Biomarker Datasheet

Human MHC II OmniVUE™ Biomarker

Major Histocompability Complex II (MHC II) molecules are heterodimer complex that presents peptide antigen on the surface of the professional antigen presenting cells (APC's) like macrophages and dendritic cells. Presentation of the antigen by MHC II complex is critical in CD4 activation and development of adaptive immune response. Along with APC's, B cells and epithelial cells also present the MHC II molecule.

Overview

Target	Other names	Isotype	Primary cell type	Subcellular location	Positive control(s)
MHC II	Major histocompatibility complex II	Mouse IgG1	Macrophages, Dendritic cells, B cells, Epithelial cells	Membrane	Tonsil/ Spleen

*Clone available upon request

Quality Control

Each lot of Antibody-barcode conjugate reagent is tested on the appropriate positive control tissue and reviewed by Ultivue's pathologists and image analysis experts to ensure expected staining pattern and positive signal intensity, through qualitative as well as quantitative analysis. Lot-to-lot consistency is evaluated and strictly maintained through quantitative comparison of a new lot of reagent with the predicate (previous lot) with an accepted variability of ±20% for positive signal intensity, which is at par with the current standards practiced in pathology.

Predicate Comparison

Serial sections of tonsil and tumor tissue controls are stained with traditional chromogenic DAB using unconjugated antibodies and InSituPlex monoplex to demonstrate concordance between staining modalities.

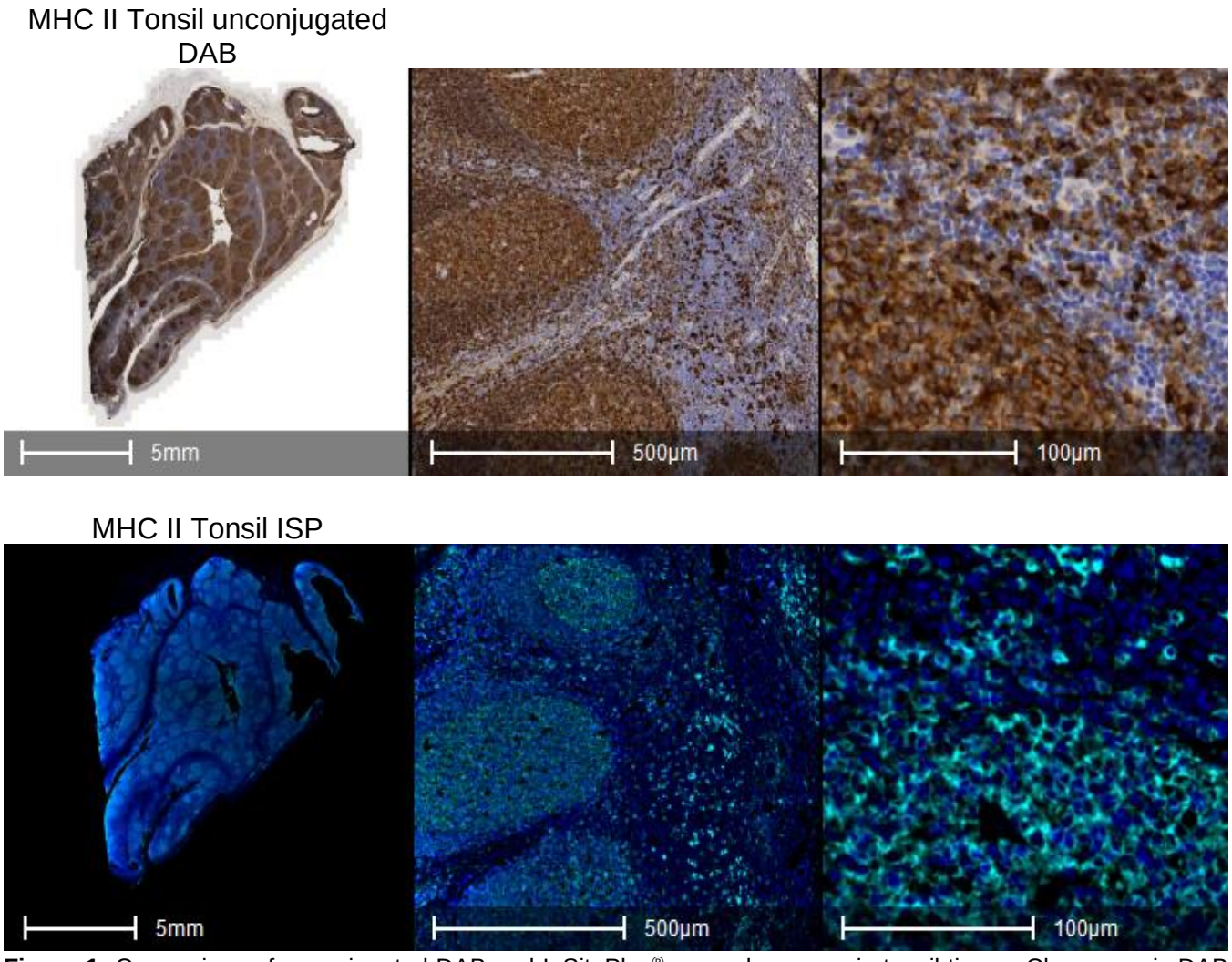


Figure 1: Comparison of unconjugated DAB and InSituPlex® monoplex assay in tonsil tissue. Chromogenic DAB (top panel), fluorescent ISP staining (bottom panel).

