



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. In 2017, to expand our services to the global market, we opened our first international laboratory in Rolle, Switzerland, and in 2019, we expanded to Singapore. NeoGenomics offers our expertise in the following technologies: Fluorescence In Situ Hybridization, Flow Cytometry, Molecular Genetics, Cytogenetics, Pathology, and Immunohistochemistry.

Common purpose

We Save Lives by Improving Patient CARE (communication, accuracy, reliability, efficiency)

Our vision

By providing uncompromising quality, exceptional service and innovative solutions, we will be the World's leading cancer testing and information company.

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 (communication, accuracy, reliability, and efficiency). 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.

Annual Notice to Clients

February 25, 2021

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. Our assigned Medical Directors for each of our major laboratory facilities and other important contact information is listed below for your convenience:

- California (Aliso Viejo) Medical Director: **Vladislav Chizhevsky, M.D. – 949.445.7300, ext. 3289**
- California (Carlsbad) Medical Director: **Yin Xu, M.D. – 949.445.7300, ext. 5142**
- California (San Diego): **Steven Brodie, Ph.D – 239.768.0600, ext. 2300**
- Florida (Fort Myers) Medical Director: **Derek Lyle, M.D. – 760.516.5145**
- Florida (Tampa/Temple Terrace) Lab Director: **John McGill, Ph.D. – 239.768.0600, ext. 2311**
- Georgia (Atlanta) Medical Director: **Yin Xu, M.D. – 949.445.7300 ext. 5142**
- 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**

Annual Notice to Clients

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 website at <https://neogenomics.com>. **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 website at <https://www.cms.gov>. 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) require that a patient sign an Advance Beneficiary Notice (“ABN”) at <https://neogenomics.com/sites/default/files/2021-07/ABNEnglish2023v508.pdf> 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.**

Annual Notice to Clients

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 may 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, a listing of all specimen requirements may be found on our website at <https://neogenomics.com/test-menu>. **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.

Annual Notice to Clients

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 IATA Dangerous Goods Regulations at <https://www.iata.org/contentassets/b08040a138dc4442a4f066e6fb99fe2a/dgr-62-en-3.6.2.pdf> 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 any 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 Client Billing website at <https://neogenomics.com/billing>.

Annual Notice to Clients

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”. In such situations, 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 which lists the non-covered tests and pricing. 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 at <https://neogenomics.com/patients/patient-billing>.

California Consumer Protection Act

In an effort to provide our clients important information about other therapeutic options for their patients, physician contact information provided with test orders may be shared with third parties, including companies that sponsor clinical trials, and these companies may contact the physician directly in connection with clinical trials that they sponsor. NeoGenomics may also sell the physician’s identifiable contact information to companies that sponsor clinical trials, and physicians who are California residents have the right to opt out of such sale, under the California Consumer Protection Act, at any time by visiting our website at <https://neogenomics.com/california-consumer-privacy-act-ccpa>.

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 and Ethics Department at **239.768.0600** or compliance@neogenomics.com.

Licensure and certification

Fort Myers, Florida

Medicare Provider:	L9228
CLIA:	10D0998082
CAP:	7178930
Florida:	800017185
California:	COS 00800251
New York:	8200
Pennsylvania:	030193
Rhode Island:	LCO00801
Maryland:	1397

Tampa, Florida

Medicare Provider:	L9228A
CLIA:	10D2031805
CAP:	N/A
Florida:	800017185
California:	N/A
New York:	N/A
Pennsylvania:	N/A
Rhode Island:	LCO01237
Maryland:	N/A

Aliso Viejo, California

Medicare Provider:	05D1021650
CLIA:	05D1021650
CAP:	7181143
Florida:	800020004
California:	CLF 00011815
New York:	8178
Pennsylvania:	029318A
Rhode Island:	LCO00650
Maryland:	1214

Carlsbad, California

Medicare Provider:	05D1018666
CLIA:	05D1018666
CAP:	7186462
Florida:	800019985
California:	CDF00011801
New York:	8227
Pennsylvania:	029366A
Rhode Island:	LCO00643
Maryland:	1236

Fresno, California

Medicare Provider:	N/A
CLIA:	05D2080677
CAP:	N/A
Florida:	N/A
California:	CLF00346503
New York:	N/A
Pennsylvania:	N/A
Rhode Island:	N/A
Maryland:	N/A

Pasadena, California

Medicare Provider:	CB231795
CLIA:	05D2083526
CAP:	N/A
Florida:	N/A
California:	CLF 00346603
New York:	N/A
Pennsylvania:	N/A
Rhode Island:	N/A
Maryland:	N/A

Houston, TX

Medicare Provider:	402013
CLIA:	45D1021782
CAP:	N/A
Florida:	N/A
California:	COS 00800255
New York:	N/A
Pennsylvania:	N/A
Rhode Island:	N/A
Maryland:	N/A

West Bloomfield, MI

Medicare Provider:	MI17129
CLIA:	23D2013964
CAP:	N/A
Florida:	N/A
California:	N/A
New York:	N/A
Pennsylvania:	N/A
Rhode Island:	N/A
Maryland:	N/A

Nashville, Tennessee

Medicare Provider:	3400014
CLIA:	44D1004543
CAP:	7181028
Florida:	800023286
New York:	8333
Tennessee:	4061
Pennsylvania:	030259
Rhode Island:	LCO00485
Maryland:	1402

Important

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: <https://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.

