

Test Requisition Form

ORDERING INSTRUCTIONS

1. Complete all fields below
2. Please include the completed Test Requisition Form, pathology report, & patient insurance card(s) along with the specimen
3. Ship to Biotheranostics via FedEx Priority Overnight

SPECIMEN RETRIEVAL OPTION

I want Biotheranostics to request the specimen from Pathology
 (Please complete and fax this form to 800-266-9607)

▶ TESTING SERVICES

CancerTYPE ID®

Molecular diagnosis of tumor type & subtype

Check below if you would like us to send the sample to our reference laboratory, NeoGenomics Laboratories* for additional testing:

- Tumor-specific biomarker testing based on CancerTYPE ID molecular diagnosis:
NSCLC, CRC, Breast, Gastric, or Melanoma (if other, no additional testing performed)
- MSI testing (for all CancerTYPE ID molecular diagnoses)
- MMR testing (for all CancerTYPE ID molecular diagnoses)

*These biomarkers will be reported and billed separately by NeoGenomics. See page 2 for list of biomarkers and specimen requirements.

SPECIAL INSTRUCTIONS:

▶ ONCOLOGIST

Name		NPI
<input type="checkbox"/> Please check if you are the ordering physician		
Email		
Practice/Facility Name		
Address		
City	State	Zip
Phone	Fax	

▶ PATHOLOGIST

Name		NPI
<input type="checkbox"/> Please check if you are the ordering physician		
Email		
Practice/Facility Name		
Address		
City	State	Zip
Phone	Fax	

▶ PATIENT INFORMATION Please include a copy of the patient face sheet

Name	
DOB	Sex <input type="checkbox"/> M <input type="checkbox"/> F
Social Security Number	
Address	
City	State Zip
Phone	Medical Record #
Next Appt. Date / /	

Please return the specimen to the location listed above once testing complete

Please return the specimen to alternate location listed below:

Address: Phone:

▶ SPECIMEN INFORMATION Reminder: Has pathologist reviewed tissue for adequacy? Yes No

Block ID Number	Date Collected
Biopsy Site	Clinical Diagnosis
Fixative Type (Recommended 10% Neutral-Buffered Formalin)	
ICD-10 Codes (Required) - List all codes that may apply (Visit CancerTYPEID.com for ICD-10 Code Reference Guide)	

▶ BILLING INFORMATION (Required) Please include a copy (front and back) of patient insurance card(s)

Bill to: <input type="checkbox"/> Insurance <input type="checkbox"/> Medicare - Part B <input type="checkbox"/> Patient <input type="checkbox"/> Hospital/Facility	Insurance Carrier Name	Policy #
Insurance Address	Group #	Phone

Medicare Status (Required) Please indicate patient's hospital status at the time of sample collection: Hospital Inpatient Non-Hospital Patient Hospital Outpatient **Date of Discharge** _____

Note: For CancerTYPE ID Medicare coverage criteria under a local coverage determination (LCD) visit www.biotheranostics.com/hcp-billing-information

▶ PHYSICIAN/PRACTITIONER CERTIFICATION (Required)

I hereby request and authorize Biotheranostics to utilize the above information to process the tumor specimen for the indicated patient. I certify the following: I am authorized by law to order the test(s); the tests ordered above are medically necessary; the results will be used in the management of the patient; and I have obtained any required patient consent for the test(s) and disclosure of test results to me. I agree to provide the necessary information and records needed for billing or reimbursement of the test(s). I have read the reverse side for additional details.

