Integrated ONCOLOGY
LabCorp Specialty Testing Group

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

GENE PROFILING ASSAYS

www.integratedoncology.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 #
☐ BM Aspirate	☐ BM Core
☐ BM Clot	☐ FNA–Source:

CLINICAL INDICATION FOR STUDY (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:

ADDITIONAL PHYSICIAN(S) TO BE COPIED

Name:

Facility Name:

Attention/Dept:

Address:

Phone Number: Fax Number:

OMNISEQ® ASSAYS (see reverse for assay details)

Note: A copy of the original pathology report is REQUIRED for OmniSeq testing.
See reverse for detailed specimen requirements

Required information for the OmniSeq Assays:

Primary Cancer Tumor Type: ☐ Lung ☐ Breast ☐ Colon ☐ Melanoma ☐ Kidney

Other: _____

Stage: _____

☐ OmniSeq Advance℠ Assay

☐ OmniSeq Comprehensive® Profile Assay

☐ OmniSeq Immune Report Card® Assay

IntelliGEN® ASSAY

Note: A copy of the original pathology report is REQUIRED for IntelliGEN® testing.

Panel:

☐ **IntelliGEN®** Oncology Therapeutic Panel (NGS)^ (489600)
(see reverse for the gene list)

Individual Assay(s):

Offered to complement the IntelliGEN® panel, which must be ordered above.

☐ HER2 expression by IHC ☐ HER2 amplification by FISH ☐ ALK rearrangements by FISH
☐ EGFR amplification by FISH ☐ ROS1 rearrangements by FISH ☐ RET rearrangements by FISH
☐ cMET expression by IHC ☐ cMET amplification by FISH

^ Investigational Use Only

PROSIGNA® ASSAY

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

Important Note:

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

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

Please request additional tests by writing in the space below:

OmniSeq Advance Assay - A single test combines the benefits of both targeted immunotherapy and genomic targeting: measures protein, RNA, and DNA. Methodology includes IHC, MSI, mutational burden, NGS sequencing of 204 genes.

OmniSeq Comprehensive Profile Assay - A NGS assay that tests tumor DNA and RNA to identify somatic mutations in 144 genes for solid tumors to help guide targeted therapeutic management decisions.

OmniSeq Immune Report Card Assay - An assay that measures multiple biomarkers present in DNA, RNA, proteins, and cells to comprehensively interrogate the cancer-immunity cycle. Methodology includes IHC, MSI, mutational burden and gene expression of 54 specific immune markers.

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 or Cytology Smears**** 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 Advance℠:** Block is preferred, or send 20 unbaked, positively charged, unstained slides cut at 5 µm. ☐ **OmniSeq Comprehensive AND Immune Report Card:** Block is preferred, or send 20 unbaked, positively charged, unstained slides cut at 5 µm. ☐ **Immune Report Card Only:** Block is preferred, or send 15 unbaked, positively charged, unstained slides cut at 5 µm. ☐ **OmniSeq Comprehensive Only (OCP):** Block is preferred, or send 10 unbaked, positively charged, unstained slides cut at 5 µm.

IntelliGEN® Gene List

ABL1	BRAF	EGFR	FGFR1	GNAQ	IDH2	KRAS	NPM1	PTPN11	SMO
AKT1	CDH1	ERBB2	FGFR2	GNAS	JAK2	MET	NRAS	RB1	SRC
ALK	CDKN2A	ERBB4	FGFR3	HNF1A	JAK3	MLH1	PDGFRA	RET	STK11
APC	CSF1R	EZH2	FLT3	HRAS	KDR	MPL	PIK3CA	SMAD4	TP53
ATM	CTNNB1	FBXW7	GNA11	IDH1	KIT	NOTCH1	PTEN	SMARCB1	VHL

IntelliGEN® Specimen Requirements

Solid Tumor (excision, core, FNA or endoscopic biopsies)

Formalin-Fixed paraffin embedded tissue. Fixative should be neutral buffered formalin. For solid tumor metastatic bone samples submit a non-decalcified FFPE sample. Decalcified bone biopsies are not acceptable sample types for this test.

Block

Tumor surface area of ≥ 4 mm^2 and tumor content ≥ 10 %; ≥ 50 % is preferred. **(SEE NOTE)**

Unstained slides

See table below as a guide to the number of slides required to meet the DNA input requirements

Measured tumor surface area	Tumor content %	Number of slides needed (each slide cut at 10 µm sections)
≥ 4 mm^2	≥ 50%	5 unstained slides and 1 H&E
1-4 mm^2	≥ 10%	10 unstained slides and 1 H&E

NOTE:

1. Tumor surface areas between 1-4 mm^2 with ≥ 10% tumor content are less likely to meet the DNA input requirements.
2. Tumor surface areas between 1-4 mm^2 and < 10% tumor or below <1 mm^2 will be considered QNS for analysis.
3. If sending a core biopsy, if tumor is less than < 0.5 cm in length it is less likely to meet the DNA input requirements.
4. If sending a cell block aspirate, at least eight tumor cell clusters providing 400-800 intact tumor cells is needed or it is less likely to meet the DNA input requirements.

Bone Marrow Aspirates

1-2 ml fresh aspirate in a Lavender top (EDTA) or a green top (sodium heparin) tube.

Fresh Tumor Aspirates (FNAs)

5-10 ml tumor in RPMI or CytoLyt® container. FNAs require sufficient tumor cells for DNA extraction.

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 ≥4mm^2.

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.

Determining Necessity of Advance Beneficiary Notice of Noncoverage (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 Noncoverage (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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