labcorp | Oncology

**Client Services**
Ph: (800) 781-1259 Fax: (888) 770-4931
MedOncSupport@labcorp.com

**For Tissue Testing Send To**
Labcorp, Attn: OmniSeq Lab
700 Ellicott Street, Buffalo, NY 14203

**For Liquid Biopsy Testing Send To**
Labcorp/PGDx
3600 Boston Street, Suite 55, Baltimore, MD 21224

# GENE PROFILING ASSAYS

oncology.labcorp.com

Highlighted fields are REQUIRED

## CLIENT INFORMATION

| ORDERING PHYSICIAN | NPI # |
|---|---|
| TREATING PHYSICIAN | NPI # |

Account #:
Account Name:
Account Address:
Phone#: Fax#:
Email:

## PATIENT INFORMATION

Name (LAST, FIRST, MIDDLE):

Date of Birth: Sex: ☐ Male ☐ Female

Address:

City, State, Zip:

Phone Number:

Med. Rec. # / Patient #:

Site/Subject ID:

## BILLING INFORMATION (attach face sheet and copy of insurance card – both sides)

Bill: ☐ My Account ☐ Insurance ☐ Medicare ☐ Medicaid ☐ Patient ☐ Workers Comp
Patient Hospital Status: ☐ In-Patient ☐ Out-Patient ☐ Non-Patient
Insurance Information: ☐ See attached Authorization # _____

| PRIMARY BILLING PARTY | SECONDARY BILLING PARTY |
|---|---|
| INSURANCE CARRIER* | INSURANCE CARRIER* |
| ID # | ID # |
| GROUP # | GROUP # |
| INSURANCE ADDRESS | INSURANCE ADDRESS |
| NAME OF INSURED PERSON | NAME OF INSURED PERSON |
| RELATIONSHIP TO PATIENT | RELATIONSHIP TO PATIENT |
| EMPLOYER NAME | EMPLOYER NAME |

*IF MEDICAID STATE | PHYSICIAN'S PROVIDER # | WORKERS COMP ☐ Yes ☐ No

## SPECIMEN INFORMATION - TISSUE TESTING

Collection Date: Send Date:

Specimen ID# (as it appears on the specimen):

Body Site/Descriptor:

Fixative: ☐ 10% Neutral Buffered Formalin ☐ Other: Hours Fixed:

☐ FFPE Block(s) # _____ ☐ Choose best block (default) ☐ Unstained slides # _____
☐ Perform test on all blocks

## SPECIMEN INFORMATION - LIQUID BIOPSY

Collection Date: Time: ☐ AM ☐ PM Send Date:

Specimen ID# (as it appears on the specimen):

☐ Whole Blood

## CLINICAL INDICATION (attach clinical history and pathology reports)

Narrative Diagnosis/Clinical Data (please attach previous test results, if applicable):

All diagnoses should be provided by the ordering physician or an authorized designee.
Diagnosis/Signs/Symptoms in ICD-CM format in effect at Date of Service (Highest Specificity Required)

ICD-CM | ICD-CM | ICD-CM

## BLOCK PROCUREMENT

**Tissue Location:** Do you have possession of the tissue block and/or slides? ☐ Yes ☐ No
If No, indicate the location (below) and fax completed requisition to your lab location (see fax #s at top of requisition).

Facility Name:
Attention/Dept:
Address:

Phone Number: Fax Number:

## STAGE AND TREATMENT INFORMATION

Disease Stage (III, IV, etc.): _____
Disease Status (choose one: primary, metastatic, recurrent, relapsed, refractory): _____
Current Therapy (including time on therapy):

Prior Therapy(s):

Prior Transplant: ☐ Yes ☐ No
Relevant Testing History (check all that apply)
☐ Testing is (e..g., SNVs, TMB, MSI) being requested to inform treatment decision
☐ Patient has not had other NGS testing within a year
☐ Limited tissue is available
☐ Patient is not eligible for surgery or biopsy
☐ Previous hotspot or single analyte testing did not identify actionable markers or treatment has been exhausted
☐ Patient has advanced or metastatic cancer
☐ Patient has progressed on current/previous therapy

## TESTING REQUESTED

### SOLID TUMOR TISSUE TESTING

☐ OmniSeq® INSIGHT (DNA & RNA-Seq for targeted therapy, TMB, MSI, PD-L1 & gene expression for immune therapy)-see reverse for test details and specimen requirements

**REQUIRED:**
Attach a copy of the final pathology report for the sample to be tested and a recent clinical note to support medical necessity for testing.

