

Biomarker Datasheet

Human PD-L1 U-VUE[®] Biomarker

Programmed cell death ligand 1 (PDL1) is a type 1 transmembrane protein (B7-H1) that belongs to the B7 ligands family and may be expressed on both, hematopoietic cells (dendritic cells, macrophages, mast cells, T cells and B cells) and non-hematopoietic cells, including endothelial, epithelial and tumor cells. It plays an immunosuppressive role by inhibiting T-cell activity. Overexpression of PD-L1 by cancer cells may enable them to evade the host immune response, conferring a growth advantage to such tumors.

Overview

Target	Other names	Isotype	Primary cell type	Subcellular location	Positive control(s)
PD-L1	CD274, B7-H, B7-H1, B7H1, PDCD1LG1, PDL1	Rabbit IgG	Epithelial, tumor and immune cells	Plasma membrane	Tonsil

*Clone available upon request

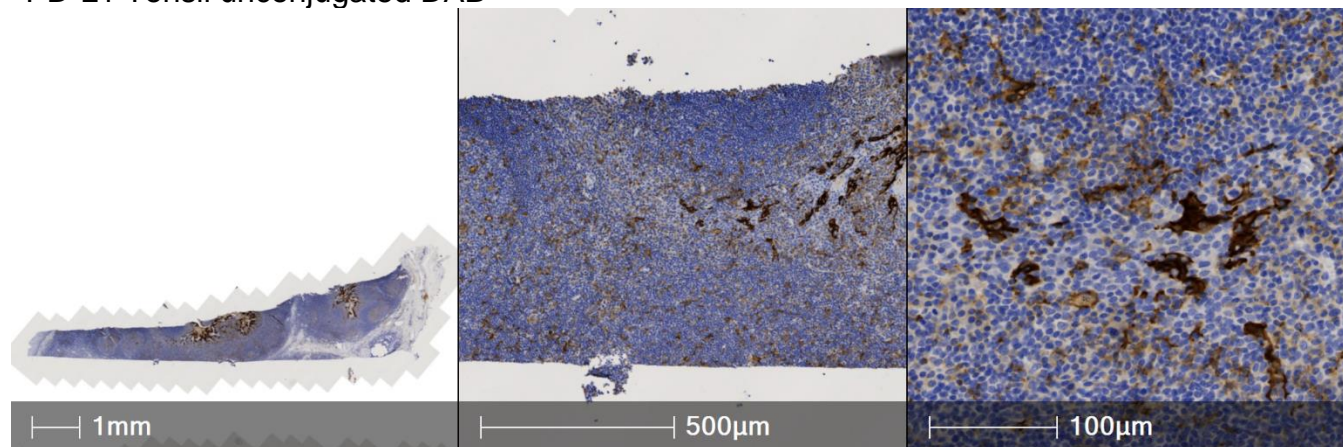
Quality Control

Each lot of antibody conjugate reagent is tested on positive control tissue and reviewed by reviewed by Ultivue's pathologists and scientists to ensure appropriate staining pattern and signal intensity by both qualitative and quantitative review.

Predicate Comparison

Serial sections of tonsil and tumor tissue controls were stained with traditional chromogenic DAB using unconjugated antibodies and with the InSituPlex® (ISP) monoplex assay to demonstrate concordance between staining modalities.

PD-L1 Tonsil unconjugated DAB



PD-L1 Tonsil ISP

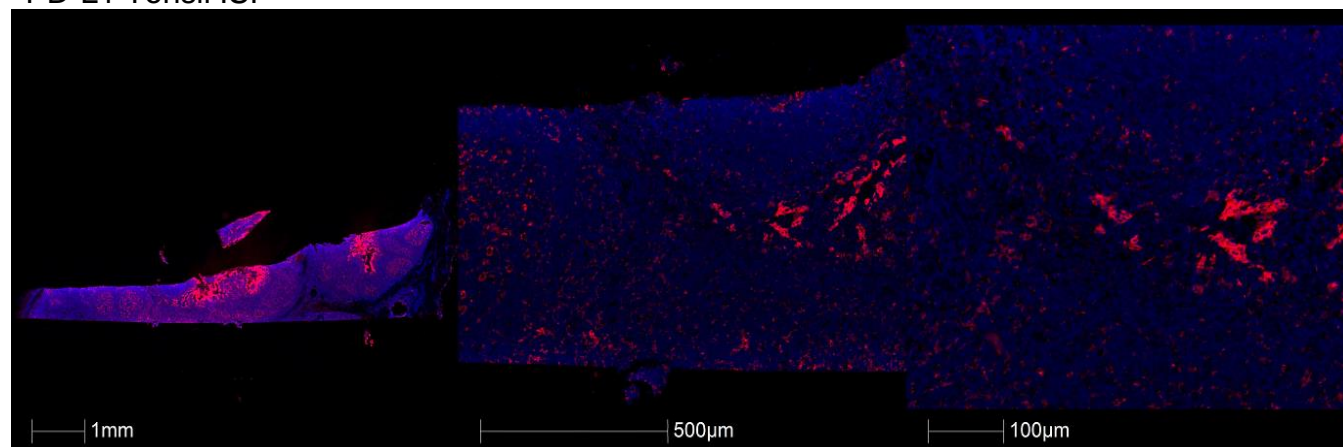


Figure 1: Comparison of unconjugated DAB and InSituPlex® monoplex assay in tonsil tissue. Chromogenic DAB(top panel), fluorescent ISP staining (bottom panel).

