Circulogene

Testing Requisition

AND STATEMENT OF MEDICAL NECESSITY

Specimen Information

Specimen Collection Date: _____

INTERNAL LAB USE ONLY

Received Date: _____ Received By: _____

1 Client Information

Client ID: _____ Client Name: _____

Fax #: _____ Phone #: _____

Street Address: _____

City / State / Zip: _____

2 Ordering Provider Information

Indicate Ordering Provider: _____

_____

_____

Other Provider and NPI#: _____

Referring Provider & Fax#: _____

3 Patient Demographics

First Name: _____ Last Name: _____

Date of Birth (MM/DD/YYYY): _____ Phone #: _____

Genetic Sex: ☐ M ☐ F Street Address: _____

MRN: _____ City / State / Zip: _____

4 Mobile Phlebotomy Requested?

Please fax completed requisition to (833) 476-0758 and the Circulogene Customer Service Team will Schedule the mobile phlebotomy appointment.

☐ Yes

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

Diagnosis:

☐ Breast ☐ Colorectal ☐ NSCLC ☐ Pancreatic ☐ Prostate

☐ None / Other: _____

Stage: _____ Dx 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): _____

Next-generation sequencing (NGS) testing is medically necessary for this patient to achieve comprehensive genomic profiling in the context of tumor heterogeneity. Tissue biopsy has recognized limitations, and liquid NGS provides a minimally invasive alternative for detecting actionable genetic alterations that can inform targeted therapy. Results from Circulogene's testing will directly guide clinical decision-making, including the selection and initiation of chemotherapeutic and other targeted treatments, in accordance with current guidelines.

ICD-10 Diagnosis Codes

_____ _____

_____ _____

_____ _____

6 Corresponding 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 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.)

Somatic Molecular Profiles:

☐ OncoGenLDx

Specimen Type: Peripheral Whole Blood
Panel Includes: DNA+RNA, MSI, TMB, PD-L1 Expression by qPCR, NTRK Gene Fusions by qPCR

☐ If the blood sample submitted does not meet the criteria for successful testing, reflex to Circulogene OncoGenDx Tissue Testing.

☐ Physician will arrange Block/Slides Specimen Shipment

☐ Requesting Circulogene procurement services (Must fill out section 9)

☐ OncoGenDx

Specimen Type: FFPE Tissue
Panel Includes: DNA + RNA + MSI + TMB + HRD

☐ If the tissue sample submitted does not meet the criteria for successful testing, reflex to Circulogene OncoGenLDx Tissue Testing.

☐ Physician will arrange for phlebotomy and Shipment

☐ Physician requests Circulogene Mobile Phlebotomy Services

☐ LungLifeAI

☐ Reflex to OncoGenLDx

When the ordering physician selects **"Reflex to OncoGenLDx,"** a request will be initiated for Circulogene to perform a Somatic Molecular Profile if a LungLifeAI result indicates **"Increased Risk."** Circulogene will coordinate specimen collection through **mobile phlebotomy services.** The following information is required to complete the LungLifeAI test.

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

History of Cancer: ☐ Yes ☐ No

History of Smoking: ☐ Current ☐ Former

Nodule Location: ☐ LUL ☐ RML ☐ RUL ☐ LLL* ☐ RLL*

* Nodule location falls outside of intended use.

Nodule Size (mm): _____

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 (MM/DD/YYYY): _____

Circulogene

Medical Director: Dr. Anthony Schmidt

Address: 219 E Garden Street Suite 300, Pensacola, FL 32502

Client Services: (855) 614-7083

Fax: (833) 476-0758

Email: support@circulogene.com

Clinical Laboratory Improvements Amendments

CLIA ID: 10D2224896

CAP ACCREDITED

CAP ID: 9191819

9 Pathology Laboratory and Procurement Services (Required Only for OncoGenDx)

Pathology Lab Name: _____

Submitting Pathologists Name (Optional): _____

Phone #: _____ Fax #: _____

Email (Preferred): _____

Primary Specimen ID: _____

Date of Collection (MM/DD/YYYY): _____

Specimen (Biopsy) Site: _____

10 FFPE Block Return Information (Required Only for OncoGenDx)

Pathology Lab Name: _____

Phone #: _____ Fax #: _____

Email (Preferred): _____

Street Address: _____

City / State / Zip: _____

11 Billing Information

SPECIMEN ORIGIN (Must Choose 1)

