CLIA ID: 10D2224896
CAP ACCREDITED
CAP ID: 9191819

Circulogene
Medical Director: Dr. Anthony Schmidt
219 E Garden Street Suite 300, Pensacola, FL 32502
Client Services: 855-380-1555
Fax: 833-476-0758
support@circulogene.com

Specimen Information

Specimen Collection Date: _____

INTERNAL LAB

Received Date: _____

Received By: _____

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: _____ Genetic Sex: ☐ M ☐ F Phone #: _____
Address: _____ City / State / Zip: _____

4 Mobile Phlebotomy Requested?

☐ Yes (Please fax completed requisition to 833.476.0758 and the Circulogene Customer Service Team will Schedule the mobile phlebotomy appointment)

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

Disease status at time of testing (Select all that apply): ☐ Highly Suspicious for Malignancy ☐ Metastatic ☐ Recurrent ☐ Unresectable ☐ None of These

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

Date of Biopsy (If Available): _____

Liquid based next-generation sequencing (NGS) testing is medically necessary for this patient due to the need for comprehensive genomic profiling due to tumor heterogeneity. Given the limitations of tissue biopsy, liquid NGS testing provides a minimally invasive alternative to detect actionable genetic alterations that can guide targeted therapy. This test is essential for optimizing treatment decisions in accordance with current guidelines. The results from Circulogene's testing will guide the patient's treatment plan, including but not limited to ordering and instituting chemotherapeutic treatments. Liquid NGS testing is also beneficial to monitor tumor evolution, assess treatment response and detect evolving resistance mutations. Given the dynamic nature of cancer, serial liquid NGS testing provides a minimally invasive method to track genomic changes over time, which is critically important in treatment strategy in alignment with current clinical guidelines

ICD-10 Diagnosis Codes						

6 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)

☐ **Attach patient's most recent physician notes and medical records that support this test order**

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

☐ **OncoGenLDx**

Somatic Molecular Profile Includes:

- **NGS DNA Panel**
- **NGS RNA Panel**
- **NTRK 1,2,3 Gene Fusions, qPCR**
- **PD-L1 Expression, qPCR**

Further panel details can be found on the back of this requisition.

☐ **LungLifeAI** ☐ Reflex to OncoGenLDx

When "Reflex to OncoGenLDx" is selected, Circulogene will automatically reflex to a Somatic Molecular Profile upon an 'Increased Risk' LungLifeAI result. If necessary, Circulogene will manage specimen collection via mobile phlebotomy services.

The following information is required for the LungLifeAI test.
Any omissions will result in a testing delay.

☐ Attach a copy of the most recent CT Radiology Report

1. History of Cancer: ☐ Yes ☐ No
2. Smoking History: ☐ Current ☐ Former ☐ Never
3. Nodule Location: ☐ LUL ☐ RML ☐ RUL ☐ LLL* ☐ RLL*
4. Nodule Size (mm): _____

**Nodule location falls outside of intended use.*

Individual Test Selection Orders

☐ (1000) NGS DNA Somatic Gene Profile
☐ (1019) NGS RNA Somatic Gene Profile
☐ (1012) PD-L1 Expression
☐ (1011) NTRK 1/2/3 Gene Fusions

