

Biomarker Datasheet

Human CD20 U-VUE[®] Biomarker

CD20 is a B cell differentiation antigen expressed in B cell development from early pre-B cell stage to mature B cell stage but lost on differentiation into plasma cells. Its role is in regulating B- cell activation, proliferation and differentiation. Aberrant CD20 expression has been described in mainly B cell tumor types such as Burkitt lymphoma, non-Hodgkin lymphoma, and chronic lymphocytic leukemia (CLL).

Overview

Target	Other names	Isotype	Primary cell type	Subcellular location	Positive control(s)
CD20	B-lymphocyte surface antigen B1	Mouse IgG2a	B cells	Plasma membrane	Tonsil/ Spleen

*Clone available upon request

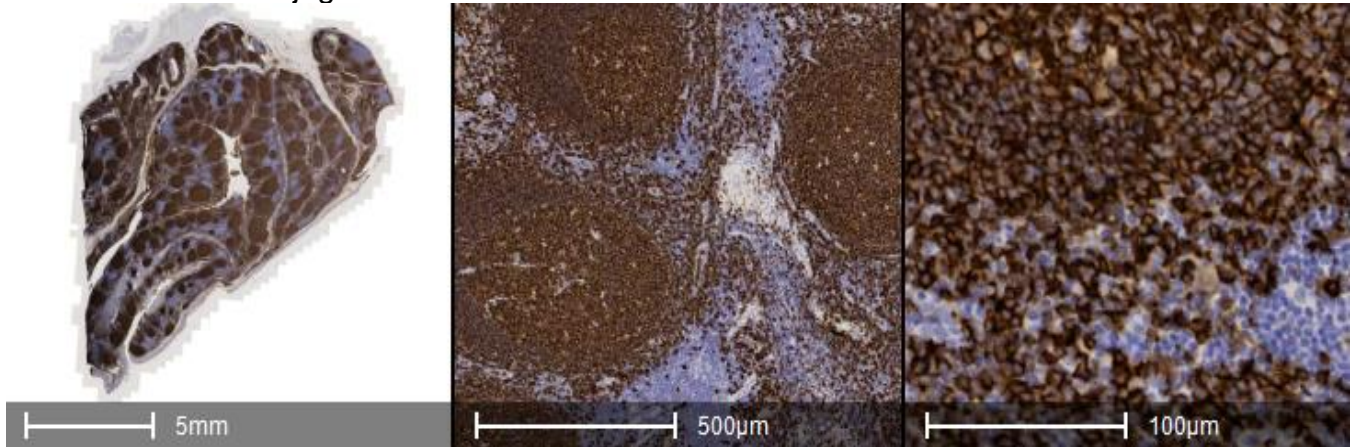
Quality Control

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.

CD20 Tonsil unconjugated DAB



CD20 Tonsil ISP

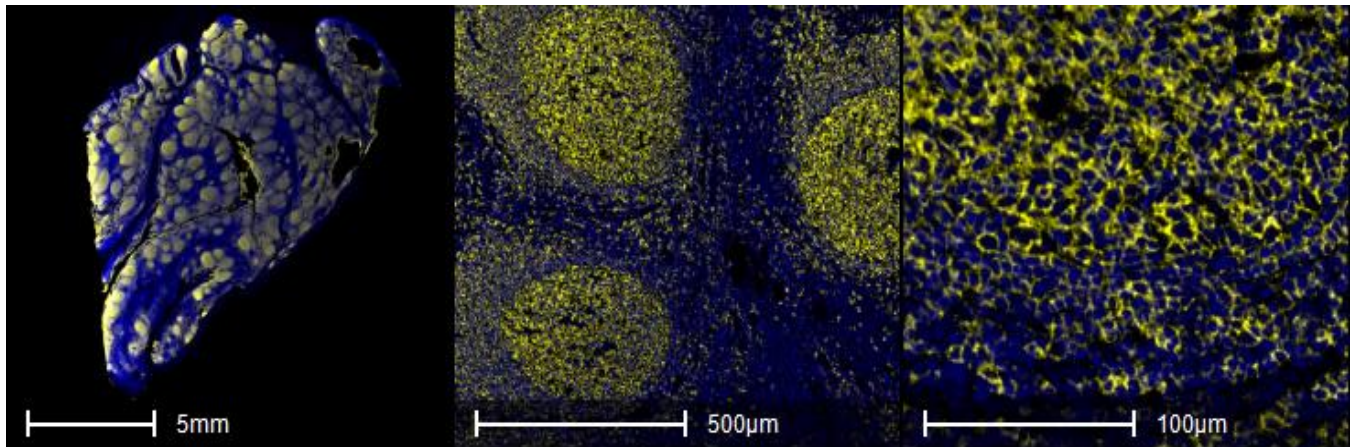


Figure 1: Comparison of unconjugated DAB and InSituPlex® monoplex assay in tonsil tissue. Chromogenic DAB (top panel), fluorescent ISP staining (bottom panel).

