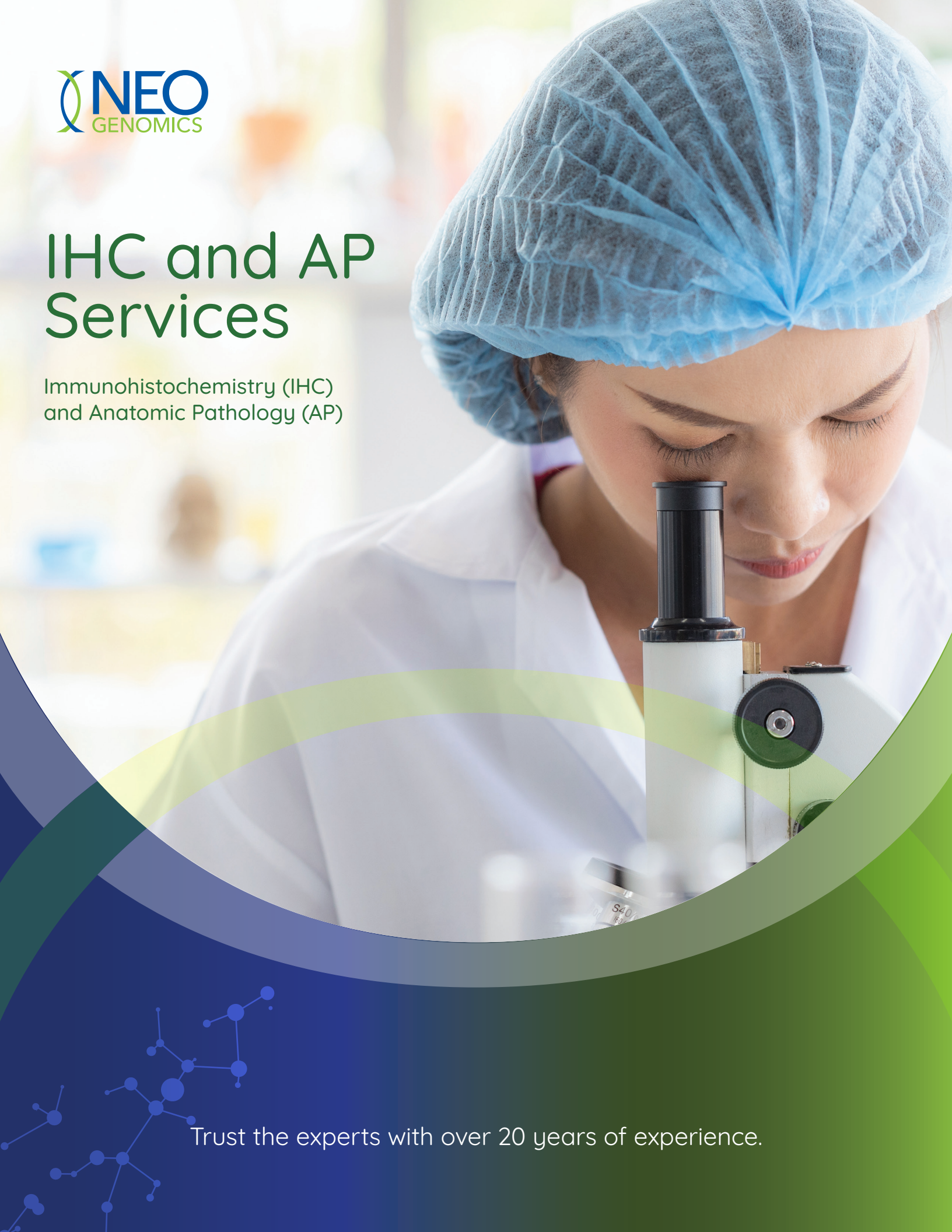




IHC and AP Services

Immunohistochemistry (IHC)
and Anatomic Pathology (AP)



Trust the experts with over 20 years of experience.

Our mission:

Saving lives by improving patient care

Because every sixth death in the world is due to cancer,¹ NeoGenomics strives to partner with pharmaceutical companies to bring new life-saving oncology drugs to market so we can help reduce cancer related deaths worldwide.

