

# The Art of Histopathology

Discover the tumor's microenvironment

# Validation of New Immunohistochemistry Assays

Immunohistochemistry biomarkers are key players in clinical development success. Tissue biomarkers can aid in the confirmation of diagnosis, patient selection, and/or for mechanistic evaluation.

## Cerba Research IHC/ISH Validation Solutions

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Catalog of available protocols

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Development of custom IHC assays and validations for pre-clinical and clinical studies FFPE and frozen tissue

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Access to numerous indications in our tissue biobank to facilitate target detection in multiple disease areas

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Guided by IHC experts

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Our IHC expert scientific team will consult and work with you on your specific needs. Flexible in our approach and delivery to provide timely and cost effective solutions to meet your clinical and commercial objectives.

**Discover the art of histopathology through the eyes of our most skilled scientists.**

More than 90%  
of our customers  
are satisfied by our  
scientific support  
during their project.

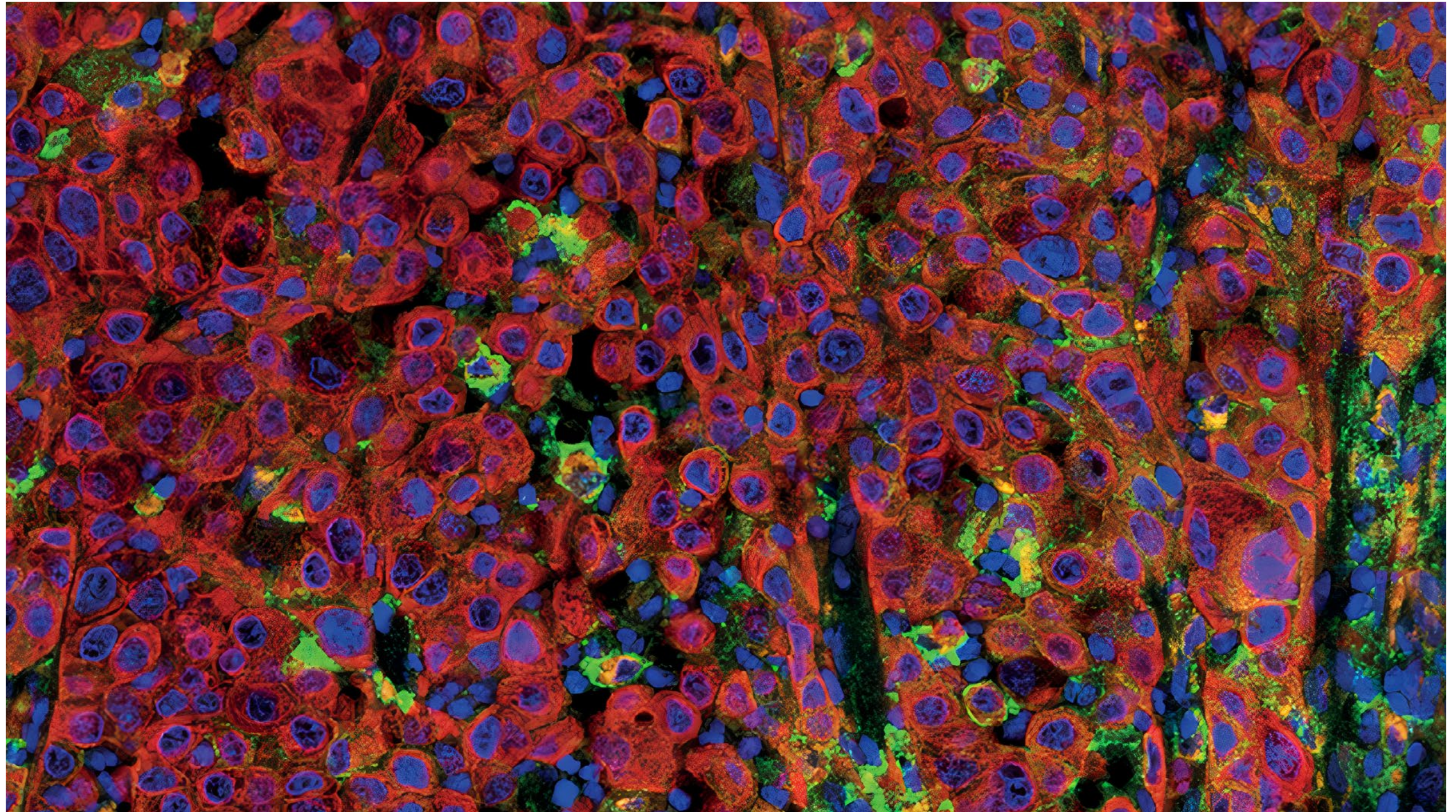


More than 90%  
of our customers  
are satisfied by the  
timeline completion  
of their project.



More than 90%  
of our customers  
are very satisfied  
by our project  
management team  
and communication  
during the project.





**PD-L1 Expression in Tumor Associated Macrophages and Tumor Cells.**

Protocol used in a Phase 1 clinical study to detect PD-L1, a common target of immune checkpoint blockade, expression in tumor cells and tumor associated macrophages in solid tumors.

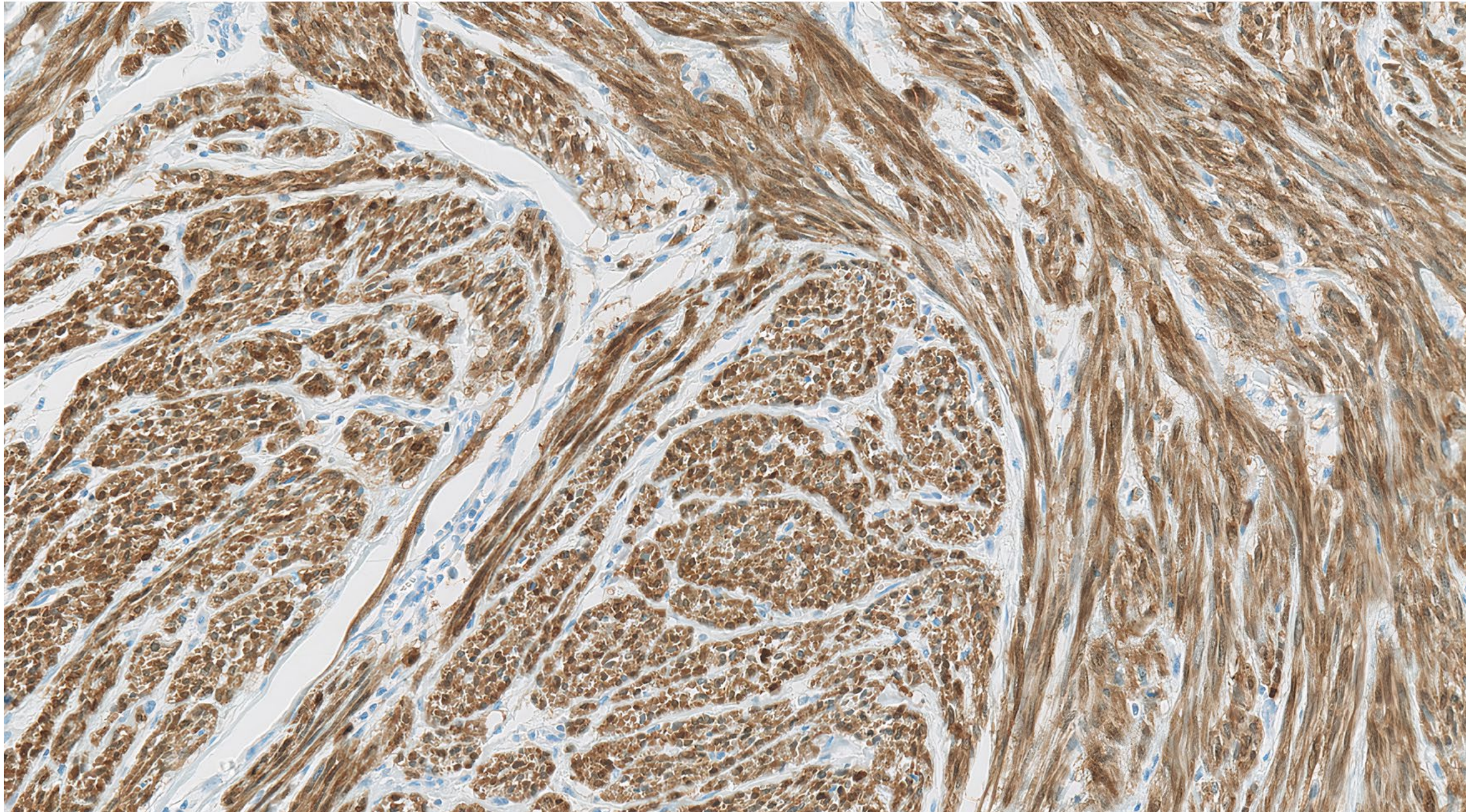
PanCK (Clone AE1/AE3, Red), CD68 (Clone KP1, Orange) and PD-L1 (Clone E1L3N, Green) multiplex IHC staining of Non-Small Cell Lung Cancer FFPE sample. Macrophages are identified by CD68 staining and Tumor by PanCK. Platform: Ventana Discovery ULTRA.



**p16 Expression in Uterine Leiomyosarcoma.**

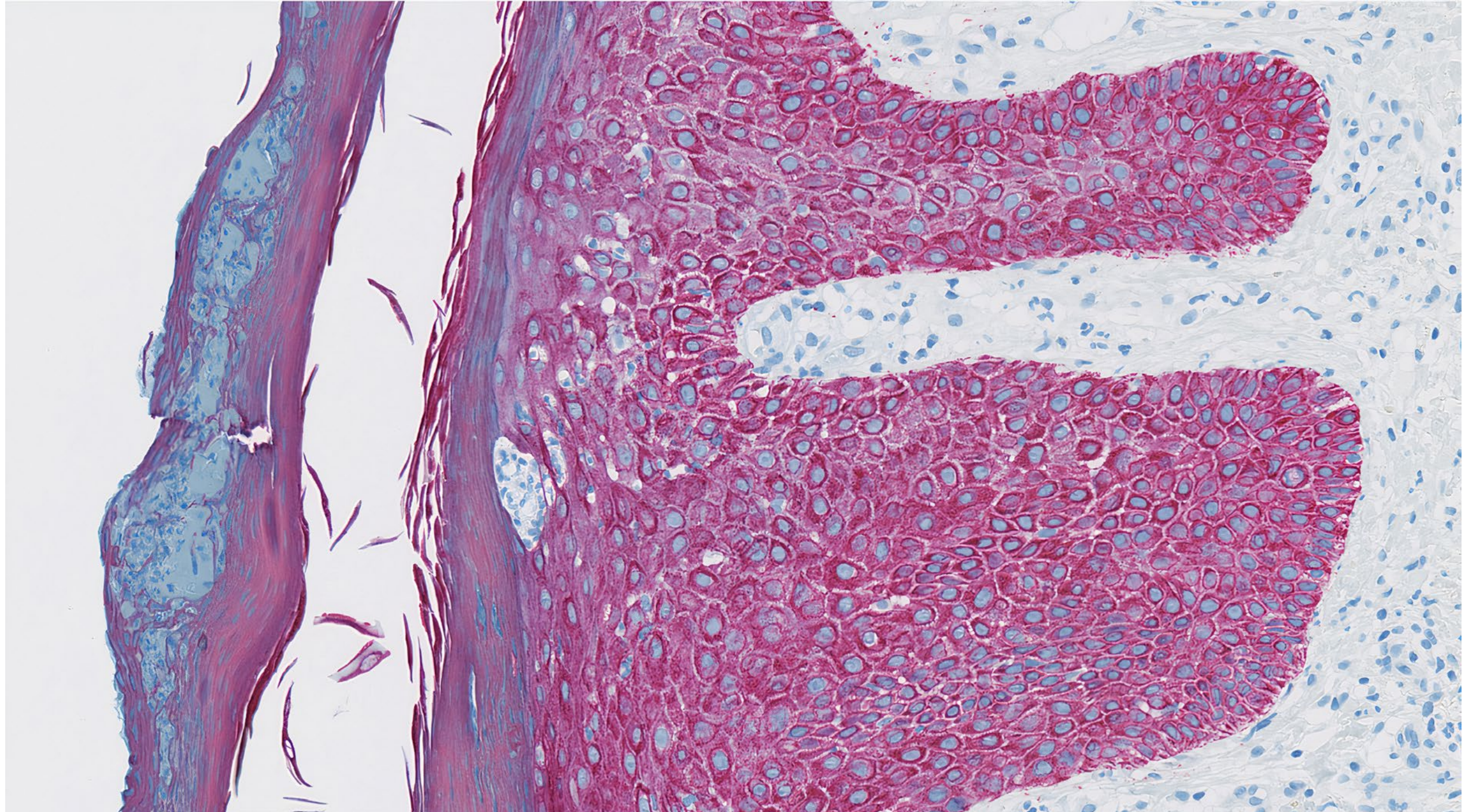
Protocol validated at a secondary endpoint level. This marker is used in the diagnosis of the human papillomavirus (HPV).

p16 (Clone E6H4) IHC staining of Uterine Leiomyosarcoma FFPE sample. Platform: Benchmark ULTRA.





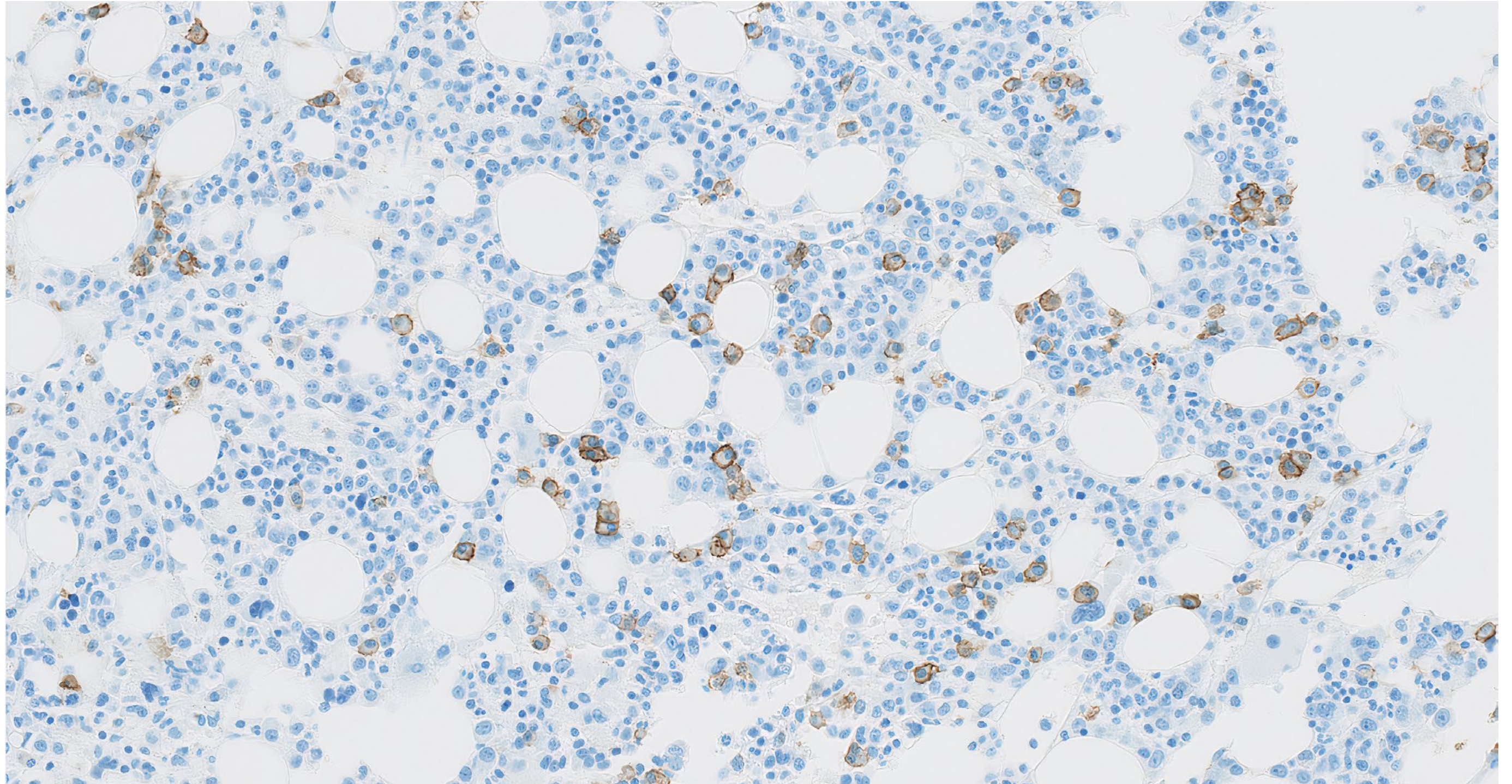
Cytokeratin16 Expression in Atopic Dermatitis Skin.  
Protocol used in Phase 2b clinical study to detect epidermal  
cells in lesional skins.