Client Services	NeoGenomics	
Telephone:	866.776.5907, option 3	
Fax:	239.690.4237	
Email:	Client.Services@neogenomics.com	
Hours of Operation:	Monday – Friday: 7:00 AM – 9:00 PM Eastern Saturday: 7:00 AM – 7:30 PM Eastern	
After Hours:	After normal business hours, 7 days per week	
Specimen Pick-Up and Couriers	NeoGenomics	
Telephone:	866.776.5907, option 1	
Hours of Operation:	24 hours per day, 7 days per week	
Client Billing Services	NeoGenomics	Genoptix
Telephone:	888.690.0043	800.755.0802
Hours of Operation:	Monday – Friday 8:00 AM – 7:00 PM Eastern	Monday – Friday 9:00 AM – 7:00 PM Eastern
Fax:	888.443.4153	
Email:	avclientbilling@neogenomics.com	billing@genoptix.com
Patient Billing Services	NeoGenomics	Genoptix
Telephone:	866.776.5907, option 2	800.755.0802
Fax:	239.690.4236	
Email:	billingpatient@neogenomics.com	billing@genoptix.com

Laboratory locations

Fort Myers, Florida

12701 Commonwealth Dr., Suite 9
Fort Myers, FL 33913
Telephone: 239.768.0600
Fax: 239.690.4237

Tampa, Florida

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

Aliso Viejo, California

31 Columbia
Aliso Viejo, CA 92618
Phone: 239.768.0600

Carlsbad, California

2131 Faraday Ave
Carlsbad, CA 92008
Phone: 1.800.755.1605
Fax: 1.888.755.1604

San Diego, California

4570 Executive Dr., 2nd Floor
San Diego, CA 92121
Phone: 1.800.755.1605

Atlanta, Georgia

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

Nashville, Tennessee

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

Houston, Texas

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

Rolle, Switzerland

A-One Business Center
Bâtiment A5, 2nd Floor
Z.A. La Pièce/Route de l'Étraz 1
1180 Rolle, Switzerland
Phone: +41.21.721.06.00

Singapore

61 Science Park Road, #02-11 The Galen
Singapore 117525

NeoLINK®

NeoLINK, our web based laboratory reporting product (formerly called APvX), offers the convenience, efficiency, and the flexibility of accessing test results any time through a secure Internet connection. Our system is designed to decrease paperwork while increasing workflow by providing a flexible and efficient means for accessing test results. NeoLINK has been developed with the contribution of medical specialists to provide conveniently 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) is the most successful messaging standard in the healthcare industry, not only in North America, but also around the world. Formed in the United States in 1987, HL7 has the goal of developing an international set of open standards for data format and content that allows different health information systems to easily and effectively communicate with one another.

At NeoGenomics Laboratories we possess the ability to generate HL7 message files for the integration of our Laboratory Information System to a client's Electronic Medical Record System. We utilize a custom HL7 Integration Engine to extract the data from our LIS system database and convert it into HL7 message files. NeoGenomics Laboratories also has the ability to generate simple CSV files or any other client requested file format to accommodate your interfacing needs. We strive to provide flexible, yet secure connection options for the retrieval of HL7 messages for our clients. Currently, NeoGenomics can utilize a myriad of connection options that suit your needs. We are able to support, but are not limited to, the following secure connection methods: Secure FTP, site-to-site VPN tunnels, and HTTPS.

For more information on NeoLINK, our Laboratory Reporting System, 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 alternative 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 Alternative Assessments to test your knowledge. Assessment certificate 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.

On-site training

For those who prefer in-person instruction, NeoUniversity On-Site will be the right choice. A member of our Medical Staff will join you at your location for FISH and flow cytometry technical training. NeoUniversity gives you the opportunity to train and collaborate with NeoGenomics Medical Staff and your peers in an educational environment. This on-site program occurs multiple times throughout the year and is appropriate for physicians who are interested in providing professional component services for FISH and flow cytometry. Custom-tailored training and curriculum allow for participants to feel confident and prepared to participate in the NeoGenomics TC/PC Program. Ask your local Territory Business Manager for details.

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.

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 AM – 7:00 PM Eastern

For NeoGenomics patient billing questions:

Phone: 866.776.5907, option 2

Fax: 239.690.4236

Email: billingpatient@neogenomics.com

For Genoptix patient billing questions:

Phone: 800.755.0802

Email: billing@genoptix.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.

Genoptix Invoices

To see payment options for Genoptix invoices, please visit: <https://genoptix.com/billing/>

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, you 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 you. In certain cases, you may also receive an invoice from Clariant Diagnostic Services, a NeoGenomics company.

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

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

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

PO Box 865586

Orlando, FL 32886-5586

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.

Pay Online: Please visit <https://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 <https://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
- Single Biomarkers and Consults Solid Tumor Pathology requisition
- NGS Solid Tumor Pathology requisition
- IHC requisition
- Oncology Office Hematology requisition
- Single Biomarkers and Consults Solid Tumor Oncology Office requisition
- NGS Solid Tumor Oncology Office requisition
- Lung Cancer Oncology Office requisition
- Breast Cancer requisition
- Hereditary Cancer Panel 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 panel	1-2 mL EDTA Provide CBC report sodium heparin is acceptable lithium Heparin and ACD not acceptable	EDTA with 4-6 smears/slides	N/A	2 mL EDTA sodium heparin OK if EDTA not available
Peripheral Blood*	2-5 mL sodium heparin Provide CBC report	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 ³ in RPMI POC: Known villi and/or fetal tissue: 1-1.5 cm	0.2 cm ³	0.5-1 cm ³ tissue in RPMI	N/A	N/A	0.5-1 cm ³
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 block preferred or 4-5 micron thick tissue sections on positively charged slides, at least 3 slides per antibody. No additives in waterbath. See article** for slide use and storage recommendations.	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

* 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.

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

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.

