NEOGENOMICS PHARMA SERVICES

PARTNERING WITH PHARMACEUTICAL COMPANIES TO

REDUCE CANCER RELATED DEATHS WORLDWIDE

COMPREHENSIVE SERVICE OVERVIEW
OUR MISSION IS TO HELP
REDUCE CANCER DEATHS ACROSS THE GLOBE.

NEOGENOMICS PHARMA SERVICES

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

As the largest oncology-focused contract research organization (CRO) in the USA, with comprehensive and global one-stop testing and over 17 years of cancer-testing experience, we have one of the most robust, clinically validated oncology diagnostic menus in the world. NeoGenomics Pharma Services takes pride in delivering an unparalleled level of expertise, flexibility, and scalability in our products. Because we are platform-agnostic, we can and will work with you to identify the best approach for your patient population.

You’ll receive our full, dedicated support from pre-clinical testing & research through FDA filing, launch preparation, and commercialization, including:

- Biomarker discovery
- Analytical validation
- Clinical validation
- Custom assay design and development
- Dx/CDx development

>2000 Biomarker projects in development & testing to date

#1 In breast cancer testing* (Data from CMS claims database)

>1500 Completed projects with a backlog of more than $145MM

>120 MDs & PhDs across pathology & scientific disciplines

~1,000,000 Cancer-related tests per year

620+ Oncology & pathology tests ready for order

DISCOVER OUR COMPREHENSIVE PRODUCT & SERVICE OFFERING

- 17 years of experience
- Platform agnostic
- Complete one-stop testing
- Custom assay design
- Global laboratory footprint

*Data from CMS claims database
OUR GLOBAL HEADQUARTERS

& LAB LOCATIONS

1 ALISO VIEJO (ORANGE COUNTY), CA
Anatomic Pathology, Molecular, Multiplexed IP, Flow Cytometry, FISH & Cytogenetics

2 LA JOLLA, CA
Molecular, FISH & Cytogenetics

3 HOUSTON, TX
Anatomic Pathology, Molecular, Immunoassays, FISH & Cytogenetics

4 FT. MYERS, FL
Anatomic Pathology, FISH & Cytogenetics

5 GENEVA, SWITZERLAND
Anatomic Pathology, Molecular*, Flow Cytometry, Immunoassays, FISH & Cytogenetics

6 SINGAPORE
Anatomic Pathology, Flow Cytometry, Molecular*, FISH & Cytogenetics

7 CHINA
Anatomic Pathology*, Molecular*, Flow Cytometry*, Immunoassays*, FISH & Cytogenetics*

* Through Collaborations
NeoGenomics provides one of the largest oncology diagnostic menus in the world, with dozens of new tests and testing enhancements added each year. We also run a wide variety of clinically validated FDA approved assays. If you don’t see a test you need, let us know and we’ll develop it for you.

Contact Us: Pharmaservices@neogenomics.com
Our comprehensive molecular menu of 160+ validated assays allows for direct use in your project, and spans from liquid biopsies (cfDNA/RNA), next-generation sequencing, Sanger sequencing, NanoString, qPCR and IVD assays. Requiring assays for novel biomarkers? Discuss your needs with our medical and scientific team to ensure that assays are developed to your standards.

**FLOW CYTOMETRY: FOR NOVEL DRUG DEVELOPMENT**

- Highly customized assay design, development and validation
- Global offering
- Rapid development
- Scientific expertise across applications
- Global expertise and offering

We provide flow cytometry services for drug and vaccine development programs at our US, Europe and Asia locations—supporting novel drug development in clinical trials across all therapeutic disciplines.

**ANATOMIC PATHOLOGY, FISH & CYTOGENETICS: LEADING EDGE TESTS**

- Breadth of menu and expertise
- Global offering
- IHC/ISH, with >350 validated IHC stains
- CDx regulatory expertise
- Imaging and Image Analysis

Our vast experience in clinical grade anatomic pathology (AP) services includes comprehensive histology services, a full immunohistochemistry (IHC) menu and image analysis/digital pathology capabilities to support oncology and inflammatory diseases. Our FISH portfolio includes single and multi-marker disease-focused panels covering hematologic diseases and solid tumor applications. With decades of experience developing and implementing leading-edge tests to service the pharma, oncology, pathology and research communities, our AP and FISH services are capable of delivering results for any project scope.