>600

projects and clinical trials in the last 5 years

Experience

spanning >25 oncology indications, including solid tumors, hematologic malignancies, and rare cancers

Supported the development of therapies that benefitted

>30,000

cancer patients globally in 2024

120+

oncology specialists, including MDs, PhDs and bioinformatician

>60 regulatory submissions for oncology therapies worldwide, with a

100%
approval rate

>270

validated IHC assays

Our unique and comprehensive product and service offerings include:

- Unparalleled expertise, flexibility, and scalability
- One unified lab with comprehensive services
- Largest oncology-focused clinical research organization (CRO) in the USA
- Medical and scientific consultation



IHC, CISH

Tissue-based view of tumors

Our vast experience in clinical-grade anatomic pathology (AP) services includes comprehensive histology services, a full IHC menu and image analysis/digital pathology capabilities to support oncology and inflammatory diseases. With decades of experience developing and implementing leading-edge tests to service the pharma, oncology, pathology and research communities, our AP services are capable of delivering results for any project scope.

Our AP services include:

- High-quality, tailored solutions for a wide range of image analysis requirements.
- Pathology + technology expertise built on decades of experience and industry leadership.
- Platform-agnostic, customizable qualitative and quantitative image analysis to support your companion diagnostic (CDx), clinical trials or development needs—delivered with rigorous, industry-leading quality standards.
- Histology (processing, embedding and microtomy), which services many downstream modalities, including FISH, MultiOmyx™/PhenolImager™ and molecular.
- Custom IHC/chromogenic in situ hybridization (CISH) development, validation and testing.
- Expert (relevant) pathologist evaluation criteria and reportable format development incorporating evaluation by a sub-specialized pathology team.
- >300 validated IHC/CISH stains across our Clinical and Pharma divisions.
- Multiple platforms for technology-agnostic development of optimal stain quality or downstream partnering with an in vitro diagnostics (IVD) partner of choice.



Anatomic pathology technologies

Capabilities and platforms

TECHNOLOGIES	CAPABILITIES	PLATFORMS
IHC/ISH	• > 2,500 IHC/ISH stains per day (in antiviral (U.S.) testing) • > 300 validated IHC assays (in AV testing) • Laboratory-developed test (LDT), IVD, clinical trial assay (CTA) and CDx options	• Dako Link 48 • Dako Omnis • Leica BOND-III/BOND RX • Ventana Benchmark ULTRA
Imaging	• Bright field	• Aperio ScanScope AT
Image analysis	• Cell morphology and cell count • Dot count (ISH) • Whole specimen analysis • Pattern recognition and tissue discrimination • Fully customizable	• Indica HALO • Visiopharm



“We chose to work with NeoGenomics due to their scientific strength, the breadth of the methods they are able to offer, and their flexibility around the customer needs.”

— Associate Director, Translational Medicine

We take an equipment and reagent agnostic approach in order to provide our clients with the highest quality of service by producing the best stain quality for each individual target.

Pharma Services relevant assays

Capabilities and assays

APPLICATIONS/CAPABILITIES	RELEVANT PHARMA IHC ASSAYS
Histology supports AP, FISH, Molecular, and Multiplex modalities	PD-L1 28-8 (Opdivo®)
Custom development and validation of novel biomarkers, fit for purpose and designed to evolve with your program	PD-L1 22C3 (Keytruda®)
Assay transfer, assay development, technical/ exploratory test development, validation, enrollment/screening and investigational use only (IUO)->CDx test development	PD-L1 SP263 (IMFINZI®)
Trial testing: disease diagnosis, prognosis, and confirmation; specific biomarker screening; tumor profiling	PD-L1 SP142 (TECENTRIQ®)
From single-plex IHC/CISH assays to supporting multiplex development	HER2 (HercepTest®, Pathway 4B5)
Qualitative and quantitative scoring and image analysis	MMR panel (Ventana)
Tissue microarray (TMA) screening (prevalence)	FOXP3
	CD3
	CD8
	CD68

Offered in the U.S. and EU

Our IHC staining and image acquisition were recognized for both assay validation and clinical study workflows in Phase I Clinical studies in TAK-981 (first-in-class inhibitor of SUMOylation) drug development and assessment of tumor and skin samples using IHC and HALO® image analysis by Vaishali Shinde, Assoc. Dir, Mol Path (CBID) Takeda; June 10, 2020.

