ELITE CLINICAL LABORATORY

OHIO RIVER LABORATORIES

Address: 3600 South Gessner Rd STE 110
Houston, TX 77063
CLIA – 45D1061571
Lab Director - Albert Chen M.D.
Phone: 281-378-2116
Fax: 281-466-2483

PLEASE SUBMIT THE FOLLOWING WITH REQUISITION FORM

- ☐ Letter of Medical Necessity (Signed by Physician)
- ☐ Informed Consent Form (Signed by Pt & Physician)
- ☐ SOAP & Progress Note (Signed by Physician)
- ☐ Summary of Active Medications
- ☐ Scanned Insurance Card Copy

CARDIO-PULMONARY TESTING REQUISITION FORM

PATIENT INFORMATION

Patient First Name	Patient Last Name	Biological Sex ☐ F ☐ M

Date of Birth (MM/DD/YYYY)	Phone Number		Email Address

Address	City	State	Zip

Ethnicity: ☐ African American ☐ Asian ☐ Caucasian ☐ Hispanic ☐ Jewish(Ashkenazi) ☐ Portuguese ☐ Other

PATIENT INSURANCE INFORMATION

☐ Insurance ☐ Self-Pay ☐ Client Bill

Name of the insurance	Secondary Insurance, If any
Insurance Policy/ID number	Name of the insured
Insurance Group number	Date of Birth of Insured

SPECIMEN INFORMATION

Date Sample Collected (mm/dd/yy) (required)

Medical Record#

☐ Buccal Swab

☐ Other (specify source)

ORDERING PHYSICIAN/SENDING FACILITY (Each Listed person will receive a copy of the report)

Facility Name (Facility Code):	Address:	City:
State/Country :	Zip:	Phone:

Ordering Licensed Provider Name (Last, First)(Code)	NPI#	Phone	Fax/Email

Additional Results Recipients

Genetic Counselor or Other Medical Provider Name (Last, First)(Code)	Phone/Fax/Email

Signature Required for Processing Medical Professional Signature: **Date :**

STATEMENT OF MEDICAL NECESSITY

By submission of this test requisition and accompanying sample(s), I: (i) authorize and direct to perform the testing indicated; (ii) certify that the person listed as the ordering provider is authorized by law to order the test(s) requested; (iii) certify that any custom panel and/or ordered test(s) requested on this test requisition form are reasonable and medically necessary for the diagnosis and/or treatment of a disease, illness, impairment, symptom, syndrome or disorder; (iv) the test results will determine my patient's medical management and treatment decisions of this patient's condition on this date of service; (v) have obtained this patient's and relatives', when applicable, written informed consent to undergo any genetic testing requested; and (vi) that the full and appropriate diagnosis code(s) are indicated to the highest level of specificity.

Signature of Provider (required) Date:

INDICATIONS FOR TESTING (CHECK ALL THAT APPLY)

☐ Diagnostic ☐ Family history ☐ Positive or normal control ☐ Other.....

Will Patient management be changed depending on the test results? ☐ Yes ☐ No

CLINICAL HISTORY (PLEASE SUPPLY CLINIC NOTES AND PEDIGREE)

☐ No personal history of Cardiopulmonary disease

Sudden Lungs Failur ☐ Y ☐ N (if yes): # Episodes:..... Age first incident:..... .

History of Cardiopulmonary ☐ Y ☐ N Age at dx:.....

Type(s) of Cardiopulmnary:.....

History of Arrhythmia ☐ Y ☐ N

Age at dx:.....

Types (s) of Arrhythmia:.....

☐ Family or personal history of chronic bronchitis? ☐ Yes ☐ No
☐ Pulmonary edema? ☐ Yes ☐ No
☐ Family history of heart failure? ☐ Yes ☐ No
☐ Family or personal history of a COPD? ☐ Yes ☐ No
☐ cardiac arrhythmias? ☐ Yes ☐ No
☐ History of right-sided heart failure? ☐ Yes ☐ No
☐ Collection of fluid in legs or belly area? ☐ Yes ☐ No
☐ Diagnosed with Emphysema? ☐ Yes ☐ No
☐ Family history show the segregation of pulmonary emphysema? ☐ Yes ☐ No
☐ Diagnosed with alpha 1-antitrypsin deficiency-related pulmonary emphysema or early onset pulmonary emphysema? ☐ Yes ☐ No
☐ Diagnosed with cor pulmonale? ☐ Yes ☐ No

CLINICAL INFORMATION (DETAILED MEDICAL RECORDS MUST BE ATTACHED)

Is this person affected: ○ Yes ○ No Clinical diagnosis:.....