Primary cancer/Diagnosis: ☐ Breast ☐ Colorectal ☐ Kidney ☐ Liver ☐ Melanoma ☐ NSCLC ☐ Other Lung Cancer ☐ Ovarian ☐ Pancreatic ☐ Prostate ☐ Neuroendocrine ☐ Other: _____

### LIQUID BIOPSY TESTING

Submit samples using the liquid biopsy specimen kit (see reverse side for specimen kit ordering information).
☐ Labcorp® Plasma Complete™ (521 gene panel - see reverse side for test description and specimen requirements).
**Patient service centers: use test code 850450.**

**REQUIRED:**
Attach a copy of the final pathology report and/or a clinical note to confirm the diagnosis and clinical necessity for testing.

Primary cancer/Diagnosis: ☐ Breast ☐ Colorectal ☐ Kidney ☐ Liver ☐ Melanoma ☐ NSCLC ☐ Other Lung Cancer ☐ Ovarian ☐ Pancreatic ☐ Prostate ☐ Neuroendocrine ☐ Other: _____

☐ Labcorp® Plasma Focus™ (33 gene panel - see reverse side for test description, gene list and specimen requirements).
**Patient service centers: use test code 850150.**

**REQUIRED:**
Attach a copy of the final pathology report and/or a clinical note to confirm the diagnosis and clinical necessity for testing.

Primary cancer/Diagnosis (test to be used for the following indications only): ☐ NSCLC ☐ Colorectal ☐ Breast ☐ Gastric ☐ Esophageal ☐ Melanoma ☐ Gastroesophageal junction

Testing will be performed and billed by Personal Genome Diagnostics Inc. (PGDx). The Labcorp Plasma Complete and Labcorp Plasma Focus tests are not available in New York state.

### IMMUNOHISTOCHEMISTRY TESTS

(Please visit oncology.labcorp.com to see a complete list of our testing services)

☐ FOLR1 by IHC – Ovarian
☐ Claudin 18 by IHC – Gastric
☐ HER2 by IHC – Pan-tumor

Please request additional tests by writing in the space below:

## PHYSICIAN'S SIGNATURE AND CONSENT

Please see consent language on reverse side.

Ordering Physician Signature _____ Printed Name _____ Date_____

☐ My patient would like to opt out of research use of any generated test results, tissues, cells, and genetic materials.

When ordering tests for which Medicare or Medicaid reimbursements will be sought, physicians should order only those tests that are medically necessary for the diagnosis or treatment of the patient.

## Consent Language

My signature certifies that I have determined that the test(s) being ordered is medically necessary for the patient, certifies that the results of this test will inform the patient's ongoing treatment plan, and certifies that I am the patient's treating physician or that I have been authorized by the patient's treating physician to pursue genomic testing. I, or the patient's treating physician, have explained to the patient the nature and purpose of the test(s) to be performed and have obtained informed consent, to the extent required under applicable law, to permit Labcorp, or any laboratory with which Labcorp has contracted, to (a) perform the test(s) specified herein, (b) analyze and report on other genetic information generated during the testing process or conduct additional analyses of the patient's sample for future diagnostic or monitoring use, and (c) release the test results and related patient information to the patient's third-party payer as needed for reimbursement purposes. Further, unless specified, the patient consents for Labcorp to retain the test results and any residual tissues, blood, plasma, cells, and genetic material, including DNA and RNA, and information generated during the testing process, for an indefinite period for internal quality assurance/operations purposes, and remove information that directly identifies the patient from the test results, tissues, blood, plasma, cells, and genetic material, including DNA and RNA, information generated during the testing process, and use or disclose such information and materials for future unspecified research or other purposes.

