

Test Requisition Form

ORDERING INSTRUCTIONS

1. Complete ALL fields below (missing information will result in delay of testing)
2. Attach patient face sheet and copy (front and back) of insurance card(s) and pathology report for the specimen requested in Section V
3. Ship with specimen to Biotheranostics' laboratory **OR** fax this form to 800-266-9607 and Biotheranostics will request the specimen from Pathology.

INFORMATION ON THIS FORM MUST BE ACCURATE TO OBTAIN RELIABLE TEST RESULTS

I. TESTING SERVICES

CancerTYPE ID®
Molecular diagnosis of tumor type & subtype

SPECIAL INSTRUCTIONS:

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

NeoTYPE® Tumor Profile
based on CancerTYPE ID result
(See page 2 for list of tumor profiles
and associated biomarkers)

For all CancerTYPE ID results:

- Tumor Mutation Burden (TMB) NeoTYPE Discovery Profile for
Solid Tumors** (includes TMB)
 Microsatellite Instability (MSI)
 Mismatch Repair (MMR)

*Biomarkers will be reported and billed separately by NeoGenomics. See page 2 for specimen requirements **Note: If a NeoTYPE Tumor Profile and NeoTYPE Discovery Profile are both selected, only the NeoTYPE Discovery Profile will be performed; see page 2 for details on NeoTYPE Discovery Profile

II. ORDERING PHYSICIAN Specialty: Oncology Pathology Surgery Other: _____

Name	NPI	Email	
Practice/Facility Name	Phone	Fax	
Address	City	State	Zip Code

III. PATHOLOGY FACILITY (Facility that will release the specimen for testing)

Name	NPI	Email	
Practice/Facility Name	Phone	Fax	
Address	City	State	Zip Code
<input type="checkbox"/> Please return the specimen to the location listed above once testing complete		<input type="checkbox"/> Please return the specimen to alternate location listed below: Address: _____ Phone: _____	

IV. PATIENT INFORMATION Please include a copy of the patient face sheet

Name		
DOB	Sex	<input type="checkbox"/> M <input type="checkbox"/> F
Address		
City	State	Zip Code
Phone		
Next Appt. Date / /		

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

Specimen ID	Date of Collection
Biopsy Site	
Clinical Diagnosis	
Fixative Type (Recommended 10% Neutral-Buffered Formalin)	
ICD-10 Codes - List all codes that may apply; please provide code with the greatest specificity, unless the anatomical site is properly designated with a general, unspecified code (Visit CancerTYPEID.com for ICD-10 Code Reference Guide)	

VI. BILLING INFORMATION

Please include a copy (front and back) of patient insurance card(s)

Bill to: Patient HMO/PA PPO
 Hospital/Facility Medicare Advantage Medicare* (complete section VII)

Prior Authorization Required? Yes - Prior Authorization # _____
 No

VII. REQUIRED FOR MEDICARE*

Medicare Status - Check box for patient's hospital status when sample was obtained:

Hospital Inpatient: Date of Discharge _____
 Hospital Outpatient

*See reverse for details of Medicare LCD coverage criteria

VIII. PHYSICIAN/PRACTITIONER CERTIFICATION

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 performing the test(s) and disclosure of test results to me as the ordering physician and to the pathologist(s) providing the testing specimen. 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 _____

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 ID or specimen ID, 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 documents submitted. The corresponding pathology report and completed Specimen Request Form must be submitted with the specimen.

FIXATION METHOD

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

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, 1 H&E slide
*Note: Testing CANNOT be performed on regular glass slides.
To request Leica Membrane slides, please contact Client Services.*

CANCERTYPE ID SPECIMEN TYPE

CancerTYPE ID testing can be performed on primary tumor or a site of metastasis. The following are acceptable specimen types when ordering CancerTYPE ID alone:

- 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)

NEOTYPE® TUMOR PROFILES (BASED ON CANCERTYPE ID RESULT)

- FFPE block preferred

TUMOR MUTATION BURDEN (TMB)

- FFPE block preferred

MICROSATELLITE INSTABILITY (MSI)

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

MISMATCH REPAIR (MMR)

- FFPE block preferred OR
- 4-8 unstained, 3-4 micron sections on positively-charged slides, and 1 H&E slide

NEOTYPE DISCOVERY PROFILE FOR SOLID TUMORS

- FFPE block preferred

NEOTYPE PRECISION PROFILE FOR SOLID TUMORS

- FFPE block preferred

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 pre-cooled cold pack for transport. Do not place cold pack in direct contact with specimen during transport. Place FFPE blocks in a plastic bag and slides in a plastic case or slide-mailer. Place the specimens, completed Test Requisition, completed Specimen Request Form, pathology report and supporting documents in a Biotheranostics Specimen Shipping Kit. Send specimens via FedEx service. A pickup may be scheduled online at www.fedex.com or by calling (800) 463-3339. To obtain specimen shipping kits 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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For Intended Use and Limitations visit www.CancerTYPEID.com

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NeoTYPE® Tumor Profiles

Corresponding NeoTYPE Profiles will be performed based on the following CancerTYPE ID molecular diagnoses. Note: Gene lists are subject to change. Please visit neogenomics.com for detailed profile information, including the current list of genes included in each profile.

