IMMUNO-ONCOLOGY BIOMARKER ASSESSMENT BY NOVEL DIGITAL IMAGING ALGORITHMS BASED ON AQUA TECHNOLOGY

Evelyn Diaz; Ju Young Kim; Lisa Adams; Jennifer Bordeaux; Nathan Roscoe; Emmanuel Pacia; Teri Johnson; Thai Tran; Beiru Chen; Bashar Dabbas; Jelveh Lameh; Shabnam Tangri and Naveen Dakkapagari

Navigate BioPharma Services, Inc., a Novartis subsidiary, Carlsbad, CA

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ABSTRACT

Background: Understanding the interplay between tumor cells and immune cells is a necessity for development and administration of cancer immunotherapies. Although recent advances in Fluorescent Immunohistochemistry (FIHC) have provided the ability to assess multiple components of tumor microenvironment, conversion of FIHC images into clinical actionable results remains a major challenge. Navigate BioPharma Services, Inc. developed a robust clinical workflow for multiplex FIHC assays and coupled with proprietary Automated Quantitative Analysis (AQUA) algorithms to define functional immune cell phenotypes, such as Myeloid-derived suppressor cell (MDSC) and spatial integration between PD-1 and PD-L1 expressing cells in tumor biopsies. Multiplex FIHC tests were carefully designed to understand the needs of Immuno-Oncology (I-O) agents in clinical trials, such as dose selection, patient stratification, secondary endpoints, and potential companion or complementary diagnostics.

Method: The AQUA workflow encompasses three primary components: Singleplex or Multiplex FIHC staining; Imaging; and Image analysis. AQUA technology is compatible with manual and automated staining platforms, as well as multiple imaging platforms. Due to minimal operator variability, AQUA technology should aid in monitoring clinical effects of cancer immunotherapies. ALGORITHMS BASED ON AQUA TECHNOLOGY

RESULTS: IMMUNO-ONCOLOGY ASSAYS

Figure 1: Overview of FIHC AQUA assay workflow

Figure 2:FIHC Multiplex staining procedure

Figure 3: AQUA image analysis is a quantitative analysis of the transverse expression within the expected cellular compartment.

Figure 4: Survey of immune markers and associated status in various tumor indications for multiplex FIHC assays with unique reportables (e.g., receptor-ligand interaction score) should aid in monitoring clinical effects of cancer immunotherapies.

Clinical utility studies are currently underway to guide I-O treatments.

CONCLUSIONS

AQUA technology is compatible with manual and automated staining platforms, as well as multiple imaging platforms. Due to minimal operator intervention in analysis, AQUA may provide increased reproducibility and low variability. Thus it may fit into current anatomic pathology laboratory operations.

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