IHC development and validation

Customizable and expandable

PROJECT TYPE	STARTING POINT	DEVELOPMENT	VALIDATION ELEMENTS
Standard LDT/CTA	Customizable	- Development and optimization - Assay transfer (and translation to IVD platform) - Pathologist evaluation criteria development/reportable format(s)	- Accuracy; clinical sensitivity, clinical specificity - Precision (repeatability intra-run replicates; reproducibility (inter-run replicates) (includes inter-operator and inter-instrument) - Antigen and reagent stability (optional)
De novo assay development and validation Usually for early phase intended use Can be amended per indication for screening/enrollment intended use	- Clone not specified - Platform not specified	- Down select/screen antibody clones - Staining platform comparison/evaluation - TMA screen for prevalence prior to validation phase — optional, per indication - Pan-tumor/multiple indications for early phase	- Accuracy; clinical sensitivity, clinical specificity - Precision (repeatability intra-run replicates; reproducibility (inter-run replicates) (includes inter-operator and inter-instrument) - Antigen and reagent stability (optional)
Assay development and validation Usually for early phase intended use Can be amended per indication for screening/enrollment intended use	- Proprietary clone - Platform not specified	- Development and optimization - Staining platform comparison/evaluation - Antibody characterization (peptide competition) - TMA screen for prevalence prior to validation phase — optional, per indication - Pan-tumor/multiple indications for early phase	- Accuracy; clinical sensitivity, clinical specificity - Precision (repeatability intra-run replicates; reproducibility (inter-run replicates) (includes inter-operator and inter-instrument) - Antigen and reagent stability (optional)
Technical Study/Amendment	CTA for early phase	- Addition of indications to existing validated test for exploratory/research use - Abbreviated validation for early phase or pre-phase research/exploratory use	Research/Exploratory use
Assay transfer and validation: support for all study phases – leading up to prospective screening for enrollment with CDx pathway	- Research use only (RUO) investigational use only (IUO) - IVD manufacturer collaboration	- Assay confirmation (sponsor assay) - Translate to IVD platform (if developed on Rx platform) - Antibody characterization (peptide competition) - Utilize all IVD partner-specific reagents - Develop pathologist criteria, reportable format(s) and training program	- Same as above with expanded precision testing - Multiple indications - Emphasis on potential cut-off during precision testing

Validation expansion

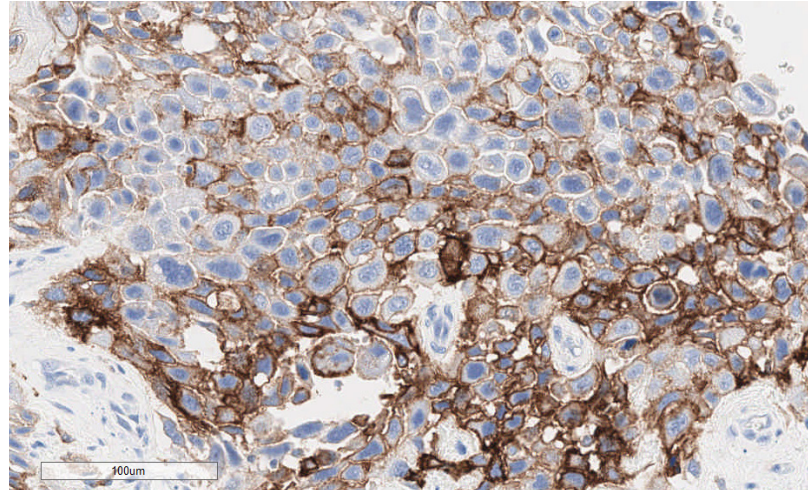
- For use in determining enrollment status, the assay is validated with an emphasis on the cutoff point during precision testing per indication.
 - Additional specimens, per indication, may need to be screened, depending on the prevalence of expression at the cutoff.
 - Additional specimens per indication at the cutoff
- Antigen Stability: real-time and/or accelerated
- Peptide competition
- Inter- and/or intra-pathologist concordance
- Pathologist training program and certification
- Inter-lot reproducibility
- Inter-lab reproducibility
- Reagent stability: real-time and/or accelerated
- Instructions for use (IFU) drafting for submissions

