

## Biomarker Datasheet

# Human CD68 U-VUE<sup>®</sup> Biomarker

CD68 is expressed on human macrophages and other mononuclear phagocytes. CD68 is a heavily glycosylated glycoprotein that is involved in ligand binding and is a member of the scavenger receptor family. CD68 functions in phagocytic activities and macrophage homing. An increased CD68+ macrophage index is associated with metastasis, shorter disease-free interval, poor prognosis, and reduced overall survival in multiple types of cancer.

### Overview

Target	Other names	Isotype	Primary cell type	Subcellular location	Positive control(s)
<b>CD68</b>	DKFZp686M18236, Macrosialin, GP110, LAMP4, SCARD1	Mouse IgG1	Macrophages	Plasma membrane, lysosomal/endosomal membranes	Tonsil/ Spleen

\*Clone available upon request

### Quality Control

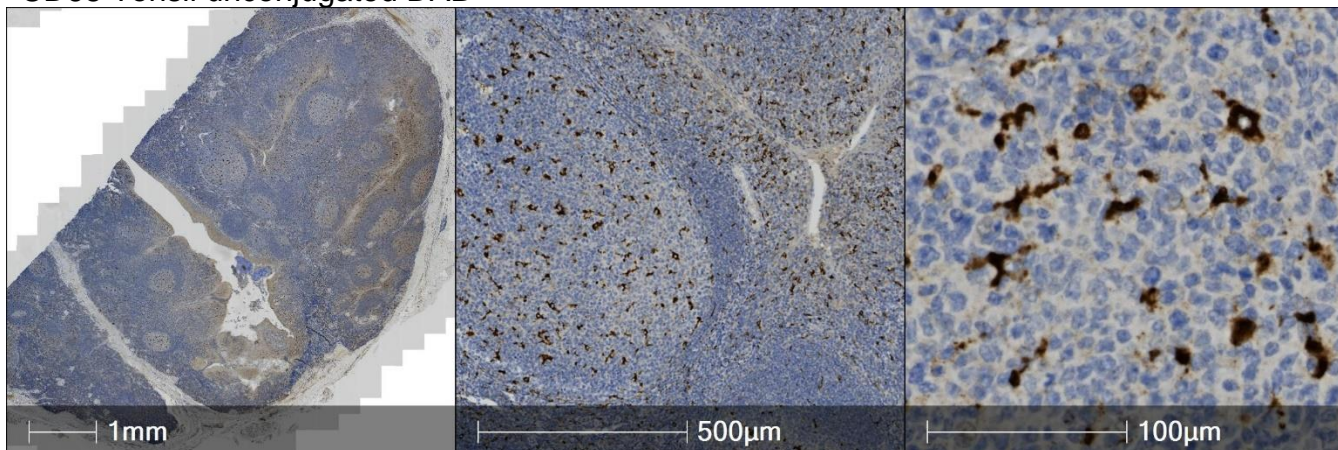
Each lot of antibody conjugate reagent is tested on positive control tissue and reviewed by reviewed by Ultivue's pathologists and scientists to ensure appropriate staining pattern and signal intensity by both qualitative and quantitative review.



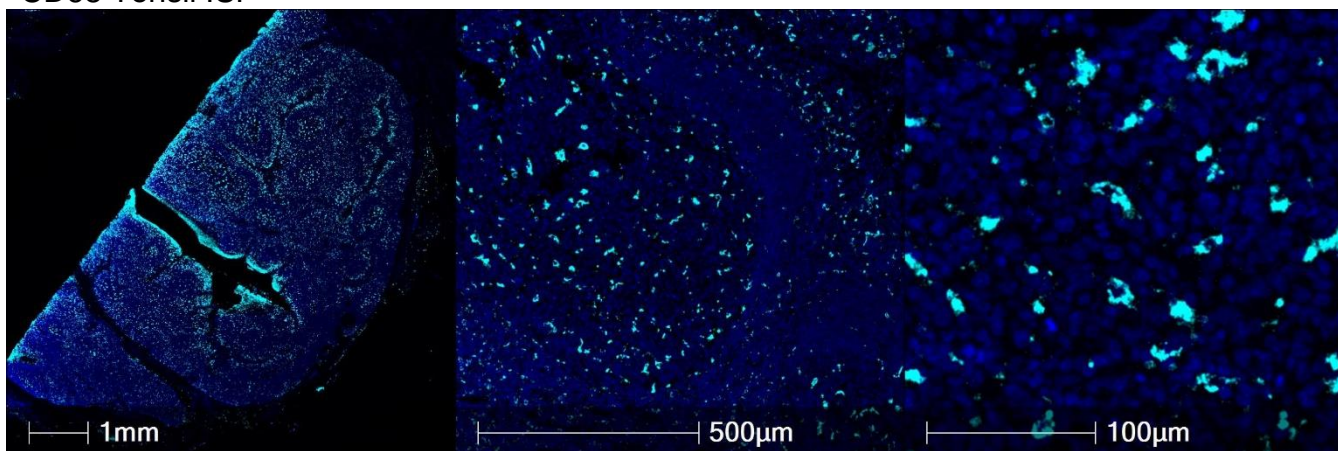
## Predicate Comparison

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.

