

# Service Guide

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### **About NeoGenomics**

### Who we are

NeoGenomics is a leading provider of cancer-focused genetic testing services in the United States, providing excellence in diagnostic, prognostic, and predictive testing. Our state-of-the-art facilities are located across the U.S., including our corporate headquarters in Fort Myers, Florida. NeoGenomics offers our expertise in the following technologies: Fluorescence In Situ Hybridization, Flow Cytometry, Molecular Genetics, Cytogenetics, Pathology, and Immunohistochemistry.

### Our mission

We save lives by improving patient care.

#### Our vision

We are becoming the world's leading provider of comprehensive cancer testing, data and solutions through uncompromising quality, exceptional customer experience, and innovative products and services.

### Our values

- Quality
- Integrity
- Accountability
- Teamwork
- Innovation

### Our quality program

NeoGenomics Laboratories strives to consistently meet or exceed customer satisfaction and service requirements by continually improving its processes for the benefit of the cancer patient. That is, we save lives by improving patient care. While quality is the shared responsibility of all employees, the Quality department supports the organization by implementing and monitoring the Quality Management System (QMS). The Quality team is responsible for maintaining and communicating metrics, including Voice of the Customer (VOC), managing document control, proficiency testing, and nonconforming event processes. Quality works extensively with the business to identify and implement process improvements and performs internal audits to verify that processes meet requirements.

At NeoGenomics Laboratories, Inc. ("NeoGenomics"), we are committed to full compliance with all applicable federal and state laws and regulations, third party payer requirements, and industry best practices. To that end, and consistent with recommendations of the Office of the Inspector General ("OIG") for the U.S. Department of Health and Human Services Compliance Program Guidance for Clinical Laboratories, the purpose of this annual letter is to inform you about certain important laboratory practices and the regulations governing them.

### **Medical Director Clinical Support**

For laboratory testing questions, we encourage you to contact NeoGenomics' Client Services department for assistance with any concerns that may arise. Our medical team members are also available for professional consultation on global tests performed (testing inclusive of technical component ("TC" or "Tech-Only") and professional component ("PC")). Questions regarding Tech-Only testing should be directed to our Client Services department, as our medical team members are unable to provide professional consultation on Tech-Only cases. Contact information for our assigned Medical Directors for each of our major laboratory facilities and other important contact information is listed below for your convenience:

- Arizona (Phoenix) Medical Director: Viera Nelson, M.D. 949.445.7300, ext. 5707
- California (Aliso Viejo) Medical Director: Vladislav Chizhevsky, M.D. 949.445.7300, ext. 3289
- California (Fresno) Medical Director: Maya Thangavelu, Ph.D. 949.445.7300, ext. 2620
- California (Carlsbad) Medical Director: Yin Xu, M.D. Ph.D. 949.445.7300, ext. 5142
- California (La Jolla): Medical Director: Thanh Ho, M.D. 949.445.7300, ext. 5046
- Florida (Fort Myers) Medical Director: Anahit Nowrouzi, M.D. 239.258.2528
- Florida (Tampa/Temple Terrace) Lab Director: John McGill, Ph.D. 239.768.0600, ext. 2311
- Georgia (Atlanta) Medical Director: Yin Xu, M.D. Ph.D. 949.445-7300, ext. 5142
- Illinois (Chicago) Medical Director: Anahit Nowrouzi, M.D. 239.768-0600 ext 2364
- North Carolina (Durham) Medical Director: Nathan Montgomery, M.D., Ph.D. 919.679-2815
- Tennessee (Nashville) Medical Director: Christopher Mixon, M.D. 615.574.6090
- Texas (Houston) Medical Director: Tricia Peters, M.D. 713.528.4363, ext. 6424
- Billing: 866.776.5907, ext. 2
- Client Services: 866.776.5907, ext. 3

### **Medical Necessity**

Consistent with coverage requirements issued by the Centers for Medicare and Medicaid Services ("CMS"), we require a completed laboratory test requisition form with each specimen submitted to us for testing that includes a diagnosis from the licensed ordering physician supporting medical necessity before we can perform a laboratory test. CMS also requires a signed physician order be maintained in the patient record for each test ordered or the signature of the ordering physician/pathologist on the test requisition form attesting to the medical necessity of each test, or panel of tests ordered. While NeoGenomics does not accept standing orders or custom profiles, our requisitions have been designed in a manner to allow clients the ability to order the combination of testing that is medically necessary for each patient's specific diagnosis or condition. When ordering panels of testing, clients should ensure that all components of the panel are medically necessary for the specific patient's diagnosis and if not, individual tests or a less inclusive panel that do meet medical necessity should be ordered. Components of all panels can be found on the NeoGenomics website. NeoGenomics Laboratories Florida NeoGenomics Laboratories California www.neogenomics.com 9490 Neogenomics Wy 31 Columbia T: 866.776.5907 Fort Myers, FL 33912 Aliso Viejo, CA 92656 F: 239.690.4237. It is important to note that the OIG takes the position that physicians and other authorized individuals who order medically unnecessary tests or who knowingly causes a false claim to be submitted to any federally funded program may be subject to sanctions or remedies available under civil, criminal and administrative law.

CMS has also developed specific National Coverage Determinations ("NCDs") for certain laboratory tests, which can be accessed on the CMS website. Further, CMS' Medicare Access Contractors ("MACs") and fiscal intermediaries have published Local Coverage Determinations ("LCD") for certain laboratory tests that are specific to a patient's geographic location or jurisdiction. Laboratory tests that do not meet applicable NCD or LCD coverage requirements are considered "non-covered tests" and, depending on the circumstances, the patient may be financially responsible. However, in order for the laboratory to bill the patient, Medicare (and other payers) may in certain instances require that a patient sign an Advance Beneficiary Notice ("ABN") informing them of the non-covered status of a test prior to the test being performed. Since we do not interact directly with patients, it is the responsibility of the ordering physician to be familiar with applicable NCD and LCD coverage rules, including ABN requirements, to ensure that informed medical necessity determinations, which take into consideration a patient's financial ability, are made for each patient and are supported by a signed order in the patient's medical record.