Signature _____ Printed Name _____ Date _____

Biomarker Testing (Note: Biomarker testing performed in order listed below; please indicate any special instructions on page 1)

NSCLC	CRC	Breast	Gastric	Melanoma	All
EGFR (Molecular) c-MET (FISH) ALK (FISH) BRAF (Molecular) ROS1 (FISH) RET (FISH) PD-L1 (IHC)	KRAS (Molecular) NRAS (Molecular) BRAF (Molecular)	HER2 (IHC) ER (IHC) HER2 (FISH)* PR (IHC)	HER2 (IHC) HER2 (FISH)*	BRAF (Molecular) PD-L1 (IHC)	MSI (Molecular) MMR (IHC)

*Confirmatory

Specimen Collection and Handling Procedures

PLEASE NOTE: Laboratory test result quality is highly dependent upon proper specimen collection and handling procedures. The specimen requirements and handling procedures are listed below. All samples must be clearly labeled with a unique block or specimen ID number, and patient name or date of birth. We are unable to accept samples that are not labeled, or samples labeled with identifiers that do not match those listed on the Test Requisition Form submitted. The corresponding pathology report must also be submitted with the specimen and Test Requisition.

FIXATION METHOD

Formalin-Fixed Paraffin-Embedded (FFPE) tissue is recommended for all testing services. Recommended fixative is 10% Neutral Buffered Formalin.

SPECIMEN TYPE

Testing can be performed on primary tumor or a site of metastasis. The following are acceptable specimen types:

- Surgical Resections • Excisional Biopsies • Core Needle Biopsies • Fine Needle Aspirations (FNA) • Cell Blocks (pleural effusions, ascites)
- Bone Biopsies decalcified in EDTA or Formic Acid (not HCl)

CancerTYPE ID®

Minimum Requirement: at least 300 non-necrotic tumor cells

- FFPE block (preferred) **OR** • 3-4 unstained, 7 micron sections on Leica Membrane slides, and 1 H&E slide

Note: Testing CANNOT be performed on regular glass slides. To request Leica Membrane slides, please contact Client Services.

TUMOR SPECIFIC BIOMARKERS

- FFPE block (preferred) **OR**
 - IHC: 2-3 unstained, 3-4 micron sections on positively-charged slides required per assay, and 1 H&E slide
 - Molecular: 5-10 unstained, >5 micron sections on positively-charged slides required per assay, and 1 H&E slide
 - FISH: 4 unstained, 4-5 micron sections on positively-charged slides required per assay, and 1 H&E slide
- Note: Total number of slides dependent on tumor-specific biomarker panel

MSI TESTING

Both tumor tissue and normal (non-tumor) tissue are required for comparison testing in MSI analysis

Tumor tissue: • FFPE block (preferred) **OR** • 5-10 unstained, >5 micron sections on positively-charged slides, and 1 H&E slide

Normal tissue: • FFPE block or tissue slides containing only non-tumor tissue (Please label these as "normal tissue")

- In cases where no alternative tissue is available, the reference laboratory can attempt to isolate non-tumor tissue from the tumor specimen submitted. Note "Use tumor sample for normal tissue" on requisition under Special Instructions

MMR TESTING

- FFPE block (preferred) **OR:** • 4-6 unstained, 3-4 micron sections on positively-charged slides, and 1 H&E slide

STORAGE CONDITIONS

Store specimen at room temperature (15-30°C).

STABILITY OF SPECIMEN

Recommend shipping of slides within 1 week of preparation. Do not freeze slides.

TRANSPORTATION

Ambient kit. Use cold pack for transport. Do not place cold pack in direct contact with specimen during transport. Place specimen blocks in a plastic bag and slides in a plastic case or slide-mailer. Place the specimens, completed Test Requisition, pathology report and supporting documents in a Biotheranostics Specimen Shipping Kit. Send specimens via FedEx "Priority Overnight" service. A pickup may be scheduled online at www.fedex.com or by calling (800) 463-3339. To obtain specimen shipping kits, Leica membrane slides, and Biotheranostics FedEx account information call Client Services at (877) 886-6739.

QUESTIONS

Medical and scientific staff are available to answer questions about specimen and sample viability prior to sending blocks or slides for testing - call Toll Free (877) 886-6739 between 7am and 4pm Pacific Time.

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