Reason for testing: ○ Diagnosis ○ Presymptomatic diagnosis Carrier/Familial Variant Testing

Please check all that apply. This is not a substitute for submitting clinical records.

Diagnosis
○ Amyloidosis
○ ARVC
○ Brugada syndrome
○ CPVT
○ DCM
○ Ehlers-Danlos syndrome
○ HCM
○ HHT
○ Hypertension
○ Loeys-Dietz syndrome
○ LQT syndrome
○ Noncompaction Cardiopulmonary (LVNC)
○ Marfan syndrome
○ PAH
○ RCM
○ SQT syndrome
○ Sudden Cardiac Arrest
○ Sudden Death

Echocardiogram
○ Aortic root dimensions: _____
  ○ Z-score: _____
○ EF%: _____
○ LVEDD: _____
  ○ Z-score: _____
○ Max LV wall thickness: _____
○ Normal
○ Report Included

ECG
○ Prolonged QTc interval:
  Max QTc: _____
○ Normal
○ Report Included

Arrhythmia/Cardiopulmonary
○ Abnormal atrioventricular conduction
○ Atrial fibrillation
○ Bradycardia
○ Fatty replacement of ventricular myocardial tissue
○ Heart transplant
○ Syncope
○ Torsades de pointe
○ Ventricular tachycardia

HHT
○ Arteriovenous malformation
○ Epistaxis
○ Telangiectasia

Dislipidemias
○ Atherosclerosis
○ Corneal Arcus
○ LDL-C levels _____
○ Xanthomatosis
○ Other: _____

Marfan/TAAD/HDCT
○ Aortic/Arterial aneurysm
○ Aortic/Arterial dissection
○ Aortic root dilation
○ Arachnodactyly
○ Arterial tortuosity/ectasia
○ Arthralgia
○ Atypical scarring of skin
○ Beighton score _____
○ Bifid uvula
○ Blue sclerae
○ Bruising susceptibility
○ Cleft lip
○ Cleft palate
○ Craniosynostosis
○ Cutis laxa
○ Dental crowding
○ Dural ectasia
○ Ectopia lentis
○ Flexion contracture
○ High palate
○ Hollow organ rupture:
  ○ Uterine rupture ○ Intestinal perforation
  ○ Other: _____
○ Hypertelorism
○ Joint contractures
○ Joint dislocations
○ Joint hypermobility
○ Meets Ghent criteria
○ Micrognathia / Retrognathia (circle what applies)
○ Midface retrusion
○ Mitral valve prolapse
○ Myopia
○ Osteoarthritis
○ Pectus carinatum
○ Pectus excavatum
○ Pes Planus
○ Pneumothorax
○ Recurrent fractures
○ Retinal detachment
○ Scoliosis/Kyphosis (circle what applies)
○ Skin findings, Specify: _____
○ Stroke
○ Tall stature
○ Velvety skin

Abnormal heart morphology
○ Bicuspid aortic valve
○ Coarctation of aorta
○ Heart murmur
○ Heterotaxy
○ Hypoplastic left heart
○ Mitral valve prolapse
○ Patent ductus arteriosus
○ Patent foramen ovale
○ Tetralogy of Fallot
○ Ventricular septal defect
○ Atrial septal defect
○ Other: _____

PAH
○ Pulmonary hypertension

Cardiopulmonary
○ Chronic bronchitis
○ Chronic obstructive pulmonary disease (COPD)
○ Congestive heart failure
○ Emphysema

Other
○ Abnormality of the periventricular white matter
○ Angiokeratomas
○ Anhydrosis
○ Café-Au-Lait Macules
○ Hearing impairment:
  ○ Sensorineural ○ Conductive
○ Craniosynostosis
○ Cystic hygroma
○ Downslanted palpebral fissures
○ Dysmorphic features:
Describe: _____
○ Elevated CPK
○ Hypotonia
○ Increase nuchal translucency
○ Intellectual disability
○ Keratoconus
○ Muscle weakness
○ Myopathy _____
○ Renal insufficiency
○ Short neck
○ Thromboembolism
○ Type: :