## Test Information

### OmniSeq® INSIGHT

Test description- A single test that combines the power of genomic and immune profiling. A next generation sequencing-based in vitro diagnostic device for the detection of genomic variants, signatures, and immune gene expression in formalin-fixed paraffin-embedded (FFPE) tumor tissue. DNA detects small variants in the full exonic coding region of 523 genes (SNVs, indels, CNVs), MSI and TMB, RNA to detect fusions in 55 genes, in addition to mRNA expression in 64 immune genes, and measures PD-L1 protein by IHC. For a complete gene list, please visit oncology.labcorp.com/omniseq

**Specimen Requirements:**

| | |
|---|---|
| Tissue Submission Guidelines | All blocks and slides must at a minimum be labeled with the pathology case number and part.<br>Reports and other provided materials must be labeled with the pathology case number and at least two patient identifiers, such as name, medical record number or date of birth. **PLEASE INCLUDE THE PATHOLOGY REPORT.** |
| Recommended Specimen Submission | ****DO NOT SUBMIT Decalcified Specimens, Cytology Smears or samples from hematologic malignancies****<br>The preferred specimen is at least one FFPE block. If a block cannot be provided, see slide requirements below. Specimens with very small amounts of tumor and/or less than requested number of slides will be accepted with the caveat that complete testing may not be possible. **Specimens should be selected by a board-certified pathologist and should contain neoplastic and normal tissue, where indicated.** It Is recommended that USS are cut using standard DNA/RNA precautions (change microtome blade, wipe stage, never re-use blade for more than one case and remove floaters in water bath between cases). |
| Slide Requirements | **OmniSeq INSIGHT:** Block is preferred, or send 15 unbaked, positively charged, unstained slides cut at 5 µm. |

**If shipping OmniSeq INSIGHT samples directly to the Buffalo NY lab, use this address:**
Labcorp, Attn: OmniSeq Lab, 700 Ellicott Street, Buffalo, NY 14203

### Labcorp® Plasma Complete™

The Labcorp® Plasma Complete™ test is a next generation sequencing based laboratory developed test for the detection of genomic sequence mutations in 521 genes including amplifications in 12 genes, translocations in 12 genes, and microsatellite instability (MSI) from plasma-derived cell-free DNA. The test is intended to be used by qualified healthcare professionals in accordance with professional oncology guidelines for patients already diagnosed with advanced stage or metastatic solid tumors. Test results are not prescriptive for the use of any specific therapeutic product.

For a complete gene list, please visit oncology.lapcorp.com.

Currently, the Labcorp Plasma Complete test is not available in the state of New York.

To order the liquid biopsy specimen kit, contact your Labcorp Oncology sales representative or visit oncology.labcorp.com/cancer-care-team/order-supplies.

**Plasma Complete samples shipment address:**
Labcorp/PGDx, 3600 Boston Street, Suite 55, Baltimore, MD 21224

### Labcorp® Plasma Focus™

Test description- A next-generation sequencing-based laboratory-developed test (LDT) for the detection of genomic sequence mutations in 33 clinically actionable or relevant genes, including amplifications in 8 genes, translocations associated with 5 genes, and microsatellite instability (MSI) using plasma-derived cell-free DNA (cfDNA). The test is intended to be used by qualified health care professionals in accordance with professional oncology guidelines for patients with advanced stage or metastatic non-small cell lung cancer, colorectal cancer, breast cancer, esophageal cancer, gastroesophageal junction cancer, gastric cancer, or melanoma. Test results are not prescriptive for the use of any specific therapeutic product.