### **Requisition Requirements**

Each test requisition form must contain complete patient demographic information including the patient's full legal name, date of birth ("DOB"), gender, hospital status (inpatient/outpatient/nonpatient), and insurance information, if applicable. If there are two insurances (e.g., Medicare and a secondary payer), all insurance information is required for both payers. For all test requisition forms that indicate that we should bill a third-party payer, do also include a copy of the patient's insurance card with each requisition form. Please note that if any required information is missing on a test requisition form, it will likely impact turnaround time for the test results while we gather the missing information.

### **Reflex Tests**

NeoGenomics offers medically necessary reflex testing to facilitate effective and efficient patient care while remaining compliant with state and federal regulations governing the ordering of laboratory tests. A reflexed test is any test that automatically results in the order of one or more secondary tests based on preset criteria applied to the initial test. The secondary tests are almost always an additional charge above the initial test. When ordering a reflexed test, clients are given the ability, on the requisition, to opt-out of the secondary tests when they are not medically necessary for the specific patient and for the specific situation in which the order is placed. Certain reflex testing has been predetermined based on specific criteria accepted as standard-of-care by the medical community. These tests will always reflex because the initial test result is not useful without the reflex test result.

### **Specimen Requirements**

Clients are responsible for submitting specimens which are properly labeled and have two patient identifiers in addition to meeting the submission requirements for all testing requested. For your convenience, specimen requirements may be found in the resources section of our <u>test menu</u>. Please do not send any specimens with biopsy needles, syringes, blades, or any other foreign objects, in the tubes. We are unable to extract tissue from these tubes, which will result in disposal of the foreign objects, which can leave less specimen for processing and can delay turnaround time. If you send two blocks for us to choose from, but do not indicate "select best" on the test requisition form, both blocks will be processed. In such case, you may be charged for duplicate processing and testing if the specimen is being submitted as a client-bill specimen. For TC testing, the client must indicate which block should be used for testing in order to avoid turnaround delays.

### Infectious Disease Testing

NeoGenomics cannot accept Category A infectious substances as defined by IATA (Dangerous Goods Regulations), which include, but not limited to, specimens that may harbor variant Creutzfeldt-Jakob disease (CJD - Mad Cow Disease), variant Creutzfeldt-Jakob disease, or tissue cultures of Mycobacterium Tuberculosis. FFPE, fresh blood or bone marrow specimens, and body fluids are acceptable from patients with tuberculosis. We will attempt to find another qualified testing lab that can pick up and process any infected specimens sent in error. Specimens from other patients received in the same package will be considered potentially contaminated and handled in the same way, regardless of origination. If no options are available, specimens will be disposed as biohazardous waste after client notification. Please refer to <u>IATA Dangerous Goods Regulations</u> for a complete list of Category A Infectious Specimens.

### Medicare Reimbursement Fee Schedules

Medicare reimburses laboratory testing services through either the Physician Fee Schedule or the Clinical Lab Fee Schedule, depending on the type of test. If you would like a copy of either of these fee schedules, please refer to the Medicare Fee-for-Service Payment section of CMS's website. Medicaid reimbursement is generally equal to or less than the amount of Medicare reimbursement.

### **Client Billing**

Unless a client indicates that it should be billed on the test requisition form or otherwise has a contract with NeoGenomics providing for a 100% client bill arrangement, we will, whenever possible and permitted by law, directly bill and collect from all insurers. One notable exception to this policy is that we must bill hospital clients for certain technical component services for Medicare or payers following Medicare guidelines on in-patients and some out-patients. Additionally, NeoGenomics is required to bill Medicare for certain molecular tests ordered for hospital outpatients. You can find detailed information about these topics on our <u>Client Billing website</u>.

### **Patient Billing**

Clients are advised that patients will receive invoices from NeoGenomics in certain situations. Although, we are an "in-network" or contracted laboratory services provider with over 225 national and regional third party payers, there are certain plans with which we do not have a contract ("out-of-network"). If we are an out-of-network laboratory with a payer and the payer makes payment directly to a patient for the lab services we perform, we must invoice the patient for such services to obtain payment. In addition, in situations in which we are an in-network provider with a patient's insurance company or government payer such as Medicare, we are contractually obligated to invoice patients for any co-payment, co-insurance or deductible that a payer determines is the patient's responsibility. Some payers for which we are an in-network laboratory may also deny payment for certain tests that we offer including, but not limited to, some of our newer and more expensive molecular profile panels, because they have not yet established reimbursement for such services or have otherwise determined that they are "non-covered services." If after adjudication the patient's insurance plan dictates so, we are legally required to make good faith efforts to collect on any amounts due directly from the patients. Although we may offer discounts and/or payment plans to patients in accordance with applicable law, many patients are concerned about the expense of such tests. As stated previously, it is the responsibility of the treating physician to inform each patient of any tests that may not be covered by their insurance and, for Medicare patients, to ask that they sign an ABN in limited circumstances as warranted. This allows each patient to make informed decisions on their care with full knowledge of the financial responsibility they may incur. You can find more information on our Patient Billing website.

Thank you for your attention in these important matters of mutual concern. To the extent you have questions, please feel free to contact our Compliance & Ethics Department at 239-768-0600 or compliance@neogenomics.com

### Licensing and Regulatory

NeoGenomics is licensed under the Clinical Laboratory Improvement Amendment of 1988 ("CLIA") and is authorized to provide diagnostic laboratory services in the states of Florida, California, New York, Rhode Island, Pennsylvania and Maryland. In addition, NeoGenomics is both a Medicare and Medicaid provider.

For any compliance or licensing issues please do not hesitate to contact NeoGenomics at 866.776.5907.

To view all licenses please visit our website at: neogenomics.com/company/regulatory-and-licensing

### **Client Services**

At NeoGenomics, we care deeply about our clients' patients. This is why we provide every client with a dedicated Client Services Advocate. In order to provide the highest level of customer service, Client Service Advocates are trained to answer questions regarding test information, specimen requirements, turnaround times, test add-on, and patient results. Client Services Advocates may also direct calls immediately to a technical or medical expert as necessary or requested. Clients may contact the lab directly at the contact information listed below.