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	NeoTYPE®- AITL/Peripheral T-Cell Lymphoma, AML Prognostic, JMML, Lymphoma, MDS/CMML, Myeloid Disorders	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	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.	<p>NGS: 20% Tumor content. >500 cells ideal but can attempt with >200 cells.</p> <p>MSI (except for Colon), MLH1 Promoter Methylation in Colon, MGMT methylation in Brain: 40% Tumor content. >200 cells</p> <p>FISH: 50-100 viable tumor cells needed per probe set.</p> <p>Fine Needle Aspirate (FNA): Requisition must note specimen is FNA. FFPE cell blocks are acceptable if pathologist attaches note verifying sample has >30% tumor or abnormal cells (required). FNA smears or cells in suspension are not accepted.</p>
	NeoTYPE® CLL Prognostic	5 mL in EDTA tube	2 mL in EDTA tube	N/A	0.5-1 cm ³ in RPMI		
	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		
Solid tumor	NeoTYPE®- Brain, Breast, Cervical, Colorectal, Endometrial, Esophageal, Gastric, GI Predictive, GIST/Soft Tissue, Head & Neck, HRD+, Liposarcoma Fusion, Liver/Biliary, Lung, Melanoma, Other Solid Tumor, Ovarian, Pancreas, Thyroid, Precision, Discovery	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® Heme - AML, BTK Inhibitor Acquired Resistance, MDS/CMML, Myeloid Disorders, FLT3, IDH1, IDH2, inv(16) CBFB-MYH11 Translocation, KIT (c-KIT), KRAS, NPM1, NRAS, PML-RARA Translocation t(15;17), RUNX1-RUNX1T1(AML1-ETO) Translocation t(8;21)	2 x 6 mL EDTA tubes (total 12 mL) or 10 mL in EDTA tube	N/A	N/A	N/A		N/A
	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.	
	PIK3CA Mutation CDx Plasma	Please contact Client Services	N/A	N/A	N/A	Please contact Client Services	

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 <https://neogenomics.com/client-services/forms-and-kits>.

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

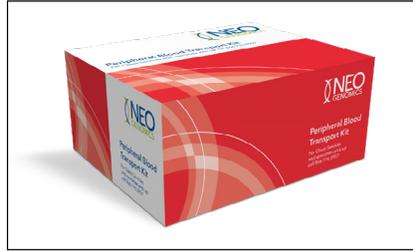
Includes box with foam insert.
Kit components must be ordered separately.

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:

- 1-8 x 8 Biohazard bag
- 2-6ml K2 EDTA Purple top tube (plastic)
- 2-6ml Sodium Heparin Green top tube (plastic)
- 1-3oz Refrigerant Pack
- 5-3 x 1 Single Frosted Slide in 5 slide plastic mailer (1)
- 1-Oncology Office Requisition
- 1-FedEx clinical pack with FedEx label



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
- 2-6ml K2 EDTA Purple top tube (plastic)
- 2-6ml Sodium Heparin Green top tube (plastic)
- 1-3oz Refrigerant Pack
- 2-10ml fill in 20ml Jar 10% NBF
- 10-3 x 1 Single Frosted Slide in 5 slide mailer (2)
- 1-Aqui-Pak 4 bay absorbent pouch
- 1-Oncology Office Requisition
- 1-FedEx clinical pack with FedEx label

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.

Specimen transport kits guide



Bladder FISH Kit

Kit inside dimensions:
4.31" L x 4.06" W x 4.69" H

Kit components included:

- NeoGenomics Bladder FISH Box with foam insert
- 10" x 10" Biohazard Bag with Pouch
- 50mL in supplied clickseal container with 30mL PreservCyt
- Refrigerant Pack, 3 oz
- Parafilm 2" x 4" piece



Liquid Biopsy Kit for InVisionFirst®-Lung

Kit Inside Dimensions:
7.75" W X 2.5" H X 5.56" L

Kit Components Included:

- Liquid Biopsy Label affixed to outside of box
- 2 Bay Aqui-Pak
- 4" x 6" Biohazard Bag
- 2-10 mL Streck Cell-Free DNA BCT® Tube – Glass
- Large Clinical Pak, FedEx
- Do Not Freeze Label
- NeoGenomics Liquid Biopsy Collection and Shipping Instructions
- Ambient Gel Wrap
- 6.5" x 5" Foil Bubble Pouch with Adhesive Seal
- Lung Cancer Oncology Office Test Requisition
- Large Clinical Pak, FedEx
- FedEx Airbill



NeoLAB® Solid Tumor Kit

Kit Inside Dimensions:
7.75" W X 2.5" H X 5.56" L

Kit Components Included:

- 2 Bay Aqui-Pak
- 4" x 6" Biohazard Bag
- 2-10 mL Streck Cell-Free DNA BCT® Tube – Glass
- 2 Tube Patient Information Labels
- Do Not Freeze Label
- Ambient Gel Wrap
- 6.5" x 5" Foil Bubble Pouch with Adhesive Seal
- NeoLAB® Solid Tumor Liquid Biopsy Collection and Shipping Instructions
- NeoLAB® Solid Tumor Liquid Biopsy Test Requisition
- Large Clinical Pak, FedEx
- FedEx Airbill

**Also available without Test Requisition and FedEx Supplies.*

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.

IHC requisition and shipping instructions

Requisition



Immunohistochemistry and Special Stain Requisition
Phone 866.776.5807 / Fax 239.630.4237
neogenomics.com

Client Information

Required Information

Account # _____ Account Name _____
 Street Address _____
 City, ST, ZIP _____
 Phone _____ Fax _____

Preparation Completed by _____ Date _____
 Ordering Physician (please print Last, First) _____ NP# _____
 Treating Physician (please print Last, First) _____ NP# _____

The following are the fields to be filled in to be submitted to the hospital and each field is mandatory unless otherwise specified.

Billing Information

Required: Please include face sheet and breakdown of patient's insurance card.

Patient Status: Outpatient Hospital Patient (In) Hospital Patient (Out) Non-Hospital Patient
 Bill to: Client Bill Insurance Medicare Medicaid Patient Self Pay
 Self Billing - Client (IC) and Insurance (PC) CP Molecular to MCR, all other testing to Client
 Bill charges to other Hospital Facility

For information: _____ See the Neogenomics web Billing section for details.

