

## Biomarker Datasheet

# Human Ki-67 U-VUE<sup>®</sup> Biomarker

Ki67 is a nuclear marker associated with cellular proliferation. Ki67 is present within the nucleus of cells undergoing division during interphase but is absent in quiescent cells. Ki67 can also be used as a prognostic indicator in certain cancers.

### Overview

Target	Other names	Isotype	Primary cell type	Subcellular location	Positive control(s)
Ki-67	MKI67	Rabbit IgG	Proliferating cells	Nuclear	Tonsil/ Spleen

\*Clone available upon request

### Quality Control

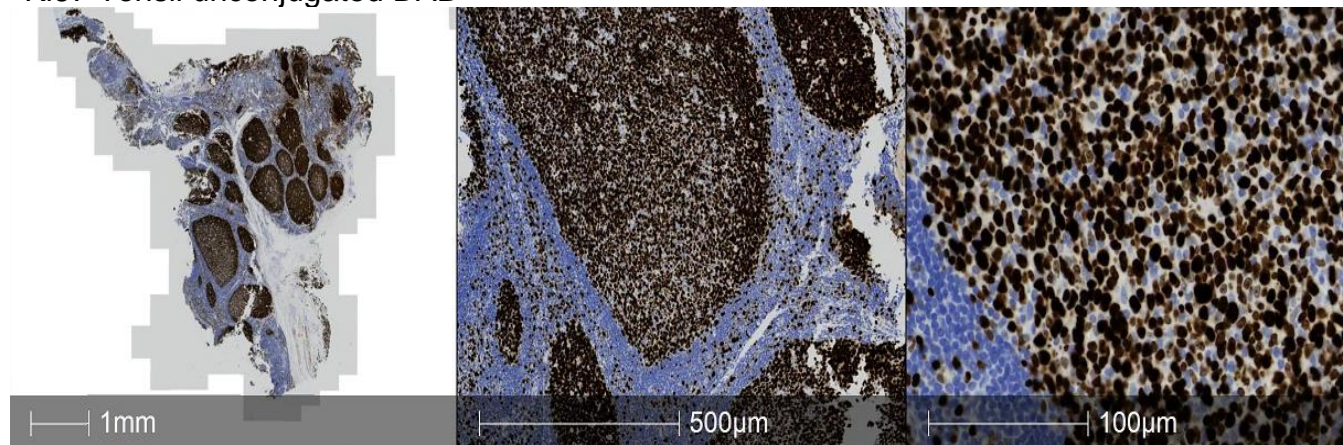
Each lot of antibody conjugate reagent is tested on positive control tissue and reviewed by reviewed by Ultivue's pathologists and scientists to ensure appropriate staining pattern and signal intensity by both qualitative and quantitative review.



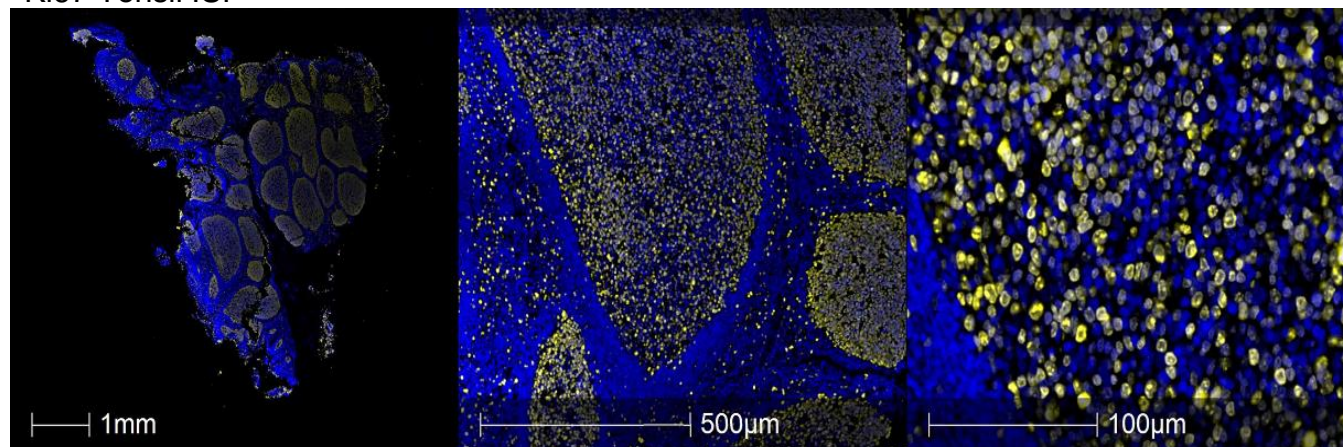
## Predicate Comparison

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.