PATIENT VISIT HISTORY

Date of the Previous Patient Visit	Date of the Last Genetic Testing, if any

Custom Cardio-Pulmonary NGS Testing (Select the genes below) or ☐ Comprehensive Cardio-Pulmonary NGS Testing Panel (Test All Genes)

CardioGenomics Genes

○ ABCC9	○ BGN	○ COL2A1	○ ELN	○ GJA5	○ KCNJ5	○ MURC	○ PLN	○ SCN4B	○ TGFBR2
○ ACTA2	○ BMPR2	○ COL3A1	○ EMD	○ GLA	○ KCNJ8	○ MYBPC3	○ PLOD1	○ SCN5A	○ TMEM43
○ ACTC1	○ BRAF	○ COL5A1	○ ENG	○ GNB5	○ KCNK3	○ MYH11	○ PPA2	○ SGCD	○ TMPO
○ ACTN2	○ CACNA1C	○ COL5A2	○ EYA4	○ GPD1L	○ KCNQ1	○ MYH6	○ PRDM16	○ SHOC2	○ TNNC1
○ ACVRL1	○ CACNA2D1	○ COL9A1	○ FBLN5	○ HCN4	○ KRAS	○ MYH7	○ PRDM5	○ SKI	○ TNNI3
○ ADAMTS2	○ CACNB2	○ COL9A2	○ FBN1	○ HFE	○ LAMA4	○ MYL2	○ PRKAG2	○ SLC2A10	○ TNNT2
○ AKAP9	○ CALM1	○ COL9A3	○ FBN2	○ HRAS	○ LAMP2	○ MYL3	○ PRKG1	○ SLC39A13	○ TNXB
○ ALDH18A1	○ CALM2	○ CRYAB	○ FHL1	○ ILK	○ LDB3	○ MYL4	○ PTPN11	○ SMAD2	○ TOR1AIP1
○ ALMS1	○ CALM3	○ CSRP3	○ FKBP14	○ JPH2	○ LDLR	○ MYLK	○ PYCR1	○ SMAD3	○ TPM1
○ ALPK3	○ CASQ2	○ CTNNA3	○ FKRP	○ JUP	○ LDLRAP1	○ MYLK2	○ RAF1	○ SMAD4	○ TRDN
○ ANK2	○ CAV1	○ DES	○ FKTN	○ KCNA5	○ LMNA	○ MYOZ2	○ RANGRF	○ SMAD9	○ TRPM4
○ ANKRD1	○ CAV3	○ DMD	○ FLNA	○ KCND3	○ LOX	○ MYPN	○ RASA1	○ SNTA1	○ TTN
○ APOB	○ CBS	○ DOLK	○ F9	○ KCNE1	○ LRRC10	○ NEBL	○ RBM20	○ SOS1	○ TTR
○ ATP6V0A2	○ CHRM2	○ DSC2	○ FLNC	○ KCNE1L	○ LTBP4	○ NEXN	○ RIN2	○ TAZ	○ TXNRD2
○ ATP6V1E1	○ CHST14	○ DSE	○ GAA	(KCNE5)	○ MAP2K1	○ NKX2-5	○ RIT1	○ TBX20	○ VCL
○ ATP7A	○ COL11A1	○ DSG2	○ GATA4	○ KCNE2	○ MAP2K2	○ NOTCH1	○ RYR2	○ TCAP	○ ZNF469
○ B3GALT6	○ COL11A2	○ DSP	○ GATA5	○ KCNE3	○ MAT2A	○ NRAS	○ SCN10A	○ TECRL	
○ B3GAT3	○ COL12A1	○ DTNA	○ GATA6	○ KCNH2	○ MED12	○ PCSK9	○ SCN1B	○ TGFB2	
○ B4GALT7	○ COL1A1	○ EFEMP2	○ GATAD1	(HERG)	○ MFAP5	○ PDLIM3	○ SCN2B	○ TGFB3	
○ BAG3	○ COL1A2	○ EIF2AK4	○ GDF2	○ KCNJ2	○ MIB1	○ PKP2	○ SCN3B	○ TGFBR1	