CancerTYPE ID Result: Brain, Meningioma NeoTYPE Brain Tumor Profile

Molecular: AKT1, ATRX, BRAF, CDK6, CDKN2A, CIC, CTNNB1, EGFR, EGFRV8 Analysis, ERBB2, ERBB4, FGFR1, FGFR2, FGFR3, FUBP1, H3F3A, HRAS, IDH1, IDH2, KRAS, MET, MGMT Promoter Methylation Analysis, MYC, MYCN, NF1, NF2, NRAS, PIK3CA, PTCH1, PTEN, RB1, SETD2, SMAD4, SMO, SRC, TERT Promoter, TP53; **FISH:** 1p/19q Deletion, BRAF, MET, MYCN, PDGFRA, PTEN; **IHC:** PD-L1

CancerTYPE ID Result: Breast Adenocarcinoma NeoTYPE Breast Tumor Profile

Molecular: AKT1, BRAF, BRCA1, BRCA2, CTNNB1, EGFR, ERBB2, ERBB4, FGFR1, FGFR2, FGFR3, HRAS, KIT, KRAS, MET, NRAS, PIK3CA, PPM1D, PTEN, SMAD4, SMO, SRC, TP53; **FISH:** HER2, MET, PTEN; **IHC:** PD-L1 **Note:** Samples with equivocal HER2 FISH results will be reflexed to the Equivocal Breast FISH Panel.

CancerTYPE ID Result: Cervix Adenocarcinoma NeoTYPE Cervical Tumor Profile

Molecular: AKT1, BRAF, CTNNB1, EGFR, ERBB2, ERBB4, FGFR1, FGFR2, FGFR3, HRAS, JAK3, KRAS, MET, NOTCH1, NRAS, PDGFRA, PIK3CA, PTEN, SMAD4, SMO, SRC, TP53; **FISH:** MET, PTEN; **IHC:** PD-L1

CancerTYPE ID Result: Intestine - Colorectal Adenocarcinoma NeoTYPE Colorectal Tumor Profile

Molecular: AKT1, APC, BRAF, EGFR, ERBB2, ERBB4, FGFR1, FGFR2, FGFR3, HRAS, JAK3, KIT, KRAS, MET, Microsatellite Instability (MSI), MLH1 Promoter Methylation, NOTCH1, NRAS, PDGFRA, PIK3CA, PTEN, SMO, SRC, TP53; **FISH:** MET, PTEN; **IHC:** PD-L1

CancerTYPE ID Result: Endometrial Adenocarcinoma NeoTYPE Endometrial Tumor Profile

Molecular: AKT1, BRAF, EGFR, FGFR1, FGFR2, FGFR3, HRAS, JAK3, KIT, KRAS, MET, Microsatellite Instability (MSI), NRAS, PDGFRA, PIK3CA, PTEN, PTPN11, SMAD4, SMO, SRC, TP53; **FISH:** MET, PTEN; **IHC:** PD-L1

CancerTYPE ID Result: Gastroesophageal Adenocarcinoma NeoTYPE Gastric Tumor Profile

Molecular: AKT1, BRAF, EGFR, ERBB2, ERBB4, FGFR1, FGFR2, FGFR3, HRAS, JAK3, KIT, KRAS, MET, Microsatellite Instability (MSI), NOTCH1, NRAS, PDGFRA, PIK3CA, PTEN, SMAD4, SMO, SRC, TP53; **FISH:** HER2, MET, PTEN; **IHC:** PD-L1

CancerTYPE ID Result: Gastrointestinal Stromal Tumor (GIST) NeoTYPE GIST Profile

Molecular: AKT1, BRAF, CTNNB1, ERBB2, ERBB4, FGFR1, FGFR2, FGFR3, KIT, PDGFRA, SRC, **IHC:** PD-L1

CancerTYPE ID Result: Liver Hepatocellular Carcinoma NeoTYPE Liver/Biliary Tumor Profile

Molecular: AKT1, ATM, BRAF, CDKN2A, CTNNB1, EGFR, ERBB2, ERBB4, FGFR1, FGFR2, FGFR3, HRAS, IDH1, IDH2, KRAS, MET, NOTCH1, NRAS, PIK3CA, PTEN, SMAD4, SMO, SRC, TP53; **FISH:** MET, PTEN; **IHC:** PD-L1