**CD138 Expression in Inflammatory Bone Marrow.**

Protocol used in Phase 1; Phase 1/2 and Phase 2 clinical studies to detect plasma cells in bone marrow samples.

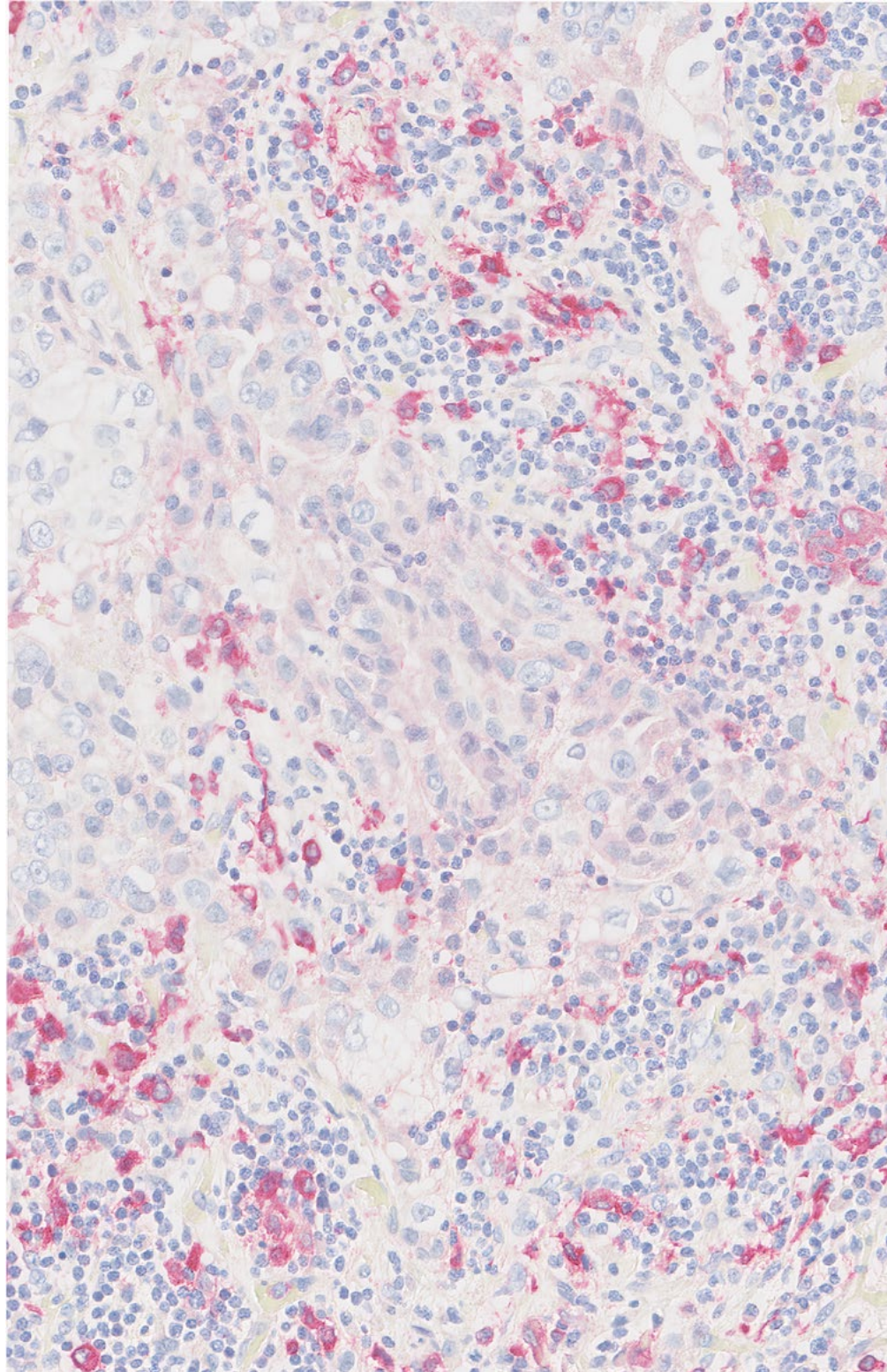


CD138 (Clone B-A38) IHC staining of inflammatory bone marrow FFPE sample. Platform: Benchmark ULTRA.

Scientist: Alexy Promonet



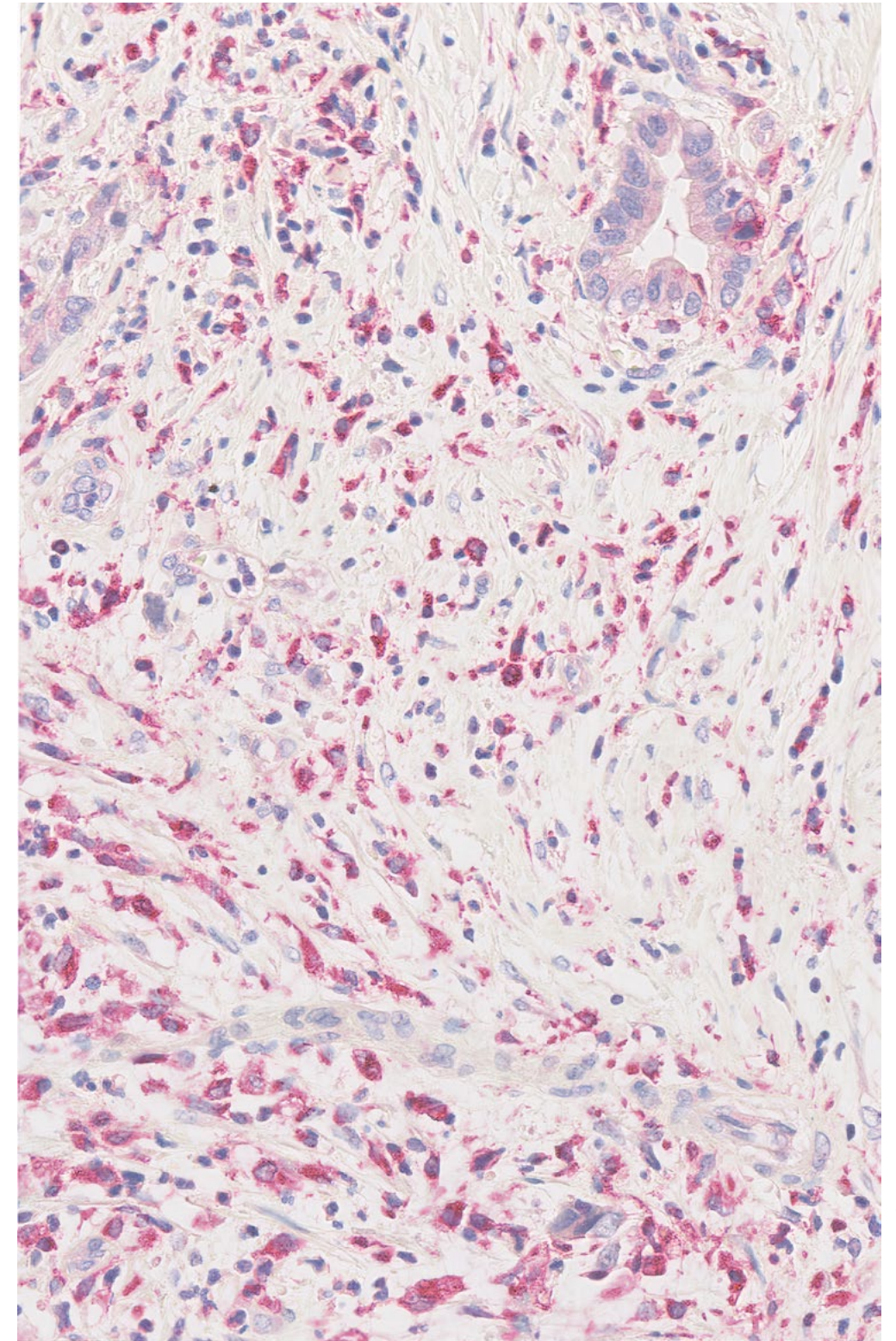
**CD163 Expression in Non-Small Cell Lung Cancer.**  
Protocol used in Phase 1/2 clinical study to detect M2  
macrophages in solid tumors.



Scientist: Marie G erus-Durand

CD163 (Clone EDHu-1) IHC staining of Non-Small Cell Lung Cancer FFPE sample. Platform: Leica Bond III.

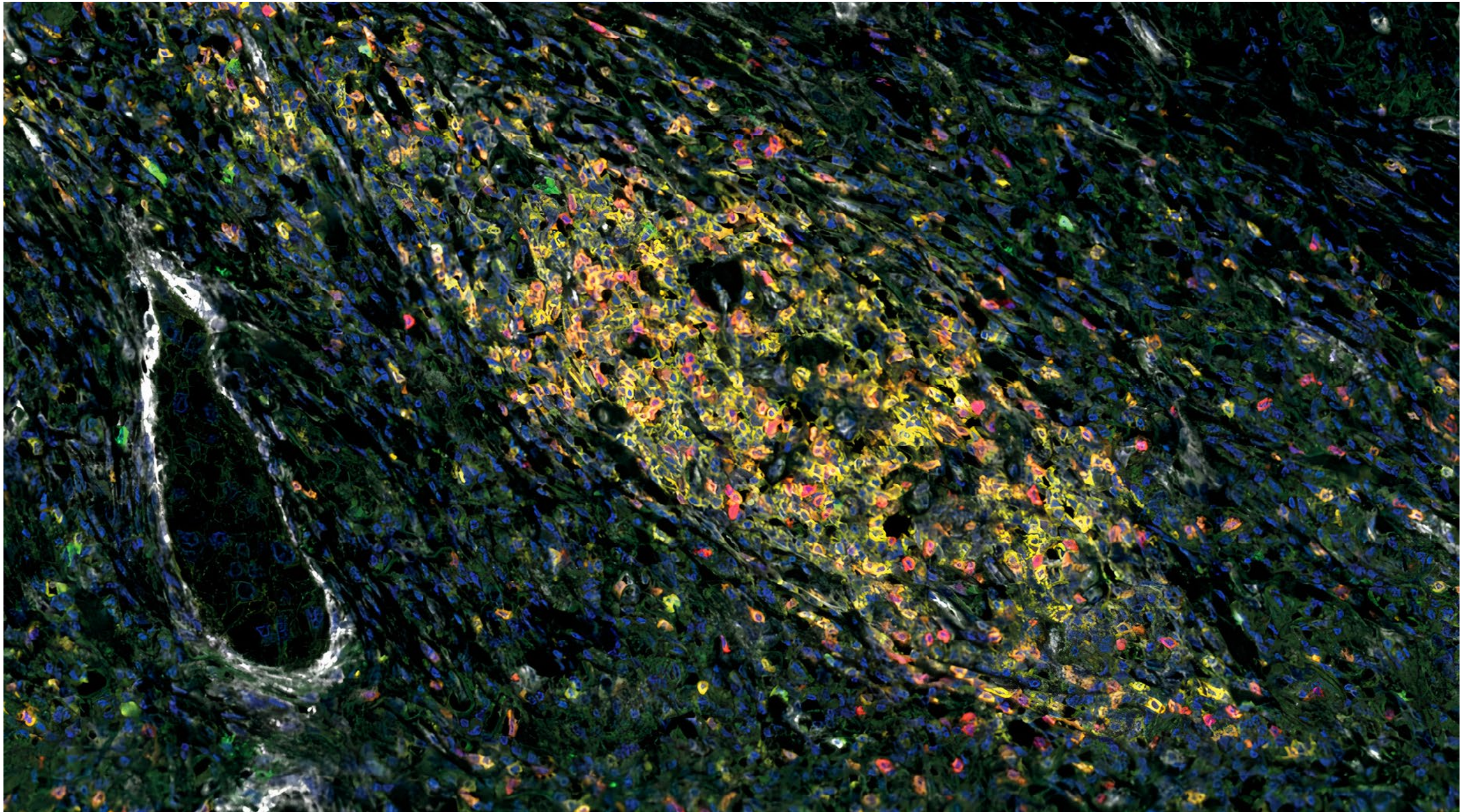
CD68 (Clone KP1) IHC staining of Non-Small Cell Lung Cancer FFPE sample. Platform: Leica Bond III.



Scientist: Marie G erus-Durand

**CD68 Expression in Non-Small Cell Lung Cancer.**  
Protocol used in Phase 1/2 clinical study to detect  
macrophages in solid tumors.