**MULTIPLEXED IMMUNOFLUORESCENCE: A COMPLETE VIEW OF TUMOR BEHAVIOR**

- Medical, scientific, & bioinformatics consultation
- Custom panel design with up to 60 markers from one FFPE slide
- Proprietary stand-out technology
- Comprehensive Immunophenotyping of protein and DNA/RNA biomarkers
- Advanced spatial single-cell level data analysis

Utilizing deep learning and advanced cell classification algorithms, multiplexed immunofluorescence spatial analysis uncovers complex interplay between multitudes of immuno-oncology biomarkers, and provides complete analysis of the tumor microenvironment. Offering comprehensive quantitative immunophenotyping from a single slide, our unique, proprietary MultiOmyx™ technology studies up to 60 biomarkers in a single tumor slice. It also uncovers the relationship between markers which could yield new insights and a more complete picture of tumor behavior.

**MOLECULAR: 160+ VALIDATED ASSAYS, READY FOR DIRECT USE**

- Custom assay and pipeline development and validation
- Solid tumor liquid biopsy by NGS
- Validated targeted NGS panels for clinical trials
- Exploratory applications: WGS, WES and RNAseq

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We offer cytokine testing (single-target ELISA and multiplexed immunoassay) as well as detection of soluble markers such as growth factors in serum, plasma and other matrices as needed. Platforms include Tecan and Luminex, and supporting applications include Immuno-oncology (IO) and Infectious diseases (ID), vaccines, autoimmune diseases and inflammation. We can manage the transfer of novel or other technologies from partners, custom assay development/optimization and validations.
As the largest oncology reference laboratory in the USA, NeoGenomics is an ideal partner for companion diagnostic CDx development. Our team of scientists, pathologists and regulatory experts take assays from preclinical stages through approval and commercialization to ensure day one support for the launch of your drug.

We can transition assays on our menu to Clinical Trial Assay (CTA) grade in support of early clinical trials or can accommodate assay transfer or de novo assay development—allowing for the flexibility and scalability you need for your clinical trial. We work with the majority of FDA cleared companion diagnostic devices (in vitro and imaging tools) for convenient and fast CDx transfers and validations, and offer several FDA approved and FDA cleared assays for research and clinical use.

CDx DEVELOPMENT, SUPPORT & SERVICES

THE FOUR C’S

We collaborate with other testing solution companies to create robust scientific solutions, from nanoString IO360 collaboration to CDx commercialization to pathology resources and more—all to deliver more effective drugs for those in need.

CONSULTATION
- Platform and technology selection
- Study Design
- Regulatory support and submission
- Bioinformatics
- Commercial Strategy

CUSTOMIZATION
- Assay design & requirements
- Assay development transfer and validation
- Global harmonization
- Clinical trial testing: Phase 1 - 3
- Project Management
- Data Management

COMMERCIALIZATION
- IVD Partnerships
- Single-site FDA approved test
- USA commercial launch
- Partnerships for Ex-US launch
- Day One Launch Program
- Sponsored testing program

CONSOLIDATION
- Consolidate diagnostic, CDx, and specialty testing with one laboratory

KEY PARTNERS & COLLABORATORS

We work with the majority of FDA cleared companion diagnostic devices (in vitro and imaging tools) for convenient and fast CDx transfers and validations, and offer several FDA approved and FDA cleared assays for research and clinical use.
ONCOLOGY DATA SERVICES

NEOGENOMICS PHARMA SERVICES

We offer actionable insights to guide your therapeutic product development, speed up clinical trial recruitment, improve biomarker testing and accelerate access to targeted therapies.

NeoGenomics oncology data services empower cancer researchers as well as pharmaceutical and biotech companies with access to best-in-class real-world data to accelerate personalized oncology care.

OUR PRODUCTS & SERVICES

CAN HELP ADVANCE YOUR TRIALS

NeoGenomics is a premier cancer diagnostics and pharma services company that provides innovative diagnostic, prognostic and predictive testing with uncompromising quality, exceptional service and innovative solutions—all to help save lives by improving patient care.

EXAMPLE USE CASES

OF REAL-WORLD DATA:

- Genomics/translational medicine
- Identify complex biomarkers
- Study optimization
- Patient and site selection
- Profile patient cohorts
NeoGenomics Laboratories is a specialized oncology reference laboratory providing the latest technologies, testing, partnership opportunities, and interactive education to the oncology and pathology communities. We offer the complete spectrum of diagnostic services in molecular testing, FISH, cytogenetics, flow cytometry, and immunohistochemistry through our nation-wide network of CAP-accredited, CLIA-certified laboratories. 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 client physicians. NeoGenomics welcomes your inquiries for collaborations. Please contact us for more information.