Cancer TYPE ID®

Test Requisition Form

Biotheranostics, Inc. • 9640 Towne Centre Dr., Suite 200 • San Diego, CA 92121, USA
Toll Free: (877) 886-6739 • Fax: (800) 266-9607 • www.CancerTYPEID.com

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

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

For all CancerTYPE ID results:
☐ Mismatch Repair (MMR)
☐ NeoTYPE Discovery Profile for Solid Tumors**

☐ I authorize all NeoGenomics testing associated with this CancerTYPE ID order to be accessioned to my NeoGenomics account number: _____

*Additional testing above not available for cases in the state of NY. Biomarkers will be reported and billed separately by NeoGenomics. See page 2 for specimen requirements. **Note: If a NeoTYPE Cancer 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/PRACTITIONER

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

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

☐ 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 ☐ M ☐ 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 - Select all codes that may apply from the list of commonly used codes below; if other, please list the code(s) with the greatest specificity in the space provided

☐ C80.1 - Malignant (primary) neoplasm, unspecified
☐ C80.0 - Disseminated malignant neoplasm, unspecified
☐ C79.51 - Secondary malignant neoplasm of bone
☐ C78.7 - Secondary malignant neoplasm of liver and intrahepatic bile duct
☐ C22.9 - Malignant neoplasm of liver not specified as primary or secondary
☐ Other (see cancertypeid.com for list of ICD-10 codes covered by Medicare*): _____

VI. BILLING INFORMATION

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

Bill to: ☐ Patient ☐ HMO ☐ IPA ☐ PPO
☐ Hospital/Facility ☐ Medicare Advantage ☐ Medicare* (complete sectionVII)

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 cancertypeid.com 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® CANCER PROFILES (BASED ON CANCERTYPE ID RESULT)

- FFPE block preferred

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 (15-30ºC).

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.

ICD-10 CODE REFERENCE

For reference only, commonly selected Medicare ICD-10 codes for ordering CancerTYPE ID testing are shown below. Please use the most specific applicable codes when ordering. The full list of ICD-10 codes can be viewed at www.Cancertypeid.com/ordering-information

ICD-10 Code	Description
C80.1	Malignant (primary) neoplasm unspecified
C78.7	Secondary malignant neoplasm of liver and intrahepatic bile duct
C80.0	Disseminated malignant neoplasm unspecified
C22.9	Malignant neoplasm of liver not specified as primary or secondary
C79.51	Secondary malignant neoplasm of bone

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NeoTYPE® Cancer 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. If Pan-TRK IHC results are equivocal, NTRK NGS Fusion Profile will be added.

CancerTYPE ID Result: Brain, Meningioma — NeoTYPE Brain Tumor Profile

NGS: AKT1, ATRX, BRAF, CDK6, CDKN2A, CIC, CTNNB1, EGFR, ERBB2, ERBB4, FGFR1, FGFR2, FGFR3, FUBP1, H3F3A, HIST1H3B, HRAS, IDH1, IDH2, KRAS, MET, Microsatellite Instability (MSI), MYC, MYCN, NF1, NF2, NRAS, NTRK1 fusions, NTRK2 fusions, NTRK3 fusions, PIK3CA, PTCH1, PTEN, RB1, SETD2, SMAD4, SMO, SRC, TERT Promoter, TP53, Tumor Mutation Burden (TMB); **Other Molecular:** EGFRvIII Analysis, MGMT Promoter Methylation Analysis; **FISH:** 1p/19q Deletion, BRAF, MET, MYCN, PDGFRA, PTEN **IHC:** PD-L1 22C3

CancerTYPE ID Result: Breast Adenocarcinoma — NeoTYPE Breast Tumor Profile

NGS: AAKT1, BRAF, BRCA1, BRCA2, CTNNB1, EGFR, ESR1, ERBB2, ERBB4, FGFR1, FGFR2, FGFR3, HRAS, KIT, KRAS, MET, Microsatellite Instability (MSI), NRAS, PIK3CA, PTEN, SMAD4, SMO, SRC, TERT Promoter, TP53, Tumor Mutation Burden (TMB); **FISH:** MET, PTEN; **IHC:** PD-L1 SP142, Pan-TRK

