

# DIGITAL PATHOLOGY

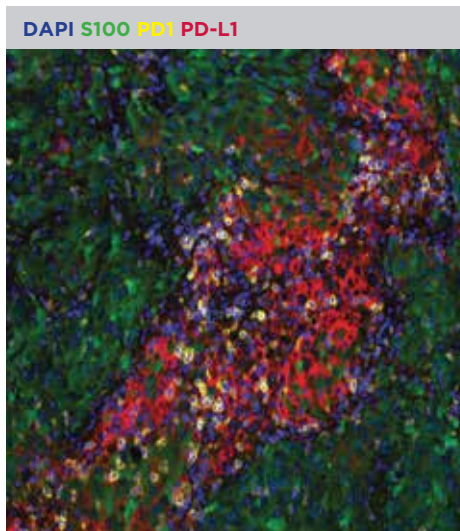
**NAVIGATE BIOPHARMA OFFERS A BROAD RANGE OF MULTIPLEX IMMUNOHISTOCHEMISTRY ASSAYS TO ANALYZE PROTEIN BIOMARKERS IN FFPE TISSUE FOR CLINICAL BIOMARKER AND DIAGNOSTIC APPLICATIONS.**

## TECHNICAL CAPABILITIES

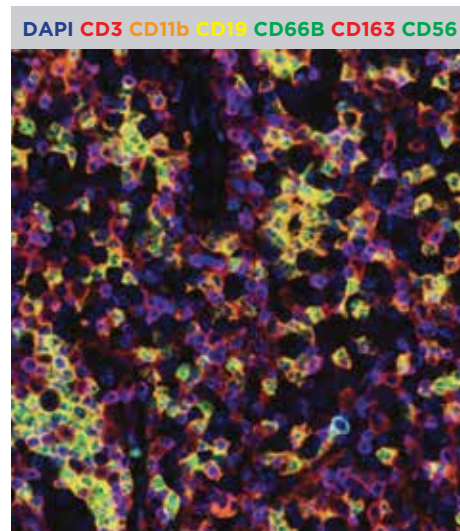
- Quantitative singleplex to multiplex (Up to 7 colors) Fluorescence IHC
- Broad portfolio of Immuno-Oncology markers for functional and phenotypic analysis
- Immune cell subset analysis
- Qualitative and semi-quantitative chromogenic IHC analysis
- Multiple state of the art staining and scanning platforms
- AQUA<sup>®</sup> Technology, inForm<sup>®</sup> and HALO<sup>®</sup> Image analysis platforms

## IMMUNO-ONCOLOGY PHENOTYPING BY FLUORESCENCE IHC

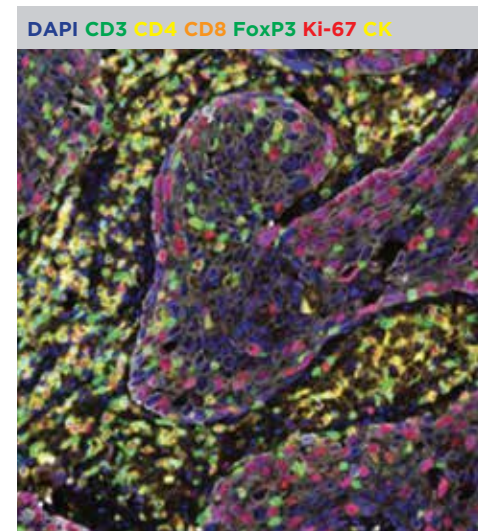
4-plex - Checkpoint Inhibitors



7-plex - Myeloid Cells



7-plex - TIL Cells



AQUA<sup>®</sup> Technology is a Proprietary Image Analysis software for Navigate Biopharma Services.

