

Order Form & Statement of Medical Necessity

PHONE 866-662-6897 FAX 602-682-5077 EMAIL oncoextra@exactsciences.com

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
(Tissue or Cell Block)

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 (Optional)
Please provide ER/PR/HER2 results as applicable

Matched Normal: Specimen ID # _____ Date of Collection _____
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 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

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 Breast²: AR, PD-L1 (22C3), MMR ¹ 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.

¹Panel of 4 IHC stains: MLH1, MSH2, MSH6, PMS2

²If ER, PR, HER2 not previously tested, the following panel will be performed: HER2, ER, PR, PD-L1 (22C3), 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 frozen 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:

FFPE Block (preferred)

- Fixed Tissue: Surface area $\geq 25\text{mm}^2$
- Cell Block: ≥ 200 malignant cells

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).

Please contact us to discuss alternative specimen types.

The molecular test generally takes 50-100 microns of tissue plus an additional 4-5 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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