

## Biomarker Datasheet

# Human Pan-CK U-VUE® Biomarker

Cytokeratins play a cytoskeletal role in epithelial tissue and are an important component of intermediate filaments. These provide a structural framework for the cell and help resist mechanical stress. The mixture of AE1 and AE3 clones can detect a mixture of low and high molecular weight cytokeratins, thus identifying a broad range of cytokeratins. This marker can be used to identify the epithelial nature of tissue and tumors.

## Overview

Target	Other names	Isotype	Primary cell type	Subcellular location	Positive control(s)
Pan-CK	pan-Cytokeratin	Mouse IgG1	Cells of epithelial origin- including most carcinomas	Cytoplasm	Tonsil

\*Clone available upon request

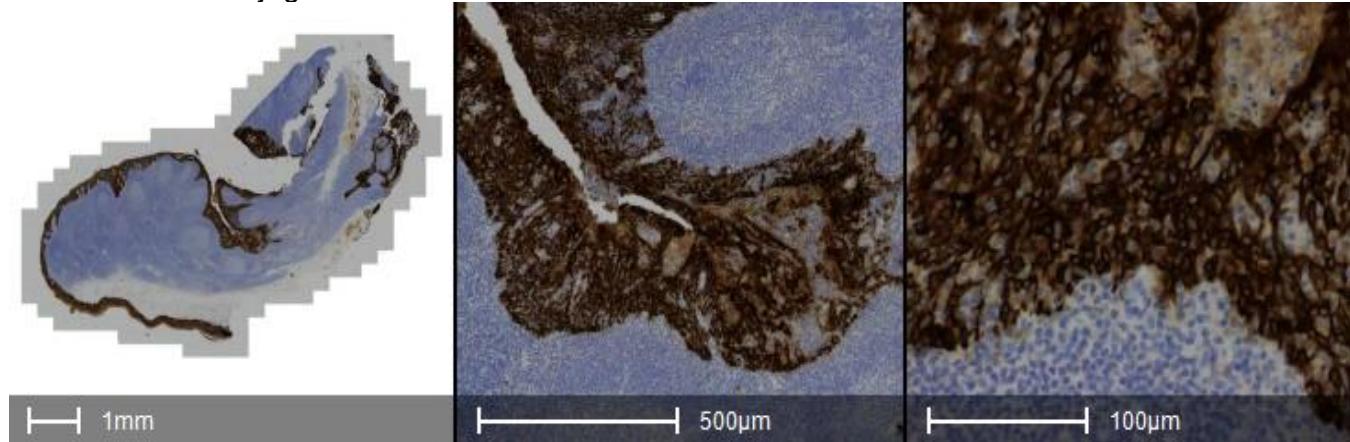
## Quality Control

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

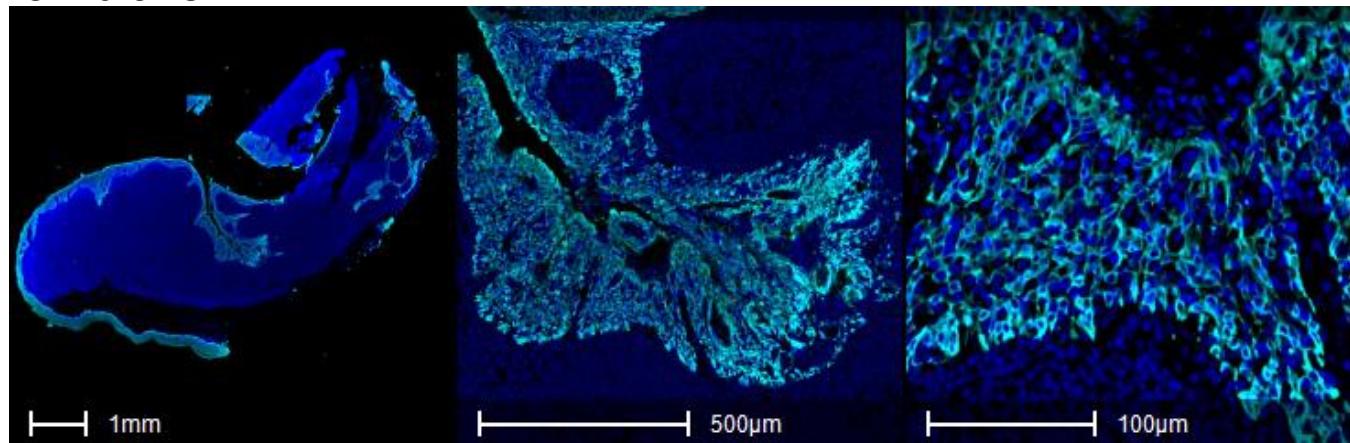
## Predicate Comparison

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.