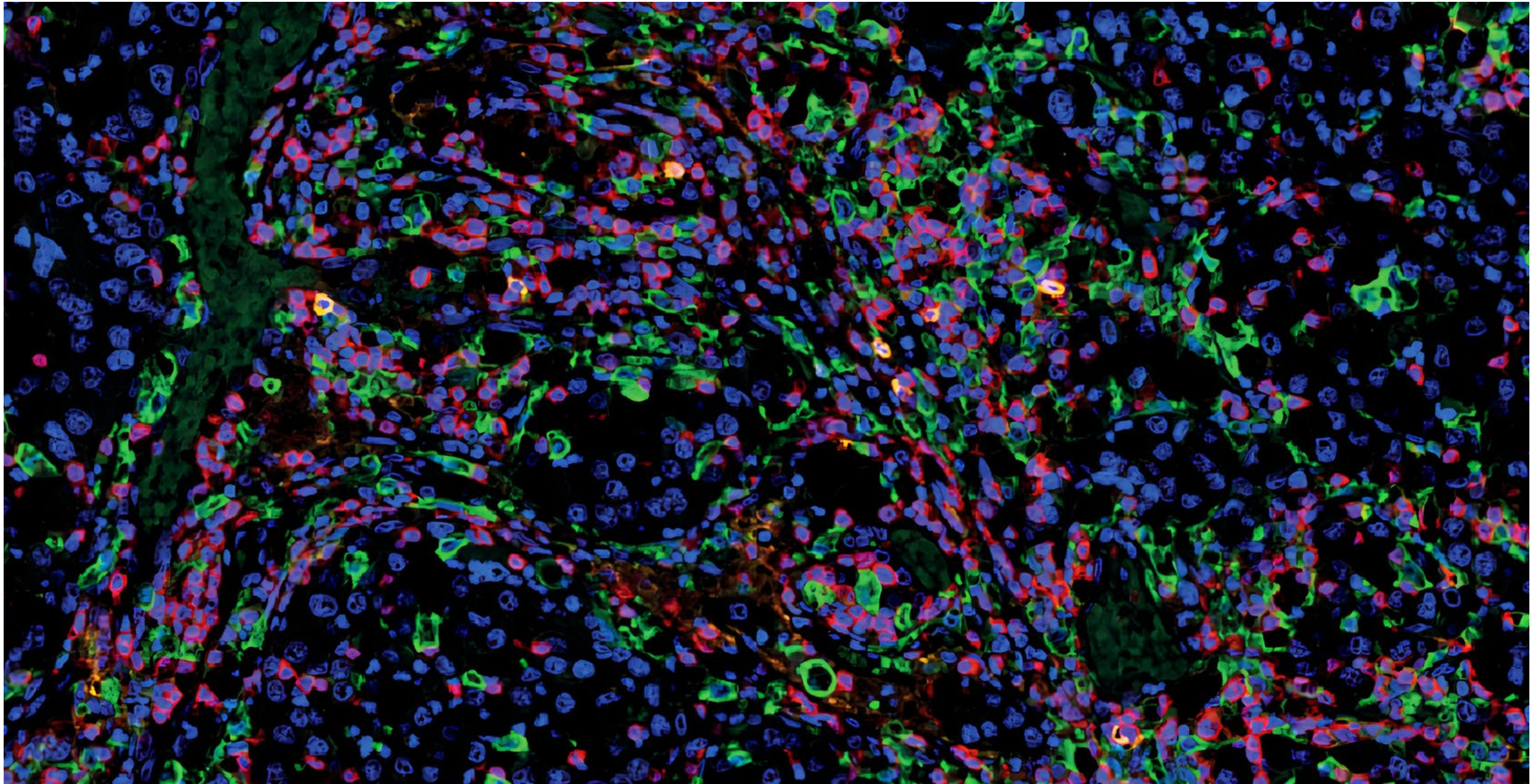
CD3 (Clone D7A6E, Red), CD8 (Clone 4B11, Orange), CD103 (Clone EPR4166(2), Green), CD69 (Clone EPR21814, Yellow), CD49a (Clone CL7207, White) multiplex IHC staining of Non-Small Cell Lung Cancer FFPE sample. Platform: Leica Bond RX.

**Tissue-Resident Memory T-Cells in Non-Small Cell Lung Cancer.**  
Assay designed for high level pheotyping of resident memory T-Cells. Able to detect all five targets on a single cell.



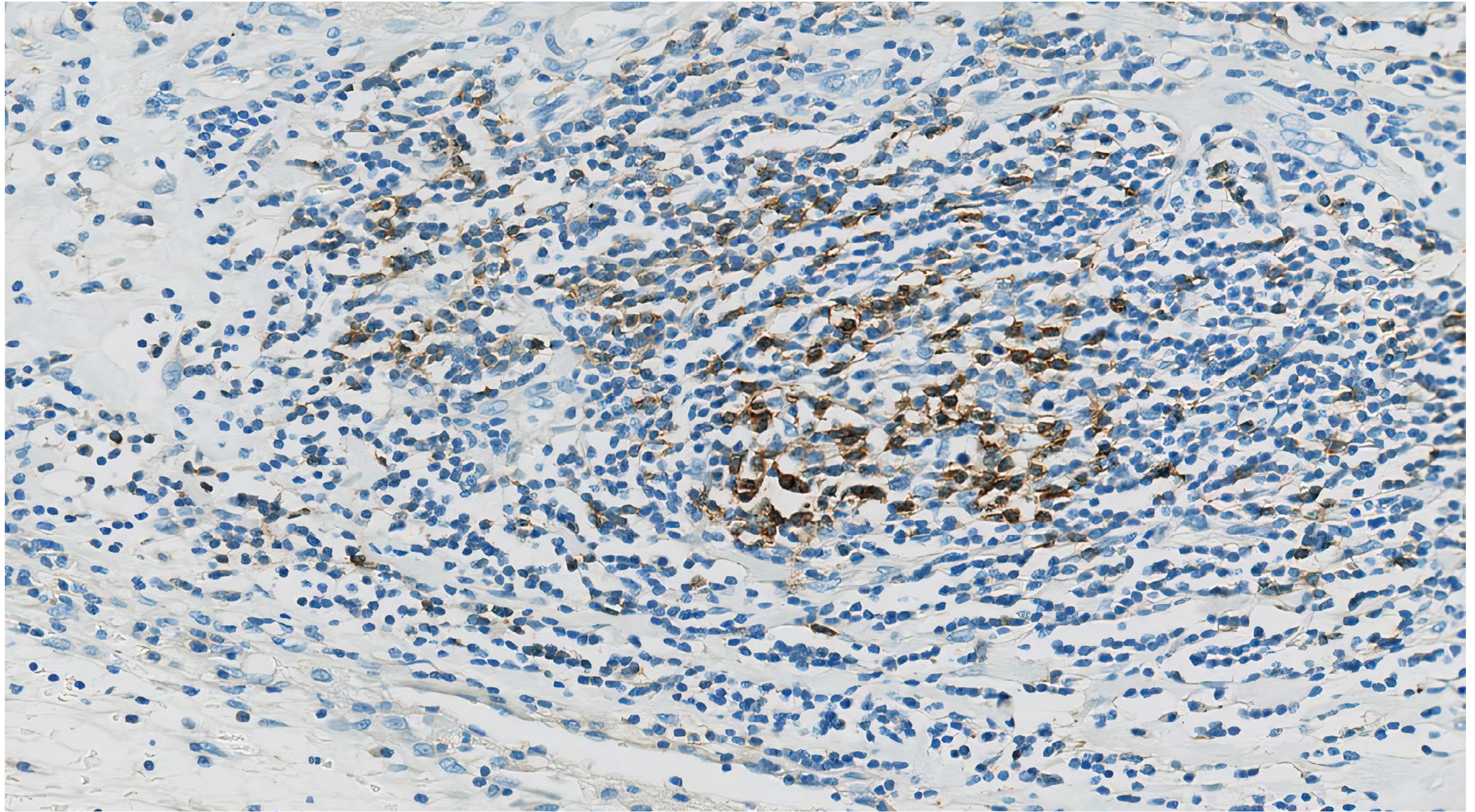
Natural Killer Cells Phenotyping in Non-Small Cell Lung Cancer.  
Assay designed to detect natural killer cells and natural killer T-Cells  
in tumor samples.

CD3 (Clone D7A6E, Red), CD16 (Clone EPR16784, Green), CD56  
(Clone MRQ-42, Orange) multiplex IHC staining of Non-Small Cell  
Lung Cancer FFPE sample. Platform: Leica Bond RX.



Scientist: Elena Barnova





**PD1 Expression in Non-Small Cell Lung Cancer.**

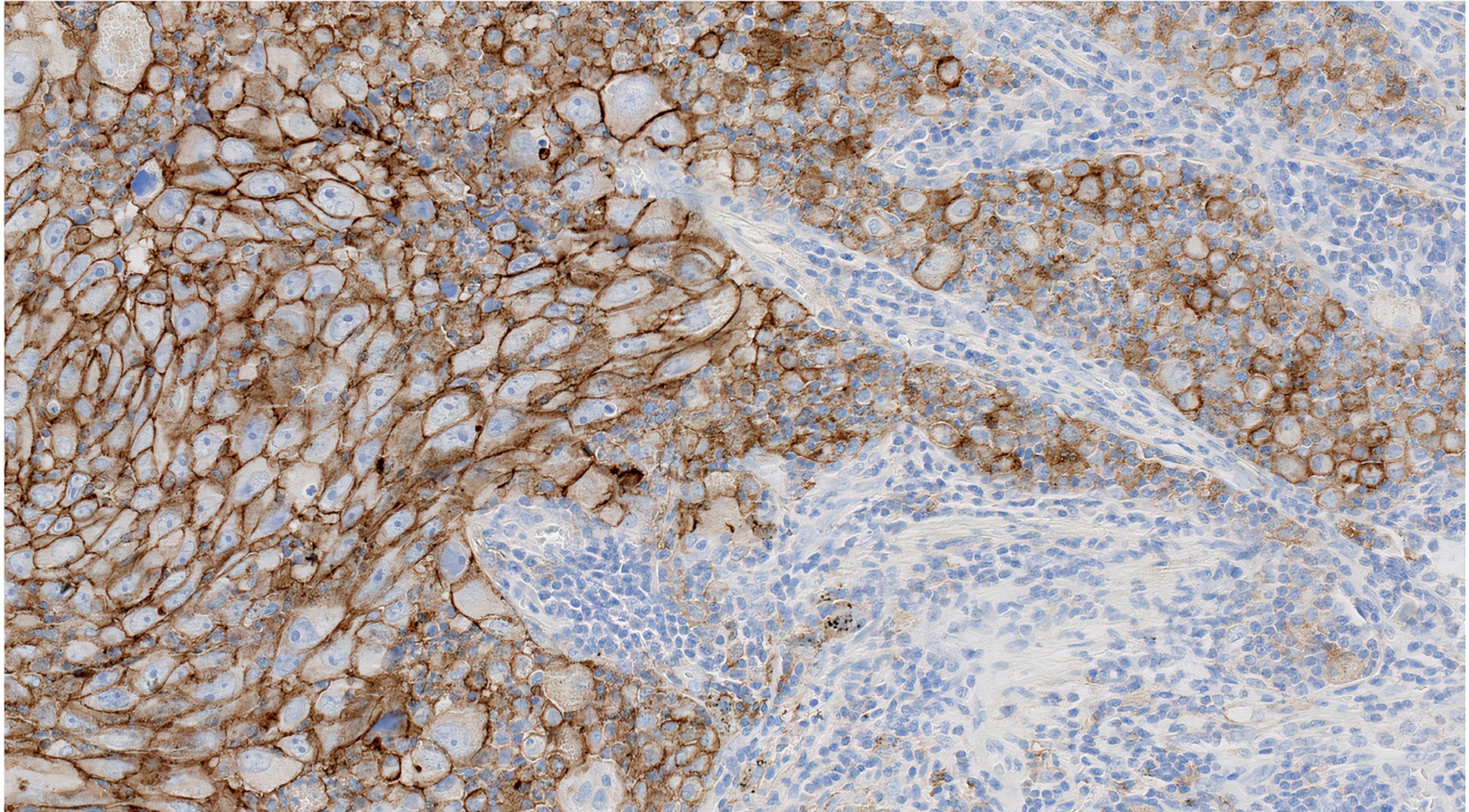
Protocol used in a Phase 1 clinical study to detect PD1, a common target of immune checkpoint blockade, expression in solid tumors.



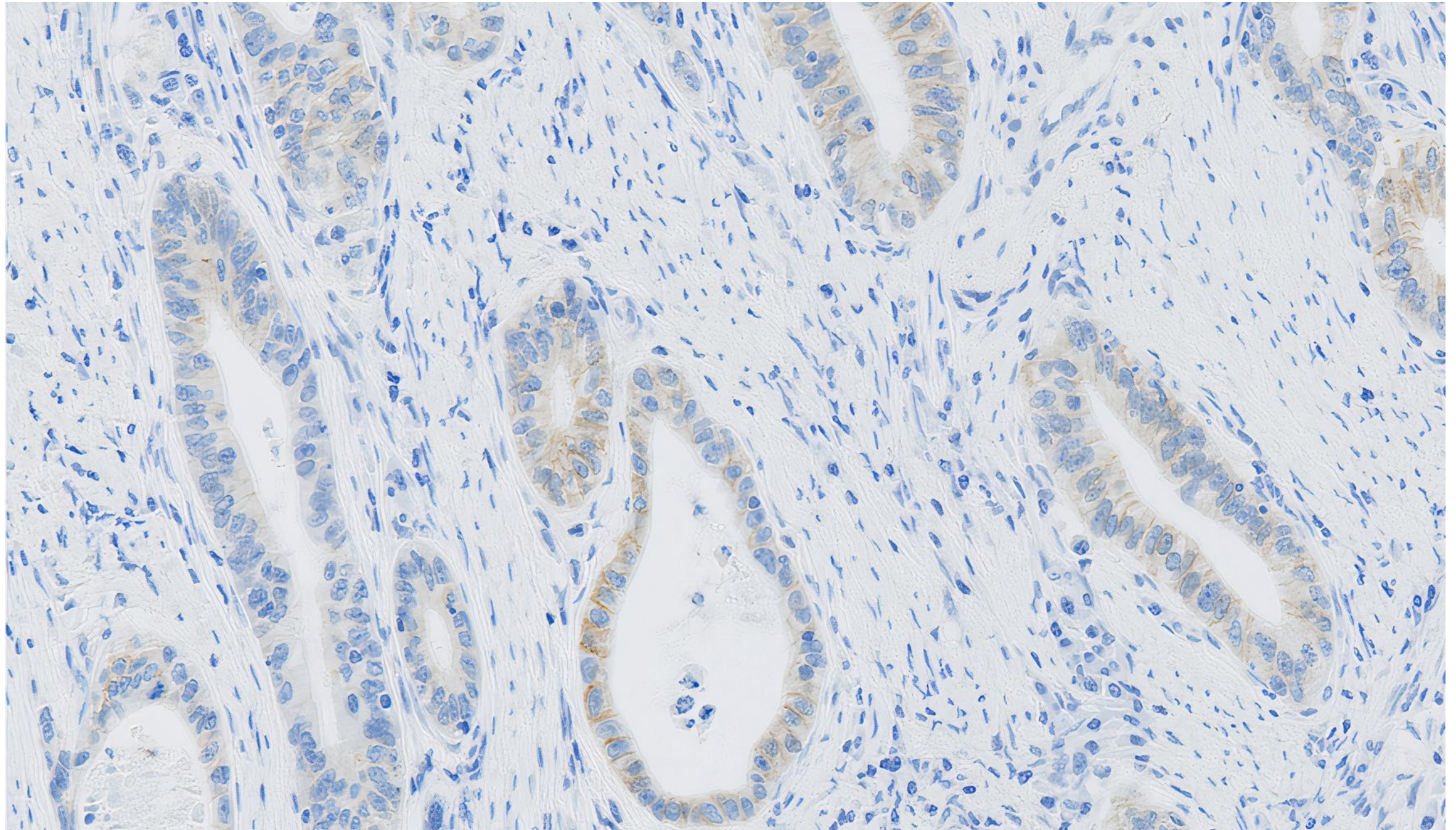
**PD-L1 Expression in Non-Small Cell Lung Cancer.**

PD-L1 IHC pharmDx is indicated as an aid in the assessment of non-small cell lung cancer patients to determine the most appropriate therapy based on the Tumor Proportion Score.

PD-L1 IHC 22C3 pharmDx (Clone 22C3) IHC staining of Non-Small Cell Lung Cancer FFPE sample. Platform: Dako Omnis.



