

## Biomarker Datasheet

# Human PD-1 U-VUE<sup>®</sup> Biomarker

Programmed cell death protein 1, also known as PD-1 and CD279, is an inhibitory receptor expressed by all T cells during activation. It regulates T cell effector functions during physiological responses, including acute and chronic infection, cancer and autoimmunity. When PD-1 is bound to his ligand PD-L1, it prevents T cells from killing target cells including cancer cells.

### Overview

Target	Other names	Isotype	Primary cell type	Subcellular location	Positive control(s)
PD-1	PDCD1, CD279, hSLE1, PD1, SLEB2	Rabbit IgG	T cells	Plasma membrane	Tonsil

\*Clone available upon request

### Quality Control

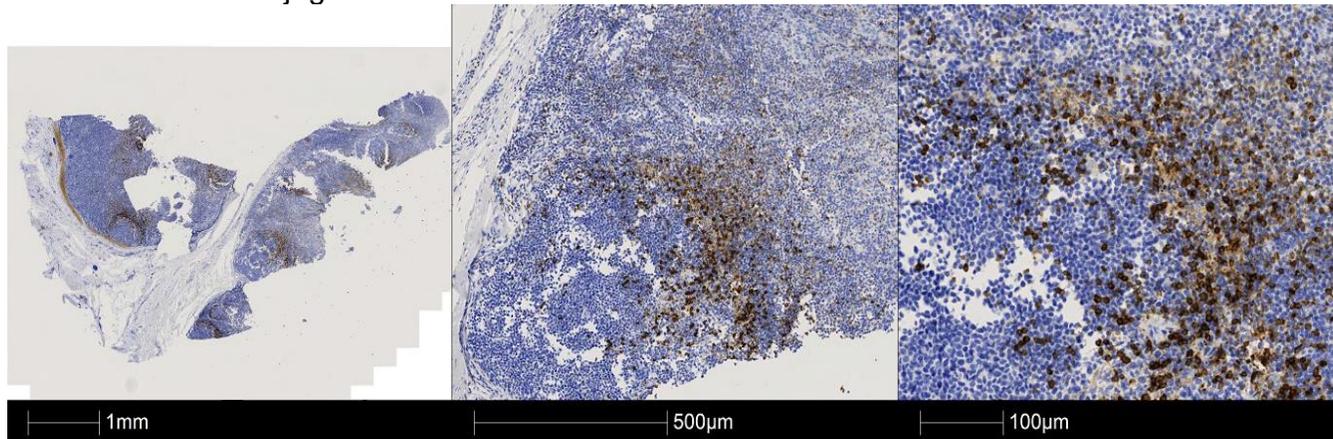
Each lot of antibody conjugate reagent is tested on positive control tissue and reviewed by reviewed by Ultivue's pathologists and scientists to ensure appropriate staining pattern and signal intensity by both qualitative and quantitative review.