8 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

OncoGenLDx - NGS DNA Somatic Gene Profile Targets

ABCB9	BARD1	CD70	CTNNB1	ERCC1	FH	HLA-C	KAT6A	MCM6	MYOCD	PDK1	PSMA5	PSMD5	RB1	SMAD2	TCP11L2	WEE1
ABL1	BCL2	CD79A	CTSB	ERCC2	FKBP9	HLA-E	KDM5A	MCM7	NBN	PHF6	PSMA6	PSMD6	RBM10	SMAD3	TDG	WT1
ABL2	BCL2L1	CD79B	CTSL	ERCC3	FLCN	HLA-F	KDM5C	MDM2	NCOR1	PIK3C2B	PSMA7	PSMD7	REL	SMAD4	TERC	XPO1
ACE2	BCL6	CD80	CTSS	ERCC4	FLT1	HLA-G	KDM6A	MDM4	NF1	PIK3CA	PSMA8	PSMD8	RET	SMARCA4	TERT	XRCC5
ACVR1B	BCOR	CD86	CUL3	ERCC5	FLT3	HMGB1	KDR	MED12	NF2	PIK3CB	PSMB1	PSMD9	RFC1	SMARCB1	TET2	ZFHX3
AKT1	BCORL1	CDC27	CUL4B	ERG	FLT4	HMGN1	KEAP1	MEF2B	NFE2L2	PIK3CG	PSMB10	PSME1	RFC2	SMC1A	TGFBR2	ZNF217
AKT2	BLM	CDC73	CUX1	ERRFI1	FOXA1	HNF1A	KEL	MEN1	NFKBIA	PIK3R1	PSMB11	PSME2	RFC3	SMC3	TNF	
AKT3	BRAF	CDH1	CYLD	ESR1	FOXL2	HRAS	KIT	MET	NKX2-1	PIK3R2	PSMB2	PSME3	RFC4	SMO	TNFAIP3	
ALK	BRCA1	CDK12	DAXX	ETV6	FOXP1	HSP90AA1	KMT2A	MICA	NOTCH1	PIM1	PSMB3	PSME4	RFC5	SOCS1	TNFRSF14	
ALPK2	BRCA2	CDK4	DDR2	EWSR1	FUBP1	ICOSLG	KMT2C	MICB	NOTCH2	PLCG2	PSMB4	PSMF1	RHEB	SOS1	TNFRSF9	
AMER1	BRD4	CDK6	DDX3X	EXO1	GABRA6	IDE	KMT2D	MITF	NOTCH3	PMS1	PSMB5	PSMG1	RHOA	SOX10	TNFSF14	
APC	BRIP1	CDK8	DICER1	EZH2	GADD45A	IDH1	KRAS	MLH1	NOTCH4	PMS2	PSMB6	PSMG2	RICTOR	SOX17	TNFSF18	
AR	BTK	CDKN1A	DIS3	FAM46C	GATA1	IDH2	LGALS9	MLH3	NPEPPS	POLB	PSMB7	PSMG3	RIT1	SOX2	TNFSF4	
ARAF	C10orf54	CDKN1B	DMD	FANCA	GATA2	IFI30	LGMN	MORC4	NPM1	POLD1	PSMB8	PSMG4	RNASEH2A	SOX9	TNFSF9	
ARID1A	CALR	CDKN2A	DNER	FANCC	GATA3	IGF1R	LIG1	MPL	NRAS	POLD2	PSMB9	PTCH1	RNF43	SPEN	TNKS	
ARID1B	CANX	CDKN2B	DNMT3A	FANCD2	GATA4	IGF2	LIG3	MR1	NRDC	POLD3	PSMC1	PTEN	ROS1	SPOP	TOP1	
ARID2	CARD11	CDKN2C	DOT1L	FANCE	GATA6	IGF2R	LMO1	MRE11A	NSD1	POLD4	PSMC2	PTGS2	RPA1	SRC	TP53	
ARID5B	CASP8	CEBPA	EED	FANCF	GLI1	IKBKE	LNPEP	MSH2	NTRK1	POLE	PSMC3	PTPN11	RPA2	SSBP1	TP53BP1	
ASXL1	CBFB	CHD4	EGFR	FANCG	GNA11	IKZF1	LPAR2	MSH3	NTRK2	POLE4	PSMC4	PTPRD	RPA3	STAG2	TP73	
ASXL2	CBL	CHEK1	EP300	FAS	GNA13	IL7R	LRP1B	MSH4	NTRK3	PPP2R1A	PSMC5	QKI	RPA4	STAT3	TPP2	
ATM	CCND1	CHEK2	EPCAM	FAT1	GNAQ	INPP4B	LZTR1	MSH5	PALB2	PRDM1	PSMC6	RAC1	RPTOR	STK11	TREX1	
ATR	CCND2	CIC	EPHA3	FBXW7	GNAS	IRF4	MAP2K1	MSH6	PARK2	PRKAR1A	PSMD1	RAD17	RUNX1	SUFU	TRRAP	
ATRX	CCND3	CNKSR1	EPHA5	FGF19	GRIN2A	IRF6	MAP2K2	MTOR	PARP1	PRKCG	PSMD10	RAD18	RUNX1T1	SUZ12	TSC1	
AURKA	CCNE1	COL5A1	EPHA7	FGF3	GSK3B	IRS2	MAP2K4	MUC17	PAX5	PRKCI	PSMD11	RAD21	SDHA	SYK	TSC2	
AURKB	CD200	CREBBP	EPHB1	FGF4	H3F3A	ITGAV	MAP3K1	MUTYH	PBRM1	PRKCZ	PSMD12	RAD50	SDHB	TAP1	TSHR	
AXIN1	CD274	CRKL	ERAP1	FGFBP1	HERC1	ITGB3	MCL1	MYB	PCNA	PRKDC	PSMD13	RAD51	SDHC	TAP2	U2AF1	
AXIN2	CD276	CRLF2	ERAP2	FGFR1	HGF	JAK1	MCM2	MYC	PDCD1LG2	PSMA1	PSMD14	RAD51C	SDHD	TAPBP	VEGFA	
AXL	CD40	CSF1R	ERBB2	FGFR2	HIST1H3B	JAK2	MCM3	MYCL	PDGFRA	PSMA2	PSMD2	RAF1	SETD2	TAPBPL	VEGFD	
B2M	CD40LG	CTCF	ERBB3	FGFR3	HLA-A	JAK3	MCM4	MYCN	PDGFRB	PSMA3	PSMD3	RARA	SF3B1	TBX3	VHL	
BAP1	CD48	CTNNA1	ERBB4	FGFR4	HLA-B	JUN	MCM5	MYD88	PDIA3	PSMA4	PSMD4	RASA1	SIRT1	TCF7L2	VTCN1	