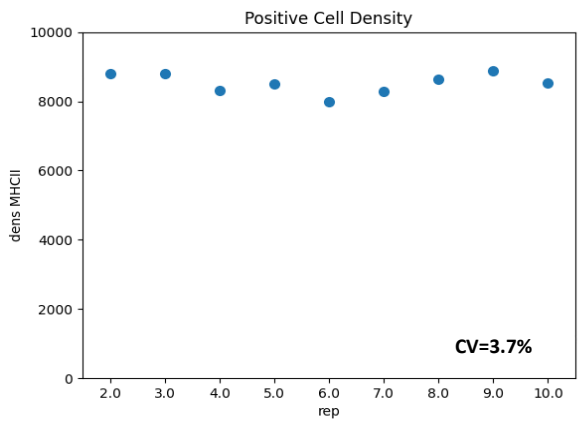
Assay Precision Testing

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

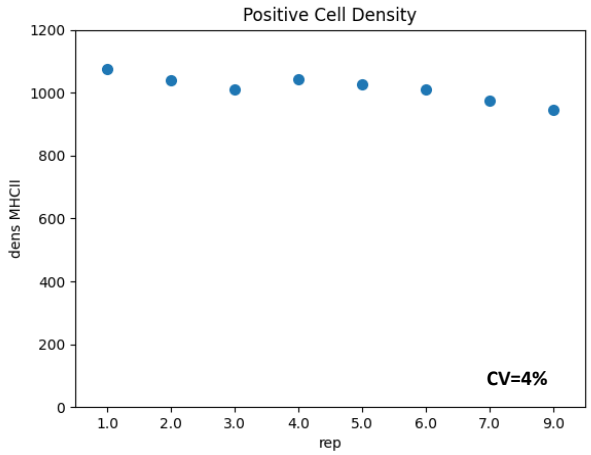
MHC II stained on Tonsil

MHC II stained on Tumor

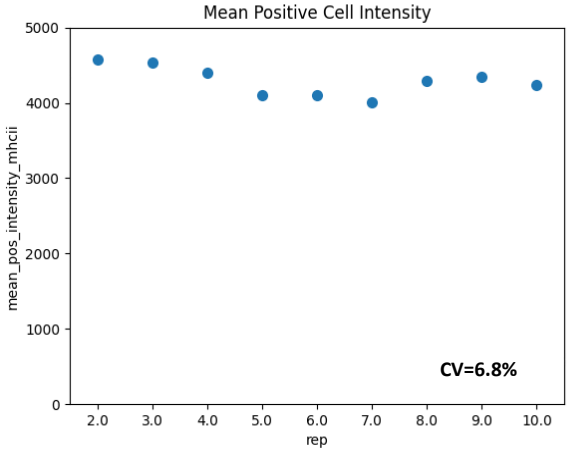
a



b



c



d

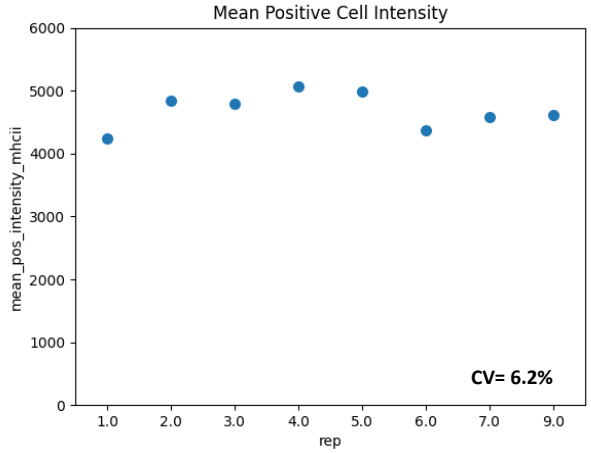


Figure 2: a. Number of positive cells/mm^2 per slide on tonsil tissue. Inter-slide coefficient of variance (CV) =3.7% **b.** Number of positive cells/mm^2 per slide on CRC tissue. Inter-slide CV = 4% **c.** Mean positive signal intensity per slide on tonsil tissue. Inter-slide CV = 6.8%. **d.** Mean positive signal intensity per slide on CRC tissue. Inter-slide CV = 6.2%.

References

1. Johnson, A. M., Boland, J. M., Wrobel, J., Klezcko, E. K., Weiser-Evans, M., Hopp, K., Heasley, L., Clambey, E. T., Jordan, K., Nemenoff, R. A., & Schenk, E. L. (2021). Cancer Cell-Specific Major Histocompatibility Complex II Expression as a Determinant of the Immune Infiltrate Organization and Function in the NSCLC Tumor Microenvironment. *Journal of thoracic oncology : official publication of the International Association for the Study of Lung Cancer*, *16*(10), 1694–1704. https://doi.org/10.1016/j.jtho.2021.05.004
2. Johnson, A. M., Bullock, B. L., Neuwelt, A. J., Poczobutt, J. M., Kaspar, R. E., Li, H. Y., Kwak, J. W., Hopp, K., Weiser-Evans, M., Heasley, L. E., Schenk, E. L., Clambey, E. T., & Nemenoff, R. A. (2020). Cancer Cell-Intrinsic Expression of MHC Class II Regulates the Immune Microenvironment and Response to Anti-PD-1 Therapy in Lung Adenocarcinoma. *Journal of immunology (Baltimore, Md. : 1950)*, *204*(8), 2295–2307. https://doi.org/10.4049/jimmunol.1900778
3. Schaafsma, E., Fugle, C. M., Wang, X., & Cheng, C. (2021). Pan-cancer association of HLA gene expression with cancer prognosis and immunotherapy efficacy. *British journal of cancer*, *125*(3), 422–432. https://doi.org/10.1038/s41416-021-01400-2