Pulmonary Genes

○ CCDC39	○ CHRND	○ DNAAF1	○ DNAI2	○ FBLN5	○ HPS4	○ NKX2-1	○ RET	○ SCNN1A	○ SFTPC	○ TERC
○ CCDC40	○ CHRNE	○ DNAAF2	○ DNAL1	○ FLCN	○ ITGA3	○ NME8	○ RSPH3	○ SCNN1B	○ SLC34A2	○ TERT
○ CFTR	○ COLQ	○ DNAH1	○ EDN3	○ FOXF1	○ LTBP4	○ PARN	○ RSPH4A	○ SERPINA1	○ SLC6A5	○ TINF2
○ CHAT	○ CSF2RA	○ DNAH11	○ EFEMP2	○ GAS8	○ MECP2	○ PHOX2B	○ RSPH9	○ SFTPA1	○ SLC7A7	○ TSC1
○ CHRNA1	○ CSF2RB	○ DNAH5	○ ELMOD2	○ GLRA1	○ NAF1	○ PIH1D3	○ RTEL1	○ SFTPA2	○ SMPD1	○ TSC2
○ CHRNB1	○ DKC1	○ DNAI1	○ ELN	○ HPS1	○ NF1	○ RAPSN	○ SCN4A	○ SFTPB	○ STAT3	○ ZEB2

ICD-10 DIAGNOSIS CODES WITH DESCRIPTION

CardioGenomics Disease

- ☐ E78.4 - Other Hyperlipidemia
- ☐ E78.5 - Hyperlipidemia, unspecified
- ☐ E87.1 - Hypo - osmolality and / or hypernatremia
- ☐ G89.29 - Other Chronic Pain
- ☐ I10 - Essential (Primary) Hypertension
- ☐ I0 - Essential (Primary) Hypertension
- ☐ I25.10 - Atherosclerotic heart disease of native coronary artery without angina pectoris
- ☐ I25.10 - Atherosclerotic heart disease of native coronary artery without angina pectoris
- ☐ I25.5 - Ischemic Cardiovascular
- ☐ I25.6 - Silent Myocardial Ischemia
- ☐ I25.89 - Other forms of chronic ischemic heart disease
- ☐ I25.9 - Chronic ischemic heart disease, unspecified
- ☐ I34.1 - Nonrheumatic mitral (valve) insufficiency
- ☐ I34.1 - Nonrheumatic mitral (valve) prolapse
- ☐ I34.2 - Nonrheumatic mitral (valve) stenosis
- ☐ I35.8 - Other nonreheumatic mitral valve disorders
- ☐ I34.9 - Nonrheumatic mitral valve disorder, unspecified
- ☐ I35.0 - Nonrheumatic aortic (Valve) stenosis
- ☐ I35.1 - Nonrheumatic aortic (Valve) Insufficiency
- ☐ I35.2 - Nonrheumatic aortic (valve) stenosis with insufficiency
- ☐ I35.8 - Other Nonrheumatic aortic (valve) disorders
- ☐ I35.9 - Nonrheumatic aortic valve disorder, unspecified
- ☐ I42.0 - dilated Cardiovascular
- ☐ I42.5 - Other restrictive Cardiovascular
- ☐ I42.9 - Supraventricular tachycardia
- ☐ I49.2 - Junctional premature depolarization
- ☐ I48.0 - Paroxysmal atrial fibrillation
- ☐ I48.2 - Chronic atrial fibrillation
- ☐ I49.91 - Unspecified atrial fibrillation
- ☐ I49.8 - Other specified cardiac arrhythmias
- ☐ R00.1 - Bradycardia, unspecified
- ☐ I50.9 - Heart Failure, unspecified
- ☐ I50.21 - Acute systolic (congestive) heart failure
- ☐ I50.22 - Chronic systolic(congestive) heart failure
- ☐ I50.32 - Chronic diastolic (congestive) heart failure
- ☐ I50.33 - Acute on chronic diastolic (congestive) heart failure
- ☐ I51.9 - Heart disease, unspecified
- ☐ I52 - Other heart diseases classified elsewhere
- ☐ R55 - Syncope and Collapse
- ☐ R60.0 - Localized edema
- ☐ I0 E78.01 - Familial hypercholesterolemia
- ☐ R60.1 - Generalized edema
- ☐ R60.9 - Edema, unspecified
- ☐ R00.2 - Palpitations
- ☐ R06.02 - Shortness of breath
- ☐ R06.00 - Dyspnea, unspecified
- ☐ R06.09 - Other forms of dyspnea
- ☐ PR06.3 - Periodic breathing
- ☐ R06.83 - Snoring
- ☐ R06.89 - Other abnormalities of breathing
- ☐ R07.9 - Chest pain, unspecified
- ☐ R07.2 - Precordial pain
- ☐ R07.82 - Intercostal pain
- ☐ R07.89 - Other chest pain
- ☐ R94.31 - Nonspecific abnormal electrocardiogram (ECG)(EKG)
- ☐ Z79.01 - Long term (current) use of anticoagulants
- ☐ Z01.810 - Encounter for preprocedural cardiovascular examination
- ☐ Z01.812 - Encounter for preprocedural laboratory examination
- ☐ Z01.818 - Encounter for other preprocedural examination