Other Information

Required: Please attach patient's pathology report (required), clinical history, and other applicable reports.

ICD 10 (Diagnostic Code/Narrative (Required)) _____

Reason for Referral: _____
 New Diagnosis Relapse Recurrence Monitoring
 Staging II III IV None

Consentation: A Neogenomics pathologist will select medically necessary tests with an exception noted below for the test to be performed. Analysis and professional interpretation is to be provided to the referring physician. Pathology and IHC only.

Special Pathology (Genetic) (FFPE only) Non-Neoplastic (Autopsy) (Frozen) (FFPE only)

Image Analysis/Quantitative IHC

GLIA: T1A: T1B: T1C: T1D: T1E: T1F: T1G: T1H: T1I: T1J: T1K: T1L: T1M: T1N: T1O: T1P: T1Q: T1R: T1S: T1T: T1U: T1V: T1W: T1X: T1Y: T1Z: T1AA: T1AB: T1AC: T1AD: T1AE: T1AF: T1AG: T1AH: T1AI: T1AJ: T1AK: T1AL: T1AM: T1AN: T1AO: T1AP: T1AQ: T1AR: T1AS: T1AT: T1AU: T1AV: T1AW: T1AX: T1AY: T1AZ: T1BA: T1BB: T1BC: T1BD: T1BE: T1BF: T1BG: T1BH: T1BI: T1BJ: T1BK: T1BL: T1BM: T1BN: T1BO: T1BP: T1BQ: T1BR: T1BS: T1BT: T1BU: T1BV: T1BW: T1BX: T1BY: T1BZ: T1CA: T1CB: T1CC: T1CD: T1CE: T1CF: T1CG: T1CH: T1CI: T1CJ: T1CK: T1CL: T1CM: T1CN: T1CO: T1CP: T1CQ: T1CR: T1CS: T1CT: T1CU: T1CV: T1CW: T1CX: T1CY: T1CZ: T1DA: T1DB: T1DC: T1DD: T1DE: T1DF: T1DG: T1DH: T1DI: T1DJ: T1DK: T1DL: T1DM: T1DN: T1DO: T1DP: T1DQ: T1DR: T1DS: T1DT: T1DU: T1DV: T1DW: T1DX: T1DY: T1DZ: T1EA: T1EB: T1EC: T1ED: T1EE: T1EF: T1EG: T1EH: T1EI: T1EJ: T1EK: T1EL: T1EM: T1EN: T1EO: T1EP: T1EQ: T1ER: T1ES: T1ET: T1EU: T1EV: T1EW: T1EX: T1EY: T1EZ: T1FA: T1FB: T1FC: T1FD: T1FE: T1FF: T1FG: T1FH: T1FI: T1FJ: T1FK: T1FL: T1FM: T1FN: T1FO: T1FP: T1FQ: T1FR: T1FS: T1FT: T1FU: T1FV: T1FW: T1FX: T1FY: T1FZ: T1GA: T1GB: T1GC: T1GD: T1GE: T1GF: T1GG: T1GH: T1GI: T1GJ: T1GK: T1GL: T1GM: T1GN: T1GO: T1GP: T1GQ: T1GR: T1GS: T1GT: T1GU: T1GV: T1GW: T1GX: T1GY: T1GZ: T1HA: T1HB: T1HC: T1HD: T1HE: T1HF: T1HG: T1HH: T1HI: T1HJ: T1HK: T1HL: T1HM: T1HN: T1HO: T1HP: T1HQ: T1HR: T1HS: T1HT: T1HU: T1HV: T1HW: T1HX: T1HY: T1HZ: T1IA: T1IB: T1IC: T1ID: T1IE: T1IF: T1IG: T1IH: T1II: T1IJ: T1IK: T1IL: T1IM: T1IN: T1IO: T1IP: T1IQ: T1IR: T1IS: T1IT: T1IU: T1IV: T1IW: T1IX: T1IY: T1IZ: T1JA: T1JB: T1JC: T1JD: T1JE: T1JF: T1JG: T1JH: T1JI: T1JJ: T1JK: T1JL: T1JM: T1JN: T1JO: T1JP: T1JQ: T1JR: T1JS: T1JT: T1JU: T1JV: T1JW: T1JX: T1JY: T1JZ: T1KA: T1KB: T1KC: T1KD: T1KE: T1KF: T1KG: T1KH: T1KI: T1KJ: T1KK: T1KL: T1KM: T1KN: T1KO: T1KP: T1KQ: T1KR: T1KS: T1KT: T1KU: T1KV: T1KW: T1KX: T1KY: T1KZ: T1LA: T1LB: T1LC: T1LD: T1LE: T1LF: T1LG: T1LH: T1LI: T1LJ: T1LK: T1LL: T1LM: T1LN: T1LO: T1LP: T1LQ: T1LR: T1LS: T1LT: T1LU: T1LV: T1LW: T1LX: T1LY: T1LZ: T1MA: T1MB: T1MC: T1MD: T1ME: T1MF: T1MG: T1MH: T1MI: T1MJ: T1MK: T1ML: T1MM: T1MN: T1MO: T1MP: T1MQ: T1MR: T1MS: T1MT: T1MU: T1MV: T1MW: T1MX: T1MY: T1MZ: T1NA: T1NB: T1NC: T1ND: T1NE: T1NF: T1NG: T1NH: T1NI: T1NJ: T1NK: T1NL: T1NM: T1NO: T1NP: T1NQ: T1NR: T1NS: T1NT: T1NU: T1NV: T1NW: T1NX: T1NY: T1NZ: T1OA: T1OB: T1OC: T1OD: T1OE: T1OF: T1OG: T1OH: T1OI: T1OJ: T1OK: T1OL: T1OM: T1ON: T1OO: T1OP: T1OQ: T1OR: T1OS: T1OT: T1OU: T1OV: T1OW: T1OX: T1OY: T1OZ: T1PA: T1PB: T1PC: T1PD: T1PE: T1PF: T1PG: T1PH: T1PI: T1PJ: T1PK: T1PL: T1PM: T1PN: T1PO: T1PP: T1PQ: T1PR: T1PS: T1PT: T1PU: T1PV: T1PW: T1PX: T1PY: T1PZ: T1QA: T1QB: T1QC: T1QD: T1QE: T1QF: T1QG: T1QH: T1QI: T1QJ: T1QK: T1QL: T1QM: T1QN: T1QO: T1QP: T1QQ: T1QR: T1QS: T1QT: T1QU: T1QV: T1QW: T1QX: T1QY: T1QZ: T1RA: T1RB: T1RC: T1RD: T1RE: T1RF: T1RG: T1RH: T1RI: T1RJ: T1RK: T1RL: T1RM: T1RN: T1RO: T1RP: T1RQ: T1RR: T1RS: T1RT: T1RU: T1RV: T1RW: T1RX: T1RY: T1RZ: T1SA: T1SB: T1SC: T1SD: T1SE: T1SF: T1SG: T1SH: T1SI: T1SJ: T1SK: T1SL: T1SM: T1SN: T1SO: T1SP: T1SQ: T1SR: T1SS: T1ST: T1SU: T1SV: T1SW: T1SX: T1SY: T1SZ: T1TA: T1TB: T1TC: T1TD: T1TE: T1TF: T1TG: T1TH: T1TI: T1TJ: T1TK: T1TL: T1TM: T1TN: T1TO: T1TP: T1TQ: T1TR: T1TS: T1TT: T1TU: T1TV: T1TW: T1TX: T1TY: T1TZ: T1UA: T1UB: T1UC: T1UD: T1UE: T1UF: T1UG: T1UH: T1UI: T1UJ: T1UK: T1UL: T1UM: T1UN: T1UO: T1UP: T1UQ: T1UR: T1US: T1UT: T1UU: T1UV: T1UW: T1UX: T1UY: T1UZ: T1VA: T1VB: T1VC: T1VD: T1VE: T1VF: T1VG: T1VH: T1VI: T1VJ: T1VK: T1VL: T1VM: T1VN: T1VO: T1VP: T1VQ: T1VR: T1VS: T1VT: T1VU: T1VV: T1VW: T1VX: T1VY: T1VZ: T1WA: T1WB: T1WC: T1WD: T1WE: T1WF: T1WG: T1WH: T1WI: T1WJ: T1WK: T1WL: T1WM: T1WN: T1WO: T1WP: T1WQ: T1WR: T1WS: T1WT: T1WU: T1WV: T1WW: T1WX: T1WY: T1WZ: T1XA: T1XB: T1XC: T1XD: T1XE: T1XF: T1XG: T1XH: T1XI: T1XJ: T1XK: T1XL: T1XM: T1XN: T1XO: T1XP: T1XQ: T1XR: T1XS: T1XT: T1XU: T1XV: T1XW: T1XX: T1XY: T1XZ: T1YA: T1YB: T1YC: T1YD: T1YE: T1YF: T1YG: T1YH: T1YI: T1YJ: T1YK: T1YL: T1YM: T1YN: T1YO: T1YP: T1YQ: T1YR: T1YS: T1YT: T1YU: T1YV: T1YW: T1YX: T1YY: T1YZ: T1ZA: T1ZB: T1ZC: T1ZD: T1ZE: T1ZF: T1ZG: T1ZH: T1ZI: T1ZJ: T1ZK: T1ZL: T1ZM: T1ZN: T1ZO: T1ZP: T1ZQ: T1ZR: T1ZS: T1ZT: T1ZU: T1ZV: T1ZW: T1ZX: T1ZY: T1ZZ