- 24/7 provider resource for inquiries on all Neo products and services related questions, and to assist getting providers the support they need from our expert medical and technical staff.
- The Client Services team is structured to provide personalized care to each client account.
- Our team is structured so that each advocate has their own list of accounts that they handle cases on remediation for daily.
- To help expedite the testing results, CS contacts clients within hours of specimen receipt to capture missing information or order clarification.
- Additionally, each advocate is placed in a "regional pod" with other advocates supporting clients in the same geographic region of the country. In most cases these advocates sit next to each other and coordinate their activities to support each other's client lists as needed.

### **Solid Tissue Acquisition**

CS works to obtain patient biopsies for solid tissue testing when it is being held by a 3rd Party.

#### **Medical Records**

CS coordinates all medical records requests following patient privacy regulations.

#### **Outreach Support**

• Outreach specialists provide communication to sales and clients on solid tumor tissue testing QNS/TNP to explore additional steps needed to get a patient a timely result.

### **Client Services**

#### **Client Services**

**Telephone:** 866.776.5907, option 3

**Fax:** 239.690.4237

Email: <u>client.services@neogenomics.com</u>

Hours of Operation: Monday - Friday: 7:00 a.m. - 9:00 p.m. Eastern

Saturday: 7:00 a.m. - 7:30 p.m. Eastern

**After Hours:** After normal business hours, 7 days per week

### Specimen Pick-Up and Couriers

**Telephone:** 866.776.5907, option 1

Hours of Operation: 24 hours per day, 7 days per week

### **Client Billing Services**

**Telephone:** 888.690.0043

Hours of Operation: Monday - Friday 8:00 a.m. - 7:00 p.m.

Eastern

Fax: 888.443.4153

**Email:** <u>avclientbilling@neogenomics.com</u>

### **Patient Billing Services**

**Telephone:** 866.776.5907, option 2

Fax: 239.690.4236

Email: billingpatient@neogenomics.com

## **Laboratory Locations**

### Fort Myers, Florida

9490 NeoGenomics Way Fort Myers, FL 33912 Telephone: 239.768.0600 Fax: 239.690.4237

#### Carlsbad, California

2173 Salk Ave. Suite 300 Carlsbad, CA 92008 Phone: 800.755.1605 Fax: 888.755.1604

### Nashville, Tennessee

618 Grassmere Park Drive, Unit 20 Nashville, TN 37211 Phone: 615.574.6090 Fax: 615.574.6094

### Chicago, Illinois

18660 Graphics Dr., Suite 201 Tinley Park, IL 60477

### Tampa, Florida

13005 N. Telecom Parkway, Suite 104 Temple Terrace, FL 33637 Phone: 239.768.0600

### San Diego, California

4570 Executive Dr., 2nd Floor San Diego, CA 92121 Phone: 800.755.1605

### Houston, Texas

7256 S. Sam Houston Pkwy W., Suite 300 Houston, TX 77085 Phone: 239.768.0600

### **RTP**

8 Davis Drive, Suite 120 Durham, NC 27709

### Aliso Viejo, California

31 Columbia Aliso Viejo, CA 92618 Phone: 239.768.0600

### Fresno, California

5 E River Park Place, Suite 102 Fresno, CA 93720

### Atlanta, Georgia

29 Upper Riverdale Road, Suite 140 Riverdale, GA 30274 Phone: 239.768.0600

### Cambridge, UK

Babraham Research Campus, Babraham Cambridge, CB22 3FH UK

### **NeoLINK®**

NeoLINK®, our web-based Laboratory Information System, offers the convenience, efficiency, and the flexibility to order testing and access results any time through a secure internet connection. Our system is designed to decrease paperwork while facilitating workflow by providing digital means of on-demand access to test menus, results, and testing progress. NeoLINK has been developed in collaboration with medical specialists to provide convenient, easy-to-use features.

### Features and Benefits

### Test ordering

- Online ordering capabilities are quick and efficient
- Add-on testing availability at your fingertips
- Real time tracking of specimen workflow and results
- Worklist management
- Powerful data mining/searching capabilities

### Access to same-patient historical reports

- Online test menu access
- 24/7 access via secure internet connection
- Email notification when cases are ready for review

### **Tech-only features**

- Client logo on tech-only report templates
- Custom electronic signatures
- Report customization with optional features case by case
- Customized macros created and stored within NeoLINK by individual or group
- On-demand re-gating for flow cytometry
- Flexible FISH image viewing filtered by color or combined

### **Collaboration**

- Simultaneous user access from multiple locations
- Add clinical notes for review and discussion within a group practice
- Help Desk assistance
- System training available

### NeoLINK, HL7®, and NeoGenomics

Health Level Seven (HL7) provides a comprehensive framework and related standards for the exchange, integration, sharing, and retrieval of electronic health information that supports clinical practice and the management, delivery and evaluation of health services.

At NeoGenomics Laboratories, we possess the ability to receive and send HL7 messages to support your order and result workflows. This allows for you to automate ordering workflows from your Electronic Health Record system or Laboratory Information System to NeoGenomics as well as automating result workflows from NeoGenomics back to your Electronic Health Record system or Laboratory Information System. NeoGenomics offers electronic ordering and resulting in a variety of message formats or file formats such as HL7 2.X, HL7 FHIR, JSON, XML, CSV, or just providing a PDF report to a secure shared drive. These data formats can be transacted through a myriad of connectivity options that suit your needs. We are able to support, but are not limited to, the following secure connection methods: SFTP, site-to-site VPN tunnels, and HTTPS.

For more information on NeoLINK please contact your local Territory Business Manager.

### **NeoUniversity®**

Accelerate your professional development with our on-demand learning portal. Acquire new skills and understanding of oncology-focused test methodologies through pre-recorded lectures, preparation for professional component case sign-out, and training assessment exams.

### Learn more about:

- Cytogenetics
- FISH (interpretation)
- Flow Cytometry (regating & 10-color)
- Digital Image Analysis with IHC
- Molecular Diagnostics

### **On-demand Training**

Our On-Demand Training provides self-paced learning modules to help you and your organization stay up-to-date with the latest advancements in pathology and oncology laboratory diagnostics. View courses on service demonstrations, FISH signal interpretive training, new assays and technologies, and complete Training Assessments to test your knowledge. Certificates of training completion PDF files are automatically emailed after assessments are successfully completed. NeoUniversity now has improved functionality for searching and selecting content, navigating on mobile devices, and tracking completed coursework.