**Reportable Gene List:**
Single nucleotide variants (SNVs) and insertions/deletions (Indels): *AKT1, ALK, APC, ARID1A, ATM, BRAF, BRCA1, BRCA2, BRIP1, CCND1, CD274, CDH1, CSF1R, EGFR, ERBB2, EZH2, FGFR1, FGFR2, HRAS, KIT, KRAS, MET, MYC, NRAS, NTRK1, PDGFRA, PIK3CA, POLD1, POLE, RAF1, RET, ROS1, TP53*
Amplifications: *CCND1, CD274, EGFR, ERBB2, FGFR2, KIT, MET, MYC*
Translocations: *ALK, FGFR2, NTRK1, RET, ROS1*

Currently, the Labcorp Plasma Focus test is not available in the state of New York.

To order the liquid biopsy specimen kit, contact your Labcorp Oncology sales representative or visit oncology.labcorp.com/cancer-care-team/order-supplies.

**Plasma Focus samples shipment address:**
Labcorp/PGDx, 3600 Boston Street, Suite 55, Baltimore, MD 21224

**Specimen Requirements:**

| | |
|---|---|
| Blood sample | 20 mL whole blood collected in 2 Streck Cell-Free DNA tubes |
| Storage and shipment | Specimens should be stored at room temperature and shipped overnight (using the provided liquid biopsy specimen kit) to the PGDx testing laboratory. Record the date and time of collection in the specimen information section. Please don't refrigerate or freeze the specimen |

Limitations of ctDNA testing: The sensitivity of liquid biopsy is related to levels of ctDNA shed by a patient's tumor. To capture and accurately measure optimal ctDNA shed, it is recommended that blood be drawn (1) at the time of diagnosis prior to initiation of therapy or (2) at a time of disease progression for patients who may be eligible for targeted therapy. Therefore, assay performance will depend upon level of ctDNA shed at time of testing and each patient's specific tumor, including stage and treatment history.

## Other Locations and Contacts:

Arizona
5005 South 40th Street
Phoenix, AZ 85040
800.710.1800
Fax 800.481.4151

Connecticut
3 Forest Parkway
Shelton, CT 06484
800.447.5816
Fax 212.258.2143

Tennessee
201 Summit View Drive, Suite 100
Brentwood, TN 37027
800.874.8532
Fax 615.370.8074

## Determining Necessity of Advance Beneficiary Notice of Non-coverage (ABN) Completion*

1. **Diagnose.** Determine your patient's diagnosis.
2. **Document.** Write the diagnosis code(s) on the front of this requisition.
3. **Verify.** Determine if the laboratory test(s) ordered for the patient is subject to the Local Coverage Determination or National Coverage Determination. This information can be located in the policies published by your Medicare Administrative Contractor (MAC), CMS, or www.Labcorp.com/MedicareMedicalNecessity.
4. **Review.** If the diagnosis code for your patient **does not** meet the medical necessity requirements set forth by Medicare or the test is being performed more frequently than Medicare allows, an ABN should be completed.

*An ABN should be completed for all tests that are considered investigational (experimental or for research use) by Medicare.

### How to Complete an Advance Beneficiary Notice of Non-coverage (ABN)

Medicare is very specific in requiring that all of the information included on the ABN must be completed. Additionally, Labcorp requests that the specimen number or bar code label be included on the form. To be valid, an ABN must:

1. Be executed on the CMS approved ABN form (CMS-R-131).
2. Identify the Medicare Part B Beneficiary, using the name as it appears on the patient's red, white, and blue Medicare card.
3. Indicate the test(s)/procedure(s) which may be denied within the relevant reason column.
4. Include an estimated cost for the test(s)/procedures(s) subject to the ABN.
5. Have "Option 1", "Option 2", or "Option 3" designated by the beneficiary.
6. Be signed **and** dated by the beneficiary or his/her representative **prior to** the service being rendered.

**Patient, client, and billing information is requested for timely processing of this case. Medicare and other third party payors require that services be medically necessary for coverage, and generally do not cover routine screening tests.**

**Refer to Determining Necessity of ABN Completion on reverse.**


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