

Biomarker Datasheet

Human HLA-DR U-VUE® Biomarker

Human leukocyte antigen (HLA) complex encodes the major histocompatibility complex (MHC). HLA-DR is the main isotype of 3 isotype (-DR, -DP, -DQ) responsible for presentation of antigens to T cells and B cells. Often, HLA-DR is used as a marker indicating the presence of antigen-presenting cells. HLA-DR expression in tumors has been shown to be positively associated with patient prognosis in some cancers such as colorectal cancer but is negatively associated with prognosis in other cancer types, such as glioma.

Overview

Target	Other names	Isotype	Primary cell type	Subcellular location	Positive control(s)
HLA-DR	HLA-DRA, HLA-DRA1	Mouse IgG1	Antigen-presenting cells (APCs)	Plasma membrane	Tonsil/ Spleen

*Clone available upon request

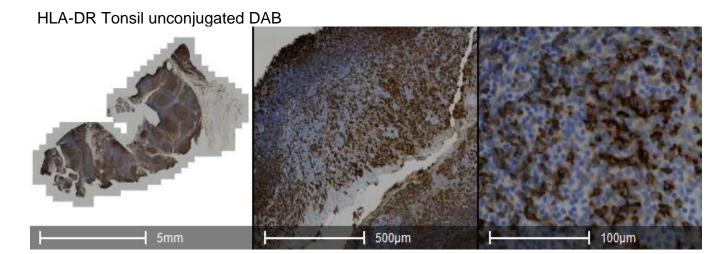
Quality Control

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.



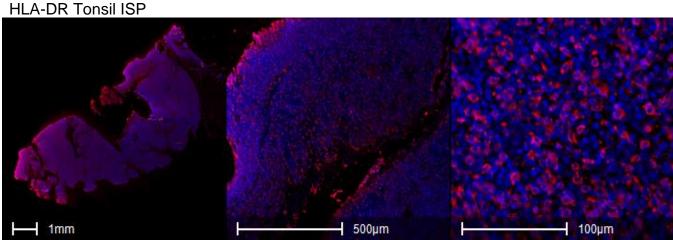


Figure 1: Comparison of unconjugated DAB and InSituPlex® monoplex assay in tonsil tissue. Chromogenic DAB (top panel), fluorescent ISP staining (bottom panel).

Assay Reproducibility

An InSituPlex® monoplex assay was performed across serial sections of tonsil and non-small cell lung carcinoma (NSCLC) 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.

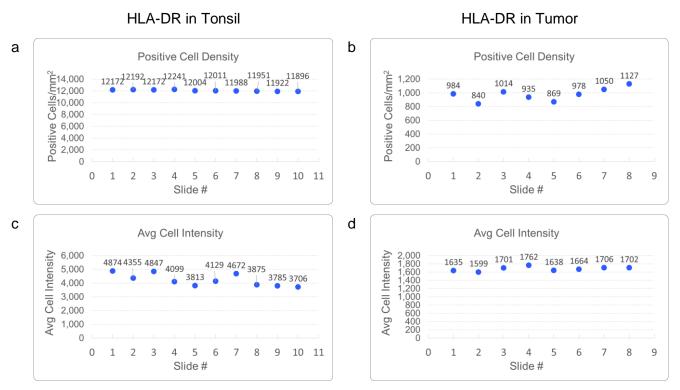


Figure 2: a. Number of positive cells/mm² per slide on tonsil tissue. Inter-slide coefficient of variance (CV) =1% **b.** Number of positive cells/mm² per slide on NSCLC tissue. Inter-slide CV = 9% **c.** Mean positive signal intensity per slide on tonsil tissue. Inter-slide CV = 10.1%. **d.** Mean positive signal intensity per slide on NSCLC tissue. Inter-slide CV = 2.9%.

References

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- Senosain, M. F., Zou, Y., Novitskaya, T., Vasiukov, G., Balar, A. B., Rowe, D. J., Doxie, D. B., Lehman, J. M., Eisenberg, R., Maldonado, F., Zijlstra, A., Novitskiy, S. V., Irish, J. M., & Massion, P. P. (2021). HLA-DR cancer cells expression correlates with T cell infiltration and is enriched in lung adenocarcinoma with indolent behavior. *Scientific reports*, 11(1), 14424. https://doi.org/10.1038/s41598-021-93807-3