Patient Information

Last Name: _____ First Name: _____ MI: _____ Other Pt ID/Case # _____
 Date of Birth: mm / dd / yyyy _____ Medical Record # _____
Client represents it has obtained informed consent from patient to perform the services described herein.

Specimen Information

Specimen ID: _____ Block ID: _____
 Collection Date: mm / dd / yyyy _____ Collection Time: _____ AM / PM
 Reviewed Date: mm / dd / yyyy _____
 Hospital Discharge Date: mm / dd / yyyy _____

Block Size: _____
 Primary Metastasis - If Metastasis, list Primary

FNA cell block Smears: Air Dried _____ Fixed _____ Stained (type of stain): _____
 Slides # _____ Unstained _____ Stained _____ (type of stain) _____
 Paraffin Block(s) # _____ Perform tests on all blocks

Stain Marker & Controls/USA HER2 Testing (CAP/ASCO Requirement)

Gold scheme time at 1 hour: Yes No Unknown
 10% neutral buffered formalin: Yes No Unknown
 HER2/ERBB2 (IHC) (Amplification) (2+ Score): Yes No Unknown

Controls: GA - Global with Image Analysis T - Test Only/Scan Only T&A - Test Only with Image Analysis
 T-Stat - Test Only with Semi-Quantitative Interpretation by client

Hold indicates global pre-emptive interpretation is available.
 Check item is still

Shipping instructions

- 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.

Single Biomarkers and Consults Solid Tumor Oncology Office Requisition and submission instructions

Requisition



**Single Biomarkers and Consults
Solid Tumor Oncology Office Requisition**

FAX: 239.690.4237
 Include fax sheet for insurance info.
 Include pathology report
 Phone: 866.776.5907
 neogenomics.com

Client Information

Required Information

Account # _____ Account Name _____

Street Address _____

City, ST, ZIP _____ Phone _____ Fax _____

Requester Completed by _____ Date _____
 Ordering Physician (please print Last, First) _____ NPI # _____
 Treating Physician (please print Last, First) _____ NPI # _____

The undersigned certifies that he/she is licensed to order the test(s) listed below and that such test(s) are medically necessary for the care/treatment of this patient.

