



CLIA ID: 10D2224896



CAP ID: 9191819



Circulogene

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Specimen Information

Specimen
Collection Date: _____

INTERNAL LAB

Received Date: _____

Received By: _____

Somatic NGS & Molecular Testing Requisition and Statement of Medical Necessity

1 Client Information

Client ID: _____
Client Name: _____
Street Address: _____
City / State / Zip: _____
Phone # _____ Fax # _____

2 Ordering Provider Information

Indicate Ordering Provider: _____

Other Provider and NPI#: _____
Referring Provider and Fax#: _____

3 Patient Demographics

Last Name: _____ First Name: _____
Date of Birth: _____ Social Security #: _____
Address: _____ City / State / Zip: _____
Phone #: _____ Genetic Sex: M F Email Address: _____

4 Diagnosis Information & Clinical Indications All required for medical coverage determination

Disease status at time of testing (Select all that apply): Metastatic Recurrent Relapsed Refractory Unresectable None of These Apply
Previous Diagnosis: NSCLC Colorectal Breast Pancreatic Prostate None / Other: _____
Stage: _____ Date: _____ Has this tumor been tested by Circulogene before? Yes No
If YES, has the disease progressed? Yes No The patient is seeking further treatment and is: Newly Diagnosed Not Responding to Therapy

LUNG ICD-10
Diagnosis Codes

C34.11

Malignant neoplasm of upper lobe, right bronchus or lung

C34.12

Malignant neoplasm of upper lobe, left bronchus or lung

C34.31

Malignant neoplasm of lower lobe, right bronchus or lung

C34.32

Malignant neoplasm of lower lobe, left bronchus or lung

C34.2

Malignant neoplasm of the middle lobe, bronchus, or lung

Other _____

Other Indication ICD-10
Diagnosis Codes

Other _____

Other _____

Other _____

Other _____

Other _____

Other _____

5 Billing Information Please print and include a copy of the patient's medical records, insurance card, and I.D. with the test order. Fill out page 2 for Patient Billing Information.

Attached face sheet with patient insurance information or complete insurance information on back of this form

Attached copy of front and back of insurance card(s)

Attached patient's medical records that support this test order

6 Test Selection Please select medically necessary test(s) for the specific patient. See page 2 for additional information.

Somatic Molecular Panel

Panel Includes:

- ALK Gene Fusion
- MSI
- NGS DNA Somatic Gene Profile
- NGS RNA Somatic Gene Profile
- NTRK 1/2/3 Gene Fusions
- PD-L1 Expression
- RET Gene Fusion
- ROS1 Gene Fusion

Individual Test Selection Orders

- (1002) ALK Gene Fusion
- (1010) MSI
- (1000) NGS DNA Somatic Gene Profile
- (1019) NGS RNA Somatic Gene Profile
- (1011) NTRK 1/2/3 Gene Fusions
- (1012) PD-L1 Expression
- (1018) RET Gene Fusion
- (1013) ROS1 Gene Fusion

7 Ordering Provider Signature Required

My signature below certifies that (1) I am the patient's treating physician and am authorized under applicable law to order the tests on this test requisition, (2) each test ordered on this test requisition is medically necessary for the patient, (3) the patient has decided to seek further cancer treatment, (4) the results of each test will inform the patient's ongoing treatment plan, (5) I have explained to the patient the nature and purpose of each test to be performed pursuant to this test requisition, and the patient has had the opportunity to ask questions regarding each test and the collection, use, and disclosure of his/her samples and data, (6) I have obtained informed consent from the patient to have each test performed, including the collection, use, and disclosure of his/her samples and data. I understand that Circulogene Theranostics, Inc. may reach out to me to request a copy of the signed consent, in which case I will furnish Circulogene Theranostics, Inc. a signed copy of the consent.

Provider Signature _____ Printed Full Name _____ Date _____

Billing Information ***Include Copy of Insurance Card and ID***

Specimen Origin (Must Choose 1)

Non-Hospital Patient Hospital Patient (In) Hospital Patient (Out)

Payment Options

Bill To: Insurance Client Bill Patient / Self Pay Bill Charges to other Hospital / Facility: _____
 Medicare Medicaid Prior Authorization # (if available) _____

Primary Insurance

Carrier: _____ Policy #: _____ Group #: _____
 Subscriber: _____ DOB: _____ Relationship to Subscriber: Self Spouse Child

Secondary Insurance

Carrier: _____ Policy #: _____ Group #: _____
 Subscriber: _____ DOB: _____ Relationship to Subscriber: Self Spouse Child

Specimen Requirements and Procedures

- 1** Use tubes provided in kit
- 2** Fill entire tube
- 3** Gently invert tube five times
- 4** Refrigerate immediately after inverting (do not freeze)
- 5** Specimen viability is 7 days NOT including collection date (if kept refrigerated)
- 6** Two unique identifiers are required, and phlebotomist signature/initials is recommended
- 7** Apply label correctly
- 8** Follow packing instructions on shipper box when ready to ship. Keep refrigerated until ready to ship

