labcorp | Oncology

Client Services
TN (800) 874-8532 fax: (615) 370-8074
AZ (800) 710-1800 fax: (800) 481-4151
CT (800) 447-5816 fax: (212) 698-9532

GENE PROFILING ASSAYS

oncology.labcorp.com

Highlighted fields are REQUIRED

CLIENT INFORMATION

ORDERING PHYSICIAN	NPI #
TREATING PHYSICIAN	NPI #

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

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

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

Body Site/Descriptor:

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

Specimen Type (for complete specimen requirements see reverse)

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

☐ Whole Blood ☐ FNA-Source: _____ ☐ Other _____

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.): _____
Therapy Status (metastatic, recurrent, etc.): _____
Current Therapy (including time on therapy):

Prior Therapy(s):

Prior Transplant: ☐ Yes ☐ No

Relevant Testing History (check all that apply)
☐ 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 not had NGS testing for this primary cancer
☐ Patient is newly diagnosed
☐ 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 assay details and specimen requirements)

REQUIRED:
Attach copy of final pathology report for the sample to be tested and other clinical documentation 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

☐ Labcorp® Plasma Focus™ test (see reverse side for test description, gene list and specimen requirements). Submit samples using the liquid biopsy specimen kit. **Patient service centers: use test code 850150**

REQUIRED:
Attach copies of clinical documentation to support medical necessity for testing

Primary Cancer/Diagnosis: ☐ NSCLC ☐ Colorectal ☐ Breast ☐ Gastric ☐ Esophageal ☐ Melanoma ☐ Gastroesophageal junction

Testing will be performed and billed by Personal Genome Diagnostics Inc. (PGDx)

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

Please request additional tests by writing in the space below:

PHYSICIAN'S SIGNATURE AND CONSENT

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.

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.

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. 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**** 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 20 unbaked, positively charged, unstained slides cut at 5 µm.

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*

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.

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.

onc-793-v18-06222023