Authorized Signature _____ Date _____

Patient Information

Last Name _____ Male Female

First Name _____ MI _____ Other P. (Suffix) # _____

Date of Birth: mm / dd / yyyy Medical Record # _____

Client agreement has been obtained informed consent from patient to perform the services described herein.

Specimen Retrieval

Client Services will request specimen from Pathology site.

Location of Specimen _____

Address _____

City _____ State _____ Zip Code _____

Phone _____ Fax _____

Name _____

Body Site _____

Primary Metastasis - # Metastasis, list Primary _____

Specimen Information

Specimen ID _____ Block ID _____

Frontal Preservation _____ Retrieved Date: mm / dd / yyyy

Hospital Discharge Date: mm / dd / yyyy

Collection Date: mm / dd / yyyy Collection Time: AM PM

Slide # _____ Unstained _____ Stained _____ H&E _____

Paraffin Block(s) # _____ Permanent on all blocks

Billing Information

Requester Please include how client will be paid at patient's insurance card.

Patient Status (check one): Outpatient Inpatient

Hospital Patient (in) Medicare Medicaid Patient/Self Pay

Hospital Patient (out) Bill charges to other Hospital/Facility

Non-Hospital Patient

Prior Authorization # _____ See the NeoGenomics.com Billing section for details.

Clinical Information

Requester Please attach patient's pathology report required, clinical history and other applicable reports. ICD-10 Diagnosis Code (Necessary Required)

Patient Referral: New Diagnosis Relapse In Remission Monitoring

Staging: I: II: III: IVA: IIB: IV: New:

Consultation

A NeoGenomics pathologist will select medically necessary tests (with any exception noted below) by the client to provide comprehensive analysis and professional interpretation for the materials submitted.

Surgical Pathology Consult (IIFE Only) Do Not Refuse (IIFE) if indicated

Differential Diagnosis

Brain Cancer

TP53 (Molecular) (FSH)

EGFR (IHC) (Mol.)

MGMT Methylation (Mol.)

Bladder Cancer

Bladder Cancer (FSH urine only)

IGF1R Cx/Molecular Analysis

PD-L1 22C3 FDA (KEYTRUDA®)

PD-L1 SP142 FDA (TECENTRIQ®)

PD-L1 28-8 (PDPV®)

PD-L1 SP283 FDA (MPRNP®)

Breast Cancer

BRCA1/2**

BRCA1/2**/V674E63

BRCA1/2**/V674E63

Individual Stains: ER PR HER2** Ki67 p53

Refer to global HER2 IHC or FISH if global BRCA1/2 panel is negative

** For global HER2 IHC with result 2+, NeoGenomics will add global HER2 FISH unless marked here: Do Not Refuse 2+

HER2 FISH

Refer to HER2 IHC if HER2 FISH result is Group 2, 3, or 4 (see back)

* For global HER2 FISH. Send path report if HER2 IHC has been interpreted elsewhere. Send IHC report and also send HER2 IHC slides if result is 2+.

PD-L1 22C3 FDA (KEYTRUDA®) for TNBC (Breast)

PD-L1 SP142 FDA (TECENTRIQ®) for TNBC (Breast)

Colorectal Cancer

MMR1 IHC

Refer to BRAF if MMR1 IHC is not expressed

Refer to MMR1/2/3/4 if MMR1

Microsatellite Instability (MSI) (Non-tumor tissue is required)

Refer to MMR1 if MSI is high

Refer to BRAF if MMR1 IHC is not expressed

Melanoma

NucleoTSM Melanoma FISH Panel

BRAF (Molecular)

KIT (Molecular)

NRAS (Molecular)

TSP1/SH2 (Molecular)

Lung Cancer

PD-L1 22C3 FDA (KEYTRUDA®)

PD-L1 28-8 FDA (PDPV®) * V674E63

PD-L1 SP142 FDA (TECENTRIQ®)

EGFR (Mol.) ALK (FSH) ROS1 (FSH) BRAF (Mol.) Results will be reported separately

MET (FSH) MET EXON 14 Deletion (Mol.) Results will be reported separately

ALK (FSH)

EGFR (Mol.)

RET (FSH)

ROS1 (FSH)

KRAS (includes G12C mutation)

Oligo/yn

PD-L1 22C3 FDA (KEYTRUDA®) for Genital

Prostate Cancer

Androgen Receptor (Molecular)

PTEN (FSH)

Sarcoma

MDM2 Amp for Liposarcoma (FSH)

CD117 (KIT) (FSH)

CD117 (KIT) (FSH)

ERG (FSH)

PDSR (FSH)

SS18/SS18 (FSH)

Other/Pan-Cancer Testing

BRAF (Mol.)

GFR2 Rearr. FSH

HPV DNA (Mol.)

KIT (Mol.)

KRAS (Exons 2-4)

NRAS (Exon 2-4)

NTRK1,2,3 FSH Panel

Pan-TRK (IHC)

If expressed/Amplified:

Refer to NTRK1,2,3 FSH

Other Molecular _____

Other FISH _____

Other IHC _____

For our complete terms, S&T, specimen requirements and more, please visit neogenomics.com. Rev 01/2011

Shipping instructions

- 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



NGS Solid Tumor Oncology Office Requisition

FAX: 239.690.4237

 Include face sheet or insurance info.
 Include pathology report
 Phone: 866.776.5907
 neogenomics.com

Client Information

Required Information

Account # _____ Account Name _____

Street Address _____

City, ST, ZIP _____ Fax _____

Phone _____

Additional Reporting Fax _____ Date _____

Requesting Physician (please print, Last, First) _____ NP # _____

Treating Physician (please print, Last, First) _____ NP # _____

The requesting center has been authorized to use the mobile-based biopsy and that each specimen is individually necessary for the complete diagnosis of a patient. Invoicing information, such as Liquid Biopsy, the professional addresses by which to bill for the specimens, will be provided to the requesting center for the Liquid Biopsy. Long Liquid Biopsy test based on the use of the NeoGenomics mobile-based biopsy kit.