CancerTYPE ID Result: Cervix Adenocarcinoma — NeoTYPE Cervical Tumor Profile

NGS: AKT1, BRAF, CTNNB1, EGFR, ERBB2, ERBB4, FGFR1, FGFR2, FGFR3, HRAS, KRAS, MET, Microsatellite Instability (MSI), NOTCH1, NRAS, PDGFRA, PIK3CA, PTEN, SMAD4, SMO, SRC, TERT Promoter, TP53, Tumor Mutation Burden (TMB); **FISH:** MET, PTEN; **IHC:** PD-L1 22C3, Pan-TRK

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

NGS: AKT1, APC, BRAF, EGFR, ERBB2, ERBB4, FGFR1, FGFR2, FGFR3, HRAS, KIT, KRAS, MET, Microsatellite Instability (MSI), MLH1, NOTCH1, NRAS, PDGFRA, PIK3CA, PTEN, SMO, SRC, TERT Promoter, TP53, Tumor Mutation Burden (TMB); **Other Molecular:** MLH1 Promoter Methylation; **FISH:** MET, PTEN, RET; **IHC:** PD-L1 22C3, Pan-TRK

CancerTYPE ID Result: Endometrial Adenocarcinoma — NeoTYPE Endometrial Tumor Profile

NGS: AKT1, BRAF, EGFR, ESR1, FGFR1, FGFR2, FGFR3, HRAS, KIT, KRAS, MET, Microsatellite Instability (MSI), NRAS, PDGFRA, PIK3CA, POLE, PTEN, PTPN11, SMAD4, SMO, SRC, TERT Promoter, TP53, Tumor Mutation Burden (TMB); **FISH:** MET, PTEN; **IHC:** PD-L1 22C3, Pan-TRK

CancerTYPE ID Result: Gastroesophageal Adenocarcinoma — NeoTYPE Gastric Tumor Profile

NGS: AKT1, BRAF, EGFR, ERBB2, ERBB4, FGFR1, FGFR2, FGFR3, HRAS, KIT, KRAS, MET, Microsatellite Instability (MSI), NOTCH1, NRAS, PDGFRA, PIK3CA, PTEN, SMAD4, SMO, SRC, TERT Promoter, TP53, Tumor Mutation Burden (TMB); **FISH:** MET, PTEN; **IHC:** PD-L1 22C3, Pan-TRK

CancerTYPE ID Result: Gastrointestinal Stromal Tumor (GIST), Sarcoma — NeoTYPE GIST/ Soft Tissue Tumor Profile

NGS: AKT1, ATM, BRAF, CDKN2A, FGFR1, FGFR2, FGFR3, GNAS, HRAS, KIT, KRAS, MAP2K1, MET, Microsatellite Instability (MSI), NF1, NRAS, NTRK1 fusions, NTRK2 fusions, NTRK3 fusions, PDGFRA, PIK3CA, PTEN, PTPN11, SDHA, SDHB, SDHC, SDHD, SMAD4, SMO, SRC, TERT Promoter, TP53, Tumor Mutation Burden (TMB); **FISH:** MET, PTEN; **IHC:** PD-L1 22C3

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

NGS: AKT1, ATM, BRAF, CDKN2A, CTNNB1, EGFR, ERBB2, ERBB4, FGFR1, FGFR2, FGFR3, HRAS, IDH1, IDH2, KRAS, MET, Microsatellite Instability (MSI), NOTCH1, NRAS, PIK3CA, PTEN, SMAD4, SMO, SRC, TERT Promoter, TP53, Tumor Mutation Burden (TMB); **FISH:** MET, PTEN; **IHC:** PD-L1 22C3, Pan-TRK

