For NeoGenomics use only

Solid Tumor Pathology Requisition Form

NEO GENOMICS

Phone: 866.776.5907/Fax: 239.690.4237 | Email: Client.Services@NeoGenomics.com | Order Online: NeoLink.NeoGenomics.com

The following supplemental documentation is attached: ☐ **Pathology Report** ☐ **Insurance Information** ☐ Clinical Notes ☐ Relevant Test Results

Please complete and return by fax or email. Incomplete or missing data may result in delayed testing. Bold fields are required.

CLIENT INFORMATION

Account Number	**Account Name**	**Phone#**	**Fax#**

Street Address	**City, State, Zip**

Req Completed By	**Date**

Ordering Physician	**NPI#**	**Treating Oncologist/Physician**	**NPI#**

PATIENT INFORMATION

First Name / Middle Initial / Last Name	**Date of Birth** MM/DD/YYYY	**Biological Sex**	**Medical Record #**
	/ /	☐ **M** ☐ **F** ☐ **Unknown**	

Street Address	**City, State, Zip**	**Phone**

BILLING INFORMATION ** Please include face sheet and insurance card **

Bill Type ☐ Medicare ☐ Insurance/Medicaid ☐ Patient Self Pay ☐ Split Billing: Client (Technical Component) and Insurance (Professional Component)
☐ Hospital/Institution If billing charges to other Hospital/Facility:_____

Patient Status at Time of Specimen Collection ☐ Office (non-hospital) ☐ Hospital Outpatient ☐ Hospital Inpatient, Date of Discharge / /

CURRENT DIAGNOSIS AND RELEVANT CLINICAL HISTORY

Date of Original Diagnosis / / | Diagnosis | **Primary ICD-10 Codes** (C & D codes only)

Type ☐ Breast ☐ Colorectal ☐ Gastric ☐ Melanoma ☐ Lung ☐ Ovarian Other:_____

Stage ☐ I ☐ II ☐ IIIA ☐ IIIB ☐ IV ☐ Unknown Note:_____

Disease Status ☐ Initial Diagnosis ☐ Progression ☐ R/R (Relapsed/Refractory)

SPECIMEN INFORMATION

Specimen ID: | Block ID: | Fixative/Preservative:

Collection Date: / / | Collection Time: _____ ☐ AM ☐ PM | Retrieved Date: / / | Body Site: _____

Streck Cell-Free DNA BCT® #: _____ ☐ Extract & Hold - ctDNA (see back for details) ☐ Slides # _____ Unstained _____ Stained _____ ☐ H&E_____

☐ Paraffin Block(s) #: _____ *For molecular/NGS testing, if NeoGenomics retrieves multiple blocks, our pathologists will combine as necessary unless alternative instructions are provided*

Instructions:

Predictive Marker Fixation (CAP/ASCO Requirement): †*Indicated markers/profiles/panels require fixation information*

Cold ischemic (mins): _____ ☐ ≤ 1 hour ☐ Unknown | Fixative: ☐ 10% NBF ☐ Other:_____ ☐ Unknown | Fixation duration (hours):_____ ☐ 6-72 hours ☐ Unknown

TEST SELECTION

Pan-Solid Tumor CGP Tests

Tissue

☐ Neo PanTracer Tissue (DNA/RNA NGS – 517 Genes with MSI and TMB)

☐ Neo PanTracer Tissue + HRD (DNA/RNA NGS – 517 Genes with MSI, TMB and HRD [Ovarian only])

☐ Reflex to liquid biopsy if tissue is insufficient for NGS

Liquid

☐ Neo PanTracer LBx (ctDNA NGS– 514 Genes with MSI and bTMB)

Add-On IHC with any PanTracer Tissue test – *IHC tests will report separately* ☐ Tech Only

☐ PD-L1 22C3† ☐ FOLR1† (Ovarian) ☐ HER2 Breast† ☐ HER2† (Gastric Scoring) ☐ Claudin18† (Gastric) ☐ c-MET CDx for NSCLC†

☐ CancerTYPE ID for unknown/uncertain tumor type with Pathologist Directed NGS with PD-L1 22C3 IHC add-on

