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 #
PHYSICIAN/AUTHORIZED SIGNATURE	

Client#

Client Name

Address

Phone Number Fax Number

PATIENT INFORMATION

Name (LAST, FIRST, MIDDLE):

Date of Birth: Sex: ☐ Male ☐ Female

Address:

City, State, Zip:

Phone Number:

Med. Rec. # / Patient #:

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: ☐ Other:

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	☐ Unstained slides #	☐ Plasma
☐ BM Aspirate	☐ BM Core	
☐ BM Clot	☐ FNA–Source:	

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	

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.

BLOCK PROCUREMENT

Block Location: Do you have possession of the block? ☐ 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:

OmniSeq INSIGHT℠ (see reverse for assay details and specimen requirements)

By selecting a test option below, the ordering provider certifies medical necessity of testing and the intent to use test results in the medical management and treatment decisions for the patient.

☐ OmniSeq INSIGHT℠ Assay (DNA & RNA-Seq for targeted therapy, TMB, MSI, PD-L1 & gene expression for immune therapy)

OmniSeq INSIGHT Reflex Option (Lung cancer only)

☐ OmniSeq INSIGHT, if tissue submitted is insufficient for testing, reflex to Resolution ctDx Lung™ Assay (liquid biopsy) *

*Labcorp Oncology Client Services will call the ordering physician if tissue is found to be insufficient to request a peripheral blood sample

REQUIRED:
Copy of final pathology report for the sample to be tested and other clinical documentation to support medical necessity for testing

Stage: _____

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

IntelliGEN® NGS ASSAY (see reverse for the gene list)

☐ IntelliGEN® Myeloid for AML, MDS, MPN (451953)
Indication: _____

PROSIGNA® ASSAY

☐ **Prosigna®** Breast Cancer Prognostic Gene Signature Assay, IVD (481210)

Important Note:
REQUIRED: Gross Tumor Size (must select one) ☐ ≤2cm ☐ > 2cm
REQUIRED: Nodal Status (must select one) ☐ Negative ☐ 1-3 nodes

RESOLUTION CTDX LUNG™ (see reverse for gene list) Blood Only; use liquid biopsy kit tubes

☐ **Resolution Bioscience ctDx Lung™ Liquid Biopsy Assay (830697)**

Stage: ☐ III ☐ IV **Current Therapy:** _____

Previous Therapy: _____

☐ Adenocarcinoma (NSCLC)
☐ Large Cell Carcinoma (NSCLC)
☐ Squamous Cell Carcinoma (NSCLC)
☐ Lung Carcinoid/Neuroendocrine Small Cell Lung Carcinoma
☐ Non-small cell lung cancer (NSCLC)

Relevant Testing History (must choose one):
☐ At Diagnosis: Patient has NOT had Comprehensive Genomic Profiling (EGFR, ALK, ROS1, BRAF) and tissue testing is not feasible or unavailable
☐ At Progression: Patient has NOT had Comprehensive Genomic Profiling (EGFR, ALK, ROS1, BRAF) and tissue testing is not feasible or unavailable
☐ At Progression: Patient progressing on tyrosine kinase inhibitors (TKIs)

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:

OmniSeq INSIGHT℠ - 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

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.

IntelliGEN® Myeloid Panel Gene List

ABL1, ASXL1, BCOR, BCORL1, BRAF, CALR, CBL, CDKN2A, CEBPA, CSF3R, CUX1, DNMT3A, ETV6, EZH2, FBXW7, FLT3, GATA1, GATA2, IDH1, IDH2, IKZF1, JAK2, JAK3, KDM6A, KIT, KMT2A, KRAS, MPL, NF1, NOTCH1, NPM1, NRAS, PDGFRA, PHF6, PML, PTEN, PTPN11, RAD21, RUNX1, SETBP1, SF3B1, SMC1A, SMC3, SRSF2, STAG2, TET2, TP53, U2AF1, WT1, ZRSR2

IntelliGEN® Myeloid Panel Specimen Requirements

Specimen: Whole blood, bone marrow, cell pellets from whole blood, or cell pellets from bone marrow
Volume: 3-5 mL (Blood), 1-2 mL (Bone Marrow)
Container: Lavender-top (EDTA) tube or green-top (heparin) tube

Prosigna® Sample Requirements

The **gross size** of the patient's primary tumor and **nodal status** are required to perform the assay. A copy of the original pathology report is required for testing. If a pathology report is not received, testing will be delayed.

Solid Tumor (SEE NOTE)

Formalin-Fixed paraffin embedded tissue. Fixative should be neutral buffered formalin.

Block

Formalin-Fixed paraffin embedded tissue block

Unstained slides

Up to six unstained slides (see table below) at 10 µM and one matching H&E-stained slide. The tumor cellularity percentage within the circled tumor area on the H&E-stained slide must be ≥10%. The circled tumor surface area on the H&E-stained slide must be ≥4mm².

Measured tumor surface area on H&E-stained slide (mm^2)	Number of unstained slides needed (each slide cut at 10 µm sections)
4-19	6
20-99	3
≥ 100	1

Note:

1. The Prosigna® assay is not intended for patients with 4 or more positive nodes.
2. Micrometastases were not considered node positive during the Prosigna® assay validation, so it should be considered as a negative node.
3. Only invasive breast carcinoma is qualified for Prosigna® assay. DCIS (ductal carcinoma in situ) is not qualified for the Prosigna® assay.
4. The Prosigna® assay is intended for use only on formalin-fixed paraffin-embedded (FFPE) breast cancer tissue specimens from surgical resections. It is not intended for use on needle biopsy samples, fresh, frozen or non-breast cancer tissue.
5. Multifocal breast tumor should not be combined. Each should be considered as an independent tumor.

Resolution ctDx Lung™ Liquid Biopsy Assay Gene List

AKT1, ALK, B2M, BRAF, EGFR, ERBB2 (HER2), FGFR1, FGFR2, FGFR3, KEAP1, KRAS, MAP2K1(MEK1), MET, MYC, NRAS, NTRK1, PIK3CA, PTEN, RET, RICTOR, ROS1, STK11, TP53

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.

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