Pulmonary Disease

- ☐ **C34.1**-Malignant Neoplasm of upper lobe, right bronchus or lung
- ☐ **C34.12**-Malignant Neoplasm of upper lobe, left bronchus or lung
- ☐ **C34.2**-Malignant Neoplasm of Middle lobe, 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
- ☐ **E84.0**-Cystic Fibrosis with pulmonary manifestations
- ☐ **G47.33**-Obstructive sleep apnea
- ☐ **I27.0**-Primary Pulmonary Hypertension
- ☐ **J44.1**-Chronic Obstructive Pulmonary Disease with acute exacerbation
- ☐ **J44.1**- Chronic Obstructive Pulmonary Disease with acute exacerbation
- ☐ **J44.9**-Chronic Obstructive Pulmonary disease NOS
- ☐ **J20.0**- Acute bronchitis due to Mycoplasma pneumoniae
- ☐ **J20.1**-Acute bronchitis due to Hemophilus influenzae
- ☐ **J20.3**-Acute bronchitis due to coxsackievirus
- ☐ **J20.4**-Acute bronchitis due to Parainfluenxa virus
- ☐ **J20.5**-Acute bronchitis due to respiratory syncytial virus
- ☐ **J20.6**-Acute bronchitis due to rhinovirus
- ☐ **J20.7**-Acute bronchitis due to echovirus
- ☐ **J20.8**-Acute bronchitis due to other specified organisms
- ☐ **J20.9**-Acute bronchitis unspecified
- ☐ **J28.0**-Acute pulmonary Edema
- ☐ **R06.02** -Shortness of Breath
- ☐ **R06.2**-Sweezing | R05-Cough
- ☐ **R07.1**-Chest pain on breathing
- ☐ **J20.5**-Acute bronchitis due to respiratory syncytial virus
- ☐ **J20.6**-acute bronchitis due to rhinovirus
- ☐ J**20.7**-Acute bronchitis due to echovirus
- ☐ **J20.8**-Acute bronchitis due to other specified organisms
- ☐ **J20.9**-Acute bronchitis, unspecified
- ☐ **J16.8**-Pneumonia due to other specified infectious organisms
- ☐ **J18.9**-Pneumonia, unspecified organism
- ☐ **J40**-Bronchitis, not specified as acute or chronic
- ☐ **J44.1**-Obstructive chronic bronchitis, with (acute) exacerbation
- ☐ **J44.1**-Obstructive chronic bronchitis, with (acute) exacerbation
- ☐ **J45.20**-Mild Intermittent Asthma
- ☐ **J45.23**-Mild Intermittent Asthma with status asthmaticus
- ☐ **J45.31**-Mild Persistent Asthma with acute exacerbation
- ☐ **J45.40**-Moderate persistent Asthma
- ☐ **J45.42**-Moderate persistent Asthma with status asthmaticus
- ☐ **J45.21**-Mild Intermittent Asthma with acute exacerbation
- ☐ **45.30**-Mild Persistent Asthma
- ☐ **J45.32**-Mild Persistent Asthma with status asthmaticus
- ☐ **J45.41**-Moderate persistent Asthma with acute exacerbation
- ☐ **J45.52**-Severe persistent Asthma with status asthmaticus
- ☐ **J45.50**-Severe persistent Asthma
- ☐ **J45.51**-Severe persistent Asthma with acute exacerbation
- ☐ **J45.909**-Unspecified asthma, uncomplicated
- ☐ **J44.9**-Chronic obstructive pulmonary disease, unspecified