CK Tonsil unconjugated DAB



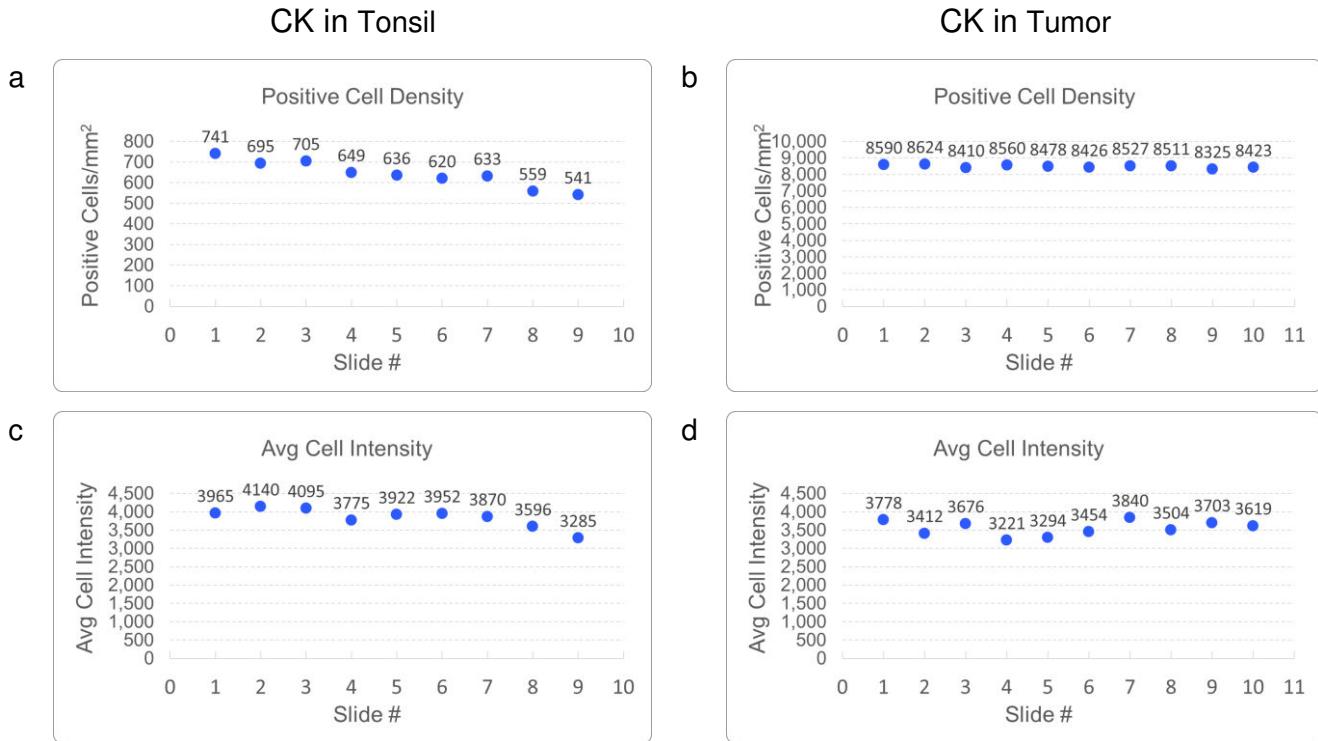
CK Tonsil ISP



**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) = 6.3% **b.** Number of positive cells/mm<sup>2</sup> per slide on CRC tissue. Inter-slide CV = 0.8% **c.** Mean positive signal intensity per slide on tonsil tissue. Inter-slide CV = 2.9%. **d.** Mean positive signal intensity per slide on CRC tissue. Inter-slide CV = 5.9%.

## References

1. Ingenwerth, M., Nyirády, P., Hadaschik, B., Szarvas, T., & Reis, H. (2022). The Prognostic Value of Cytokeratin and Extracellular Collagen Expression in Urinary Bladder Cancer. *Current molecular medicine*, 22(10), 941–949. <https://doi.org/10.2174/156652402166210225100041>
2. Menz, A., Weitbrecht, T., Gorbokon, N., Büscheck, F., Luebke, A. M., Kluth, M., Hube-Magg, C., Hinsch, A., Höflmayer, D., Weidemann, S., Fraune, C., Möller, K., Bernreuther, C., Lebok, P., Clauditz, T., Sauter, G., Uhlig, R., Wilczak, W., Steurer, S., Minner, S., Simon, R. (2021). Diagnostic and prognostic impact of cytokeratin 18 expression in human tumors: a tissue microarray study on 11,952 tumors. *Molecular medicine (Cambridge, Mass.)*, 27(1), 16. <https://doi.org/10.1186/s10020-021-00274-7>
3. Shibayama, T., Shimoji, T., Mori, T., Noguchi, E., Honma, Y., Hijioka, S., Yoshida, M., Ogawa, C., Yonemori, K., Yatabe, Y., & Yoshida, A. (2022). Cytokeratin-positive Malignant Tumor in the Abdomen with EWSR1/FUS-CREB Fusion: A Clinicopathologic Study of 8 Cases. *The American journal of surgical pathology*, 46(1), 134–146. <https://doi.org/10.1097/PAS.0000000000001742>