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.

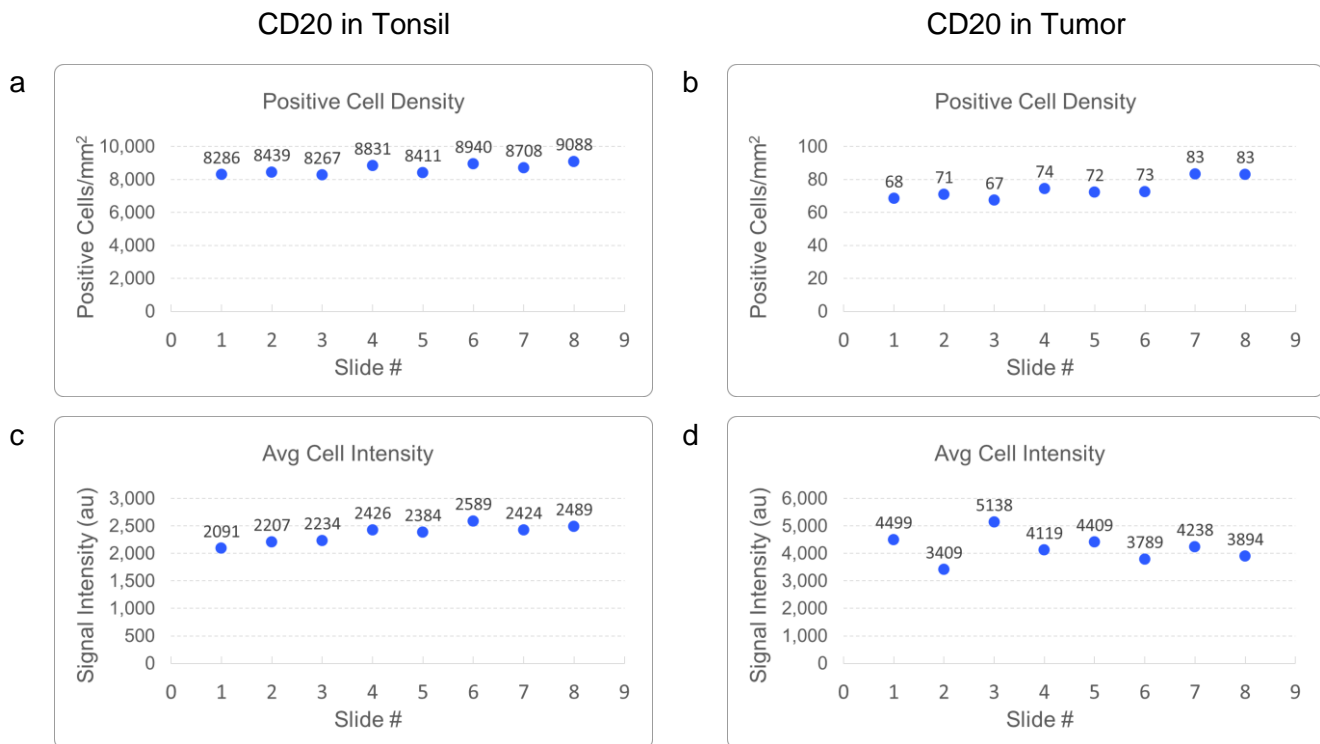


Figure 2: **a.** Number of positive cells/mm² per slide on tonsil tissue. Inter-slide coefficient of variance (CV) = 3.4% **b.** Number of positive cells/mm² per slide on CRC tissue. Inter-slide CV = 7.7% **c.** Mean positive signal intensity per slide on tonsil tissue. Inter-slide CV = 6.5%. **d.** Mean positive signal intensity per slide on CRC tissue. Inter-slide CV = 11.7%.

References

1. Greve, P., Meyer-Wentrup, F. A. G., Peperzak, V., & Boes, M. (2021). Upcoming immunotherapeutic combinations for B-cell lymphoma. *Immunotherapy Advances*, 1(1). <https://doi.org/10.1093/immadv/ltab001>
2. Kläsener, K., Jellusova, J., Andrieux, G., Salzer, U., Böhrer, C., Steiner, S. N., Albinus, J. B., Cavallari, M., Süß, B., Voll, R. E., Boerries, M., Wollscheid, B., & Reth, M. (2021). CD20 as a gatekeeper of the resting state of human B cells. *Proceedings of the National Academy of Sciences of the United States of America*, 118(7), e2021342118. <https://doi.org/10.1073/pnas.2021342118>
3. Pavlasova, G., & Mraz, M. (2020). The regulation and function of CD20: an "enigma" of B-cell biology and targeted therapy. *Haematologica*, 105(6), 1494–1506. <https://doi.org/10.3324/haematol.2019.243543>