### Registration

You can sign up for and access NeoUniversity On-Demand Training at training.neogenomics.com. Please allow up to 24 hours to process a new registration request.

### **Patient Services**

### Clinical Trials Matching

Through our partnerships, we evaluate results and provide clinical trial options that your patient may be eligible for. Based on our NeoGenomics test results, our clinical trials matching team will reach out to inform you of potential trials and eligibility for your patients.

### Testing and Cancer Education

Our patient resources are designed to provide meaningful information for your patients based on where they are in their cancer journey.

### Peer-peer Support and Cancer Group Support

Through our broad network of partners, we connect your patients with peer-to-peer support and other cancer support groups based on individual needs.

### In Home Blood Draws and Site Draws

Scheduling and specimen retrieval based on the patients' needs to support testing ordered.

### **Care Navigation**

Support in obtaining diagnostic testing, reducing barriers to your patient's care.

### **Financial Assistance Programs**

Our dedicated team is here to support your patient. We offer prompt pay discounts, no interest payment plans, sponsored testing programs and more.

### **Sponsored Testing Programs**

We work with industry partners to create pathways to emerging advances in personalized medicine. These programs create awareness and access to reduced or no-cost testing for qualified patients.

### Comprehensive Payor Coverage

We are a participating provider with Medicare, Medicaid, in addition to a large number of private insurance and managed care organizations. We accept assignments on all insurance payers.

### **Billing Services**

Our Billing Department serves clients, patients, and third party payers, including Medicare and Medicaid. In this section you will find detailed information on:

- Client Billing
- Patient Billing
- Third Party Billing (Managed Care, Medicaid, Medicare, Private Insurance)

### For billing questions, please contact our billing team.

### For client billing questions:

Phone: 888.690.0043 Fax: 888.443.4153

Email: avclientbilling@neogenomics.com

Hours of Operation: Monday - Friday 8:00 a.m. - 7:00 p.m. Eastern

### For NeoGenomics patient billing questions:

Phone: 866.776.5907, option 2

Fax: 239.690.4236

Email: billingpatient@neogenomics.com

## Client Billing

Clients will be billed by an itemized invoice that includes the date, patient's name, accession number, test(s) performed, and the test fees for each specimen completed during the month. Please note that these invoices are payable upon receipt. If you have any questions pertaining to your account, please notify us immediately so that we may resolve them in a timely manner.

### **Payment Options**

If you receive a bill, there are several options for payment:

### **NeoGenomics invoices**

Make the check or money order payable to NeoGenomics Laboratories, and mail it to:

#### **NeoGenomics Laboratories**

P.O. Box 864403 Orlando, FL 32886-4403

Credit or debit card: You may complete the form on your invoice. Or, to pay by phone, please call us at the number below. A receipt can be mailed to you upon request.

## Patient Billing

NeoGenomics makes billing as flexible as possible by providing many different payment options to our patients and customers. Depending on the arrangement your clinic, hospital, or health insurance plan has with us, your patient may or may not receive a bill directly from NeoGenomics for all or part of the services provided by us. We do our best to obtain reimbursement from insurers without contacting your patient. In certain cases, your patient may also receive an invoice from Clarient Diagnostic Services, a NeoGenomics company.

### Some of the circumstances that can result in your patient receiving a bill from us are:

- Your patient has non-government insurance and are responsible for a co-payment, co-insurance, deductible, and/or non-covered services.
- Your patient has Medicare and are responsible for 20% of the amount Medicare has set as the cost of the test.
- Your patient has Medicare and have signed an ABN (advanced beneficiary notice). In this case, your patient may
  owe the difference between what Medicare paid and what they have set as the cost of the test.

### **Payment Options**

If your patient receives a bill, there are several options for payment:

#### **NeoGenomics invoices**

Make the check or money order payable to NeoGenomics Laboratories, and mail it to:

#### **NeoGenomics Laboratories**

PO Box 865586 Orlando, FL 32886-5586

Credit or debit card: Your patient may complete the form on your invoice. Or, to pay by phone, please call us at the number below. A receipt can be mailed upon request.

Pay Online: Please visit neogenomics.com/billing/patient-billing

### Please see our website for the following forms:

- Financial Hardship Form (English)
- Financial Hardship Form (Spanish)

For full details, see neogenomics.com/billing/patient-billing

## Third Party Billing

NeoGenomics Laboratories is a participating provider with Medicare and Medicaid, in addition to a large number of private insurance companies and managed care organizations. NeoGenomics accepts assignment on all insurance payers.

### Private Insurance and Managed Care Organizations

As a service to your patients and in compliance with agreements established with insurance and managed care companies, NeoGenomics will bill your patient's primary insurance or managed care organization directly when provided with complete and accurate billing information. For those insurance companies and managed care organizations where an agreement does not exist with NeoGenomics, we will still file a claim to those carriers.

### Medicaid

Medicaid is medical assistance for those people who cannot afford their own health care. Medicaid claims can only be filed after all other third party resources have been exhausted. Patients should be asked at the time of service if there is other coverage, such as Medicare, Medicaid HMO, or private insurance. When applicable, any Medicare, private insurance, or managed care (HMO) information should also be provided. Medicaid is also for persons that have applied for social security disability, but have not met the 18th month waiting period for Medicare eligibility.

If Medicaid denies payment for non-covered services or eligibility reasons, the patient may be responsible for the payment. Medicaid is always the last source of payment.

### Medicare

Medicare continues to reimburse for these procedures based on the members eligibility and plan coverage.

## Specimen Requirements

This section contains logistical details regarding specimen collection and transportation for specimens being sent to NeoGenomics Laboratories. In the following pages we detail specimen requirements, Specimen Transport Kits, orderable kit components, and how to complete a Test Requisition form.

