

## Patient Information

Name (Last, First, MI)		DOB (MM/DD/YYYY)	Medical Record #	Sex at Birth <input type="checkbox"/> Female <input type="checkbox"/> 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

<input type="checkbox"/> Insurance/Medicare/Medicaid	<input type="checkbox"/> Patient Self-pay	<input type="checkbox"/> Account Bill	Primary Insurance	Member ID
Patient Status (at sample collection) <input type="checkbox"/> Non-hospital <input type="checkbox"/> Outpatient <input type="checkbox"/> Inpatient		Discharge Date (inpatient only)	Group #	Primary Policy Holder
				DOB (MM/DD/YYYY)

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	
<b>Additional Report Recipient (Optional)</b>				
Name	Phone	Fax		

## Pathology & Specimen Retrieval

<input type="checkbox"/> Exact Sciences to request tumor specimen from Pathology		<input type="checkbox"/> Ordering Provider to request tumor specimen from Pathology		
Office / Practice / Institution	<b>Tumor:</b> Format(s) Submitted <input type="checkbox"/> FFPE Block <input type="checkbox"/> Unstained Slides <input type="checkbox"/> Fresh Frozen <input type="checkbox"/> H&E Included			Specimen ID #
Phone	Fax	Tissue Source	Date of Collection	Date Block Pulled from Archive
Address	Processing: Fixed per ASCO/CAP guidelines: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown		Decalcification: <input type="checkbox"/> None <input type="checkbox"/> EDTA <input type="checkbox"/> Other	
<b>Previous result recipient (Optional)</b> Please provide ER/PR/HER2 results as applicable		<b>Matched Normal:</b>		Date of Collection
<a href="#">PLEASE ATTACH PATHOLOGY REPORT</a>		Peripheral blood in EDTA	Specimen ID #	

## Testing Options

**OncoExTra**  
Tumor/Normal Exome (DNA) and Transcriptome (RNA)  
To add-on specific IHC stains, please select from the right.

**OncoExTra + IHC panel**  
Tumor/Normal Exome (DNA) and Transcriptome (RNA) + IHC panel  
An Exact Sciences Pathologist will select an IHC panel based on the available clinical information. IHC panels can be located on page 2.  
To add-on specific IHC stains, please select from the right.

### For individual IHCs, choose from below

<input type="checkbox"/> ALK	<input type="checkbox"/> HER2	<input type="checkbox"/> MLH1	<input type="checkbox"/> PD1	<input type="checkbox"/> PD-L1 (SP263)	<input type="checkbox"/> PTEN
<input type="checkbox"/> AR	<input type="checkbox"/> IDO	<input type="checkbox"/> MSH2	<input type="checkbox"/> PD-L1 (22C3)	<input type="checkbox"/> PMS2	<input type="checkbox"/> TRKpan
<input type="checkbox"/> ER	<input type="checkbox"/> MET	<input type="checkbox"/> MSH6	<input type="checkbox"/> PD-L1 (SP142)	<input type="checkbox"/> PR	