Objective	Multiplex FIHC Tests (Up to 7 colors)	Novel Results
<b>Immune Checkpoint</b>	PD-1 + PD-L1 + CK or S100 CD11b + HLA-DR + IDO1 + CK or S100	<b>Interaction Score (Proximity)</b>  <b>Frequencies of Cell Populations</b>  <b>Expression Intensity</b>
<b>TIL Enumeration</b>	CD3 + CD4 + CD8 + FoxP3 + Ki-67 + CK or Pan Mel CD3 + CD11b + CD19 + CD56 + CD66B + CD163	
<b>T-Cell Suppression</b>	PD-1 + PD-L1 + CD3 LAG3 + TIM3 + CD3	
<b>T-Cell Modulation</b>	CD3 + CD56 + Granzyme B + CK CD3 + CD4 + CD8 + FoxP3 + Ki-67 + CK or Pan Mel CD4 + CD8 + Granzyme B + Ki-67 + CK	
<b>Myeloid Subsets</b>	CD11b + HLADR + IDO1 + CK or S100 CD68 + CD163 + CK or S100 CD3 + CD11b + CD19 + CD56 + CD66B + CD163 CD3 + CD11b + CD19 + HLA-DR + IDO-1 + CK or Pan Mel	

## PUBLICATIONS

Publications: Selected Multiple FIHC by AQUA Publications (>100)
PD-1/PD-L1 expression and interaction in the microenvironment of DLBCL by Quantitative Immunofluorescent Analysis. <i>Ling Li, et al, Modern Pathology, 2019</i>
Improved prognosis and increased tumor infiltrating lymphocytes in small cell lung cancer patients with neurologic paraneoplastic syndromes. <i>Wade Iams, et al, Journal of Thoracic Oncology, 2019</i>
Tumor-specific major histocompatibility complex class II (MHC-II) expression drives a unique pattern of adaptive resistance to immunotherapy through MHC-II receptor engagement. <i>Douglas Johnson, et al, Journal of Clinical Investigations Insights, 2018</i>
A dormant TIL phenotype defines non-small cell lung carcinomas sensitive to immune checkpoint blockers. <i>S.N. Gettinger, et al, Nature Communications, 2018</i>
Quantitative Spatial Profiling of PD-1/PD-L1 Interaction and HLA-DR/IDO-1 Predicts Improved Outcomes of anti-PD-1 Therapies in Metastatic Melanoma. <i>Johnson et al, Clin Can Research, 2018</i>
Deep exploration of the immune infiltrate and outcome prediction in testicular cancer by quantitative multiplexed immunohistochemistry and gene expression profiling. <i>Siska PJ, Johnpulle RAN, Zhou A, et al, Onco-Immunology 6:e1305535, 2017</i>
Clinical and immunologic correlates of response to PD-1 blockade in a patient with metastatic renal medullary carcinoma. <i>Beckermann KE, Jolly PC, Kim JY, et al, J Immunotherapy Cancer 5:1, 2017</i>
Multiplexed ion beam imaging analysis for quantitation of protein expression in cancer tissue sections. <i>Rost S, Giltnane J, Bordeaux JM, et al, Lab Invest 97:1263, 2017</i>

## SERVICES



## CUSTOM ASSAY DEVELOPMENT

Navigate BioPharma offers diverse and custom development for clinical biomarkers and diagnostic solutions for use in investigational clinical trials. Our highly skilled, responsive and dedicated team of scientists, project managers and pathologists partner with our pharma and biotech sponsors to create innovative and differentiated solutions.

## CLINICAL TRIAL TESTING

Navigate BioPharma provides a broad portfolio of advanced laboratory capabilities utilizing state of the art, diverse technologies that can address clinical biomarker and precision medicine testing needs for every phase of clinical trials (first in human to global pivotal trials). Our integrated solutions address various sponsor needs such as biomarker identification, pharmacodynamics, efficacy readouts, patient inclusion, diagnosis and prognosis. Our comprehensive services team supports end-to-end clinical trial testing from sample logistics to project and data management for global clinical trials.

## COMPANION DIAGNOSTICS (CoDx)

Navigate BioPharma has broad experience in the development and support of companion diagnostics and CE marking submissions. Our team can support your regulatory needs through its experience in performing risk assessments, IDE, PMA, IRBs as well as CE marking submissions. Our quality systems are designed to ensure compliance with applicable regulatory requirements for drug and diagnostic approvals.