Continued To Next Page

- ☐ **R07.81**-Pleurodynia
- ☐ **J45.20** Mild Intermittent Asthma
- ☐ **J45.23**-Mild Intermittent Asthma with status asthmaticus
- ☐ **J45.31**-Mild Persistent Asthma with acute exacerbation
- ☐ **J45.40**-Moderate persistent Asthma
- ☐ **J45.42**-Moderate persistent Asthma with status asthmaticus
- ☐ **J45.21**-Mild Intermittent Asthma with acute exacerbation
- ☐ **J45.30**-Mild Persistent Asthma
- ☐ **J45.32**-Mild Persistent Asthma with status asthmaticus
- ☐ **J45.41**-Moderate persistent Asthma with acute exacerbation
- ☐ **J45.52**-Servere persistent Asthma with status asthmaticus
- ☐ **J45.50**-Servere persistent Asthma
- ☐ **J45.51**-Servere persistent Asthma with acute exacerbation
- ☐ **R22.2**-Localized swelling, mass and lump, trunk
- ☐ **R09.02** Hypoxemia
- ☐ **R91.8**-Nonspecific abnormal finding of lung field in diagnostic imaging
- ☐ **R94.2**-Abnormal results of pulmonary function studies
- ☐ **A41.9**-Sepsis, unspecified organism Malignant neoplasm of trachea, bronchus, lung
- ☐ **C33-T**rachea
- ☐ **C34.00**-Unspecified main bronchus
- ☐ **C34.10**-Upper lobe unspecified bronchus or lung
- ☐ **C34.2**-Middle lobe bronchus or lung
- ☐ **C34.30**-Lower lobe bronchus or lung
- ☐ **C34.80**-Overlapping sites of unspecified bronchus or lung
- ☐ **E84.0**-Cystic fibrosis with pulmonary manifestation
- ☐ **G47.33**-Obstructive sleep apnea (adult) (pediatric)
- ☐ **I26.99**-Other pulmonary embolism without acute corpulmonale
- ☐ **I27.0**-Primary pulmonary hypertension
- ☐ **I95.9**-Hypotension, unspecified
- ☐ **J20.0**-Acute bronchitis due to Mycoplasma pneumoniae
- ☐ **J20.0**-Acute bronchitis due to Mycoplasma pneumoniae
- ☐ **J20.1**-Acute bronchitis due to Hemophilius influenzae
- ☐ **J20.2**-Acute bronchitis due to streptococcus
- ☐ **J20.3**-Acute bronchitis due to coxsackievirus
- ☐ **J20.4**-Acute bronchitis due to parainfluenza virus
- ☐ **J90**-Pleural effusion, not elsewhere classified
- ☐ **J98.11**-Atelectasis
- ☐ **J98.19**-Other pulmonary collapse
- ☐ **J98.2**-Interstitial emphysema
- ☐ **J81.0**-Acute pulmonary edema
- ☐ **J95.84**-Transfusion related acute lung injury (TRALI)
- ☐ **J96.00**-Acute respiratory failure, unspecified whether with hypoxia or hypercapnia
- ☐ **J96.0**-Acute respiratory failure
- ☐ **J96.02**-Acute respiratory failure with hypercapnia
- ☐ **J98.4**-Other disorders of lung
- ☐ **J96.10**- Chronic respiratory failure, unspecified whether with hypoxia or hypercapnia
- ☐ **J96.11**- Chronic respiratory failure with hypoxia
- ☐ **J96.12**-Chronic respiratory failure with hypercapnia
- ☐ **J96.20**- Acute/Chronic respiratory failure, unspecified whether with hypoxia or hypercapnia
- ☐ **J96.21**-Acute/Chronic respiratory failure with hypoxia
- ☐ **J96.22**-Acute/Chronic respiratory failure with hypercapnia
- ☐ **J98.4**-Other disorders of lung
- ☐ **N17.9**-Acute kidney failure, unspecified
- ☐ **R06.02**-Shortness of breath |
- ☐ **R06.2**-Wheezing
- ☐ **R09.89**-Other specified symptoms and signs involving the circulatory and respiratory systems
- ☐ **R05**-Cough
- ☐ **R07.1**-Chest pain on breathing
- ☐ **R07.81**-Pleurodynia
- ☐ **R22.2**-Localized swelling, mass and lump, trunk (chest mass)(localized swelling of chest)
- ☐ **R91.8**-Other nonspecific abnormal finding of lung field(lung mass)
- ☐ **R91.1**-Solitary pulmonary nodule
- ☐ **R91.8**-Other nonspecific abnormal finding of lung field
- ☐ **R94.2**-Abnormal results of pulmonary function studies
- ☐ **R09.02**-Hypoxemia
- ☐ **J98.4**-Other disorders of lung
- ☐ **R65.20**-Severe sepsis without septic shock (sequence the underlying infection first)
- ☐ **Z85.118**-Personal history of malignant neoplasm of bronchus and lung
- ☐ **Z79.01**-Long-term (current) use of anticoagulants