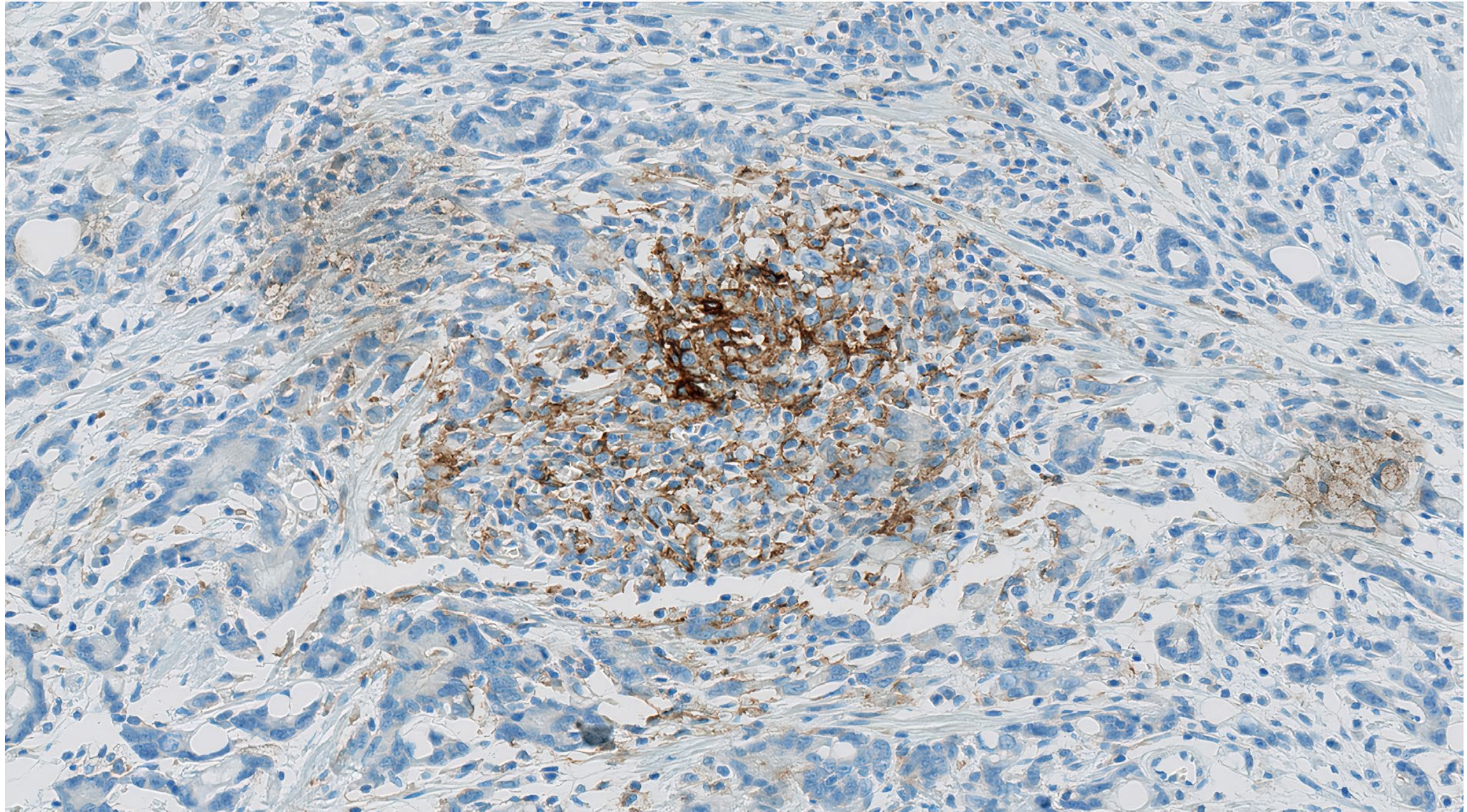




HercepTest™ mAB pharmDx Human Epidermal growth factor Receptor 2 (HER2) (Clone DG44) IHC staining of Gastric Cancer FFPE sample. Platform: Dako Omnis.

**Human Epidermal Growth Factor Receptor 2 Expression in Gastric Cancer.**  
HercepTest™ mAB pharmDx is indicated as an aid in the assessment of gastric cancer patients to determine the most appropriate therapy.





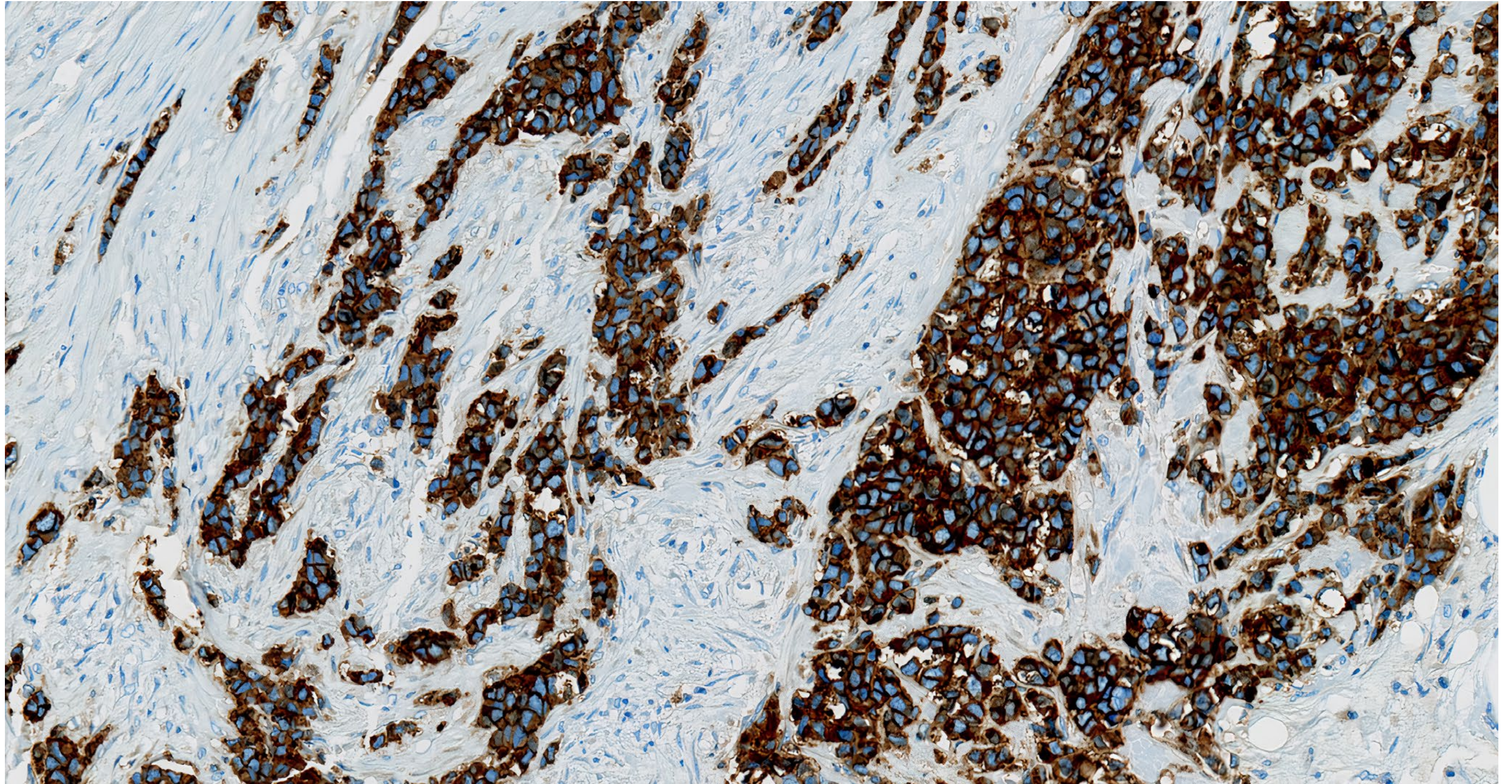
**PD-L1 Expression in Gastric Cancer.**

Protocol used in a Phase 1 clinical study to detect PD-L1, an immune inhibitory receptor ligand expressed in T and B cells as well as in various types of tumor cells.



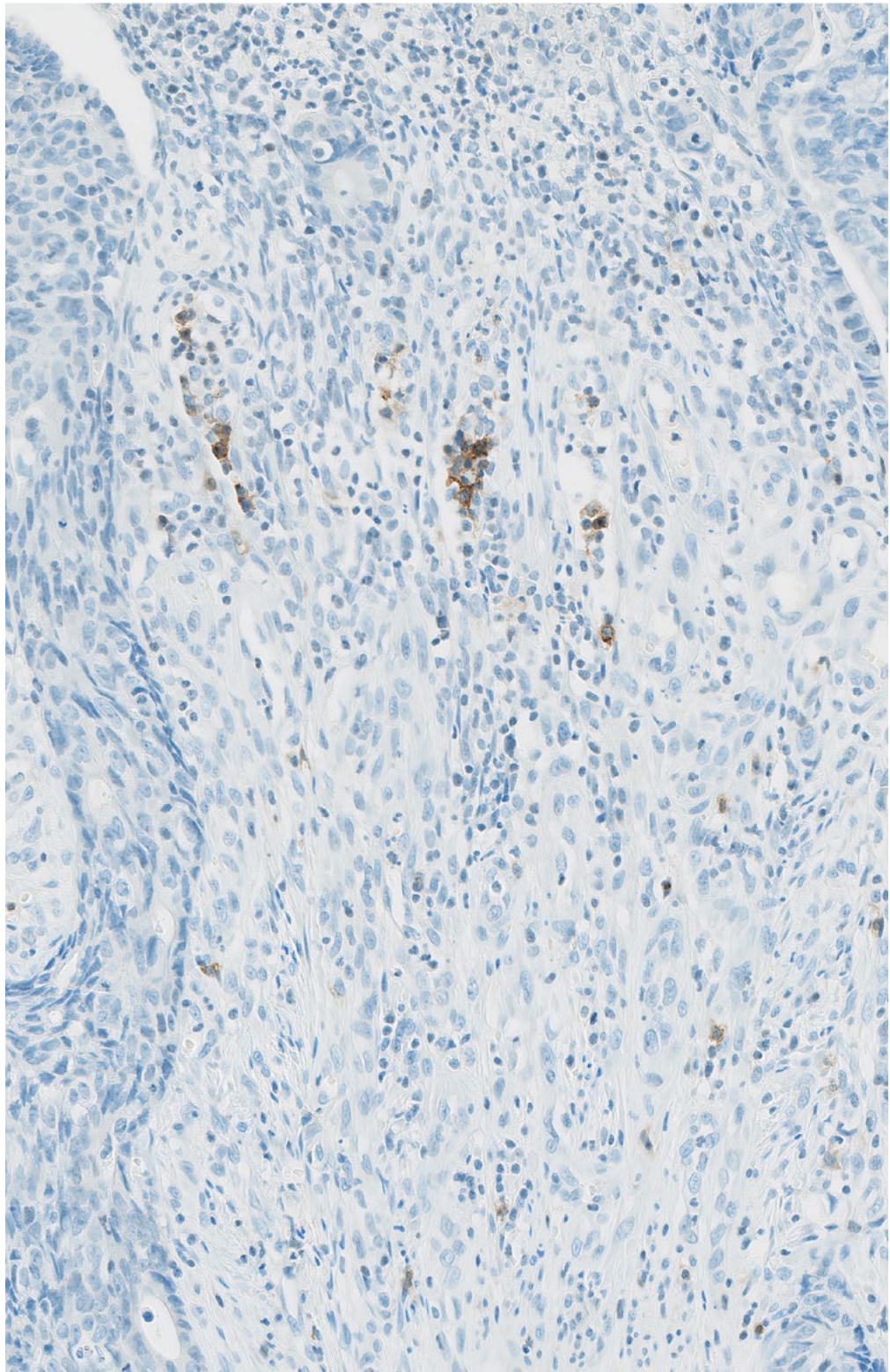
Carcino-Embryonic Antigen Expression in Colorectal Cancer.  
Protocol used as an inclusion criteria in Phase 3 clinical study.

Carcino-Embryonic Antigen (CEA) (clone CEA31) IHC staining of Human colon adenocarcinoma FFPE blocks. Platform: Benchmark XT.



Scientists: Alexy Promonet



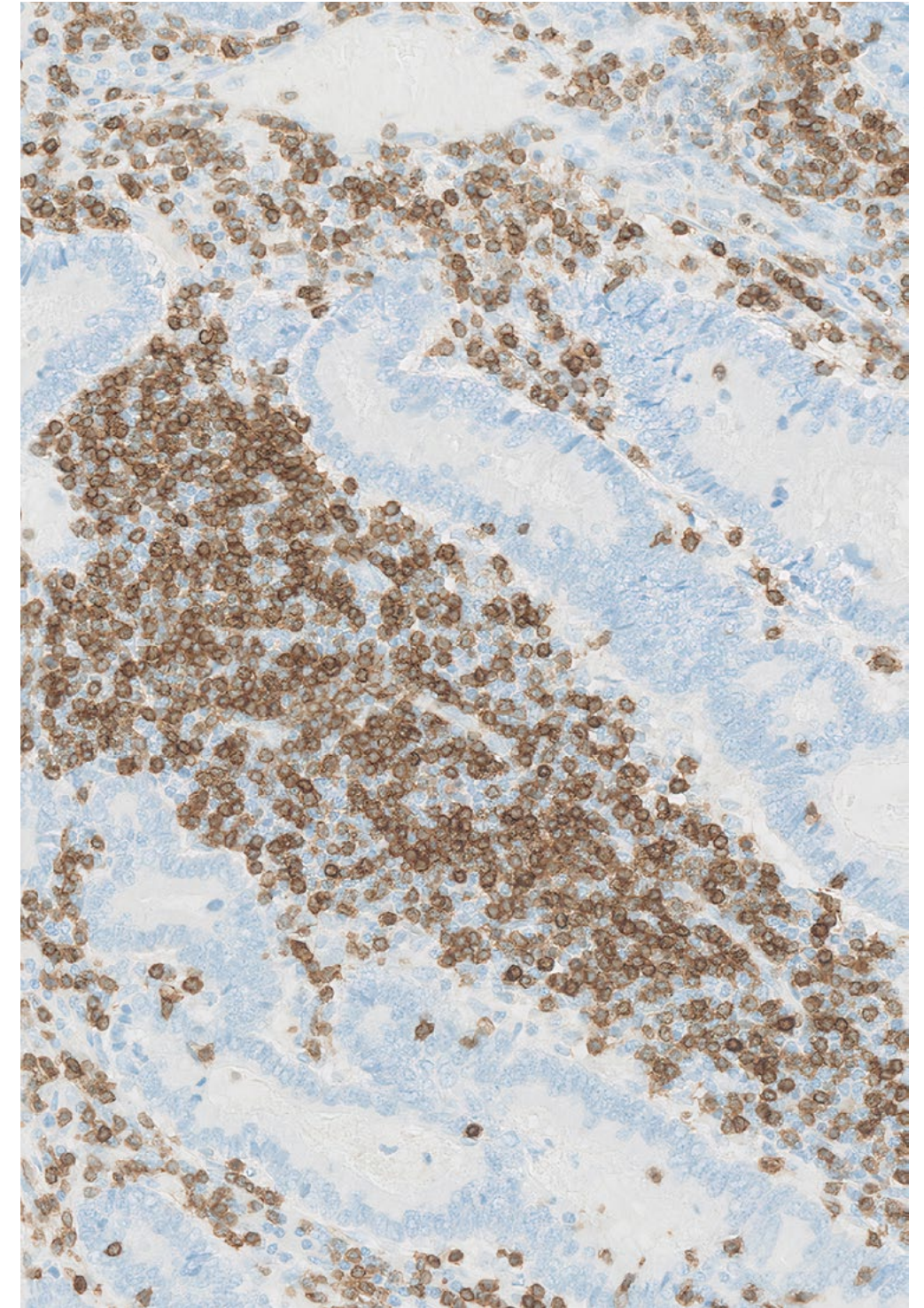


CD30 (Clone Ber-H2)  
IHC staining of colorectal  
adenocarcinoma FFPE  
sample. Platform:  
Benchmark ULTRA.

Scientist: Nicolas Goulange

**Cd30 Expression in Colorectal Adenocarcinoma.**  
Protocol validated at a secondary endpoint level.

**CD3 Expression in Colorectal Adenocarcinoma.**  
Protocol used in Phase 2 clinical studies for Pan T-Cells  
detection in atopic dermatitis and tumor samples.