(1000) NGS DNA Somatic Gene Profile (81455) *Includes SNV's, Indels, CNV's

| | | | | | | | | |
|--------|--------|--------|-------|-------|--------------|--------|---------|-------|
| AKT1 | BRAF | CHEK1 | EZH2 | HRAS | MAP2K1 | NRAS | PTPN11 | SRC |
| ALK | BCRA1 | CHEK2 | FBXW7 | IDH1 | MAP2K2 | NTRK1 | RB1 | STAT3 |
| AR | BRCA2 | CRKL | FGFR1 | IDH2 | MET(Incl. Ex | NTRK2 | RAF1 | STK11 |
| ARAF | CCND1 | CSF1R | FGFR2 | IGF1R | 14 Skip) | NTRK3 | RET | TERT |
| ARID1A | CCNE1 | CTNNB1 | FOXL2 | JAK2 | MAPK3 | PALB2 | ROS1 | TOP1 |
| ATM | CDH1 | DDR2 | FGFR3 | JAK3 | MLH1 | PDGFRA | SETD2 | TP53 |
| ATR | CDK4 | EGFR | GNA11 | KDR | MTOR | PIK3CA | SMAD4 | TSC1 |
| AXL | CDK6 | ERBB2 | GNAQ | KEAP1 | MYC | POLD1 | SMARCA4 | TSC2 |
| BAP1 | CDK12 | ERBB4 | GNAS | KIT | NF1 | POLE | SMARCB1 | VHL |
| BARD1 | CDKN2A | ESR1 | HNF1A | KRAS | NOTCH1 | PTEN | SMO | |

(1012) PD-L1 Expression (81479)

Detects RNA expression of Programmed Death Ligand 1 (PD-L1) in ctRNA (NSCLC), indicating a possible response to immunotherapies (e.g., Keytruda) in the appropriate clinical setting as determined by the treating physician.

(1002) ALK Gene Fusion (81479)

Detects RNA intergenic fusions associated with ALK (anaplastic lymphoma kinase; receptor tyrosine kinase) gene and a different gene; results in overexpression of the ALK gene product > cancer.

(1010) MSI (81301) Detects of microsatellite alterations in DNA which are due to mutations in genes associated with mismatch repair.

(1013) ROS1 Gene Fusion (81479)

Detects RNA intergenic fusions associated with the ROS1 (ROS Proto-Oncogene 1, receptor tyrosine kinase) gene; results in overexpression of the ROS1 gene product > cancer.

(1019) NGS RNA Somatic Gene Fusion Profile (81456)

| | | | | | | | | |
|---------|---------|---------|----------|--------|----------|---------|---------|--------|
| ABL1 | BCR | CREB3L2 | FGFR1 | MGA | NTRK1 | PRKARIA | SQSTM1 | TPR |
| ACTB | BICC1 | CRTC1 | FGFR2 | MGMT | NTRK2 | PTPRZ1 | SS18 | TRIM24 |
| AFAP1 | BRAF | DDIT3 | FGFR3 | MIR143 | NTRK3 | QKI | SSX1 | TRIM33 |
| AGK | BRD3 | DNAJB1 | FLI1 | MITF | NUTM1 | RAF1 | SSX4 | TRIO |
| AKAP12 | BRD4 | EGFR | FN1 | MKL2 | PAX3 | RANBP2 | STAT6 | VGLL2 |
| AKAP4 | CAMTA1 | EML4 | FOXO1 | MYB | PAX7 | RARA | STRN | WT1 |
| AKAP9 | CCAR2 | EPC1 | GPR128 | MYC | PAX8 | RELA | SUZ12 | WWTR1 |
| AKT2 | CCDC6 | ERBB2 | HMGA2 | NAB2 | PDGFB | RELCH | SXX2 | YAP1 |
| AKT3 | CCDC88A | ERBB4 | JAZF1 | NCOA1 | PDGFRA | RET | TACC1 | YWHAE |
| ALK | CCNB3 | ERG | KIAA1549 | NCOA2 | PDGFRB | ROS1 | TACC3 | ZMYM2 |
| ASPSCR1 | CCND1 | ESR1 | KIF5B | NCOA4 | PHF1 | RREB1 | TAF15 | ZNF703 |
| ATF1 | CD74 | ETV1 | LMNA | NFIB | PIK3CA | RSPO2 | TCF12 | ZFTA |
| ATP1B1 | CIC | ETV4 | LPP | NOTCH2 | PLAG1 | RSPO3 | TERT | |
| ATRX | CLTC | ETV5 | MAGI3 | NPM1 | PML | SDC1 | TFE3 | |
| BAG4 | CNTRL | ETV6 | MAML1 | NR4A3 | POU5F1 | SDC4 | TFG | |
| BCL2 | COL1A1 | EWSR1 | MAML2 | NRG1 | PPARGC1A | SHTN1 | THADA | |
| BCOR | CREB1 | EZR | MAML3 | NRG2 | PPP1CB | SLC34A2 | TMPPSS2 | |
| BCORL1 | CREB3L1 | FEV | MET | NSD3 | PRKACA | SND1 | TPM3 | |

Test Combination / Profile Policy

Circulogene's policy is to provide ordering providers, in each instance, with the flexibility to choose appropriate tests for the appropriate patient at the appropriate time to assure that the convenience of ordering test combinations/profiles does not distance ordering providers who wish to order a test combination/profile from making deliberate decisions regarding which tests are truly medical necessary. All the tests offered in test combination/profiles may be ordered individually. Circulogene encourages clients to contact their local Circulogene representative if the testing configurations shown here do not meet individual needs for any reason, or if some other combination of procedures is desired.

In an effort to keep our clients fully informed of the content, charges, and CPT codes included in its test combinations/profiles when billed to Medicare or other third-party payers, Circulogene periodically sends notices concerning customized chemistry test combinations/profiles.

The CPT code(s) listed are in accordance with the current edition of Current Procedural Terminology, a publication of the American medical Association. CPT codes are provided here for the convenience of our clients; however, correct coding often varies from one carrier to another. Consequently, the codes presented here are intended as general guidelines and shouldn't be used without confirming with the payer that their use is appropriate in each case. All laboratory procedures will be billed to third-party carriers (including Medicare and Medicaid) at fees billed to patients and in accordance with the specific CPT coding required by the carrier.