

Patient Information

Name (Last, First, MI)		DOB (MM/DD/YYYY)	MR#	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

Medicare	Private insurance	Medicaid	Patient (Domestic-US)	Patient (Non-US)	Account (restricted to contracted accounts on file)	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 Physician

Name	NPI	Email			
Office / Practice / Institution	Phone	Fax			
Address	Contact Name	Contact Phone	Contact Email		
Additional Physician/Report Recipient (Optional)					
Name	Address	Office/Practice/Institution	Phone	Fax	Email

Pathology & Specimen Retrieval

Exact Sciences to request tumor specimen from pathology.		Ordering Physician 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*:		Decalcification:			
		Yes	No	Unknown	None	EDTA	Other
Previous results		Matched Normal:		Specimen ID #		Date of Collection	
Please provide ER/PR/HER2 results as applicable		Peripheral blood in EDTA					
PLEASE ATTACH PATHOLOGY REPORT.							

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

ALK	HER2	MLH1	PD1	PD-L1 (SP263)	PTEN
AR	IDO	MSH2	PD-L1 (22C3)	PMS2	TRKpan
ER	MET	MSH6	PD-L1 (SP142)	PR	

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

With my signature below, I certify that: (1) I am the treating practitioner, 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 Physician Signature	Printed Name	Date

IHC Panels

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

¹ 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
Exact Sciences
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 ≥ 25mm²
Core Needle Biopsy: 3-5 cores from a single tumor
Unstained Slides: 10 from a single tumor, ≥ 50 microns total + 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).

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