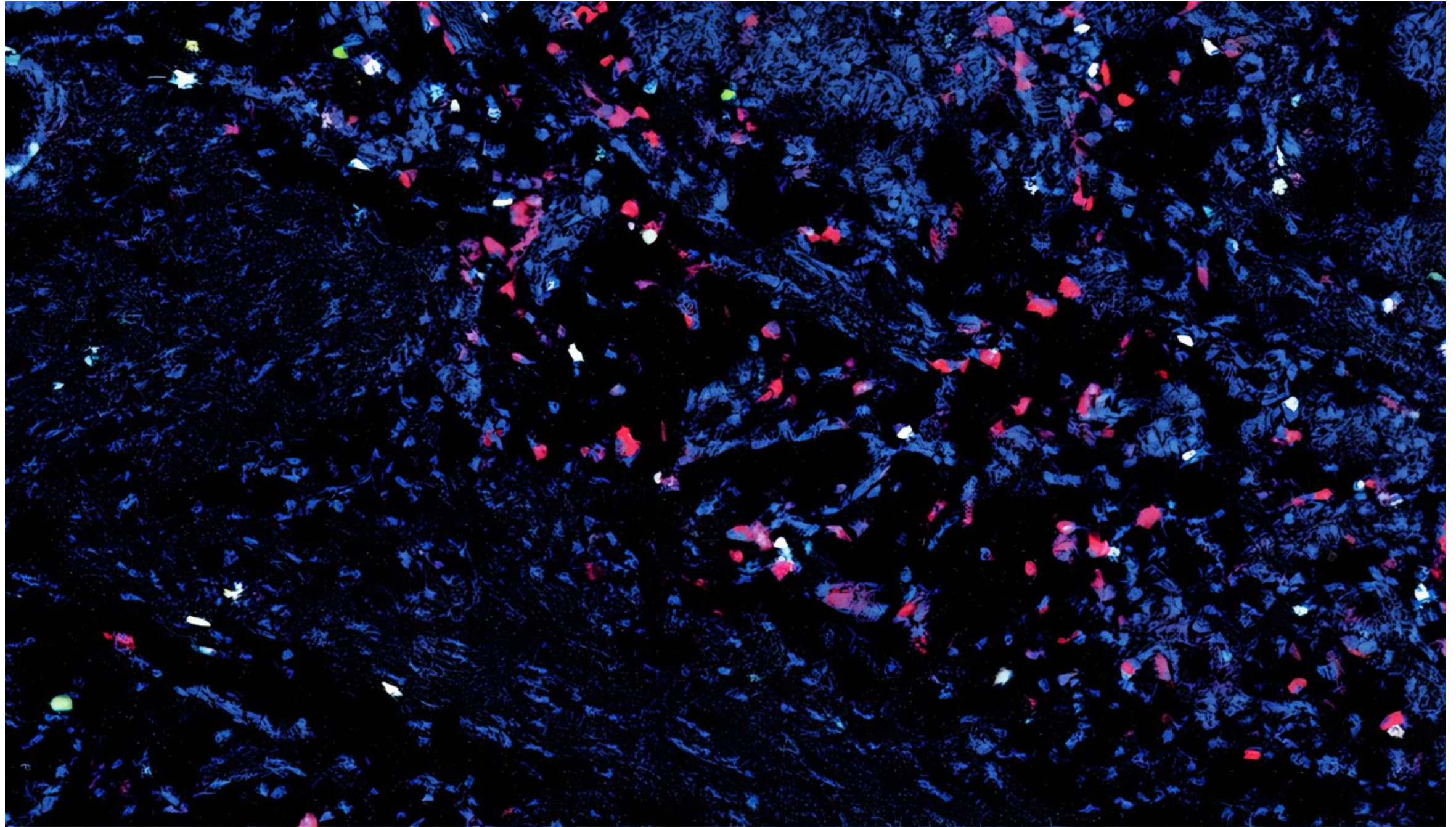
CD3 (Clone 2GV6) IHC  
staining of colorectal  
adenocarcinoma FFPE  
sample. Platform:  
Benchmark ULTRA.

Scientist: Alexy Promonet



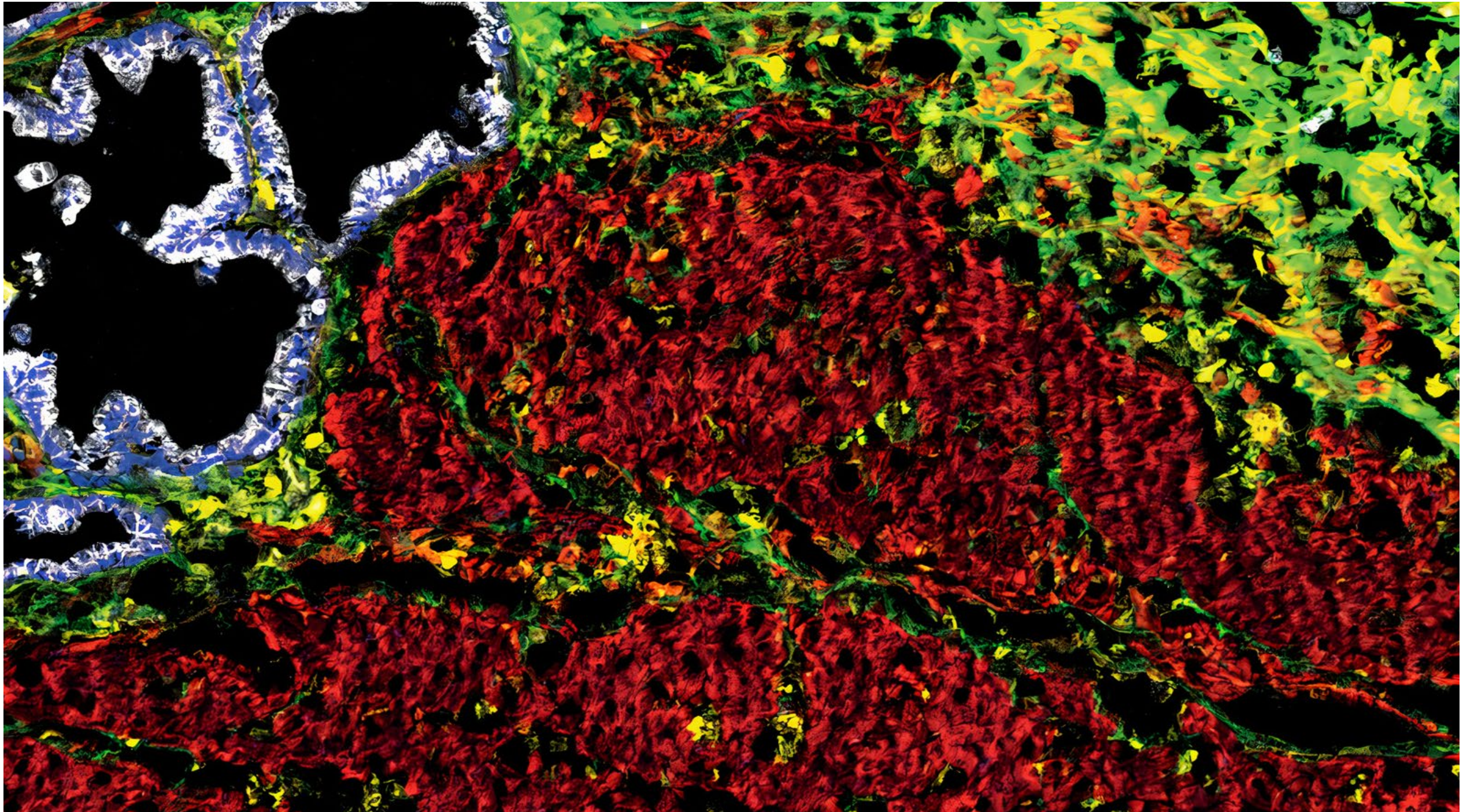
**Imaging Mass Cytometry Multiplex in Healthy Frozen Tissues.**  
Assay designed to detect different types of immune cells and to show tissue architecture.

Representative image of 5 targets in a 12plex. CD45 (Clone D9M81, Cyan), CD68 (Clone KP1, Red), CD8 (Clone RPA-T8, Yellow), KI67 (Clone B56, Lime green), CD3 (Clone UCHT1, White) multiplex IMC staining of Frozen Pancreas sample. Platform: Discovery ULTRA. Image acquired on Fluidigm Hyperion Platform.



Scientist: Elena Baranova

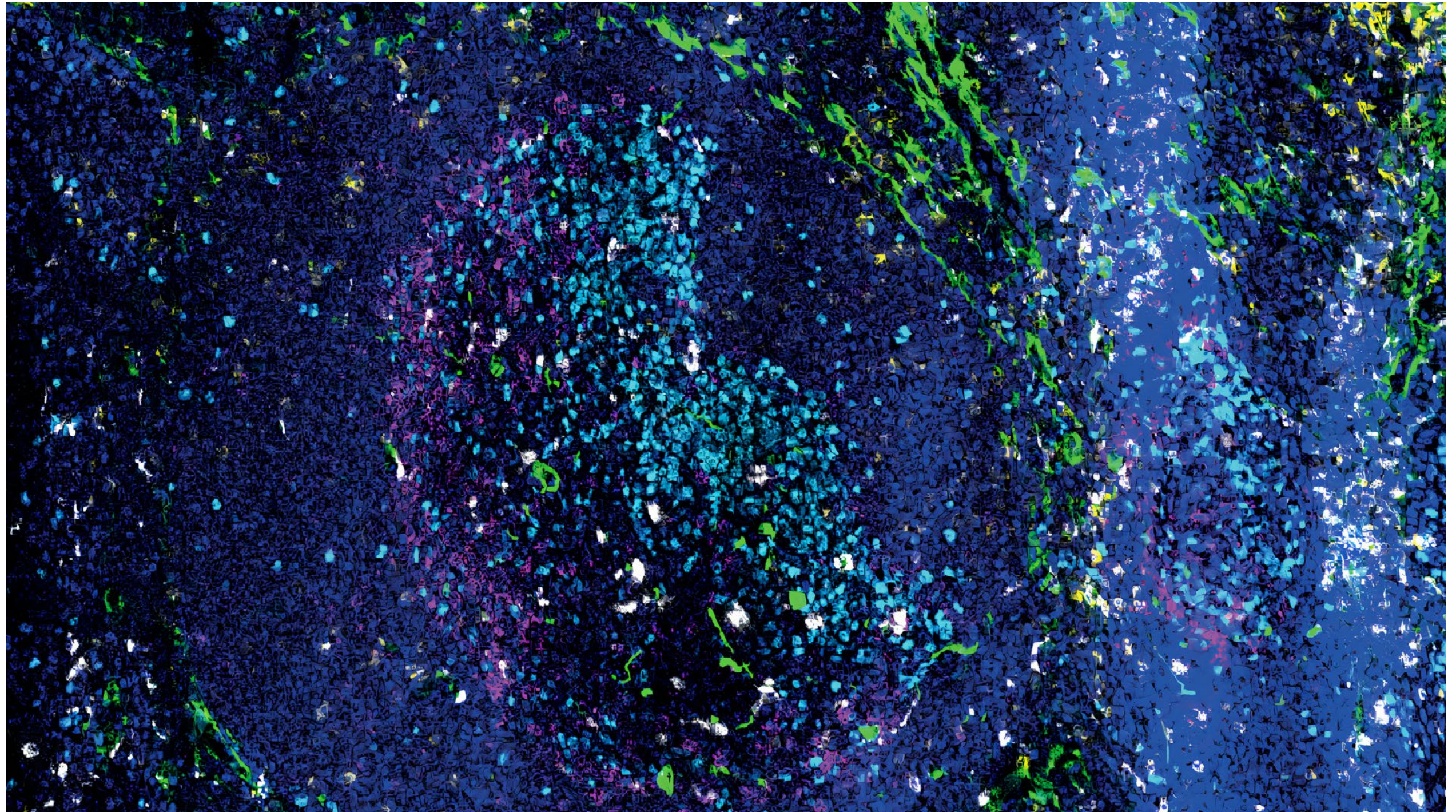




Representative image of 4 targets in a 12plex. Alpha-SMA (Clone 1A4, Red), Vimentin (Clone RV202, Yellow), PanCK (Clone C11, White), Collagen I (Polyclonal, Lime green) multiplex IHC staining of Frozen Pancreas sample. Platform: Discovery ULTRA. Image acquired on Fluidigm Hyperion Platform.

**Imaging Mass Cytometry Multiplex in Healthy Frozen Tissues.**  
Assay designed to detect different types of immune cells and to show tissue architecture.





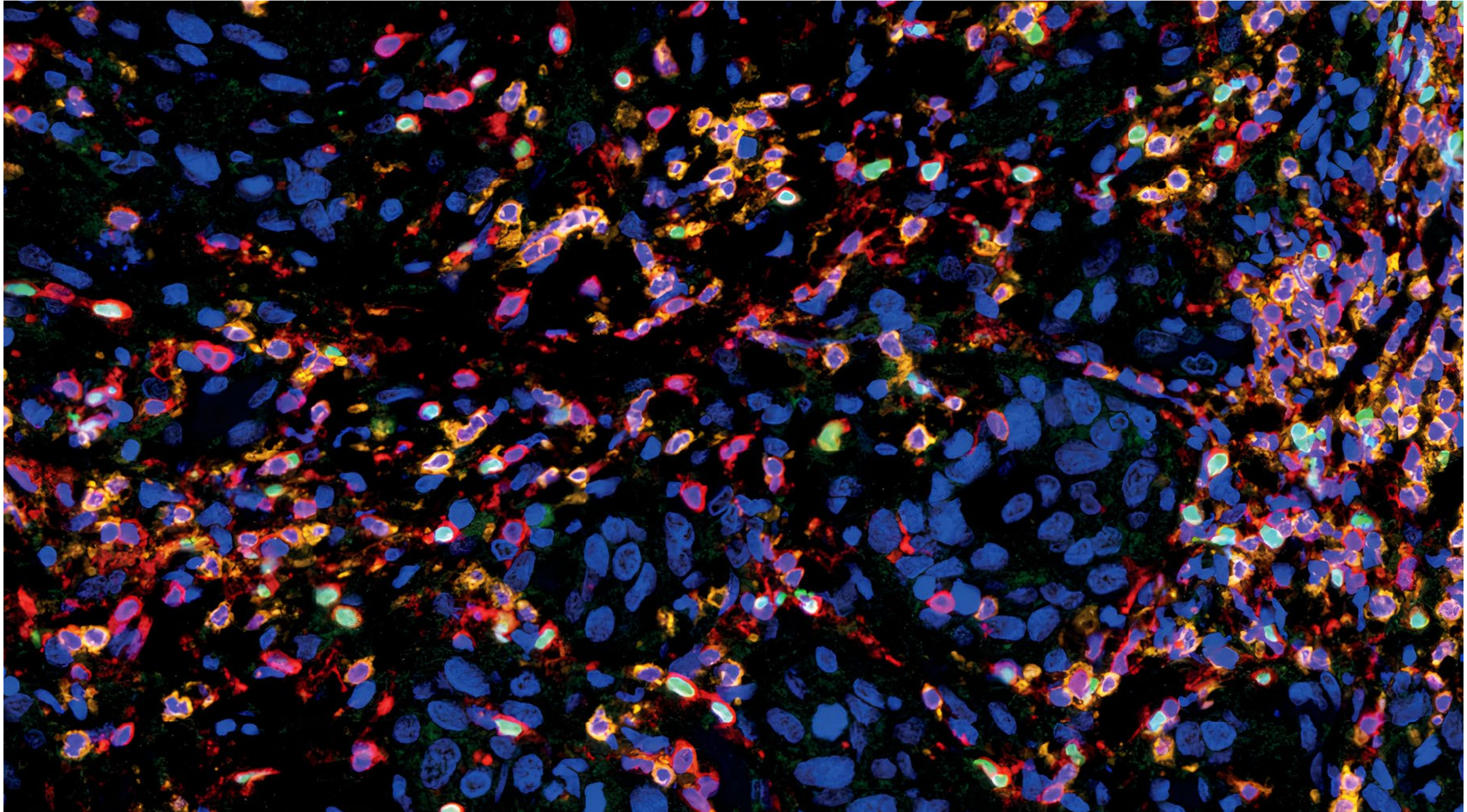
Representative image of 5 targets in a 12plex. CD68 (Clone KP1, White), CD8 (Clone RPA-T8, Yellow), PD1 (Clone EH12.2H7, Magenta), KI67 (Clone B56, Cyan), Collagen (Polyclonal, Lime green) multiplex IMC staining of Frozen Tonsil sample. Platform: Discovery ULTRA. Image acquired on Fluidigm Hyperion Platform.