### Specimen Requirements and Handling Procedures

- Specimen requirements and handling procedures General
- Tumor Profiles and Liquid Biopsy Specimen requirements and handling procedures

### Specimen Transport Kits Guide

- General Specimen Transport Kit
- Peripheral Blood Kit
- Bone Marrow Kit
- Bladder FISH Kit
- Liquid Biopsy Kit for InVisionFirst®-Lung
- NeoLAB® Solid Tumor Kit

### Test Requisitions and Shipping Instructions

- Hematopathology requisition (non-New York and New York versions)
- Single Biomarkers and Consults Solid Tumor Pathology requisition (non-New York and New York versions)
- NGS Solid Tumor Pathology requisition
- IHC requisition
- Oncology Office Hematology requisition (non-New York and New York versions)
- Single Biomarkers and Consults Solid Tumor Oncology Office requisition (non-New York and New York versions)
- NGS Solid Tumor Oncology Office requisition (non-New York and New York versions)
- Lung Cancer Oncology Office requisition
- Breast Cancer requisition
- Hereditary Cancer Panel requisition
- InvisionFirst® Lung requisition

## Specimen Requirements and Handling Procedures

The quality of laboratory results is highly dependent upon proper specimen collection and handling. Listed below are specimen requirements and handling procedures for tests performed by NeoGenomics Laboratories.

Specimen Type	Cytogenetics	FISH	Flow Cytometry	Bone Marrow Morphology	IHC	Molecular
Bone Marrow Aspirate*	1-2 mL sodium heparin	1-2 mL sodium heparin EDTA OK if sodium heparin not available FISH Non-PCE: 0.5- 1 mL single probe,	1-2 mL EDTA Provide CBC report sodium heparin is acceptable lithium Heparin and ACD not acceptable		N/A	2 mL EDTA sodium heparin OK if EDTA not available
Peripheral Blood*	2-5 mL sodium heparin Provide CBC report	1-2 mL panel 1-5 mL sodium heparin EDTA OK if sodium heparin not available FISH Non-PCE: 0.5- 1 mL single probe, 1-2 mL panel	1-2 mL EDTA Provide CBC report sodium heparin is acceptable lithium Heparin and ACD not acceptable	EDTA with 2-3 smears/slides	N/A	5 mL EDTA sodium heparin OK if EDTA not available For Liquid Biopsy requirements, please contact Client Services.
Bone Marrow Core Biopsy and/or Aspirate Clot (10% NBF)*	N/A	N/A	N/A	>1.5 cm core (length) 10x formalin to specimen volume. Additional 2 touch imprints preferred.	1-2 cm core (length) core and clot sent in separate formalin containers	N/A
Fresh Bone Marrow Core Biopsy*	1-2 cm core (length) tissue in RPMI	0.5 cm core (length) tissue in RPMI	1-2 cm core (length) tissue in RPMI	N/A	N/A	1-2 cm core (length) tissue in RPMI
Fresh/Unfixed Tissue*	>0.3 cm <sup>3</sup> in RPMI	0.2 cm <sup>3</sup>	0.5-1 cm³ tissue in RPMI	N/A	N/A	0.5-1 cm <sup>3</sup>
Fluids*	CSF: 1-3 mL All other fluid: 5-10 mL	50-100 mL	50-100 mL	N/A	N/A	50-100 mL
Paraffin Block or Cut Slide* (For cut slides, place sections from only one block on each slide.)	N/A	Suitable only for select assays; see website to confirm. Paraffin block preferred.  Please use positively-charged slides and 10% NBF fixative. Do not use zinc or mercury fixatives (B5).	N/A	N/A  Paraffin blocd preffered or 4-5 micron the sissue section positively chassides, at least slides per an No additives waterbath. Se article** for use and stora recommendate.		Suitable for select assays: see website to confirm. Paraffin block preferred. Please use positively-charged slides and 10% NBF fixative. Do not use zinc or mercury fixatives (B5).
Voided Urine*	N/A	33-60 mL voided urine mixed 2:1 with supplied PreservCyt within 30 minutes of collection for total volume ≥50 mL	N/A	N/A	N/A	N/A
Decalcified Specimens*	N/A	Not acceptable	N/A	Acceptable	Acceptable for bone; inquire for non-bone	Not acceptable

### Storage and Transportation

NeoGenomics cannot accept category A infectious substances as defined by IATA (Dangerous Goods Regulations 3.6.2.1.1 Definition — Infectious Substances), including, but not limited to, specimens that may harbor variant Creutzfeldt-Jakob Disease (mad cow disease), variant Creutzfeldt-Jakob Disease, or microbiologic cultures of Mycobacterium Tuberculosis. FFPE, fresh blood or bone marrow specimens, and body fluids are acceptable from patients with tuberculosis.

<sup>\*</sup> Use cold pack for transport, making sure cold pack is not in direct contact with specimen. For fresh specimens, ship same day as drawn whenever possible. EXCEPTION-For Liquid Biopsy specimens, please contact Client Services for special kit and instructions.

<sup>\*</sup> Refrigerate and use cold pack for transport. For fresh specimens, ship same day as drawn whenever possible.

# Tumor Profiles and Liquid Biopsy Specimen Requirements and Handling Procedures

The quality of laboratory results is highly dependent upon proper specimen collection and handling. Listed below are specimen requirements and handling procedures for Tumor Profiles and Liquid Biopsies.