CancerTYPE ID Result: Lung Adenocarcinoma, Squamous Cell Carcinoma - Lung NeoTYPE Lung Tumor Profile

Molecular: AKT1, BRAF, EGFR, ERBB2, ERBB4, FGFR1, FGFR2, FGFR3, KIT, KRAS, MET, MET Exon 14 Deletion analysis, NOTCH1, NRAS, PDGFRA, PIK3CA, PTEN, SMAD4, SMO, SRC, TP53; **FISH:** ALK, HER2, MET, PTEN, RET, ROS1; **IHC:** PD-L1

CancerTYPE ID Result: Lymphoma NeoTYPE Lymphoma Tumor Profile

Molecular: BCL1, BCL2, BRAF, CARD11, CD79B, EZH2, MYD88, NRAS

CancerTYPE ID Result: Melanoma NeoTYPE Melanoma Tumor Profile

Molecular: AKT1, BRAF, CTNNB1, EGFR, ERBB2, ERBB4, FGFR1, FGFR2, FGFR3, GNA11, GNAQ, KIT, NRAS, PDGFRA, PTEN, SMO, SRC, TERT Promoter; **FISH:** PTEN; **IHC:** PD-L1

CancerTYPE ID Result: Ovary NeoTYPE Ovarian Tumor Profile

Molecular: AKT1, BRAF, BRCA1, BRCA2, CTNNB1, EGFR, ERBB2, ERBB4, FGFR1, FGFR2, FGFR3, HRAS, JAK3, KRAS, MET, Microsatellite Instability (MSI), NRAS, PIK3CA, PPM1D, PTEN, SMAD4, SMO, SRC, TP53; **FISH:** MET, PTEN; **IHC:** PD-L1

CancerTYPE ID Result: Sarcoma NeoTYPE Soft Tissue Tumor Profile

Molecular: AKT1, BRAF, FGFR1, FGFR2, FGFR3, GNAS, HRAS, JAK3, KIT, KRAS, MET, NRAS, PDGFRA, PIK3CA, PTEN, SMAD4, SMO, SRC, TP53; **FISH:** MET, PTEN; **IHC:** PD-L1

CancerTYPE ID Result: Thyroid NeoTYPE Thyroid Profile

Molecular: AKT1, ALK, BRAF, CTNNB1, ERBB2, ERBB4, HRAS, KRAS, MET, NRAS, PIK3CA, RET, SMAD4, SMO, SRC, TERT Promoter; **FISH:** MET, RET; **IHC:** PD-L1

CancerTYPE ID Result: Adrenal, Germ Cell, Head&Neck Salivary Gland Carcinoma, Intestine - Small Intestine Adenocarcinoma, Kidney, Mesothelioma, Neuroendocrine, Pancreaticobiliary, Prostate Adenocarcinoma, Sex Cord Stromal Tumor, Skin Basal Cell Carcinoma, Squamous Cell Carcinoma - Cervix, Squamous Cell Carcinoma - Head&Neck/Skin, Thymus, Urinary Bladder NeoTYPE Other Solid Tumor Profile

Molecular: AKT1, BRAF, EGFR, FGFR1, FGFR2, FGFR3, GNAS, HRAS, IDH1, IDH2, JAK3, KIT, KRAS, MET, NOTCH1, NRAS, PDGFRA, PIK3CA, PTEN, PTPN11, SMAD4, SMO, SRC, TP53; **FISH:** MET, PTEN; **IHC:** PD-L1

CancerTYPE ID Result: Indeterminate NeoTYPE Precision Profile for Solid Tumors + MSI

Molecular: ABL1, AKT1, ALK, APC, ATM, BRAF, CDH1, CDKN2A, CSF1R, CTNNB1, EGFR, ERBB2, ERBB4, FBXW7, FGFR1, FGFR2, FGFR3, FLT3, GNA11, GNAQ, GNAS, HNF1A, HRAS, IDH1, JAK2, JAK3, KDR, KIT, KRAS, MET, MLH1, MPL, NOTCH1, NPM1, NRAS, PDGFRA, PIK3CA, PPM1D, PTEN, PTPN11, RB1, RET, SMAD4, SMARCB1, SMO, SRC, STK11, TP53, VHL; **IHC:** PD-L1 IHC + Microsatellite Instability (MSI)

Not dependent on CancerTYPE ID result NeoTYPE Discovery Profile for Solid Tumors

Next-gen sequencing of 315 genes + Tumor Mutation Burden + 9 FISH + PD-L1 IHC
Visit www.Neogenomics.com for full list of genes and biomarkers