**Imaging Mass Cytometry Multiplex in Healthy Frozen Tissues.**  
Assay designed to detect different types of immune cells and to show tissue architecture.



**Cytotoxic and Regulatory T-Cells Identification in Solid Tumors.**  
Protocol used in a Phase 1 clinical study to detect cytotoxic T-Cells and regulatory T-Cells in solid tumors.

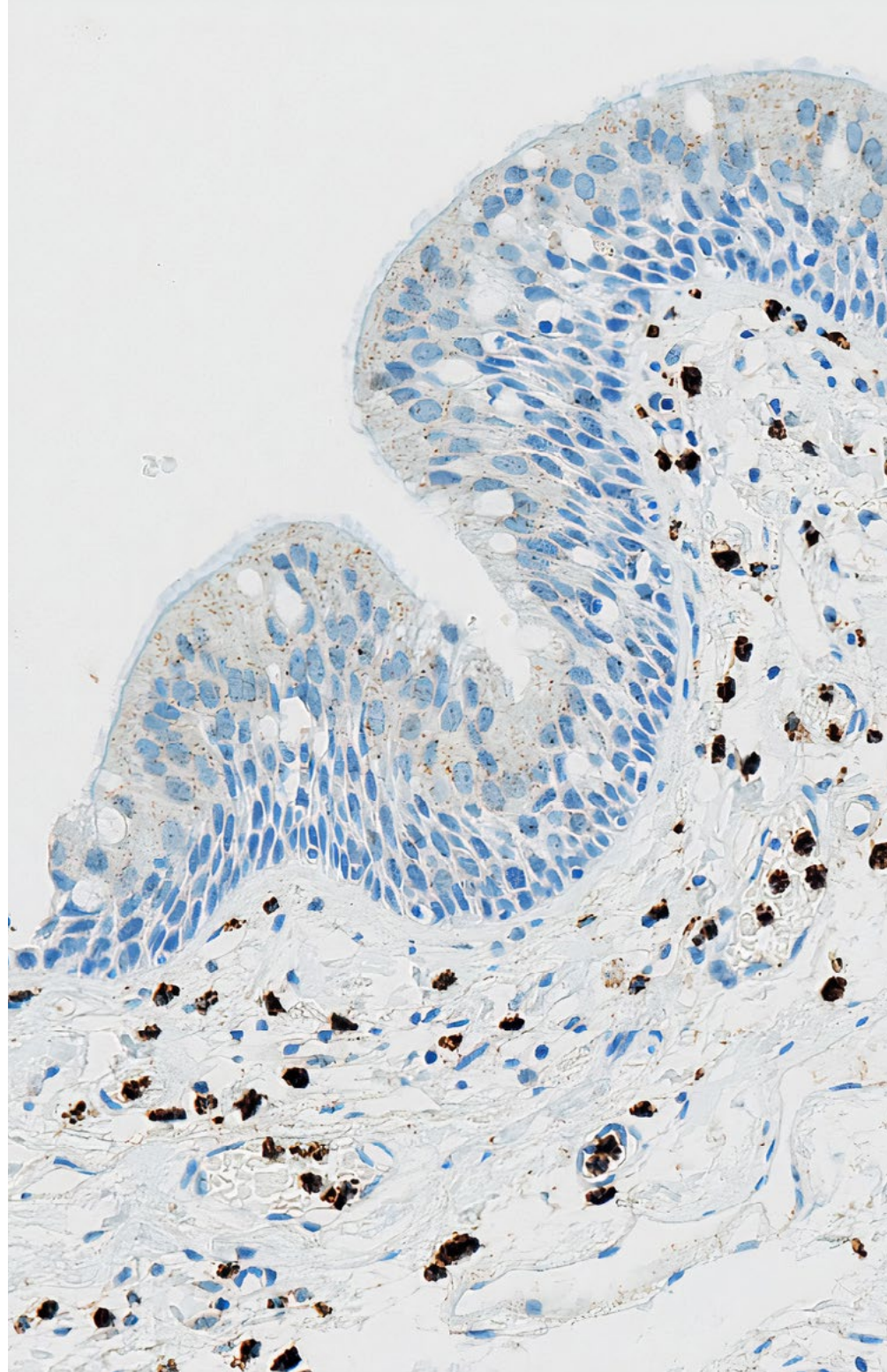
CD3 (Clone 2GV6, Red), CD8 (Clone AMC908, Orange) and FoxP3 (Clone 236A/E7, Green) multiplex IHC staining of Head and Neck Squamous Cell Carcinoma FFPE sample. T-Cells are identified by CD3 staining, Cytotoxic and regulatory subpopulations are identified by CD8 and FoxP3 staining respectively. Platform: Ventana Discovery ULTRA.



Scientist: Elena Baranova & Marie G rus-Durand



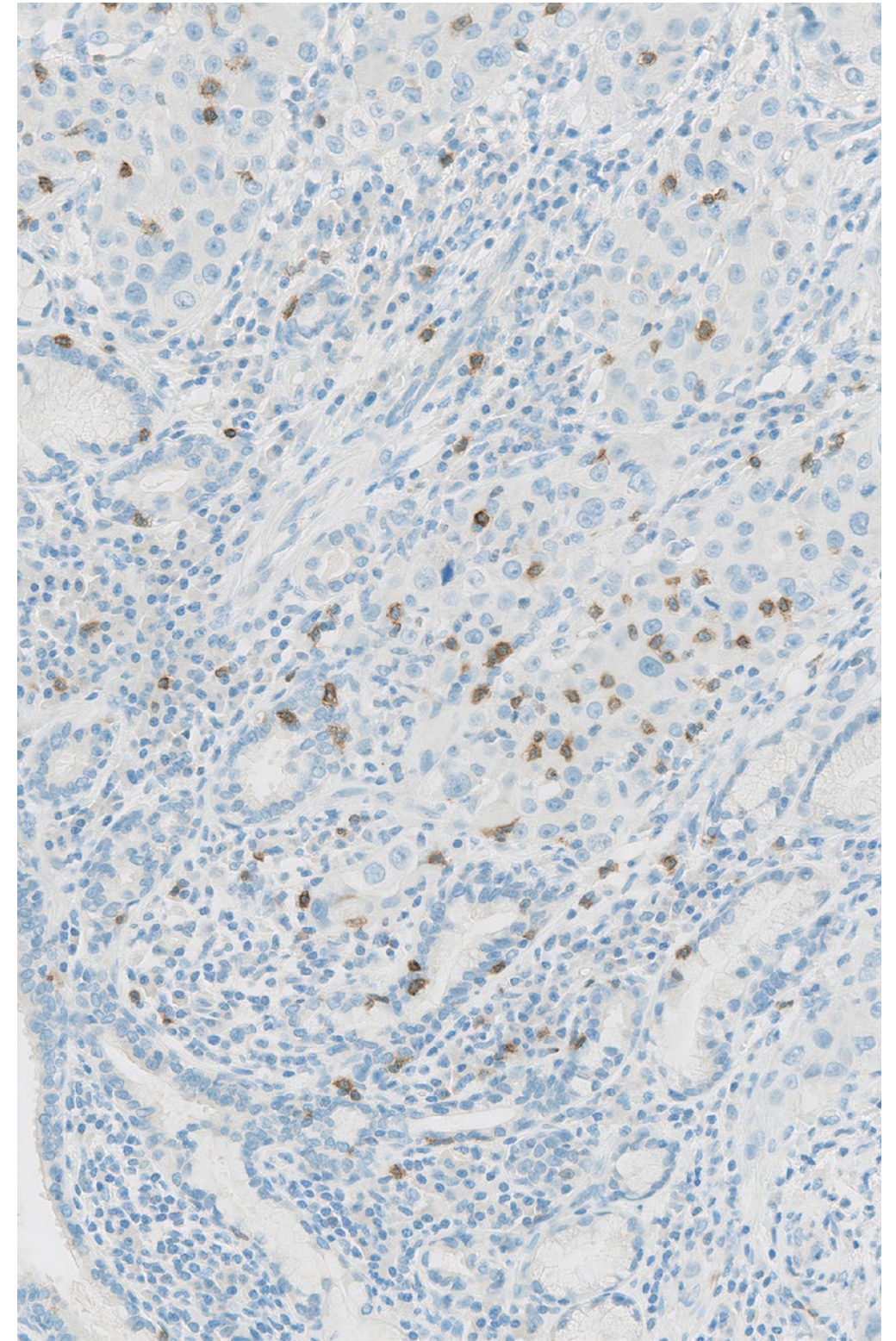
**Neutrophil Elastase Expression in Head and Neck Squamous Cell Carcinoma.**  
Protocol used in a Phase 1 clinical study to detect neutrophil infiltration in solid tumors.



Scientist: Alexy Promonet

Neutrophil Elastase (Clone SP203) IHC staining of Larynx squamous cell carcinoma FFPE sample. Platform: Benchmark ULTRA.

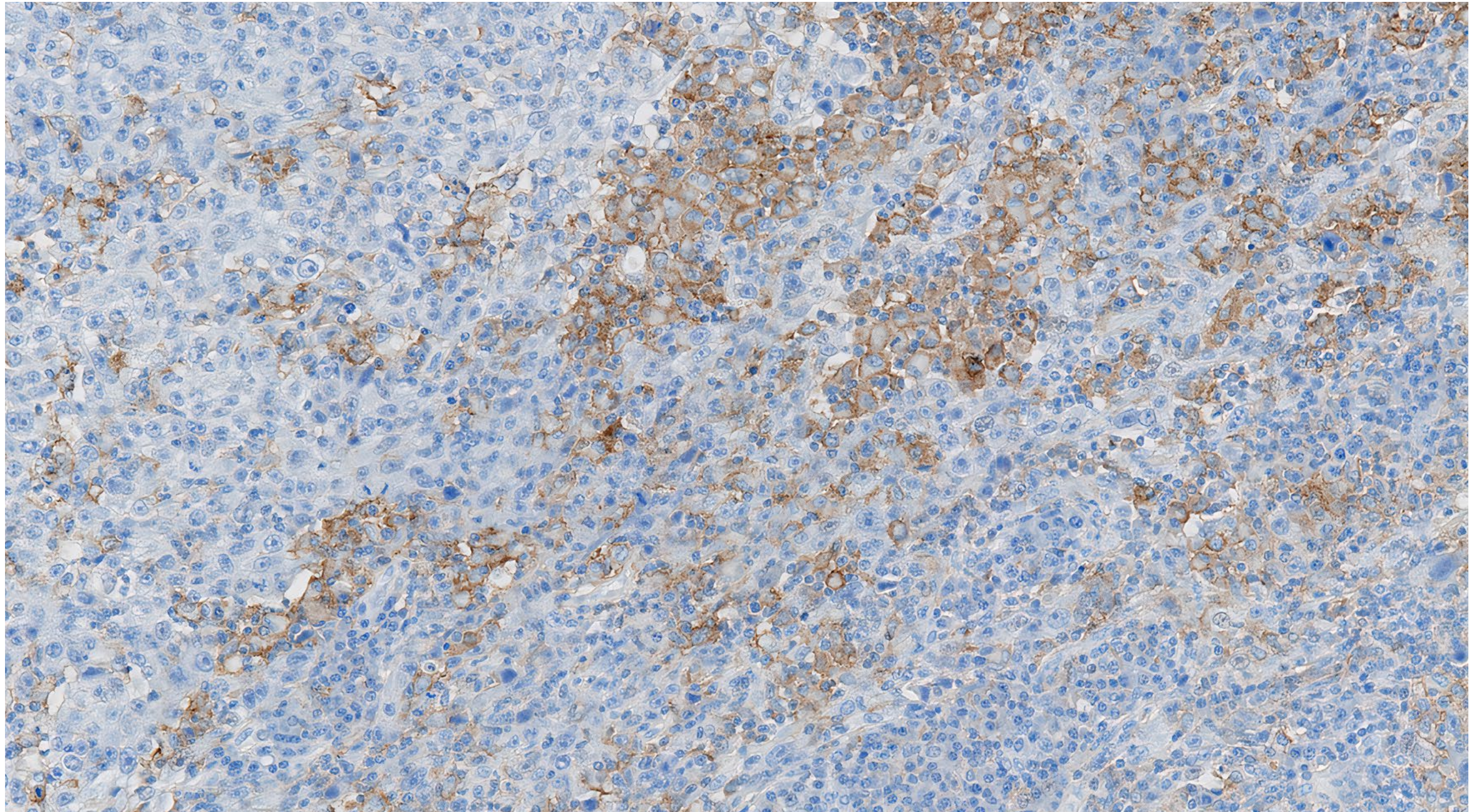
NKp46 (Clone EPR2240357) IHC staining of Larynx Squamous Cell Carcinoma FFPE sample. Platform: Benchmark ULTRA.



Scientist: Alexy Promonet

**Natural Killer Cells in Head and Neck Squamous Cell Carcinoma.**  
Assay designed to be used in a Phase 1b clinical study to detect NK cells in solid tumors.