	Profile	Peripheral Blood	Bone Marrow	FFPE Block or Cut Slides	Fresh Tissue	Storage & Transportation	FFPE Additional Requirements
Heme	Neo Comprehensive™ — Heme Cancers Neo Comprehensive™ — Myeloid Disorders  NeoTYPE® — AITL/Peripheral T-Cell Lymphoma, ALL, AML Prognostic, Discovery Profile for Hematologic Cancers, JMML, Lymphoid Disorders, Lymphoma, MDS/CMML	5 mL in EDTA tube	2 mL in EDTA tube	Paraffin block preferred. Please use positively- charged slides and 10% NBF fixative. Do not use zinc or mercury fixatives (B5).	N/A		Biopsies and other surgical specimens: Minimum of ≥10mm² surface area with ≥20% tumor nuclei*  Cytology cell blocks or FNA FFPE: Minimum ≥500 tumor cellswith ≥20% tumor nuclei* I Available for select tests, see website to confirm before sending - Requisitions must note specimen is FNA - FNA smears, unembedded FNA samples, or cytology cells in suspension are not accepted  FISH and IHC requirements for NeoTYPE® Cancer Profiles:  FISH: 50-100 viable tumor cells per probe set  IHC: The minimum number of viable tumor cells varies between 50-200 depending on the test requested. It is recommended for all IHC testing to submit >200 viable tumor cells.  *10% NBF fixative only, decalcified samples not accepted. The following components of NeoTYPE® Cancer Profiles require ≥40% tumor nuclei: MSI (excluding Colon) if no paired normal is available, and MGMT Promoter Methylation in brain.
	NeoTYPE® CLL	5 mL in EDTA tube	2 mL in EDTA tube	N/A	0.5-1 cm <sup>3</sup> in RPMI	Use cold pack for transport, making	
	NeoTYPE* Follicular Lymphoma	N/A	N/A	Paraffin block preferred. Please use positively- charged slides and 10% NBF fixative. Do not use zinc or mercury fixatives (B5).	N/A	sure cold pack is not in direct contact with specimen. For fresh specimens, ship same day as drawn whenever possible. (See notes below)	
Solid Tumor	Neo Comprehensive™ — Solid Tumor  NeoTYPE® DNA & RNA — Brain, Lung  NeoTYPE® — Breast, Cervical, Colorectal, Endometrial, Esophageal, Gastric, GI Predictive, GIST/Soft Tissue, Head and Neck, HRR, Liposarcoma Fusion, Liver/Biliary, Lung, Melanoma, Other Solid Tumor, Ovarian, Pancreas, Thyroid, Precision	N/A	N/A	Paraffin block preferred. Please use positively- charged slides and 10% NBF fixative. Do not use zinc or mercury fixatives (B5).	N/A		
Liquid Biopsy	NeoLAB® Solid Tumor and InVisionFirst® – Lung	Two x 10 mL Streck Cell-Free DNA BCT® tubes	N/A	N/A	N/A	Do not refrigerate. Special collection tubes and shipping requirements apply. Please contact Client Services for kits and see instructions provided in kit.	N/A

NeoGenomics cannot accept any specimens (fresh or fixed) infected with Category A pathogens including, but not limited to, variant Creutzfeldt-Jakob (mad cow), Tularemia, Brucella, etc. FFPE specimens are acceptable for Tuberculosis only. For full details, see <a href="https://neogenomics.com/client-services/forms-and-kits">https://neogenomics.com/client-services/forms-and-kits</a>.

## Specimen Transport Kits Guide



### **General Specimen Transport Kit** (Large & Small)

Large kit inside dimensions: 7.75" W x 2.5" H x 5.56" L

Small kit inside dimensions: 5.31" W x 2.37" H x 4.37" L

Includes box with foam insert. Kit components must be ordered separately.

#### Available kit components:

- 13" x 18" biohazard bag (50 pack)
- \*6" x 9" biohazard bag, 3 walls with absorbent (50 pack with absorbent)
- \*4" x 6" plain ziplock bag (100 pack)
- \*Refrigerant Pack, 3 oz (approximately 48/box)
- 4 mL sodium heparin green-top tube (10 pack)
- 4 mL K2-EDTA lavender top tube (10 pack)
- \*6 mL sodium heparin green-top tube (100 pack in rack)
- \*6 mL K2-EDTA lavender top tube (100 pack in rack)
- 5-slide slide mailer with 5 slides (10 pack)
- \*5-slide slide mailer, empty (10 pack)
- 40 mL vial with 20 mL fill of 10% NBF (12 pack)
- 40 mL vial with 10 mL fill of 10% NBF (24 histopack)
- 120 mL ClickSeal container, sterile
- PreservCyt vials (10 pack)

\*Commonly ordered with the General Specimen Transport Kit.

We recommend the General Specimen Transport Kit and ordering individual components if you previously used: Neo Heme Basic Kit (small blue kit); HemePlus Kit (small red kit), Neo Solid Tumor Kit (small green kit), Neo FlexKIT (small/large purple kit), NeoSITE BE Kit (gray kit), NeoGenomics IHC Kit (orange kit), NeoGenomics Flow/Cyto Molecular Fresh Kit (blue kit); BE Esophagus FISH Kit.



### Peripheral Blood Kit

Kit inside dimensions: 5.31" W x 2.37" H x 4.37" L

#### Kit components included:

- COMPASS Peripheral Blood Kit with foam insert
- One 6 mL EDTA tube (purple top)
- Two 6 mL sodium heparin tube (green top)
- Slide holder w/ slides (optional)



#### **Bone Marrow Kit**

Kit inside dimensions: 7.75" W x 2.5" H x 5.56" L

Kit components included:

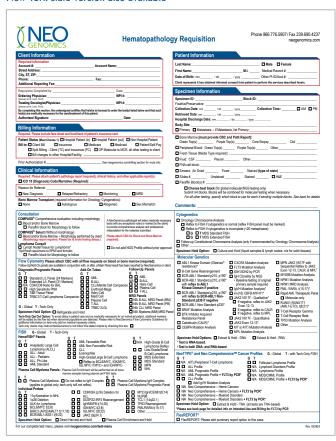
- 1-10 x 10 biohazard bag with pouch
- 2-3 x 4 zip closure bags
- 3-4ml K2 EDTA tubes
- 2-6ml Sodium Heparin tubes
- 1-6ml K2 EDTA tube
- 1-Aqui-Pack 4 bay absorbent pouch
- 2-Five slide-slide mailers with sliders
- 2-10ml fill in 20ml Jar 10% NBF

NeoGenomics supplies are subject to change at any time. Please communicate with your TBM for any new kits/options or kits that may be discontinuing in the near future.

# Hematopathology Requisition and Shipping Instructions

### Requisition

New York state version also available

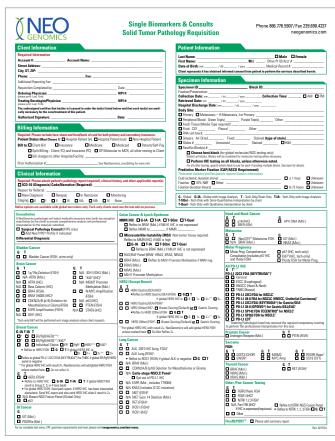


- Complete Hematopathology requisition, making sure all sections are completed in their entirety which includes client, patient, coding, specimen, and billing information sections, reason for referral, and tests requested. Write patient name and DOB on appropriate number of labels provided with the requisition.
- Place a label on each tube, jar and/or slide. (Each label should have a requisition number, patient name, and DOB). A minimum of two patient identifiers is REQUIRED for each specimen.
- Ensure tube tops and/or slide holders are sealed tightly. Place labeled tubes and/or slide holders into foam insert. Ensure formalin jars are sealed tightly. Place labeled formalin jars separately into small biohazard bag before placing into foam cut-out. Ensure the lid of specimen jar is tightened past the "click" to prevent leakage in transit. Place strip of Parafilm around the lid where it meets the jar for additional protection.
- Remove as much air as possible from the biohazard bag and seal it. Place folded test requisition and/or manifest in pocket on side of biohazard bag.
- Place sealed bag with requisition back into box.
- Place cool pack in box, on top of biohazard bag. Do not allow cool pack to be in direct contact with specimen.
- Close box and tuck tabs into place. No tape necessary.

