1301 HIGH-THROUGHPUT ANALYSIS OF IMMUNE BIOMARKERS FROM BRIGHTFIELD WHOLE TUMOR IMAGES USING INDICA HALO®

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Background A comprehensive understanding of the tumor microenvironment (TME) empowers researchers/scientists in the field of immuno-oncology to develop clinical diagnostic tests and targeted therapeutic interventions. Historically, such research relied on the manual examination of pathological tissue biopsy sections by medical pathologists. By combining whole-slide imaging with quantitative tissue analysis using machine learning, digital pathology offers the potential to transform this tedious, manual-practice into a scalable/high-throughput, easy to use process and enable deeper insight into TME oncology studies. A major challenge to realizing this potential is the development of image analysis (IA) algorithms capable of faithfully replicating manual interpretation of the specimen. Here, we present a workflow for the development and validation of IA algorithms for the detection of molecular biomarkers from digitized whole-slide image/specimens of tumor tissues acquired by brightfield microscopy that has been validated for clinical sample testing.

Methods Digitized whole-slide images of NSCLC tissues stained with CD8 and corresponding serial H&E images were used in this study. CD8 IHC images were sent to pathologist for manual scoring. The pathologist provided the estimation for percent positive cells within randomly chosen regions of interest encompassing both tumor and stromal regions. Pathologist scored images were then divided into training and validation sets for algorithm development. IA algorithms were developed in the HALO® platform which has been previously GxP validated by NeoGenomics. Tissue segmentation and biomarker detection algorithms were developed on the training set to classify tumor and stromal regions and identify CD8 positive cells. Algorithm performance was visually inspected by a pathologist and CD8 detection evaluated for concordance with pathologist manual scores. Once the algorithms were established against the training set, they were validated on the validation image set. For all images, analysis results provided counts, percentages and densities for all tumor and stromal regions in the tissue specimen.

Results The concordance of pathologist manual scores and Halo algorithmic results were evaluated using the Pearson correlation coefficient. The results showed concordance above 85% for percent CD8 positive cells in the validation dataset, indicating robust algorithm performance.

Conclusions Pathologist-guided IA development yields tissue classifiers and biomarker-specific algorithms capable of segmenting and analyzing tissue image/specimens with a high-degree of accuracy and precision. This validated workflow provides a robust, scalable solution for discovery-based research efforts and clinical drug trials.

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