Additional ICD10 codes:

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INFORMED CONSENT

For the purposes of this consent, "I", "my", and "your" will refer to me or to my child, including my unborn child, if my child is the person for whom the healthcare provider has ordered testing.

PURPOSE OF THIS TEST - The purpose of this test is (a) to see if I may have a genetic variant or chromosome rearrangement causing a genetic disorder; or (b) to evaluate the chance that I will develop or passon a genetic disorder in the future. If I already know the specific gene variant(s) or chromosome rearrangement that causes the genetic disorder in my family, I agree to inform the laboratory of this information.

WHAT TYPE OF TEST RESULTS CAN I EXPECT FROM GENETIC TESTING?

1. Positive: A change in your DNA was found, which is very likely the cause of your features/symptoms. This is the most straightforward test result, which can be used as the basis to test other family members to determine their chances of having either the disease or a child with the disease.

2. Negative: No variants were found to explain your symptoms. This does not mean that you do not have a genetic condition. It is still possible that there is a genetic variant not found by the test that was ordered. Your healthcare provider or genetic counselor may discuss more testing either now or in the future.

3. Variant of Uncertain Significance (VUS): A change in a gene was found. However, we are not sure whether this variant is the cause of your symptoms/features. More information is needed. We may suggest testing other family members to help figure out the meaning of the test result.

4. Unexpected Results: In rare instances, this test may reveal an important genetic change that is not directly related to the reason for ordering this test. For example, this test may find you are at risk for another genetic condition I am not aware of or it may indicate differences in the number or rearrangement of sex chromosomes. We may disclose this information to the ordering healthcare provider if it likely affects medical care. Because medical and scientific knowledge is constantly changing, new information that becomes available may supplement the information **Elite Clinical Laboratory** used to interpret my results.

Healthcare providers can contact **Elite Clinical Laboratory** at any time to discuss the classification of an identified variant.

WHAT IS TRIO/DUO-BASED GENETIC TESTING?

For some genetic tests, including samples from the biological parents and/or other biological relatives along with the patient's sample can help with the interpretation of the test results. These tests are often referred to as "trio tests" since they typically include samples from the patient and both parents. Samples from relatives should be submitted with the patient's sample. Clinical information must be provided for the patient and any relative who submits a sample.

I understand that **Elite Clinical Laboratory** will use the relative sample(s) when needed for the interpretation of my test results and that my test report may include clinical and genetic information abouta relative when it is relevant to the interpretation of the test results. I further understand that relatives will not receive an independent analysis of data nor a separate report.

RISKS AND LIMITATIONS OF GENETIC TESTING

1. In some cases, testing may not identify a genetic variant even though one exists. This may be due to limitations in current medical knowledge or testing technology.

2. Accurate interpretation of test results may require knowing the true biological relationships in a family. I understand that if I fail to accurately state the biological relationships in my family, it could lead to incorrect interpretation of the test results, incorrect diagnoses, and/or inconclusive test results. If genetic testing reveals that the true biological relationships in a family are not as I reported them, including non-paternity (the reported father is not the biological father) and consanguinity (the parents are related by blood), I agree to have these findings reported to the healthcare provider who ordered the test.