☐ Non-Hospital Patient ☐ Hospital Patient (Out) ☐ Hospital Patient (In) Date of Discharge: _____

Bill To:

☐ Client Bill ☐ Patient / Self Pay ☐ Bill Charges to other Hospital / Facility: _____

☐ Insurance ☐ Medicare ☐ Medicaid ☐ Prior Authorization # (If Available): _____

PRIMARY INSURANCE

Carrier: _____ Policy #: _____ Group #: _____

Subscriber: _____ Date of Birth (MM/DD/YYYY): _____ Relationship to Subscriber: ☐ Self ☐ Spouse ☐ Child

SECONDARY INSURANCE

Carrier: _____ Policy #: _____ Group #: _____

Subscriber: _____ Date of Birth (MM/DD/YYYY): _____ Relationship to Subscriber: ☐ Self ☐ Spouse ☐ Child

Specimen Requirements

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. Ensure Collection Date is specified on
6. Specimen viability is 7 days for OncGenLDx and 5 days for LungLifeAI NOT including collection date (if kept refrigerated)
7. Two unique identifiers are required, and phlebotomist signature/initials is recommended (name & DOB or MRN)
8. Apply label correctly
9. Follow packing instructions on shipper box when ready to ship (keep refrigerated until ready to ship)

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.

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Test Descriptions

OncoGenLDx

The Circulogene Liquid CGP is a next-generation sequencing (NGS) assay that provides a comprehensive analysis of solid tumors from peripheral whole blood. The Panel analyzes 486 relevant genes from DNA and 72 genes from RNA, covering four classes of genomic alterations (short variants, rearrangements, copy number alterations, and complex genomic signatures) including Tumor Mutational Burden (TMB) and Microsatellite Instability (MSI), The profile also includes PD-L1 Expression by qPCR and NTRK 1,2,and 3 Gene Fusions by qPCR. For a complete and updated list of genes, please visit our website at www.circulogene.com.

OncoGenDx

The Circulogene Tissue CGP is a next-generation sequencing (NGS) assay that provides a comprehensive analysis of solid tumors from formalin-fixed paraffin-embedded (FFPE) tissue-derived DNA and RNA samples. The Panel analyzes 335 relevant genes from DNA and 72 genes from RNA. Included are four classes of genomic alterations, including single nucleotide variations (SNVs), insertions and deletions (Indels), copy number variations (CNVs), and structural variations (SVs, e.g. fusions). Additionally, the test provides 3 complex genomic signatures for Tumor Mutational Burden (TMB), Microsatellite Instability (MSI), and Homologous Recombination Deficiency Signature (HRD). For a complete and updated list of genes, please visit our website at www.circulogene.com.

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 comect there mismatches during cell division.

PD-L1 Expression by qPCR

Detects RNA expression of Programmed Death Ligand 1 (PD-L1) in the blood of patients with NSCLC. Presence indicates a possible response to immunotherapies (e.g. Keytruda)

PD-L1 Expression by IHC

Assessing Programmed Death-Ligand 1 (PD-L1) expression with 22C3 helps identify patients who are likely to benefit from PD-1 inhibitor treatments such as pembrolizumab (Keytruda). The PD-L1 IHC test employs monoclonal antibodies to bind to PD-L1 antigens on the surface of tumor cells, and in some cases, tumor-infiltrating immune cells. IHC involves the use of formalin-fixed, paraffin-embedded (FFPE) tissue sections as the sample source.

LungLifeAI

The LungLifeAI® test is a qualitative fluorescence in-situ hybridization (FISH) test (LDT) used to identify regions of the genome amplified in lung cancer (Katz R.L., Zaidi T.M., et al 2008). It utilizes the FISH probe-based technology to identify circulating genetically abnormal cells (CGAC) enriched from peripheral blood. The identification of CGACs is combined with algorithmic incorporation of 3 different clinical factors (age, nodule location and smoking status) to provide a risk outcome. It is intended to be used in conjunction with radiological findings (CT scan) as an aid in the clinical evaluation of indeterminate lung nodules less than 15 mm in size, not located in the lower lung lobes, and in people less than 80 years of age; it is not intended as diagnostic for the presence or absence of disease.