NRDC = NRD1; VEGFD = FIGF

OncoGenLDx - NGS RNA Fusions

ALK	BCL11A	CD74	EML4	FER	GOPC	KANSL1	LMNA	NCOA4	NTRK3	RAD51	RUNX1	SLC3A2	TACC3	TPM3
ARL17A	BRAF	CLIP4	ERG	FGFR1	HIP1	KIAA1217	LRIG3	NRG1	NUTM1	RET	SDC4	SLC45A3	TCF3	TPR
BAG4	BRD4	DNAH5	ETV6	FGFR2	HLA-DRB1	KIF5B	MET	NTRK1	PAX8	ROS1	SEPTIN14	STARD3NL	TGF	TRA2B
BAIAP2L1	CCDC6	EGFR	EZR	FGFR3	IRF2BP2	KLC1	MPRIP	NTRK2	PBX1	RSPO3	SLC34A2	STRN	TMPRSS2	TRIM33

PD-L1 Expression

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.

TumorMutation Burden (TMB)

Reflects the number of mutations in the DNA of cancer cells. A high TMB may reflect response to immunotherapy treatments.

Microsatellite Instability (MSI)

Reflects changes in the microsatellite regions of DNA from what is inherited. It is a result of breakdown in mismatch repair genes (MMR) that code for proteins that identify and correct there mismatches during cell division.

NTRK 1,2,3 Gene Fusions, qPCR

The presence of NTRK fusions can indicate a more agressive tumor phenotype, and can identify actionable targets for TRK inhibitors.

LungLifeAI

The LungLB test is a four probe (3q29, 3p22.1, 10q22.3, 10cen) Circulating Genetically Abnormal Cell (CGAC) fluorescence in-situ hybridization (FISH) assay utilizing the Allegro Plus Platform and novel AI-derived image analysis algorithm to identify and genotype CGACs in blood and is performed by LungLife AI, Inc., 2545 W. Hillcrest Dr. Suite 140, Thousand Oaks, CA 91320, CLIA #: 05D2176566, CAP #: 8606116, CA #: CDF-00354661, NYS CLEP: PFI 9576 It is intended to be used as an aid to the clinical evaluation of indeterminate lung nodule(s) less than 15 mm in size, not located in the lower lung lobes, identified with a CT scan in people less than 80 years of age. The LungLB test results are not by themselves diagnostic of the presence or absence of disease. The results can only be considered as an aid to diagnosis, detection or monitoring of disease in relation to the history, medical signs and symptoms, and the overall condition of the patient.

Test Combination / Profile Policy

Circulogene's policy is to provide ordering providers, in each instance, with the flexibility to choose appopriate 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 medicall 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 publicaiton of the American medical Association. CPT codes are provided here for the convenience of our clients; however, correct coding often varies form 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.