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

NGS: AKT1, BRAF, EGFR, ERBB2, ERBB4, FGFR1, FGFR2, FGFR3, KIT, KRAS, MET, Microsatellite Instability (MSI), NOTCH1, NRAS, PDGFRA, PIK3CA, PTEN, SMAD4, SMO, SRC, TERT Promoter, TP53, Tumor Mutation Burden (TMB); **Other Molecular:** MET Exon 14 Deletion Analysis; **FISH:** ALK, HER2, MET, PTEN, RET, ROS1; **IHC:** PD-L1 22C3, Pan-TRK

CancerTYPE ID Result: Lymphoma — NeoTYPE Lymphoma Profile

Molecular: BCL1, BCL2, BCL6, BRAF, CARD11, CD79B, EZH2, MYD88, NOTCH1, NOTCH2, NRAS, TP53

CancerTYPE ID Result: Melanoma — NeoTYPE Melanoma Profile

NGS: AKT1, BRAF, CTNNB1, EGFR, ERBB2, ERBB4, FGFR1, FGFR2, FGFR3, GNA11, GNAQ, KIT, Microsatellite Instability (MSI), NRAS, PDGFRA, PTEN, SMO, SRC, TERT Promoter, Tumor Mutation Burden (TMB); **FISH:** PTEN; **IHC:** PD-L1 28-8, Pan-TRK

CancerTYPE ID Result: Ovary — NeoTYPE Ovarian Tumor Profile

NGS: AKT1, ARID1A, ATM, ATR, BRAF, BRCA1, BRCA2, CDK12, CDKN2A, CDKN2B, CTNNB1, EGFR, ERBB2, ERBB4, ESR1, FGFR1, FGFR2, FGFR3, HRAS, KIT, KRAS, MET, Microsatellite Instability (MSI), NF1, NRAS, PIK3CA, POLE, PTEN, RAD51B, RAD51C, RB1, SMAD4, SMO, SRC, STK11, TERT Promoter, TP53, Tumor Mutation Burden (TMB); **FISH:** EGFR Amplification, HER2, MET, MYC, PTEN, RET; **IHC:** PD-L1 22C3, Pan-TRK

CancerTYPE ID Result: Thyroid — NeoTYPE Thyroid Profile

NGS: AKT1, ALK, BRAF, CTNNB1, ERBB2, ERBB4, HRAS, KRAS, MET, Microsatellite Instability (MSI), NRAS, PIK3CA, RET, SMAD4, SMO, SRC, TERT Promoter, Tumor Mutation Burden (TMB); **FISH:** MET, RET; **IHC:** PD-L1 22C3, Pan-TRK

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

NGS: AKT1, BRAF, EGFR, FGFR1, FGFR2, FGFR3, GNAS, HRAS, IDH1, IDH2, KIT, KRAS, MET, Microsatellite Instability (MSI), NOTCH1, NRAS, PDGFRA, PIK3CA, PTEN, PTPN11, SMAD4, SMO, SRC, TERT Promoter, TP53, Tumor Mutation Burden (TMB); **FISH:** MET, PTEN; **IHC:** PD-L1 22C3, Pan-TRK

CancerTYPE ID Result: Indeterminate — NeoTYPE Precision Profile for Solid Tumors

NGS: AKT1, ALK, APC, ATM, BRAF, CDH1, CDKN2A, CSF1R, CTNNB1, EGFR, ERBB2, ERBB4, ESR1, FBXW7, FGFR1, FGFR2, FGFR3, GNA11, GNAQ, GNAS, HNF1A, HRAS, IDH1, IDH2, KDR, KIT, KRAS, MET, Microsatellite Instability (MSI), MLH1, NOTCH1, NRAS, PALB2, PDGFRA, PIK3CA, PTEN, PTPN11, RB1, RET, SMAD4, SMARCB1, SMO, SRC, STK11, TERT Promoter, TP53, Tumor Mutation Burden (TMB), VHL **IHC:** PD-L1 22C3, Pan-TRK

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

Next-gen sequencing of 323 genes + MSI + Tumor Mutation Burden (TMB) + 9 FISH + PD-L1 and Pan-TRK IHC