Disease-Specific Profiles

☐ NeoTYPE DNA & RNA - Lung (NGS – 50 genes with MSI and TMB)
☐ *Add-On:* PD-L1 22C3 FDA for NSCLC†
☐ Reflex to EGFR Mutation Analysis by PCR if tissue is insufficient for NGS

☐ NeoTYPE DNA & RNA - Brain (NGS - 83 genes with MSI and TMB)
☐ *Add-On:* PD-L1 LDT IHC†
☐ *Add-On:* MGMT Promoter Methylation Analysis

NeoTYPE Disease-Specific Profiles *(Multi-modal genomic profiling, DNA, FISH, IHC)*

☐ Tech Only – *IHC and FISH*

☐ Breast ☐ Cervical ☐ Cholangiocarcinoma ☐ Colorectal ☐ Endometrial ☐ Esophageal ☐ Gastric
☐ GI Predictive ☐ GIST & Soft Tissue ☐ Head & Neck ☐ HRR ☐ Liver/Biliary ☐ Lung ☐ Melanoma
☐ Ovarian ☐ Pancreas ☐ Thyroid

NeoTYPE Panel *Modifications and Additions*

☐ Reflex to HER2 FISH if global HER2 IHC is
☐ 0 ☐ 1+ ☐ 2+ (default) ☐ 3+ ☐ Do not reflex 2+

☐ Opt out of HER2

☐ Opt out of FOLR1 IHC (Ovarian Only)

☐ Reflex to NTRK 1-3 FISH Panel† instead of NTRK NGS if Pan-TRK IHC is positive or equivocal

RNA-Based Fusion Panels

☐ Universal Solid Tumor NGS Fusion Panel
☐ Sarcoma Comprehensive NGS Fusion Panel
☐ NTRK NGS Fusion Panel (NTRK 1-3)
☐ NTRK & RET NGS Fusion Panel
☐ Other: _____

PHYSICIAN SIGNATURE & CONSENT

Ordering Physician Signature	**Printed Name**	**Date**

Full test menu at **NeoGenomics.com**

My signature certifies that (1) I am the patient's treating physician and am authorized under applicable law to order the tests on this test requisition, (2) each test ordered on this test requisition is medically necessary for the patient, (3) the results of each test will inform the patient's ongoing treatment plan, (4) I have explained to the patient the nature and purpose of each test to be performed pursuant to this test requisition, and the patient has had the opportunity to ask questions regarding each test and the collection, use, and disclosure of his/her samples and data, (5) I have obtained informed consent from the patient, (6) If ordering Neo PanTracer LBx, the undersigned additionally certifies that he/she understands Medicare's medical necessity criteria for the Neo PanTracer LBx Liquid Biopsy test listed on the back of this form.

Solid Tumor Pathology Requisition Form

Additional Billing Information: Any organization referring specimens for testing services pursuant to this Requisition Form ("Client") expressly agrees to the following terms and conditions.

1. **Binding Service Order.** This Requisition Form is a contractually binding order for the services ordered hereunder ("Services") and Client agrees that it is financially responsible for all tests billable to Client hereunder.
2. **Third-Party Billing by NeoGenomics and Right to Bill Client.** Client agrees to accurately indicate on the front of the Requisition Form that either Client should be billed (e.g., Client receives reimbursement pursuant to a non-fee-for-service basis, including, but not limited to, a capitated, diagnostic related group ("DRG"), per diem, all-inclusive, or other such bundled or consolidated billing arrangement) or NeoGenomics should bill the applicable federal, state, or commercial health insurer or other third-party payer (collectively, "Payers") for all Services ordered pursuant to this Requisition Form. For all such Services billable to Payers, Client agrees to provide all billing information necessary for NeoGenomics to bill such payer. In the event that NeoGenomics: (i) does not receive the billing information required for it to bill any Payers within ten (10) days of the date that any Services are reported by NeoGenomics; (ii) the Services were performed for patients who have no Payer coverage arrangements; or (iii) the Payer identified by Client denies financial responsibility for the Services and indicates that Client is financially responsible, NeoGenomics shall have the right to bill such Services to Client.