### CD68 Tonsil unconjugated DAB



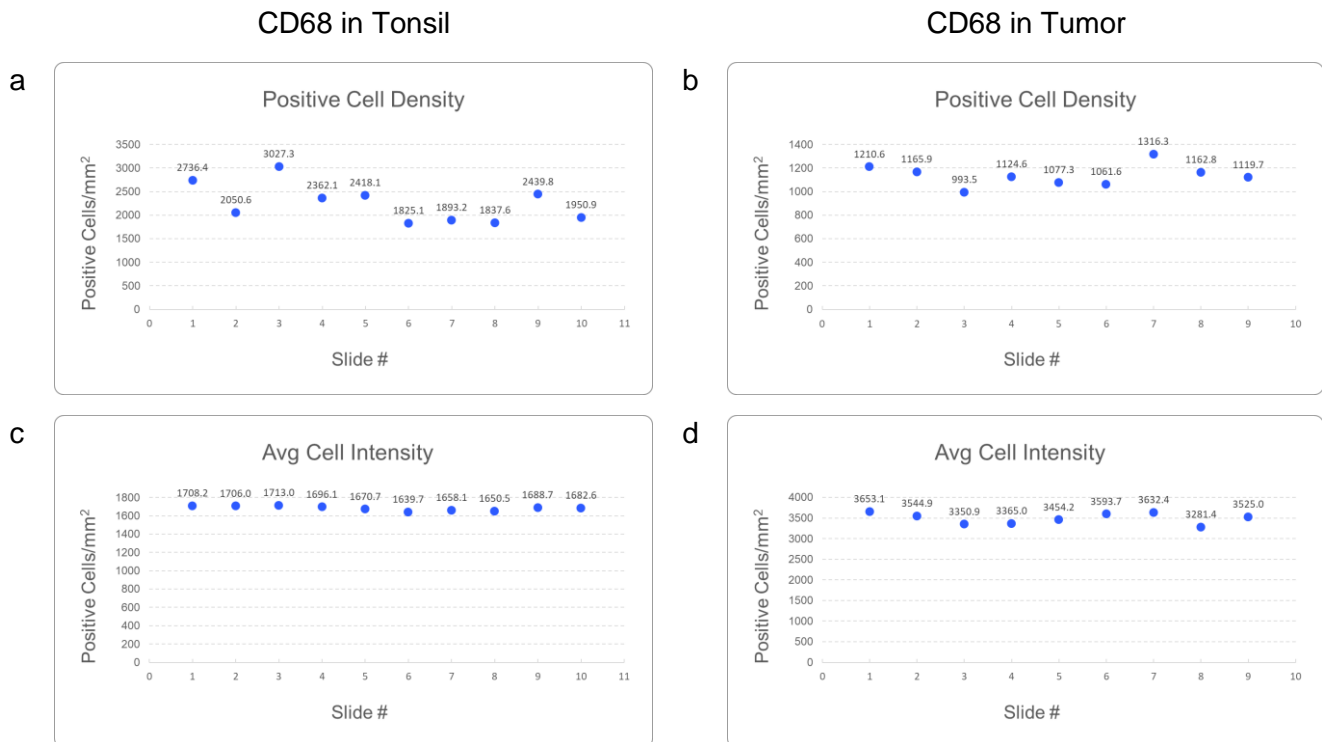
### CD68 Tonsil ISP



**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 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/mm<sup>2</sup> per slide on tonsil tissue. Inter-slide coefficient of variance (CV) = 17.3% **b.** Number of positive cells/mm<sup>2</sup> per slide on NSCLC tissue. Inter-slide CV = 7.7% **c.** Mean positive signal intensity per slide on tonsil tissue. Inter-slide CV = 1.5%. **d.** Mean positive signal intensity per slide on NSCLC tissue. Inter-slide CV = 3.6%.

## References

1. Dancsok, A. R., Gao, D., Lee, A. F., Steigen, S. E., Blay, J. Y., Thomas, D. M., Maki, R. G., Nielsen, T. O., & Demicco, E. G. (2020). Tumor-associated macrophages and macrophage-related immune checkpoint expression in sarcomas. *Oncoimmunology*, 9(1), 1747340. <https://doi.org/10.1080/2162402X.2020.1747340>
2. Rashed, R. A., Zaki, M., Mohamed, N., Mansou, O. M., & Refaey, F. (2021). Prognostic Value of Tumor Associated Macrophage Markers CD163 and CD68 Immunohistochemistry in Classical Hodgkin Lymphoma. *Clinical laboratory*, 67(5), 10.7754/Clin.Lab.2020.200920. <https://doi.org/10.7754/Clin.Lab.2020.200920>
3. Tremble, L. F., McCabe, M., Walker, S. P., McCarthy, S., Tynan, R. F., Beecher, S., Werner, R., Clover, A., Power, X., Forde, P. F., & Heffron, C. (2020). Differential association of CD68+ and CD163+ macrophages with macrophage enzymes, whole tumour gene expression and overall survival in advanced melanoma. *British journal of cancer*, 123(10), 1553–1561. <https://doi.org/10.1038/s41416-020-01037-7>