Assay transfer

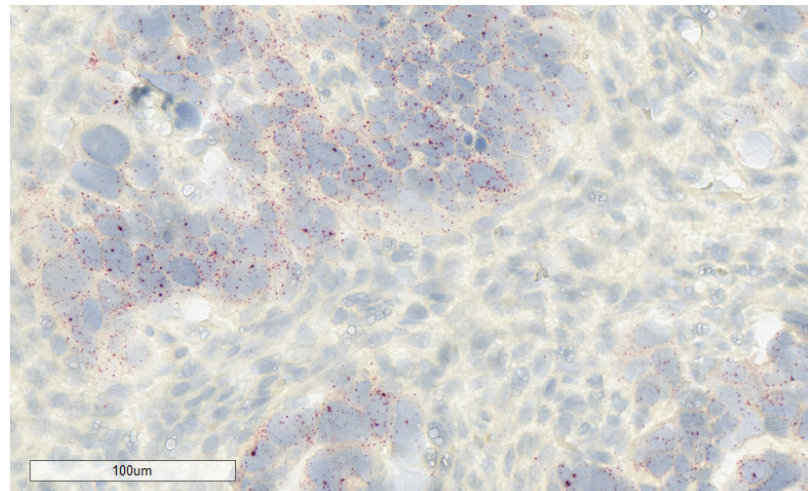
- Sponsor-developed assays may require:
 - Assay Translation to an IVD version of the staining platform (i.e., Bond RX > Bond III; Ventana Discovery > Ventana Benchmark).
 - Assay Confirmation to ensure no additional adjustments are necessary prior to initiating the validation phase.
 - Confirmation of pathologist evaluation criteria and reportable format(s) per indication and per subcellular compartment and cell type.

Technical studies for research use

- Addition of indications for research/exploratory use—precision testing can be optional for added indications.
- Prevalence testing: transcription mediated amplification (TMA) screening to estimate prevalence prior to validation phase, but subsequent to assay development approval.
- CTAs, where one or more elements of validation are not performed at NeoGenomics, under sponsor direction; in some cases, these may also be used for prospective patient screening.



PD-L1 tumor positive IHC stain



RNAScope Tumor Staining

IHC menu

Assays available

- AAT
- AFP (Alpha-1-fetoprotein)
- ACTH (Adrenocorticotropin Hormone)
- Adenovirus
- AE1/AE3
- ALK (D5F3) CDx (Lung Ca)
- ALK-1(for Lymphoma cases)
- Amyloid A
- Amyloid P
- Annexin A1
- AR (Androgen Receptor)
- Arginase 1
- ATRX
- B72.3 (TAG-72)
- BAP1
- BCL1/Cyclin D1
- BCL10
- BCL2
- BCL-6
- BCMA
- BerEP4
- Beta Catenin
- BOB1
- BRAF V600E
- BRCA1
- Breast Triple Stain
- BRG1 (SMARCA4)
- CA125
- CA19.9
- Calcitonin
- Caldesmon
- Calponin
- Calretinin

- | | | |
|-------------------------------|--------------|--|
| • Carbonic Anhydrase IX (CA9) | • CD20 | • CD5 |
| • Carcinoma Micromets | • CD21 | • CD56 |
| • CD10 | • CD22 | • CD57 |
| • CD103 | • CD23 | • CD61 |
| • CD117 (c-kit) | • CD25 | • CD68 |
| • CD11c | • CD3 | • CD7 |
| • CD123 | • CD30 | • CD71 |
| • CD138 | • CD31 | • CD79a |
| • CD14 | • CD33 | • CD8 |
| • CD15 | • CD34 | • CD99 |
| • CD163 | • CD35 | • CDK4 |
| • CD19 | • CD38 | • CDX2 |
| • CD1a | • CD4 | • CEA Mono (Carcinoembryonic Antigen (Mono)) |
| • CD2 | • CD42B | • CEA Poly (Carcinoembryonic Antigen (Poly)) |
| | • CD43 | • Chromogranin A |
| | • CD44 | • CK 17 (Cytokeratin 17) |
| | • CD45 (LCA) | |