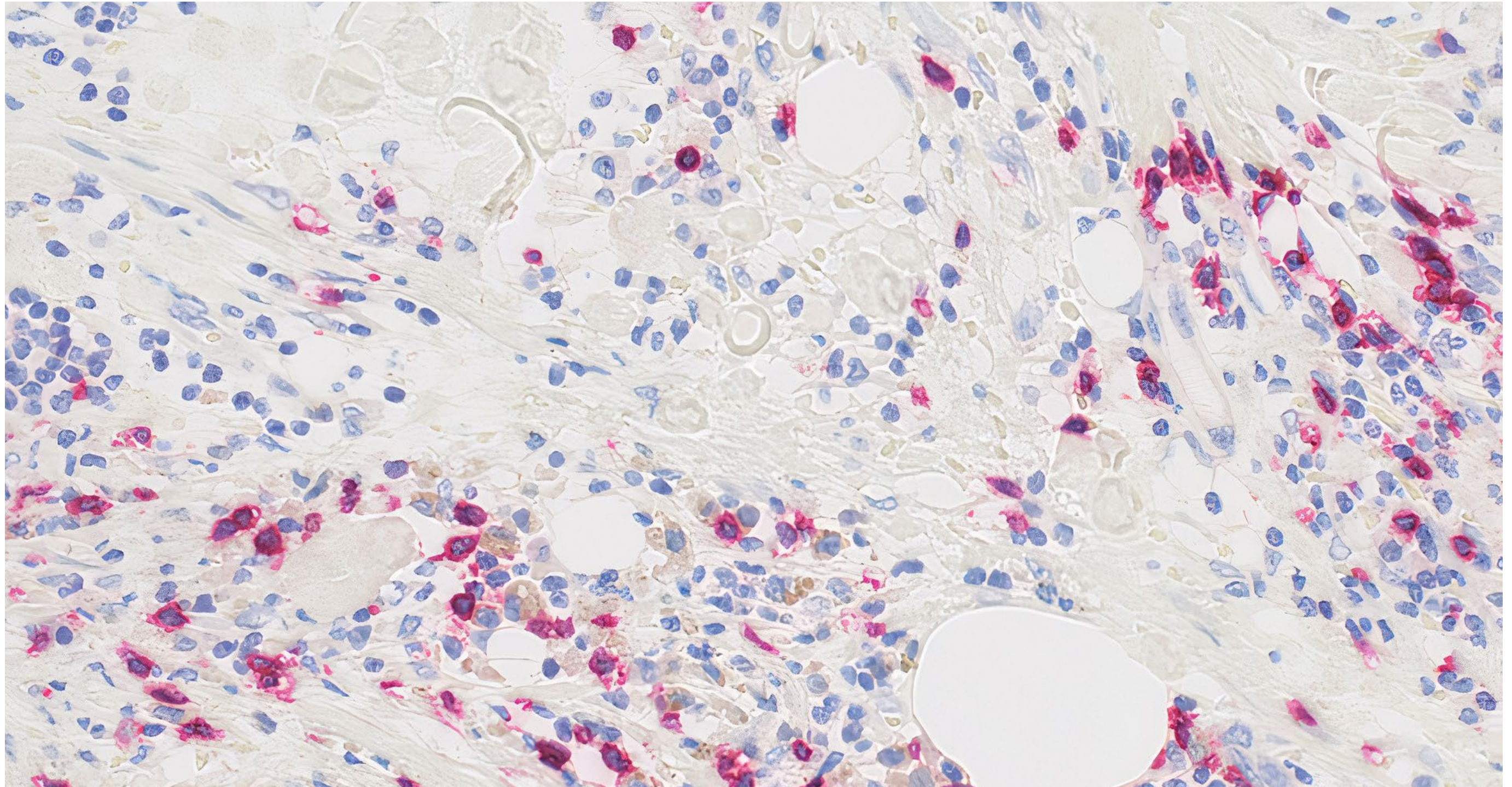
PD-L1 IHC 22C3 pharmDx (Clone 22C3) IHC staining of Pharynx Cancer FFPE sample. Platform: Dako Omnis.

#### **PD-L1 Expression in Head and Neck Cancer.**

PD-L1 IHC pharmDx is indicated as an aid in the assessment of head and neck cancer patients to determine the most appropriate therapy based on the Combined Positive Score.



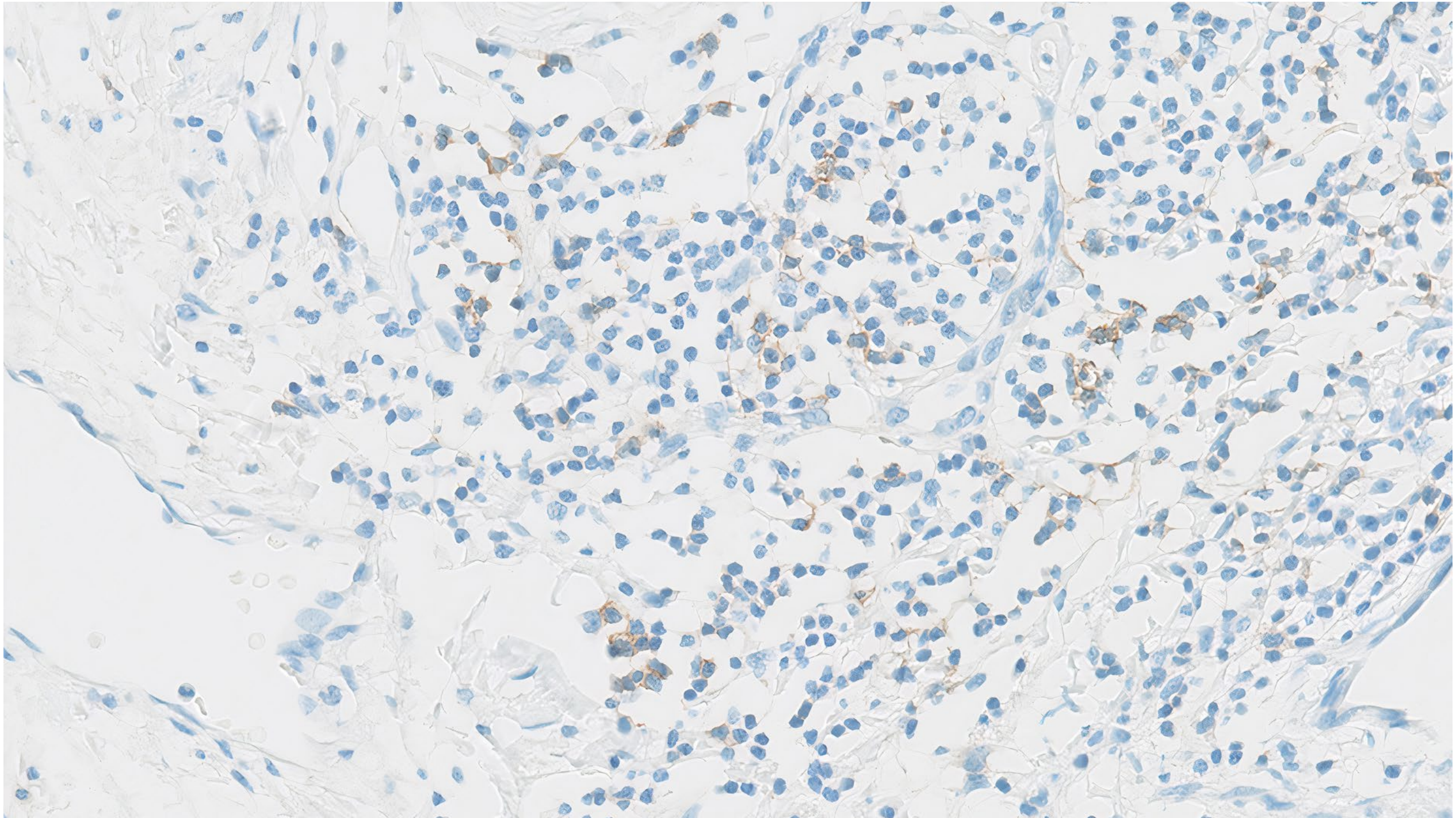
**Cd8 Expression in Pancreatic Ductal Adenocarcinoma.**  
Protocol used in Phase 1/2 clinical study to detect activated T-Cells in solid tumors.



CD8 (Clone 4B11) IHC staining of Pancreatic Ductal AdenoCarcinoma FFPE sample. Platform: Leica Bond III.

Scientists: Nicolas Goulange





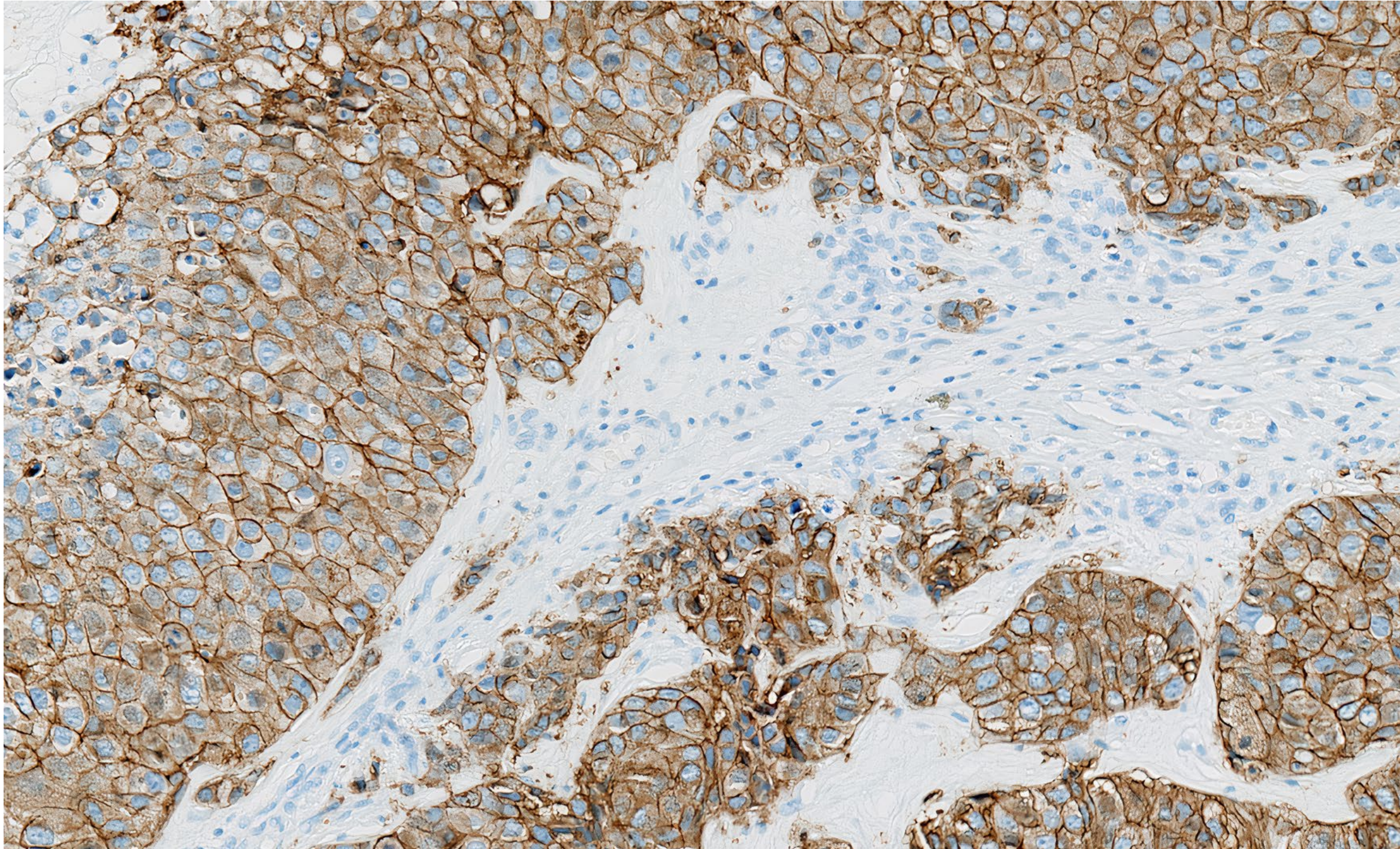
PD1 (Clone NAT105) IHC staining of Pancreatic Ductal Adenocarcinoma FFPE sample.  
Platform: Ventana Benchmark ULTRA.

**PD1 Expression in Pancreatic Ductal Adenocarcinoma.**  
Protocol used in a Phase 1 clinical study to detect PD1,  
a common target of immune checkpoint blockade,  
expression in solid tumors.

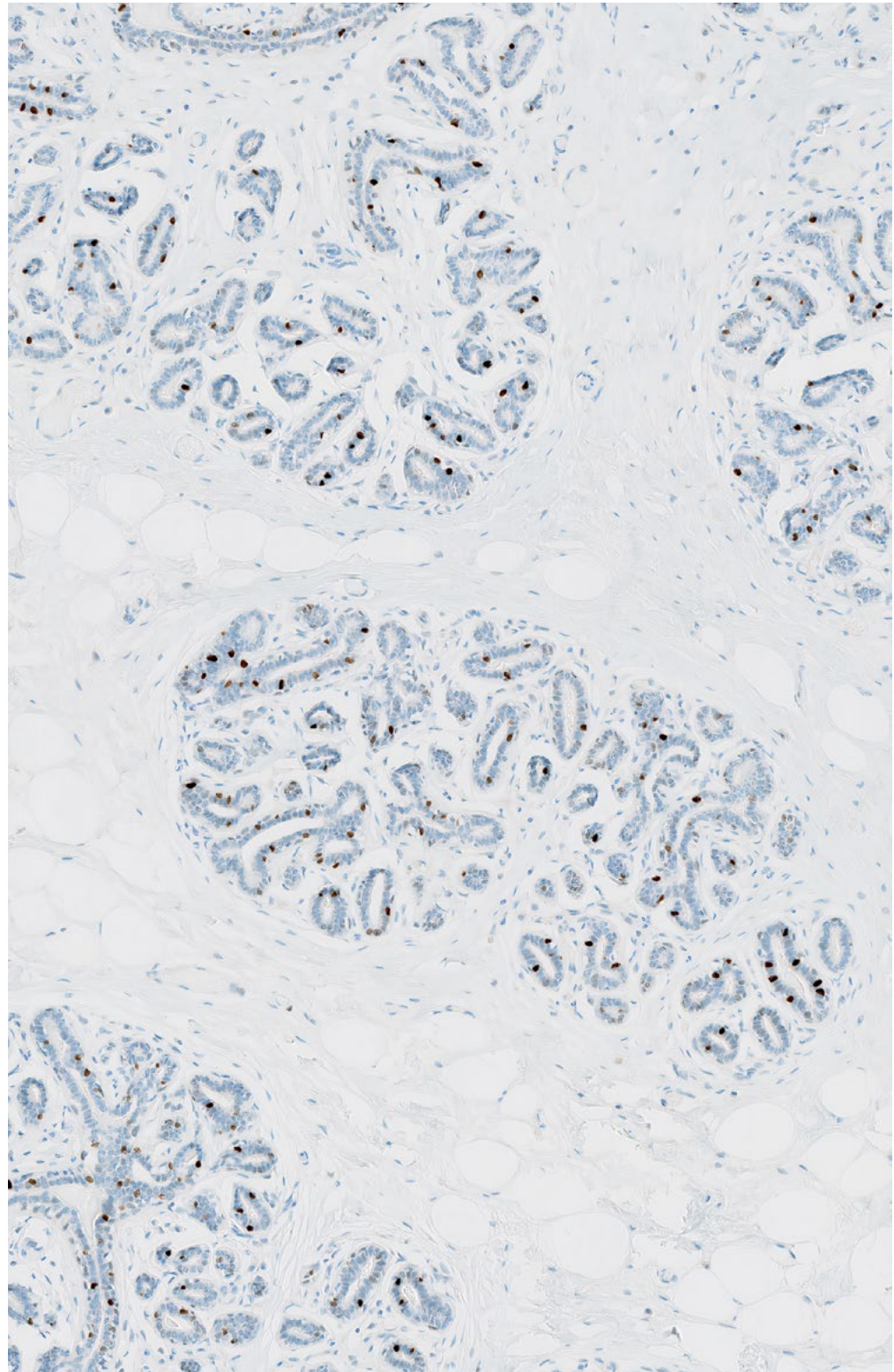


Human Epidermal Growth Factor Receptor 2 Expression in Breast Cancer.  
IVD protocol used in breast cancer hormone receptor status.

Human Epidermal growth factor Receptor 2 (HER2) (Clone 4B5) IHC staining of Breast Cancer  
FFPE sample. Platform: Ventana Benchmark ULTRA.