Authorized Signature _____ Date _____

3rd Party Specimen Location **ONCOLOGY OFFICE TO COMPLETE**

Client Services will request specimen from Pathology site.

Pathology Site: _____

Address: _____

Phone: _____ Fax: _____

Body Site: _____

Mobile Phlebotomy Request **ONCOLOGY OFFICE TO COMPLETE IF NEEDED**

Patient Phone: _____ mobile preferred

Patient Email (optional): _____

Patient Home Address: _____

City, ST, ZIP: _____

NeoGenomics InVisionFirst® Lung Liquid Biopsy collection and shipping kit was provided to the patient.

Order Liquid Biopsy below and please fax this completed requisition, pathology report, and face sheet or insurance information to 330.654.4237.

Client represents it has obtained patient's consent to be contacted by third-party service.

Patient Information

Last Name: _____ M Male Female

First Name: _____ M Male Female

Date of Birth: mm / dd / yy _____ mm _____ Medical Record # _____

Client agreement has been obtained informed consent from patient to perform the services described herein.

Specimen Information **ONCOLOGY OFFICE & PATHOLOGY TO COMPLETE**

Oncotherapy office to complete Specimen ID and Collection Date when possible.

Specimen ID: _____ Block ID: _____

Fastidiousness: _____

Retrieved Date: mm / dd / yy _____

Hospital Discharge Date: mm / dd / yy _____

Collection Date: mm / dd / yy _____ Collection Time: _____ AM PM

Primary Metastasis - If Metastasis, list Primary _____

Site # _____ Unstained _____ Stained _____

Perifluic Blood # _____ Choose best block

Peripheral Blood # _____ Blocks will be combined for molecular testing when necessary.

Breast Marker & Genetic/SEA HER2 FISH (CAP/ASCO Requirement)

Perform on all blocks

Call reference time in hour: Yes No Unknown

10% neutral buffered formalin: Yes No Unknown

HER2/NEU FISH: duration of 4 to 72 hours: Yes No Unknown

Billing Information

Request: Please attach face sheet and feedback of patient's insurance card.

Payment Method (check all that apply):

Bill to: Cash Bill Insurance/Medicaid

Hospital Patient (in) Medicare Patient Self Pay

Hospital Patient (out) Medicaid Patient Self Pay

Non-Hospital Patient Bill charges to other Hospital/ Facility

AD required for InVisionFirst® Lung Liquid Biopsy in Medicare/Medicaid. Advise the patient who is not covered under Medicare when consented to mobile-based biopsy testing is ordered (see last). ADH included. Yes No

ADH required for InVisionFirst® Lung Liquid Biopsy in Medicare/Medicaid. Advise the patient who is not covered under Medicare when consented to mobile-based biopsy testing is ordered (see last). ADH included. Yes No

Phys. Authorization # _____ See the NeoGenomics.com Billing section for more info.

Clinical Information

Request: Please attach patient's pathology report (required), clinical history, and other applicable reports.

ICD-10 (Diagnosis Code/Narrative) (Required)

Reason for Referral: _____

New Diagnosis Relapse In Remission Monitoring

Staging: I II III IV Note: _____

NeoTYPE® Cancer Profiles with RNA-Based NGS Fusion Panels

Comprehensive multi-gene cancer profiling. See reverse side for HER2 reflex information. *Reflex to NTRK 1-3 FISH Panel instead of NTRK NGS if Pan-TRK IHC is positive or equivocal.

Broad-Reach Profiles

Discovery Profile (20+ genes)* Universal Solid Tumor Fusion Panel

Primary Tumor: Breast Lung Other _____

Neo-HER2HC

Targeted Profile (7+ genes)* Targeted Solid Tumor NGS Fusion Panel

Targeted Profiles Continued

Lung Tumor Profile* Neo-HER2HC

Melanoma Profile* Other Solid Tumor Profile*

Stomach Tumor Profile* Neo-HER2HC

Pancreas Tumor Profile* Neo-HER2HC

Targeted Profile* Targeted NGS Fusion Panel

Other RNA-Based NGS Fusion Panels

Living Sarcoma NGS Fusion Panel

Non-Ewing Sarcoma NGS Fusion Panel

NTRK NGS Fusion Panel

NTRK & RET NGS Fusion Panel

Prostate NGS Fusion Panel

Rhabdomyosarcoma NGS Fusion Panel

Salivary Gland NGS Fusion Panel

Sarcoma Comprehensive NGS Fusion Panel

Targeted Solid Tumor NGS Fusion Panel

Liquid Biopsy and Reflex Testing

NeoLAMP® Solid Tumor Liquid Biopsy

See InVisionFirst® Lung-Additional info on back for AEM requirements.

InVisionFirst® Lung-Liquid Biopsy (test upon receipt)

NeoTYPE® Lung Tumor Profile* on tissue, reflex to InVisionFirst® Lung-Liquid Biopsy if tissue NGS is insufficient

NeoTYPE® Discovery Profile* on tissue, reflex to InVisionFirst® Lung-Liquid Biopsy if tissue NGS is insufficient

Other Testing

BRCA1/2 Mutation Analysis for Tumors

CancerTYPE (CP) with reflex to NeoTYPE Cancer Profile based on CancerTYPE CP result

- Tumor of uncertain origin classification followed by targeted biomarkers
- To order CancerTYPE (CP) as a stand-alone test, visit www.cancerpanel.com

Chromine Du® Target Test (for NSCLC)

Prosigna® Assay (for breast cancer)

Patient and specimen must meet following criteria:

Check all that apply (required):

- Post-menopausal female
- ER, PR, Ki67 (one or both must be positive)
- Stage and lymph node status (choose one)
 - For 1+ with 0 positive nodes
 - 1+ with 1+ positive nodes (all nodes ineligible)
- Tumor type (choose one)
 - Invasive ductal
 - Invasive lobular
 - Invasive ductal & lobular
 - Invasive carcinoma, NGS (not otherwise specified)
- Pathology report is attached (required)

Gross tumor size: <2cm >2cm

NGS/RTF Panel

Breast Cancer Index® (BCI) & Thermal Sponsored Testing Program: separate requisition required, see website.