Neo PanTracer LBx Conditions for Medicare Coverage: Neo PanTracer LBx is a plasma-based, somatic comprehensive genomic profiling test (CGP) intended to assist physicians caring for patients with advanced solid tumors. In accordance with Medicare's MolDX Noridian LCD L39230, testing is appropriate under the following circumstances:

- Patient has been diagnosed with a recurrent, relapsed, refractory, metastatic, or advanced solid tumor that did not originate from the central nervous system. Patients who would meet all the indications on the Food and Drug Administration (FDA) label for larotrectinib if they are found to have a neurotrophic receptor tyrosine kinase (NTRK) mutation may be considered to have advanced cancer, and
- Patient has not previously been tested with Neo PanTracer LBx for the same genetic content. For a patient who has been tested previously using Neo PanTracer LBx for cancer, that patient may not be tested again unless there is clinical evidence that the cancer has evolved wherein testing would be performed for different genetic content. Specifically, in patients with previously tested cancer, who have evidence of new malignant growth despite response to a prior targeted therapy, that growth may be sufficiently genetically different to require additional genetic testing, and
- Patient is untreated for the cancer being tested, or the patient is not responding to treatment (e.g., progression or new lesions on treatment), and
- The patient has decided to seek further cancer treatment with the following conditions:
  - The patient is a candidate for further treatment with a drug that is either FDA-approved for that patient's cancer, or has a National Comprehensive Cancer Network (NCCN) 1 or NCCN 2A recommendation for that patient's cancer, and
  - The FDA-approved indication or NCCN recommendation is based upon information about the presence or absence of a genetic biomarker tested for in the Neo PanTracer LBx, and
- Tissue-based, comprehensive genomic profiling (CGP) is infeasible (e.g., quantity not sufficient for tissue-based CGP or invasive biopsy is medically contraindicated) or specifically in NSCLC Tissue-based CGP has shown no actionable mutations.

A patient signed ABN is required if patient does not meet the coverage criteria. ABN is also required if ordering Neo PanTracer LBx concurrently with tissue testing that includes EGFR, BRAF, ALK, and ROS1.

Specimen Requirements & Usage : NeoGenomics makes every effort to preserve and not exhaust tissue, but in small and thin specimens, there is a possibility of exhausting the specimen in order to ensure adequate material and reliable results.

PanTracer™ LBx: Peripheral blood: 2 x 10-mL Streck Cell-Free DNA BCT® tubes. Do not refrigerate. Special collection tubes and shipping requirements apply.

For molecular/NGS tissue testing, the following is requested: A single block for large resections where tumor is abundant, or up to 4 blocks from procedures with smaller specimens (e.g. Core biopsy, cell block). Only blocks from the same procedure and same tumor should be submitted together. Please call the Client Services team with any questions regarding specimen information.

Exact & Hold - ctDNA: ctDNA will be isolated from plasma and stored in freezer. PanTracer LBx analysis is not performed until the client test order is received. Processed samples will be retained for 90 days.

All other tests: Refrigerate specimen if not shipping immediately and use cool pack during transport. A block is preferred for testing; please see individual test webpages for specimen requirements.

Please call our Client Services team with questions regarding specimen requirements or shipping instructions at 866.776.5907, option 3.

Please refer to **NeoGenomics.com** for specific details on each specimen.

PanTracer Tissue and NeoTYPE® DNA & RNA Profiles: If the sample is insufficient to produce either DNA or RNA results, the available results will be reported and alternate CPT® Codes may apply.

CancerTYPE ID® with reflex to pathologist directed NGS option, with PD-L1 22C3 added if not already included in NGS test. NGS Cancer Profile determined by the CancerTYPE ID® result. CancerTYPE ID® will be performed, reported, and billed separately by Biotheranostics, Inc. For comprehensive details about CancerTYPE ID® including test description, intended use, and limitations, visit **cancertypeid.com.**

Test Descriptions: For our complete test menu, turnaround times, specimen requirements, and more, please visit **NeoGenomics.com/Test-Menu**