### Ki67 Tonsil unconjugated DAB



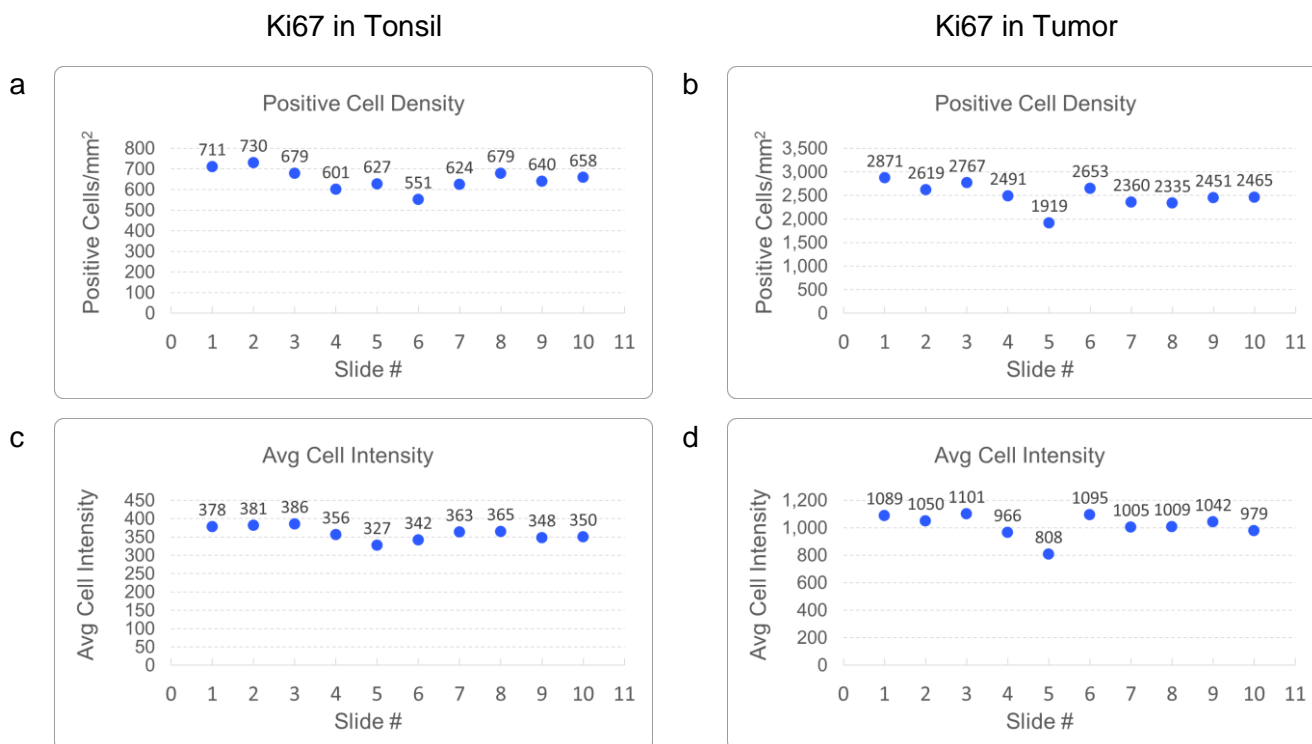
### Ki67 Tonsil ISP



**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) = 7.8% b. Number of positive cells/mm<sup>2</sup> per slide on CRC tissue. Inter-slide CV = 10.1% c. Mean positive signal intensity per slide on tonsil tissue. Inter-slide CV = 4.9%. d. Mean positive signal intensity per slide on CRC tissue. Inter-slide CV = 8.1%.

## References

1. Li, Z., Li, F., Pan, C., He, Z., Pan, X., Zhu, Q., Wu, W., & Chen, L. (2021). Tumor cell proliferation (Ki-67) expression and its prognostic significance in histological subtypes of lung adenocarcinoma. *Lung cancer (Amsterdam, Netherlands)*, 154, 69–75. <https://doi.org/10.1016/j.lungcan.2021.02.009>
2. Li, Z., Li, F., Pan, C., He, Z., Pan, X., Zhu, Q., Wu, W., & Chen, L. (2021). Tumor cell proliferation (Ki-67) expression and its prognostic significance in histological subtypes of lung adenocarcinoma. *Lung cancer (Amsterdam, Netherlands)*, 154, 69–75. <https://doi.org/10.1016/j.lungcan.2021.02.009>
3. Nielsen, T. O., Leung, S., Rimm, D. L., Dodson, A., Acs, B., Badve, S., Denkert, C., Ellis, M. J., Fineberg, S., Flowers, M., Kreipe, H. H., Laenholm, A. V., Pan, H., Penault-Llorca, F. M., Polley, M. Y., Salgado, R., Smith, I. E., Sugie, T., Bartlett, J., McShane, L. M., ... Hayes, D. F. (2021). Assessment of Ki67 in Breast Cancer: Updated Recommendations From the International Ki67 in Breast Cancer Working Group. *Journal of the National Cancer Institute*, 113(7), 808–819. <https://doi.org/10.1093/jnci/djaa201>