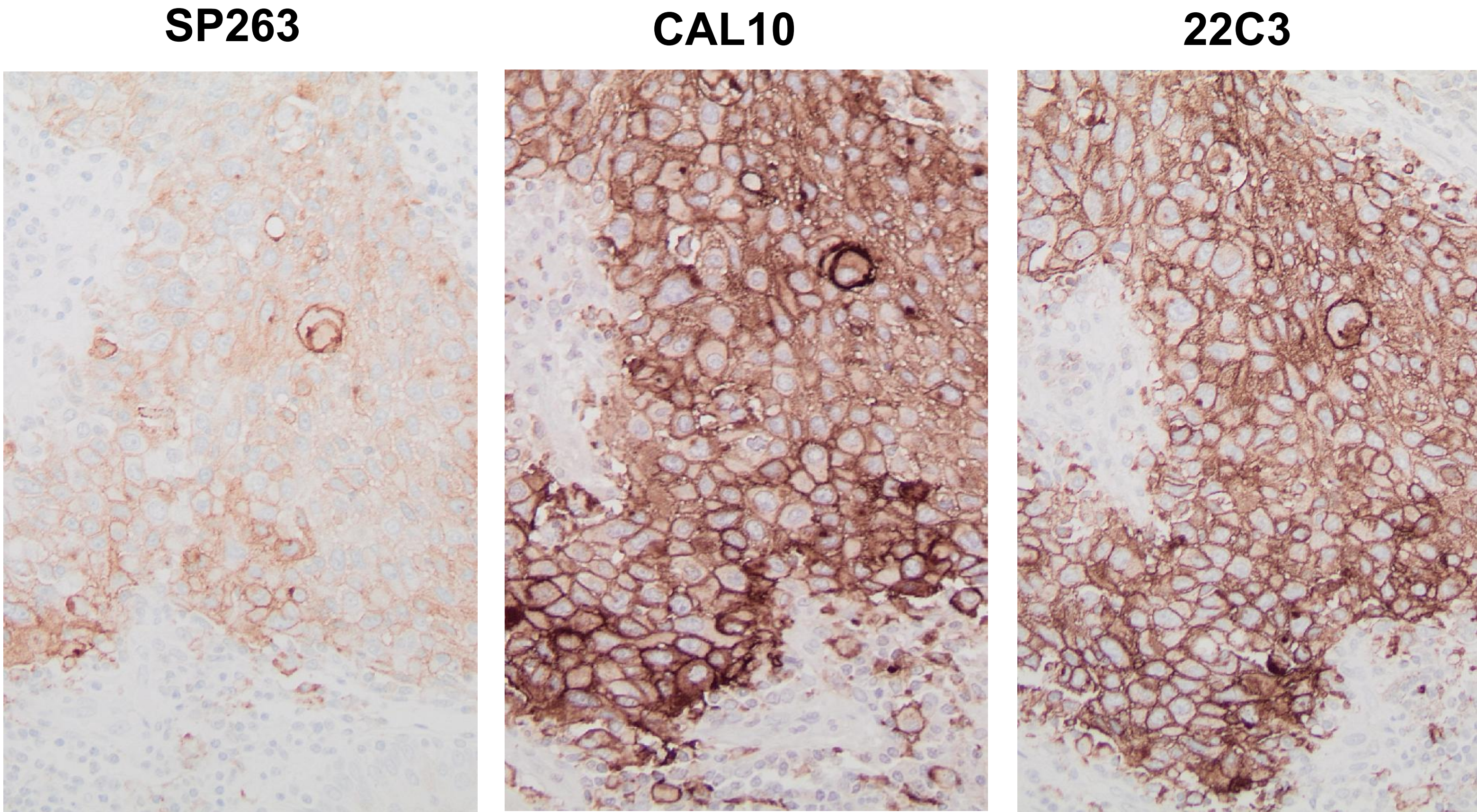


Figure 1. Representative images of concordant positive PD-L1 status of the CAL10 assay with the SP263 and 22C3 comparator assays. Positive 100% TPS at 20x magnification

PD-L1 CAL10 showed similar inter-assay and inter-reader variability compared with SP263 and 22C3 (Table 1).

Table 1. TPS agreement rates

Inter-assay	CAL10 vs SP263	CAL10 vs 22C3	SP263 vs 22C3
≥1% TPS	Substantial	Substantial	Moderate
	k=0.70	k=0.74	k=0.58
	OPA 85.9%	OPA 86.9%	OPA 78.8%
≥50% TPS	Substantial	Almost perfect	Substantial
	k=0.61	k=0.83	k=0.62
	OPA 89.9%	OPA 94.9%	OPA 90.9%
Inter-pathologist	CAL10	SP263	22C3
≥1% TPS	Moderate	Substantial	Moderate
	k=0.59	k=0.74	k=0.53
≥50% TPS	Moderate	Substantial	Moderate
	k=0.60	k=0.68	k=0.58

TPS, tumor proportion score; OPA, overall percent agreement, k, Cohen's kappa statistic k; almost perfect=0.81-0.99, Substantial=0.61-0.80, and Moderate= 0.41-0.60

KEY FINDINGS

CAL10 achieved **substantial to almost-perfect concordance** with both SP263 and 22C3 at clinically relevant TPS cutoffs.

CAL10 demonstrated **moderate and reproducible inter-pathologist agreement**, on par with the established 22C3 assay

Highest concordance was observed between CAL10 and 22C3 at the **≥50% cutoff (κ=0.83; OPA 94.9%)**

CONCLUSION

PD-L1 CAL10 Assay

Strong inter-assay concordance

Comparable inter-reader reproducibility with established assays

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- These initial results suggest that the performance of the in-development PD-L1 CAL10 assay is comparable to the other tested PD-L1 assays in NSCLC specimens and may be a suitable option for further translational research evaluations.
 - Further analytical and clinical validation would be required to support future regulatory or clinical-use claims.

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