## Single Biomarkers and Consults Solid Tumor Pathology Requisition and Shipping Instructions

### Requisition

New York state version also available

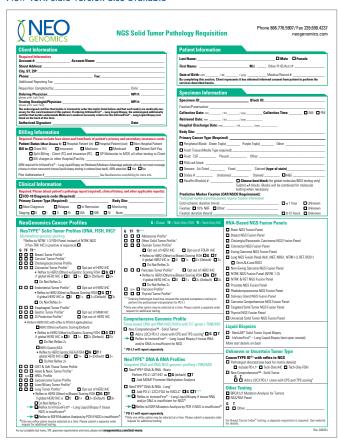


- Complete Single Biomarkers and Consults Solid Tumor requisition, making sure all sections are completed in their
  entirety which includes client, patient, coding, specimen, and billing information sections, reason for referral, and
  tests requested. Write patient name and DOB on appropriate number of labels provided with the requisition.
- Place a label on each slide holder and/or block. (Each label should have a requisition number, patient name, and patient DOB). A minimum of two patient identifiers is REQUIRED for each slide holder and/or block.
- Ensure slide holders are closed and sealed tightly. Ensure block cassettes are protected in gauze or individual small sealed bags. Place slides and/or blocks into foam insert.
- Lift foam insert from box and place into biohazard bag along with absorbent sheet.
- Remove as much air as possible from the biohazard bag and seal it. Place folded test requisition and/or manifest in pocket on side of biohazard bag.
- Place sealed bag with requisition back into box.
- Place cool pack in box, on top of biohazard bag. Do not allow cool pack to be in direct contact with specimen.
- Close box and tuck tabs into place. No tape necessary.

# NGS Solid Tumor Pathology Requisition and Shipping Instructions

### Requisition

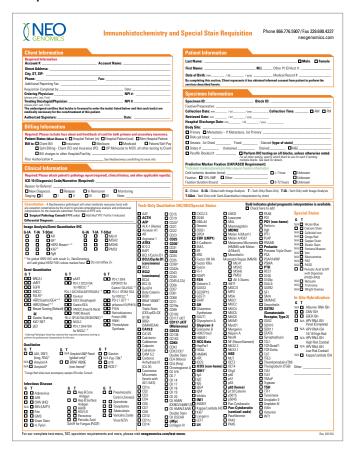
New York state version also available



- Complete NGS Solid Tumor Pathology requisition, making sure all sections are completed in their entirety which includes client, patient, coding, specimen, and billing information sections, reason for referral, and tests requested. Write patient name and DOB on appropriate number of labels provided with the requisition.
- Place a label on each slide holder and/or block. (Each label should have a requisition number, patient name, and patient DOB). A minimum of two patient identifiers is REQUIRED for each slide holder and/or block.
- Ensure slide holders are closed and sealed tightly. Ensure block cassettes are protected in gauze or individual small sealed bags. Place slides and/or blocks into foam insert.
- Lift foam insert from box and place into biohazard bag along with absorbent sheet.
- Remove as much air as possible from the biohazard bag and seal it. Place folded test requisition and/or manifest in pocket on side of biohazard bag.
- Place sealed bag with requisition back into box.
- Place cool pack in box, on top of biohazard bag. Do not allow cool pack to be in direct contact with specimen.
- Close box and tuck tabs into place. No tape necessary.

## IHC Requisition and Shipping Instructions

### Requisition

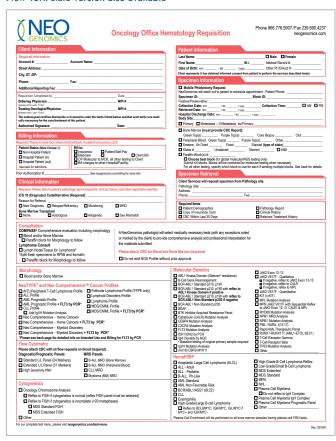


- Complete IHC requisition, making sure all sections are completed in their entirety which includes client, patient, coding, specimen, and billing information sections, reason for referral, and tests requested. Write patient name and DOB on appropriate number of labels provided with the requisition.
- Place a label on each slide holder and/or block. (Each label should have a requisition number, patient name, and patient DOB). A minimum of two patient identifiers is REQUIRED for each slide holder and/or block.
- Ensure slide holders are closed and sealed tightly. Ensure block cassettes are protected in gauze or individual small sealed bags. Place slides and/or blocks into foam insert.
- Lift foam insert from box and place into biohazard bag along with absorbent sheet.
- Remove as much air as possible from the biohazard bag and seal it. Place folded test requisition and/or manifest in pocket on side of biohazard bag.
- Place sealed bag with requisition back into box.
- Place cool pack in box, on top of biohazard bag. Do not allow cool pack to be in direct contact with specimen.
- Close box and tuck tabs into place. No tape necessary.

