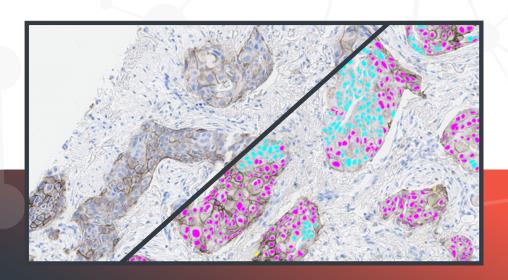
# **LUNG PD-L1 AI**

HALO Clinical Al Solutions



Lung PD-L1 AI is an automated, AI-powered application for IHC slides that analyzes PD-L1 expression in cases of non-small cell lung cancer. It is seamlessly integrated into the CE-IVDR marked HALO AP® diagnostic digital pathology platform. Lung PD-L1 AI is For Research Use Only and not intended for clinical diagnostic use.

#### PUT AI TO WORK IN YOUR ANATOMIC PATHOLOGY LABORATORY

#### Inputs

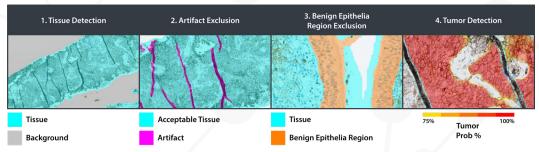
 Non-small cell lung cancer biopsies and/or resections

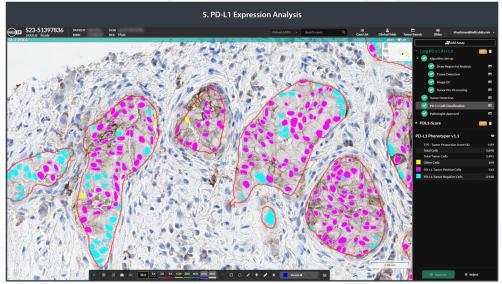
### **Supported Scanners**

- + 3DHISTECH P1000
- + Leica Aperio GT 450

#### **Key Output Metrics**

 Tumor Proportion Score (TPS)







# STANDARDIZE PD-L1 EVALUATION

Standardization facilitates comparison across individuals, laboratories, and institutes, which in turn enables collaborative research, enhances data reliability, and ultimately advances scientific understanding.



# INCREASE YOUR WORKFLOW EFFICIENCY

Lung PD-L1 AI can assist pathologists and researchers in conducting more efficient PD-L1 expression evaluation. The algorithm can be run on slides before they are released for review, so you can make faster and more informed decisions.



#### **COMPLEMENT YOUR EXPERTISE**

Lung PD-L1 AI complements your expertise and provides an easy-to-read visual mask that highlights tumor areas and positive and negative cells with colorimetric feedback. Analysis results include cell-level information, informing your PD-L1 IHC evaluation process.

#### DECREASE VARIABILITY IN YOUR PD-L1 EXPRESSION ANALYSIS

#### **Accurate Comparative Studies**

By eliminating inter-observer scoring variability through automated analysis, Lung PD-L1 AI allows for accurate comparisons enabling the identification of meaningful correlations between PD-L1 expression and various clinical or experimental outcomes.

### **Quality Control PD-L1 Scoring**

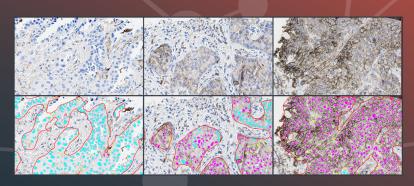
Lung PD-L1 AI analyzes every cell selected within automatically segmented tumor regions of interest, ensuring that minute areas of expression don't go missed, no matter how small. It can also be run after case sign-out as a post-analysis quality control check.

#### Multiclonal Analysis

Lung PD-L1 AI is validated on two of the most common PD-L1 clones available, SP263 and 22C3.

#### Seamlessly Integrated into HALO AP®

Lung PD-L1 AI deploys seamlessly in HALO AP, where users can take advantage of a wide variety of tools for further analysis, collaboration, and research.

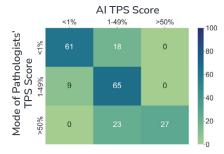


Lung PD-L1 AI assists pathologists in arriving at more reliable and reproducible PD-L1 results.

#### PERFORMANCE & VALIDATION

SP263 Clone Validation (Institute 1)

Percent Agreement	
Pathologist A vs Lung PD-L1 AI	71.4
Pathologist B vs Lung PD-L1 AI	66.0
Pathologist C vs Lung PD-L1 AI	78.3
Mode of pathologists' score vs Lung PD-L1 AI	75.4



Analysis of SP263-stained whole slide images unseen to the algorithm during development scanned on a 3DHISTECH P1000 scanner. Pairwise agreement between each pathologist and Lung PD-L1 AI and confusion matrix plot for the agreement between the mode of the pathologists' TPS score and Lung PD-L1 AI at clinically relevant cut-offs.

Agreement of Lung PD-L1 AI with the mode of the pathologists' TPS score was 75.4% overall (95% CI 0.69 - 0.81).

### Lung PD-L1 Al agrees with pathologist TPS scores in routine diagnostic cases

ICC between the pathologists was 0.96 (95% CI 0.93 – 0.97).

ICC between the pathologists and Lung PD-L1 AI was 0.95 (95% CI 0.93 – 0.97), indicating high reliability.

All Pathologists	0.96	⊢++
Pathologists A & B + Lung PD-L1 Al	0.93	<b>├</b>
Pathologists A & C + Lung PD-L1 Al	0.94	<b>├──</b>
Pathologists B & C + Lung PD-L1 Al	0.93	<b>├──</b>
All Pathologists + Lung PD-L1 Al	0.95	H=-1
Confidence interval plot for the intraclass correlation coefficient		0.8 0.85 0.9 0.95 1 Confidence Interval 95%

Use of Lung PD-L1 AI has the potential to support pathologists scoring PD-L1, saving pathologists' time and ensuring consistency in the reported results.

## PERFORMANCE & VALIDATION

22C3 Clone Validation (Institute 2)

Preliminary results on 22C3-stained whole slide images unseen to algorithm during development scanned on an Aperio GT 450 scanner show that the overall percent agreement with the reported TPS score was 72.7. The ICC agreement was 0.95 (95% CI 0.93-0.96), indicating high reliability.



# Ready to learn more?

Contact us to schedule a demo of Lung PD-L1 AI and HALO AP®.



Lung PD-L1 AI is For Research Use Only and not intended for clinical diagnostic use. Lung PD-L1 AI is accessed via the HALO AP® enterprise digital pathology platform.

HALO AP® is CE-IVDR marked for in-vitro diagnostic use in Europe, the UK, and Switzerland. HALO AP is For Research Use Only in the US and is not FDA cleared for clinical diagnostic use. In addition, HALO AP provides built-in compliance and certifications with FDA 21 CFR Part 11, HIPAA, and GDPR.

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