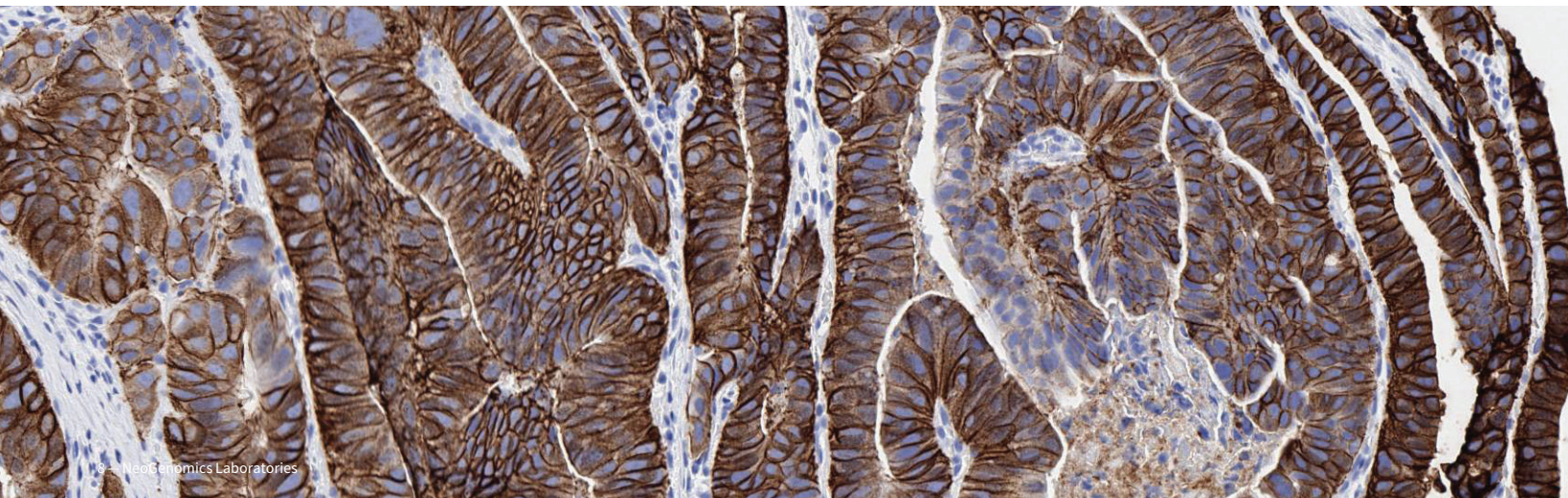
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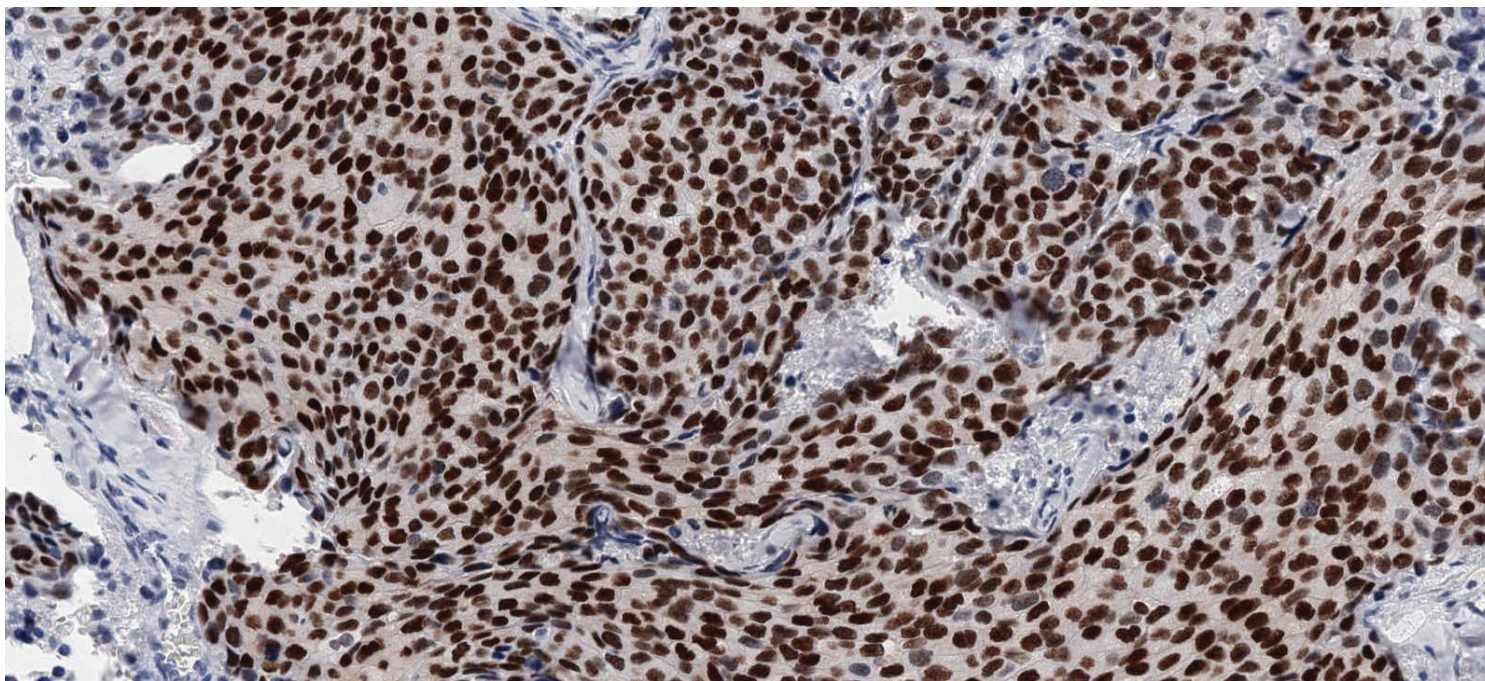
IHC assays, continued