# Oncology Office Hematology Requisition and Shipping Instructions

### Requisition

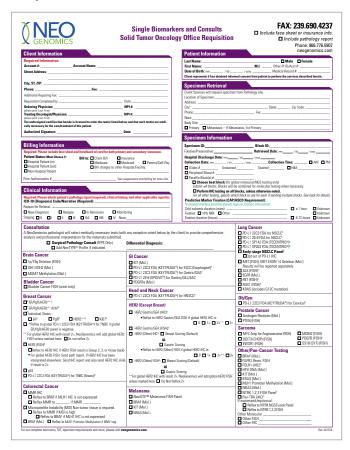
New York state version also available



- Complete Oncology Office Hematology requisition, making sure all sections are completed in their entirety which includes client, patient, coding, specimen, and billing information sections, reason for referral, and tests requested. Write patient name and DOB on appropriate number of labels provided with the requisition.
- Place a label on each tube, jar and/or slide. (Each label should have a requisition number, patient name, and DOB). A minimum of two patient identifiers is REQUIRED for each specimen.
- Ensure tube tops and/or slide holders are sealed tightly. Place labeled tubes and/or slide holders into foam insert. Ensure formalin jars are sealed tightly. Place labeled formalin jars separately into small biohazard bag before placing into foam cut-out. Ensure the lid of specimen jar is tightened past the "click" to prevent leakage in transit. Place strip of Parafilm around the lid where it meets the jar for additional protection.
- Remove as much air as possible from the biohazard bag and seal it. Place folded test requisition and/or manifest in pocket on side of biohazard bag.
- Place sealed bag with requisition back into box.
- Place cool pack in box, on top of biohazard bag. Do not allow cool pack to be in direct contact with specimen.
- Close box and tuck tabs into place. No tape necessary.

## Single Biomarkers and Consults Solid Tumor Oncology Office Requisition and Submission Instructions

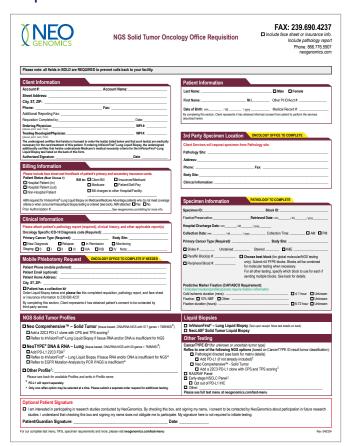
### Requisition



- Complete Single Biomarkers and Consults Solid Tumor Oncology Office requisition, making sure all sections are completed in their entirety which includes client, patient, coding, specimen, and billing information sections, reason for referral, and tests requested.
- Fax completed form to the NeoGenomics fax number at 239.690.4237.

# NGS Solid Tumor Oncology Office Requisition and Submission Instructions

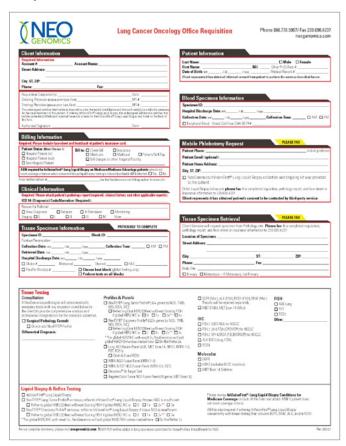
### Requisition



- Complete NGS Solid Tumor Oncology Office requisition, making sure all sections are completed in their entirety which includes client, patient, coding, specimen, and billing information sections, reason for referral, and tests requested.
- Fax completed form to the NeoGenomics fax number at 239.690.4237.

# Lung Cancer Oncology Office Requisition and Submission Instructions

### Requisition



- Complete Lung Cancer Oncology Office requisition, making sure all sections are completed in their entirety which includes client, patient, coding, specimen, and billing information sections, reason for referral, and tests requested. Write patient name and DOB on appropriate number of labels provided with the requisition.
- If ordering InVisionFirst® Lung Liquid Biopsy, see complete Collection and Shipping Instructions included in the liquid biopsy kit and available on our website.
- If using this form to order testing on tumor tissue, fax completed form to the NeoGenomics fax number at 239.690.4237.

# Breast Cancer Requisition and Shipping Instructions

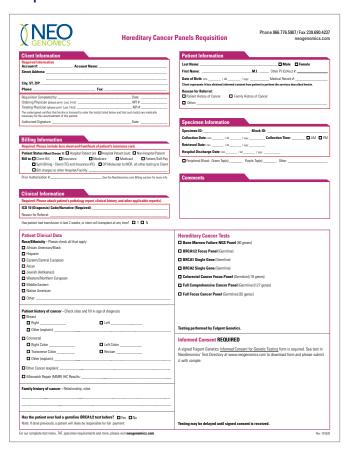
### Requisition



- Complete Breast Cancer requisition, making sure all sections are completed in their entirety which includes client, patient, coding, specimen, and billing information sections, reason for referral, and tests requested. Write patient name and DOB on appropriate number of labels provided with the requisition.
- Place a label on each slide holder and/or block. (Each label should have a requisition number, patient name, and patient DOB). A minimum of two patient identifiers is REQUIRED for each slide holder and/or block.
- Ensure slide holders are closed and sealed tightly. Ensure block cassettes are protected in gauze or individual small sealed bags. Place slides and/or blocks into foam insert.
- Lift foam insert from box and place into biohazard bag along with absorbent sheet.
- Remove as much air as possible from the biohazard bag and seal it. Place folded test requisition and/or manifest in pocket on side of biohazard bag.
- Place sealed bag with requisition back into box.
- Place cool pack in box, on top of biohazard bag. Do not allow cool pack to be in direct contact with specimen.
- Close box and tuck tabs into place. No tape necessary.

# Hereditary Cancer Panels Requisition and Shipping Instructions

### Requisition



- Complete Hereditary Cancer Panels requisition, making sure all sections are completed in their entirety which includes client, patient, coding, specimen, and billing information sections, reason for referral, and tests requested. Write patient name and DOB on appropriate number of labels provided with the requisition.
- Place a label on each tube, jar and/or slide. (Each label should have a requisition number, patient name, and DOB). A minimum of two patient identifiers is REQUIRED for each specimen.
- Ensure tube tops and/or slide holders are sealed tightly. Place labeled tubes and/or slide holders into foam insert. Ensure formalin jars are sealed tightly. Place labeled formalin jars separately into small biohazard bag before placing into foam cut-out. Ensure the lid of specimen jar is tightened past the "click" to prevent leakage in transit. Place strip of Parafilm around the lid where it meets the jar for additional protection.
- Remove as much air as possible from the biohazard bag and seal it. Place folded test requisition and/or manifest in pocket on side of biohazard bag.
- Place sealed bag with requisition back into box.
- Place cool pack in box, on top of biohazard bag. Do not allow cool pack to be in direct contact with specimen.
- Close box and tuck tabs into place. No tape necessary.

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 nationwide network of CAP-accredited, CLIA-certified laboratories.



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