For complete terms, conditions, specimen requirements and more, please visit neogenomics.com. TEGEP (PCR) will be added to lung specimens submitted for these Profiles if sufficient for NGS. Rev 07/21

Shipping instructions

- 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



Lung Cancer Oncology Office Requisition
Phone 866.776.5907 / Fax 239.690.4237
neogenomics.com

Client Information

Required Information

Account # _____ Account Name _____
 Street Address _____
 City, ST, ZIP _____
 Phone: _____ Fax: _____

Requisition Completed by _____ Date _____
 Ordering Physician (please print Last, First, MI) _____
 Treating Physician (please print Last, First, MI) _____
The undersigned certifies that he/she is licensed to order the tests listed below and that he/she is not a medical professional in the jurisdiction of the state of ordering institution. The undersigned also certifies that he/she understands Medicare's medical necessity criteria for the InVisionFirst® Lung Liquid Biopsy test listed on the back of this form.
 Authorized Signature _____ Date _____

Patient Information

Last Name: _____ Male Female
 First Name: _____ MI: _____ Other P. (Suffix) # _____
 Date of Birth: mm / dd / yy _____ Medical Record # _____
Client represents he has obtained informed consent from patient to perform the services described herein.

Billing Information

Request: Please include check and back of patient's insurance card.

Patient State (Must Check 1) PA NJ DE MD VA DC HI AK VT NH ME CT RI MA NY CT NY NJ PA DE MD VA DC HI AK VT NH ME CT NY NJ PA DE

Hereditary Cancer Panels requisition and shipping instructions

Requisition



Hereditary Cancer Panels Requisition

Phone 866.776.5907 / Fax 239.690.4237
 neogenomics.com

Client Information
Required: Please indicate face sheet and front back of patient's insurance card.

Required Information
 Account #: _____ Account Name: _____
 Street Address: _____
 City, ST, ZIP: _____
 Phone: _____ Fax: _____
 Requisition Completed by: _____ Date: _____
 Ordering Physician (please print Last, First, Middle Initial): _____ NPI #: _____
The undersigned certifies that he/she is licensed to order the test(s) listed below and that such test(s) are medically necessary for the care/treatment of this patient.
 Authorized Signature: _____ Date: _____

Billing Information
Required: Please indicate face sheet and front back of patient's insurance card.

Patient Status (What Charge to) Hospital/Patient (in) Hospital/Patient (out) Non-Hospital Patient
Bill to: Client Bill Insurance Medicare Medicaid Patient/Self Pay
 Split Billing - Client (C) and Insurance (I) OP Molecular to MD, all other testing to Client
 Bill charges to other Hospital/Facility: _____
Please Authorize # _____ See the NeoGenomics.com Billing section for more info.

Clinical Information
Required: Please attach patient's pathology report, clinical history, and other applicable reports.

ICD 10 (Diagnosis) Code/Narrative (Required)
 Reason for Referral: _____
Has patient had transfusion in last 2 weeks, or stem cell transplant at any time? Y N

Patient Clinical Data
Race/Ethnicity - Please check all that apply
 African American/Black
 Hispanic
 Eastern/Central European
 Asian
 Jewish (Ashkenazi)
 Western/Northern European
 Middle Eastern
 Native American
 Other _____

Patient history of cancer - Check sites and fill in age of diagnosis
 Breast
 Right _____ Left _____
 Other (specify) _____
 Colorectal
 Transverse Colon _____ Left Colon _____
 Right Colon _____ Sigmoid _____
 Other (specify) _____
 Other Cancer (specify) _____
 Mismatch Repair (MMR)/IHC Results: _____

Family history of cancer - Relationship, sites

Has the patient ever had a germline BRCA1/2 test before? Yes No
Note: If done previously, a patient will likely be responsible for full payment.

Patient Information
 Last Name: _____ Male Female
 First Name: _____ M.I. _____ Other PI (S) (Last #) _____
 Date of Birth: mm / dd / yy _____ Medical Record # _____
Clear requisition in has obtained informed consent from patient to perform the services described herein.

Reason for Referral:
 Patient History of Cancer Family History of Cancer
 Other _____

Specimen Information

Specimen ID: _____ Block ID: _____
 Collection Date: mm / dd / yy _____ Collection Time: _____ AM PM
 Received Date: mm / dd / yy _____
 Hospital Discharge Date: mm / dd / yy _____
 Peripheral (Blood - Green Top) _____ Urine _____ Other _____

Comments

Hereditary Cancer Tests
 Bone Marrow Failure NOS Panel (60 genes)
 BRCA1/2 Focus Panel (Germline)
 BRCA1 Single Gene (Germline)
 BRCA2 Single Gene (Germline)
 Colorectal Cancer Focus Panel (Germline) (18 genes)
 Full Comprehensive Cancer Panel (Germline) (122 genes)
 Full Focus Cancer Panel (Germline) (50 genes)

Testing performed by Fulgent Genetics.

Informed Consent REQUIRED
A signed Fulgent Genetics Informed Consent for Genetic Testing form is required. See test in NeoGenomics Test Directory at www.neogenomics.com to download form and please submit it with sample.

Testing may be delayed until signed consent is received.

For our complete test menu, TAT, specimen requirements and more, please visit neogenomics.com Rev 10/2020

Shipping instructions

- 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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