

Order Form & Statement of Medical Necessity

All fields required unless noted as optional

Patient Information

Name (Last, First, MI) _____ DOB (MM/DD/YYYY) _____ Medical Record # _____ Sex at Birth Female Male

Phone (Primary) _____ Street Address _____ City _____ State _____ ZIP _____

Email _____ Primary Cancer Diagnosis _____ Primary ICD-10 Code _____

Does the patient have any of the following: recurrent, relapsed, refractory, advanced (Stage III/IV) or metastatic cancer? Yes No (If No, you may be contacted)

Billing Information

Insurance/Medicare/Medicaid Patient Self-pay Account Bill Primary Insurance _____ Member ID _____

Patient Status (at sample collection) _____ Discharge Date (inpatient only) _____ Group # _____ Primary Policy Holder _____ DOB (MM/DD/YYYY) _____

Non-hospital Outpatient Inpatient

IF PRIMARY INSURANCE IS LEFT BLANK, OR IF SECONDARY INSURANCE IS AVAILABLE, ENSURE A FACE SHEET AND COPY OF INSURANCE CARD ARE ATTACHED, OR YOU MAY BE CONTACTED.

Treating Provider

Name _____ NPI _____ Email _____

Office / Practice / Institution _____ Phone _____ Fax _____

Address _____ Contact Name _____ Contact Phone _____ Contact Email _____

Additional Report Recipient (Optional)
Name _____ Phone _____ Fax _____

Pathology & Specimen Retrieval

Exact Sciences to request tumor specimen from Pathology Ordering Provider to request tumor specimen from Pathology

Office / Practice / Institution _____ Tumor: Format(s) Submitted _____ Specimen ID # _____

FFPE Block Unstained Slides Fresh Frozen H&E Included

Phone _____ Fax _____ Tissue Source _____ Date of Collection _____ Date Block Pulled from Archive _____

Address _____ Processing: Fixed per ASCO/CAP guidelines: Yes No Unknown Decalcification: None EDTA Other

Previous results

Please provide ER/PR/HER2 results as applicable

PLEASE ATTACH PATHOLOGY REPORT

Matched Normal:

Specimen ID # _____

Date of Collection _____

Peripheral blood in EDTA _____

Testing Options

*OncoExTra
Tumor/Normal Exome (DNA) and Transcriptome (RNA)

Specimen Requirements

Tumor (FFPE)

FFPE Block (preferred)
Fixed Tissue: Surface area ≥ 25mm²
Core Needle Biopsy: 3-5 cores from a single tumor
Unstained Slides: 10 (charged, unbaked) from a single tumor, ≥50 microns total and 1 H&E.

Matched normal (whole blood)

Minimum 3-5mL in EDTA
Clotted or hemolyzed specimens are not accepted.
Refrigerate until time of shipment, needs to be ≤7 days old at time of receipt.
Storage of blood samples should be at standard lab protocols (2-8 °C).

*New York State validation of OncoExTra includes complete exome results and select clinically relevant fusions from transcriptome. Please see OncoExTra NYS results below for details.

Please contact us to discuss alternative specimen types.

The molecular test generally takes 50-100 microns of tissue. Submitted tissue may be exhausted to perform requested testing.

Certificate of medical necessity, consent for testing, and Provider signature

With my signature below, I certify that: (1) I am the treating Provider, and this testing is medically necessary and appropriate for this patient and the results will be used to determine the patient's treatment plan; (2) I have educated the patient and have received the patient's informed consent to proceed with testing; (3) I have received the patient's consent for your laboratory to release test results and to submit all necessary information to insurance for payment; and (4) I understand that this testing will be based on the most updated requisition and test description available.

Please attach the following:

- Pathology report
- Clinical progress note
- Front and back of insurance card

Treating Provider Signature _____ Printed Name _____ Date _____

OncoExTra New York State Results

OncoExTra has been validated according to the guidelines set forth by the New York State Department of Health. Whole exome (DNA) events have been validated to include point mutations, indels, and copy number alterations, as well as MSI analysis and TMB calculation. Whole transcriptome (RNA) has been validated to report on only the following fusion genes and special transcripts:

ALK	ARV7	BRAF	CIC	COL1A1	DDIT3	DNAJB1	EGFR	EGFRvIII	EGFRvIV
ERG	EWSR1	FGFR1	FGFR2	FGFR3	FOXO1	JAZF1	MDM2	MET	METe14
MYB	NRG1	NTRK1	NTRK2	NTRK3	NUTM1	RAF1	RET	ROS1	RSPO2
RSPO3	SS18	STAT6	TFE3						

OncoExTra™ Assay

1. Assay criteria: The test is considered reasonable and medically necessary for patients diagnosed with advanced (Stage III, Stage IV) solid tumor malignancies to aid in the selection of therapeutic options or available clinical trials.
2. Coverage of the OncoExTra test by Medicare applies under the following conditions:
 - a. Patient has recurrent, relapsed, refractory, metastatic, or advanced cancer (stages III or IV)
 - b. Patient has not been previously tested by the same test using NGS for the same cancer genetic content
 - c. Patient is seeking treatment for their advanced cancer (e.g., therapeutic chemotherapy)

Shipping Instructions

Ship samples overnight to:

ATTN: Accessioning
Genomic Health, Inc.
445 N 5th Street
Phoenix, AZ 85004

Ship Blood, and FFPE on cold packs (provided in kit)
Ship Fresh Frozen Tissue on dry ice
Specimens accepted Monday – Saturday
Please do not ship the day before a holiday

Rendering Provider Address

Genomic Health Inc.
445 N 5th Street
Phoenix AZ, 85004
PLA Code: 0329U
CPT Code: 81479, 81455
GHI Provider ID: 1215003603