- CK 5/6 (Cytokeratin 5/6)
- CK OSCAR (Cytokeratin OSCAR)
- CK19 (Cytokeratin 19)
- CK20 (Cytokeratin 20)
- CK7 (Cytokeratin 7)
- Claudin 18 (FDA)
- C-MET
- CMV
- cMyc
- CXCL13
- Cyclin E1
- Cytokeratin - High Molecular Weight (CK HMW)
- D2-40
- DBA.44
- Desmin
- DLL3
- DOG-1
- DPC4
- EBV by IHC
- E-Cadherin
- EMA (Epithelial Membrane Antigen)
- Epidermal Growth Factor Receptor (EGFR)
- ER (Estrogen Receptor (6F11))
- ERG
- Factor VIII-Related Antigen
- Factor XIIIa
- Fli-1
- FOLR1 FDA
- FOXP1
- FOXP3
- FSH (Follicle Stimulating Hormone)
- Galectin-3
- Gastrin
- GATA3
- GCDFP15 (Gross Cystic Disease Fluid Protein)
- GCET1
- GFAP (Glial Fibrillary Acidic Protein)
- GH (Growth Hormone)
- GLUT1
- Glutamine Synthetase
- Glycophorin A
- Glypican-3
- Granzyme B
- H3K27me3
- HBME1
- HCG-Beta (Human Chorionic Gonadotropin Beta)
- Helicobacter Pylori
- Hepatitis B Core Antigen
- Hepatitis B Surface Antigen
- HepPar1 (Hepatocyte Specific Antigen)
- Her2 (Hercep Test)
- Her2/neu (PATHWAY) (4B5)
- HGAL
- HHV8 (Human Herpes Virus, Type 8)
- HMB45
- HPL (Human Placental Lactogen)
- HSV I/II (Herpes Simplex 1 and Herpes Simplex 2 Cocktail)
- ICOS
- IDH1
- IgA (Immunoglobulin A)
- IgD (Immunoglobulin D)

Availability is subject to change. For a current listing, please contact a NeoGenomics representative.

HER2 stain





ER stain

IHC assays, continued

- IgG (Immunoglobulin G)
- IgG4 (Immunoglobulin G4)
- IgM (Immunoglobulin M)
- Inhibin
- INI1
- INSM1
- Kappa Light Chain Immunoglobulin by IHC
- Ki-67
- Ki67 NET
- LAG3
- Lambda Light Chain Immunoglobulin by IHC
- Langerin
- LEF1
- LH (Luteinizing Hormone)
- LMO2
- Lysozyme
- MAL
- Mammaglobin
- MDM2
- Melan A (Mart 1)
- Melan A/Ki67
- (Pan-Melanoma + Ki67)
- Melanoma Micromets
- Mesothelin
- MITF
- MLH1
- MMR
- MOC31
- MPO (Myeloperoxidase)
- MSA (Muscle Specific Actin)
- MSH2
- MSH6
- MUC-1
- MUC2
- MUC4
- MUC5
- MUC6
- MUM1
- MyoD1
- Myogenin
- Napsin A
- NeuN
- NF (Neurofilament)
- NKX2.2
- NKX3.1
- NSE (Neuron Specific Enolase)
- OCT2
- OCT4
- Olig2
- P120 Catenin
- P16 (P16INK4A)
- p40
- P501S
- P504S
- P53
- p57
- P63
- pAKT (Phosphorylated AKT)
- Pan-TRK
- Parafibromin

Availability is subject to change. For a current listing, please contact a NeoGenomics representative.