## 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
_____	_____	_____

## IHC Panels

<b>Anal:</b> PD-1, PD-L1(22C3), MMR <sup>1</sup>	<b>GIST:</b> PD-L1(22C3), MMR <sup>1</sup>	<b>Prostate:</b> AR, PD-L1(22C3), MMR <sup>1</sup>
<b>Appendix:</b> HER2, PTEN, MMR <sup>1</sup>	<b>Head and neck, salivary gland:</b> HER2, AR, MMR <sup>1</sup>	<b>Skin, non-melanoma:</b> PD-L1(22C3), MMR <sup>1</sup>
<b>Bladder:</b> PD-L1(22C3), PD-L1(SP142), MMR <sup>1</sup>	<b>Head and neck, squamous:</b> PD-L1(22C3), MMR <sup>1</sup>	<b>Small bowel:</b> HER2, PTEN, MMR <sup>1</sup>
<b>Bone:</b> MMR <sup>1</sup>	<b>Hepatocellular:</b> HER2, PD-L1(22C3), MMR <sup>1</sup>	<b>Soft tissue:</b> MMR <sup>1</sup>
<b>Breast:</b> AR, PD-L1 (22C3), MMR <sup>1</sup> Previously tested for ER/PR/HER2. Otherwise HER2, ER, PR, PD-L1(22C3), MSH6, PMS2	<b>Kidney:</b> PD-L1(22C3), MET, MMR <sup>1</sup>	<b>Testicular:</b> PD-L1(22C3), MMR <sup>1</sup>
<b>Cervical:</b> PD-L1(22C3), ER, MMR <sup>1</sup>	<b>Melanoma:</b> PD-L1(22C3), PTEN, MMR <sup>1</sup>	<b>Thymus:</b> PD-L1(22C3), MMR <sup>1</sup>
<b>Cholangiocarcinoma:</b> HER2, PD-L1(22C3), MMR <sup>1</sup>	<b>Mesothelioma:</b> PD-L1(22C3), MMR <sup>1</sup>	<b>Thyroid:</b> PD-L1(22C3), ALK, MMR <sup>1</sup>
<b>CNS/Brain:</b> MMR <sup>1</sup>	<b>Neuroendocrine:</b> PD-L1(22C3), PTEN, MMR <sup>1</sup>	<b>Uterine:</b> ER, HER2, MMR <sup>1</sup>
<b>Colorectal:</b> HER2, PTEN, MMR <sup>1</sup>	<b>NSCLC:</b> PD-L1(22C3), PD-L1(SP142), ALK, MSH6, PMS2	<b>Vulvar:</b> PD-L1(22C3), ER, MMR <sup>1</sup>
<b>Esophagus:</b> HER2, PD-L1(22C3), MMR <sup>1</sup>	<b>Other solid tumors:</b> PD-L1(22C3), HER2, MMR <sup>1</sup>	
<b>Gallbladder:</b> HER2, PD-L1(22C3), MMR <sup>1</sup>	<b>Ovarian:</b> ER, HER2, MMR <sup>1</sup>	
<b>Gastric:</b> HER2, PD-L1(22C3), MMR <sup>1</sup>	<b>Pancreatic:</b> MMR <sup>1</sup> , PTEN	
	<b>Penile:</b> PD-L1(22C3), MMR <sup>1</sup>	

\* ASCO/CAP Guidelines: Breast specimens that will be subject to ER/PR and HER2 testing should be fixed in neutral buffered formalin for a minimum of six hours and a maximum of 72 hours. This fixation time begins when the specimen is initially placed in formalin (not when the specimen is sectioned during gross examination) and ends when the cassettes are no longer in formalin.

<sup>1</sup>Panel of 4 IHC stains: MLH1, MSH2, MSH6, PMS2

### 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

## Specimen Requirements

### For OncoExTra: Tumor (FFPE)

FFPE Block (preferred)  
Fixed Tissue: Surface area  $\geq 25\text{mm}^2$   
Core Needle Biopsy: 3-5 cores from a single tumor  
Unstained Slides: 10 (charged, unbaked) from a single tumor,  $\geq 50$  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  $\leq 7$  days old at time of receipt.  
Storage of blood samples should be at standard lab protocols (2-8 °C).

Please contact us to discuss alternative specimen types.

The molecular test generally takes 50-100 microns of tissue plus an additional 5-10 microns per immunohistochemical stain. Submitted tissue may be exhausted to perform requested testing.

### For IHC testing: IHC panel

FFPE block or additional 8 unstained slides from a single tumor.

### Individual IHC stain

FFPE block or 2 additional unstained slides from one tumor block per IHC stain.

Additional material may be required for FISH reflex if HER2 IHC equivocal.

## Rendering Provider Address

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

OncoExTra is a trademark of Genomic Health, Inc., a wholly-owned subsidiary of Exact Sciences Corporation. Exact Sciences is a registered trademark of Exact Sciences Corporation.

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