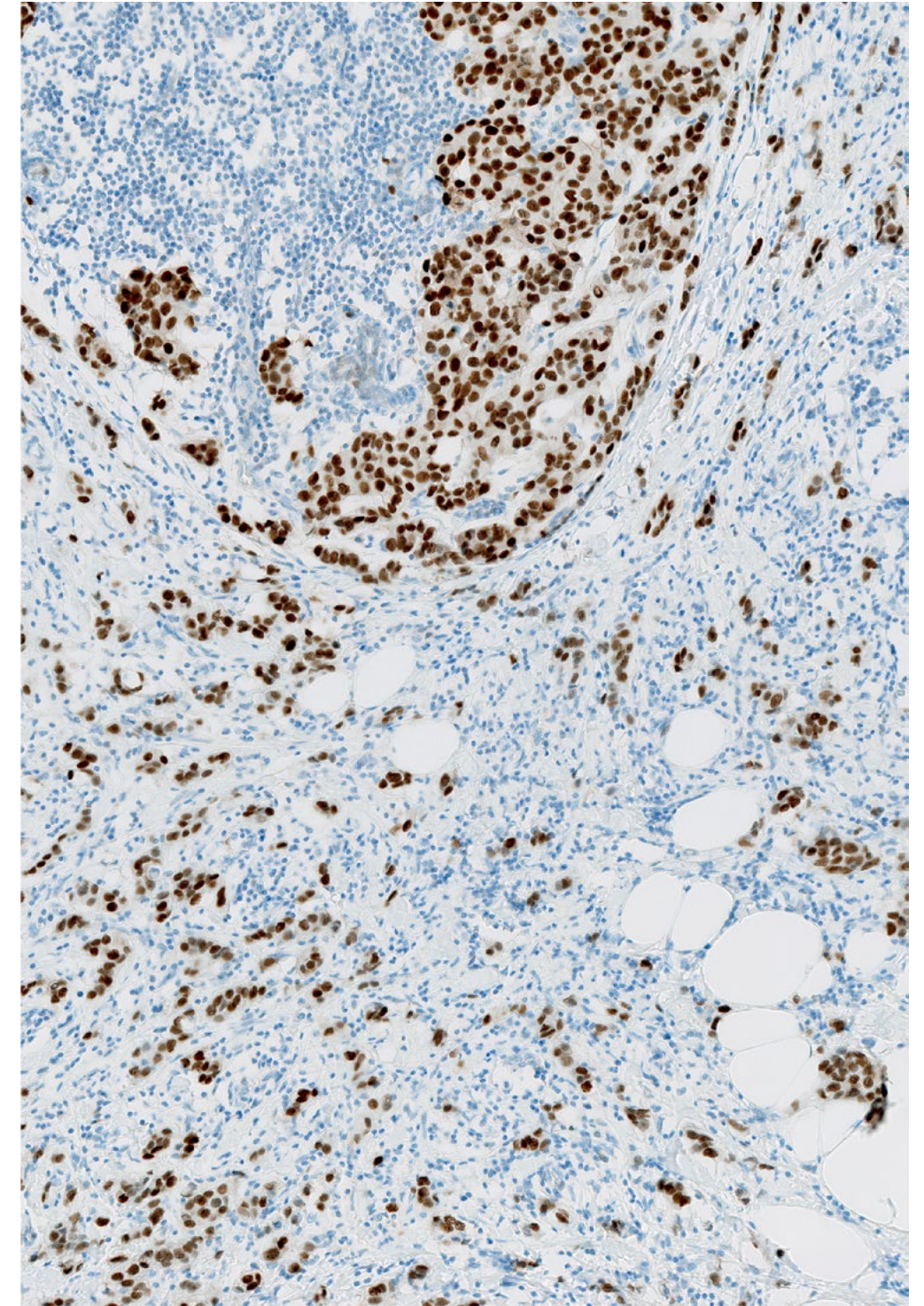


Progesterone Receptor (PR)  
(Clone 1E2) IHC staining  
of Breast Cancer FFPE  
sample. Platform: Ventana  
Benchmark ULTRA.

Scientist: Elena Baranova

**Progesterone Receptor Expression in Breast Cancer.**  
IVD protocol used in breast cancer hormone receptor status.

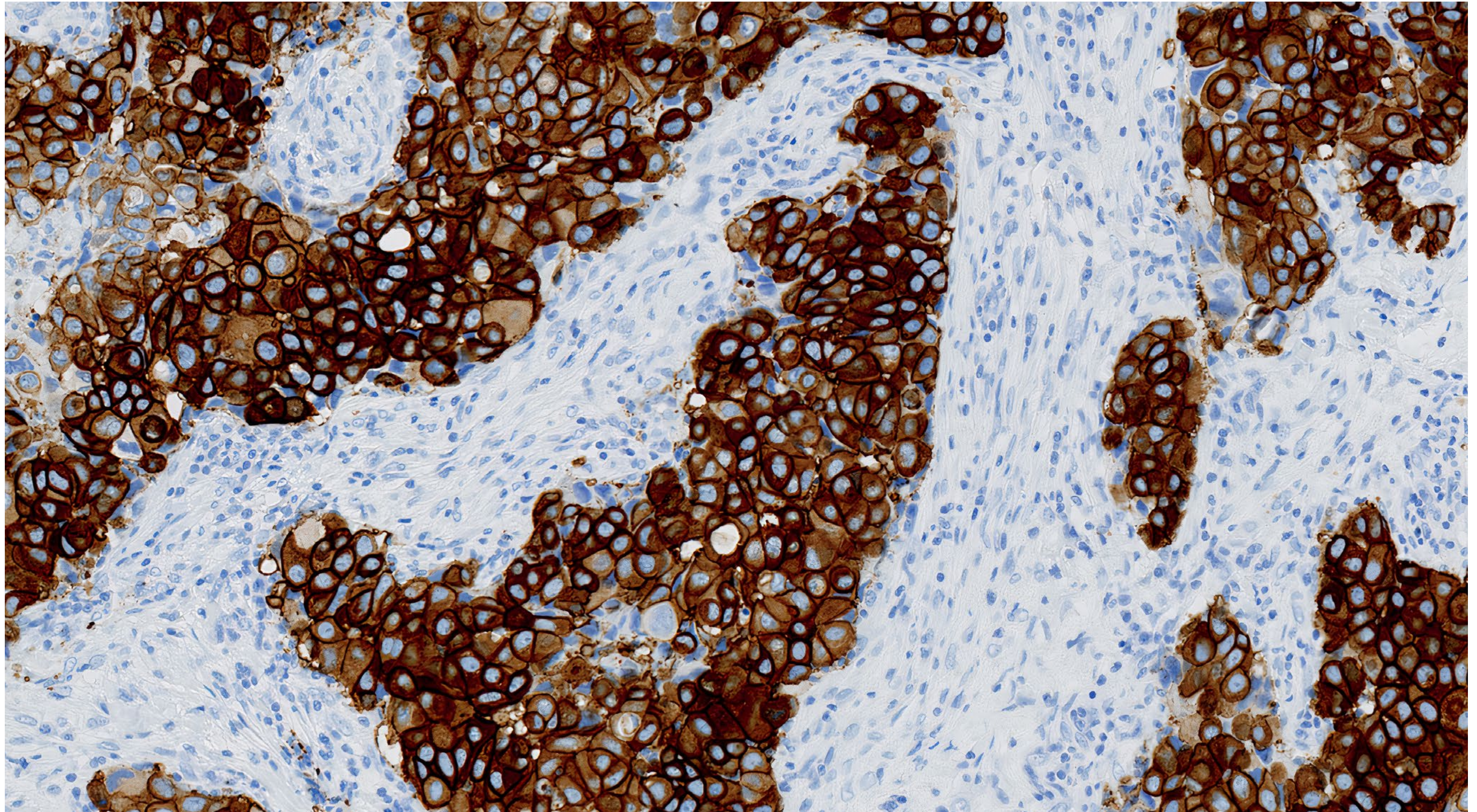
**Estrogen Receptor Expression in Breast Cancer.**  
IVD protocol used in breast cancer hormone receptor status.



Scientist: Elena Baranova

Estrogen Receptor (ER)  
(Clone SP1) IHC staining  
of Breast Cancer FFPE  
sample. Platform: Ventana  
Benchmark ULTRA.

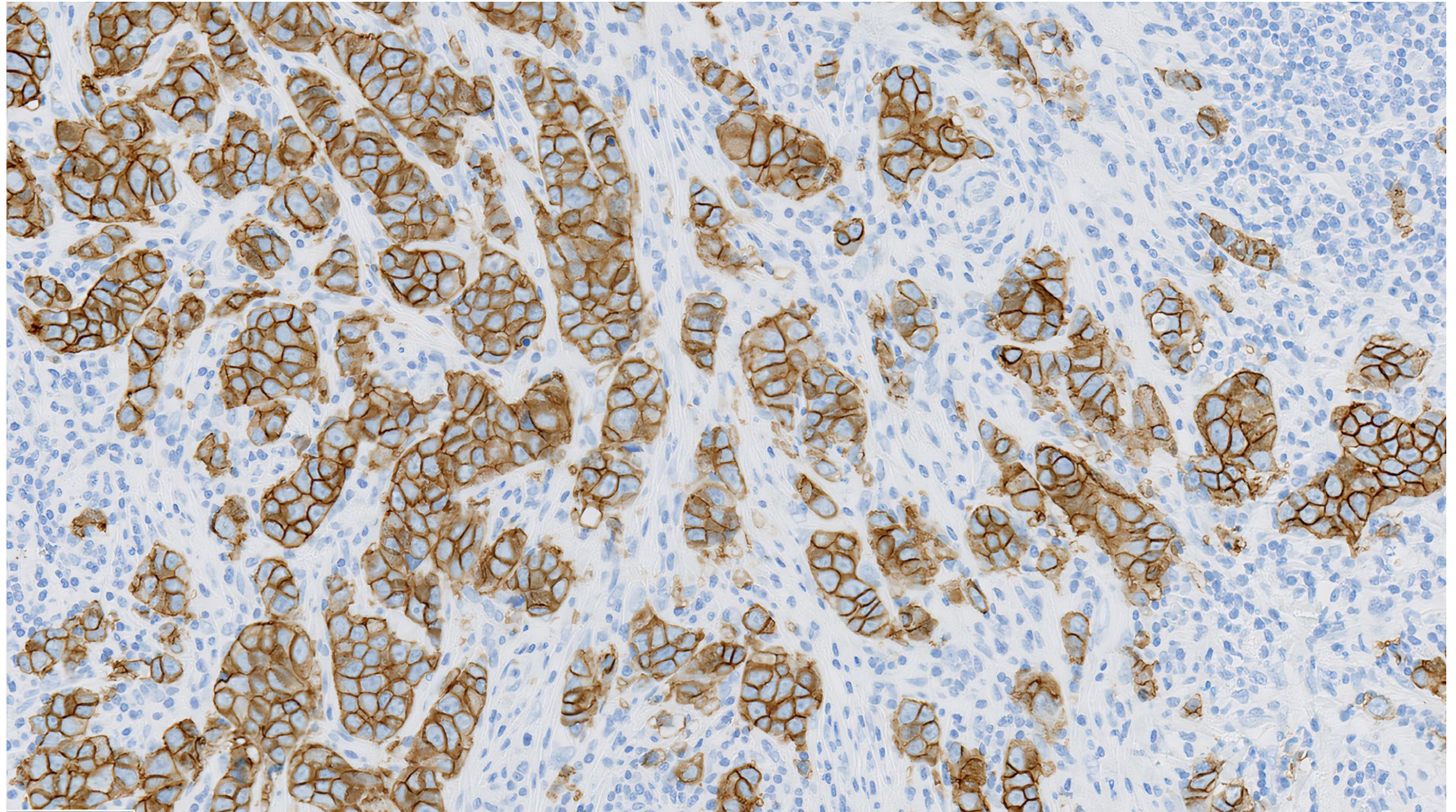




Human Epidermal Growth Factor Receptor 2 Expression in Breast Cancer. HercepTest™ mAB pharmDx is indicated as an aid in the assessment of breast cancer patients to determine the most appropriate therapy.

HercepTest™ mAB pharmDx Human Epidermal growth factor Receptor 2 (HER2) (Clone DG44) IHC staining of Breast Cancer FFPE sample. Platform: Dako Omnis.





HercepTest™ mAB pharmDx Human Epidermal growth factor Receptor 2 (HER2) (Clone DG44) IHC staining of Gastric Cancer FFPE sample. Platform: Dako Omnis.

**Human Epidermal Growth Factor Receptor 2 Expression in Breast Cancer.**  
HercepTest™ mAB pharmDx is indicated as an aid in the assessment of breast cancer patients to determine the most appropriate therapy.

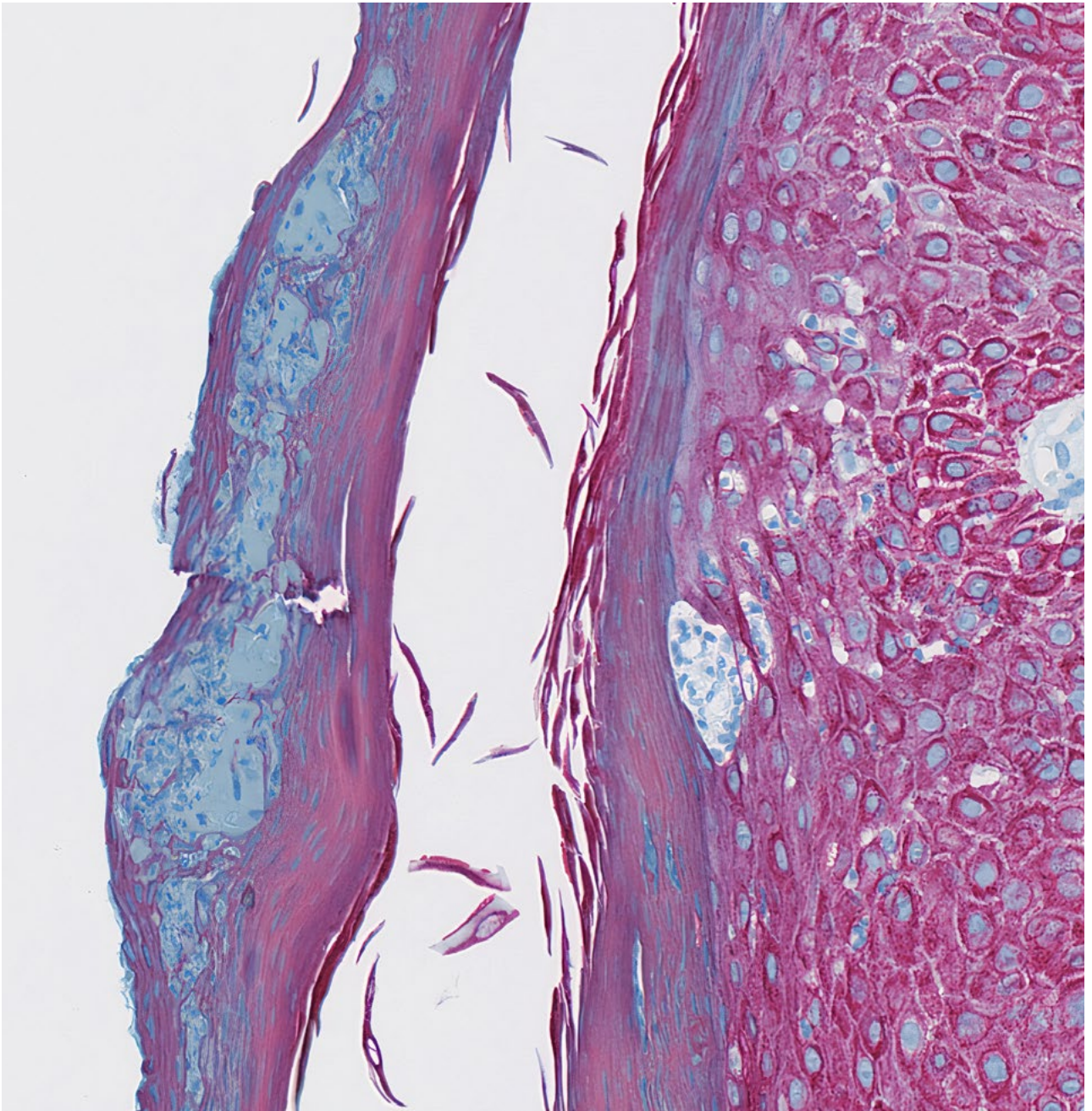


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