IHC assays, continued

- Parvovirus
- PAX2
- PAX5
- PAX8
- PD1
- PD-L1 SP263 (IVD Kit)
- PD-L1, 22C3 pharmDx FDA (KEYTRUDA® CDx)
- PD-L1, 28-8 pharmDX FDA - for urothelial carcinoma (OPDIVO®)
- PD-L1, E1L3N (Phospho-p44/42)
- PD-L1, SP142FDA - for urothelial carcinoma and NSCLC (TECENTRIQ™)
- PD-L1, SP263FDA - for urothelial CA (IMFINZI™)
- PD-L1 LDT
- Perforin
- pERK (Phospho-p44/42)
- pHistone-H3
- PIT1
- PLAP (Placental Alkaline Phosphatase)
- PMS2
- Pneumocystis Carinii (Jiroveci)
- PRAME
- Progesterone Receptor (PR)
- Prolactin
- Prostate Specific Antigen
- Prostate Triple Stain
- PSAP/HPAP
- PSMA (Prostate Specific Membrane Antigen)
- PTEN
- PTH (Parathyroid Hormone)
- RCC1 (Renal Cell Carcinoma)
- Retinoblastoma Protein (RB)
- ROS1
- S-100
- S100p
- SALL4
- SAT B2
- SF1
- SMA (Smooth Muscle Actin)
- SMMHC (Smooth Muscle Myosin, Heavy Chain)
- Somatostatin
- Somatostatin Receptor, Type 2
- SOX2
- SOX-10
- SOX-11
- Spirochete
- STAT6
- Survivin
- Synaptophysin
- TCL1
- TCR Delta
- TCRbF1
- Terminal Deoxynucleotidyl Transferase (TdT)
- TFE3
- Thrombomodulin {TM}
- Thyroglobulin (TGB)
- TIA1
- TLE1
- Topoisomerase I (TOPO1)
- Toxoplasma
- Tryptase
- TS (Thymidylate Synthase)
- TSH (Thyroid Stimulating Hormone)
- TTF1 (Thyroid Transcription Factor-1)
- Tuberculosis
- Tyrosinase
- Uroplakin II
- Uroplakin III
- Varicella Zoster Virus
- Villin
- Vimentin
- WT1

Availability is subject to change. For a current listing, please contact a NeoGenomics representative.





ISH and CISH menu

- Albumin ISH
- CMV ISH
- EBER
- HPV HR 16/18 CISH
- HPV HR 18 CISH
- HPV LR 10 CISH
- HPV 16 (E6/E7) ISH
- Kappa
- Lambda

Availability is subject to change. For a current listing, please contact a NeoGenomics representative.



About NeoGenomics Pharma Services

NeoGenomics' Pharma Services unifies several innovative companies' scientific and medical leadership under one leading brand, offering one of the most comprehensive laboratory services menu available for biomarker testing supporting oncology clinical trials globally. We provide our clients with an unparalleled level of expertise, service, flexibility, and scalability. Additionally, we offer alternative business models and solutions across the continuum of development, from pre-clinical research and development through commercialization.

Committed to research as the means to improve patient care, we provide Pharma Services for pharmaceutical companies, in vitro diagnostic manufacturers, and academic scientist-clinicians. We promote joint publications with our clients. NeoGenomics welcomes your inquiries for collaborations. Please contact us for more information.

1. Bray F. et al. CA: A Cancer Journal for Clinicians, 74, 229-263

To learn more about NeoGenomics Pharma Services, visit us online at neogenomics.com/pharma-services, call us at 866.776.5907, option 3 or email us at ContactPharma@NeoGenomics.com

NeoGenomics, Inc. is a premier cancer diagnostics company specializing in cancer genetics testing and oncology data solutions. We offer one of the most comprehensive oncology-focused testing menus across the cancer continuum, serving oncologists, pathologists, hospital systems, academic centers, and pharmaceutical firms with innovative diagnostic and predictive testing to help them diagnose and treat cancer. Headquartered in Fort Myers, FL, NeoGenomics operates a network of CAP-accredited and CLIA-certified laboratories for full-service sample processing and analysis services throughout the US and a CAP-accredited full-service, sample-processing laboratory in Cambridge, England, United Kingdom. ©2025 NeoGenomics Laboratories, Inc. All rights reserved.



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