Assay Reproducibility

An InSituPlex® monoplex assay was performed across serial sections of tonsil and colorectal cancer (CRC) tissue on the Leica BOND RX autostainer. Staining was found to be qualitatively and quantitatively equivalent across all slides in the run as demonstrated by coefficient of variance (CV) of positive cell density and signal intensity.

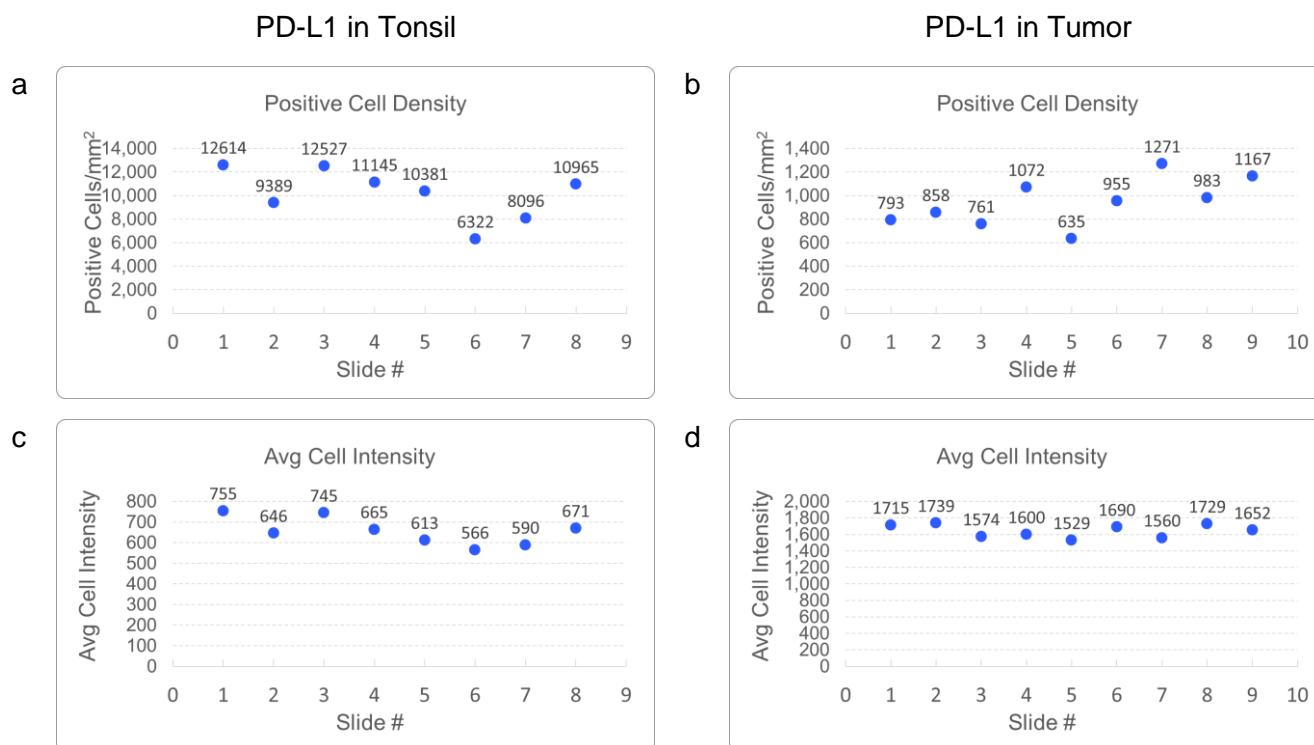


Figure 2: **a.** Number of positive cells/mm² per slide on tonsil tissue. Inter-slide coefficient of variance (CV) = 19.9% **b.** Number of positive cells/mm² per slide on CRC tissue. Inter-slide CV = 20.4% **c.** Mean positive signal intensity per slide on tonsil tissue. Inter-slide CV = 9.7%. **d.** Mean positive signal intensity per slide on CRC tissue. Inter-slide CV = 4.6%.

References

1. Cai, H., Zhang, Y., Wang, J., & Gu, J. (2021). Defects in Macrophage Reprogramming in Cancer Therapy: The Negative Impact of PD-L1/PD-1. *Frontiers in immunology*, 12, 690869. <https://doi.org/10.3389/fimmu.2021.690869>
2. Huang, R., Haberberger, J., Severson, E., Duncan, D. L., Hemmerich, A., Edgerly, C., Ferguson, N. L., Williams, E., Elvin, J., Vergilio, J. A., Killian, J. K., Lin, D. I., Tse, J., Hiemenz, M., Owens, C., Danziger, N., Hegde, P. S., Venstrom, J., Alexander, B., Ross, J. S., ... Ramkissoon, S. H. (2021). A pan-cancer analysis of PD-L1 immunohistochemistry and gene amplification, tumor mutation burden and microsatellite instability in 48,782 cases. *Modern pathology : an official journal of the United States and Canadian Academy of Pathology, Inc*, 34(2), 252–263. <https://doi.org/10.1038/s41379-020-00664-y>
3. Yi, M., Niu, M., Xu, L., Luo, S., & Wu, K. (2021). Regulation of PD-L1 expression in the tumor microenvironment. *Journal of hematology & oncology*, 14(1), 10. <https://doi.org/10.1186/s13045-020-01027-5>