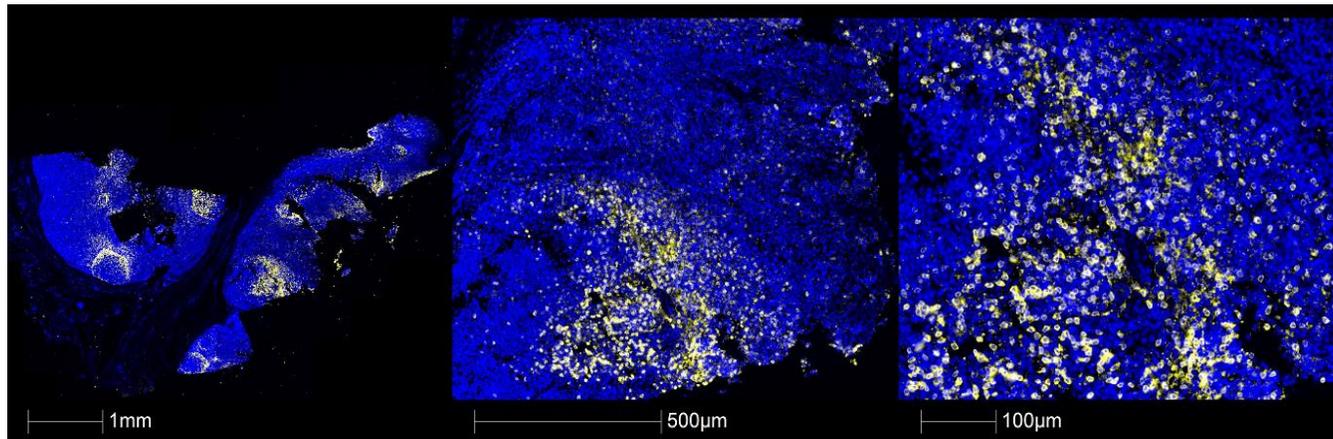
## Predicate Comparison

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-1 Tonsil unconjugated DAB



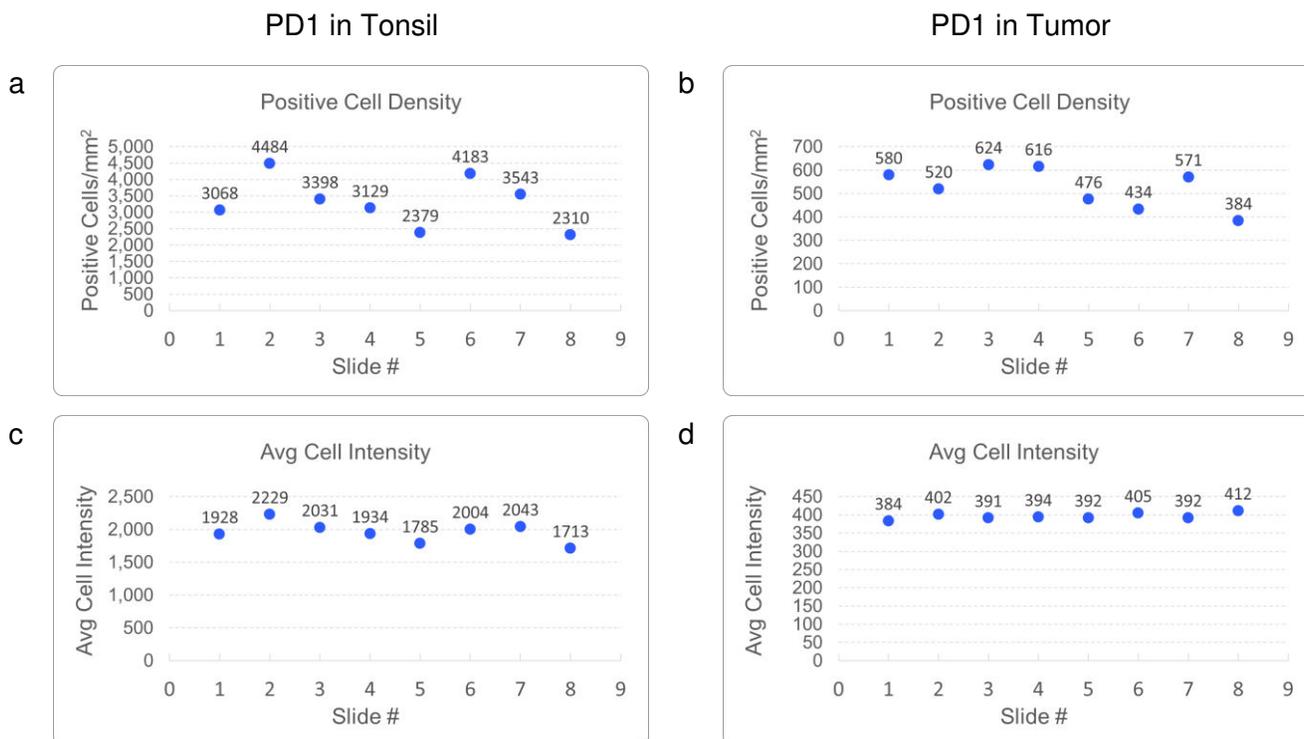
### PD1 Tonsil ISP



**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/mm<sup>2</sup> per slide on tonsil tissue. Inter-slide coefficient of variance (CV) = 21.8% **b.** Number of positive cells/mm<sup>2</sup> per slide on CRC tissue. Inter-slide CV = 12.2% **c.** Mean positive signal intensity per slide on tonsil tissue. Inter-slide CV = 7.7%. **d.** Mean positive signal intensity per slide on CRC tissue. Inter-slide CV = 1.7%.

## References

1. Fan, P., Li, X., Feng, Y., Cai, H., Dong, D., Peng, Y., Yao, X., Guo, Y., Ma, M., Dong, T., & Wang, R. (2021). PD-1 Expression Status on CD8+ Tumour Infiltrating Lymphocytes Associates With Survival in Cervical Cancer. *Frontiers in oncology*, 11, 678758. <https://doi.org/10.3389/fonc.2021.678758>
2. Munari, E., Marconi, M., Querzoli, G., Lunardi, G., Bertoglio, P., Ciompi, F., Tosadori, A., Eccher, A., Tumino, N., Quatrini, L., Vacca, P., Rossi, G., Cavazza, A., Martignoni, G., Brunelli, M., Netto, G. J., Moretta, L., Zamboni, G., & Bogina, G. (2021). Impact of PD-L1 and PD-1 Expression on the Prognostic Significance of CD8+ Tumor-Infiltrating Lymphocytes in Non-Small Cell Lung Cancer. *Frontiers in immunology*, 12, 680973. <https://doi.org/10.3389/fimmu.2021.680973>
3. Vidula, N., Yau, C., & Rugo, H. S. (2021). Programmed cell death 1 (PD-1) receptor and programmed death ligand 1 (PD-L1) gene expression in primary breast cancer. *Breast cancer research and treatment*, 187(2), 387–395. <https://doi.org/10.1007/s10549-021-06234-3>