3. Although genetic testing is highly accurate, inaccurate results may occur. These reasons include, but are not limited to mislabeled samples, inaccurate reporting of clinical/medical information, rare technical errors, or other reasons.

4. I understand that this test may not detect all of the long-term medical risks that I might experience. The result of this test does not guarantee my health and that additional diagnostic tests may still need to be done.

5. I agree to provide an additional sample if the initial sample is not adequate.

PATIENT CONFIDENTIALITY AND GENETIC COUNSELING

It is recommended that I receive genetic counseling before and after having this genetic test. I can find a genetic counselor in my area at www.nsgc.org. Further testing or additional consultations with a healthcare provider may be necessary.

To maintain confidentiality, test results will only be released to the referring healthcare provider, the ordering laboratory, to me, to other healthcare providers involved in my care, diagnosis and treatment, or to others with my consent or as permitted or required by law. Federal laws prohibit unauthorized disclosure of this information. More information can be found at: www.genome.gov/10002077

Continued To Next Page

INTERNATIONAL SAMPLES

If I reside outside the United States, I attest that by providing a sample for testing, I am not knowingly violating any export ban or other legal restriction in the country of my residence.

SAMPLE RETENTION

After testing is complete, my sample may be de-identified and be used for test development and improvement, internal validation, quality assurance, and training purposes. **Elite Clinical Laboratory** will not return DNA samples to you or to referring healthcare providers, unless specific prior arrangements have been made. I understand that samples from residents of New York State will not be included in the de-identified research studies described in this authorization and will not retain them for more than 60 days after test completion, unless specifically authorized by my selection. The authorization is optional, and testing will be unaffected if I do not check the box for the New York authorization language. **Elite Clinical Laboratory** will not perform any tests on the biological sample other than those specifically authorized.

DATABASE PARTICIPATION

De-identified health history and genetic information can help healthcare providers and scientists understand how genes affect human health. Sharing this de-identified information helps healthcare providers to provide better care for their patients and researchers to make new discoveries. **Elite Clinical Laboratory** shares this type of information with healthcare providers, scientists, and healthcare databases. **Elite Clinical Laboratory** will not share any personally identifying information and will replace the identifying information with a unique code not derived from any personally identifying information. Even with a unique code, there is a risk that I could be identified based on the genetic and health information that is shared. **Elite Clinical Laboratory** believes that this is unlikely, though the risk is greater if I have already shared my genetic or health information with public resources, such as genealogy websites.

INFORMED CONSENT

EXOME/GENOME SEQUENCING SECONDARY FINDINGS

• Applicable Only for Full Exome Sequencing and Genome Sequencing Tests. • Does not pertain to Xpanded® or Slice tests

As many different genes and conditions are analyzed in an exome or genome sequencing test, these tests may reveal some findings not directly related to the reason for ordering the test. Such findings are called "incidental" or "secondary" and can provide information that was not anticipated.

Secondary findings are variants, identified by an exome or genome sequencing test, in genes that are unrelated to the individual's reported clinical features.

The American College of Medical Genetics and Genomics (ACMG) has recommended that secondary findings identified in a specific subset of medically actionable genes associated with various inherited disorders be reported for all probands undergoing exome or genome sequencing. Please refer to the latest version of the ACMG recommendations for reporting of secondary findings in clinical exome and genome sequencing for complete details of the genes and associated genetic disorders. Reportable secondary findings will be confirmed by an alternate test method when needed.

WHAT WILL BE REPORTED FOR THE PATIENT? - All pathogenic and likely pathogenic variants associated with specific genotypes identified in the genes (for which a minimum of 10X coverage was achieved by exome sequencing or a minimum of 15X coverage was achieved by genome sequencing), as recommended by the ACMG.

WHAT WILL BE REPORTED FOR RELATIVES? - The presence or absence of any secondary finding(s) reported for the proband will be provided for all relatives analyzed by an exome or genome sequencing test.

LIMITATIONS - Pathogenic and/or likely pathogenic variants may be present in a portion of the gene not covered by this test and therefore are not reported. The absence of reportable secondary findings for any particular gene does not mean there are no pathogenic and/or likely pathogenic variants in that gene. Pathogenic variants and/or likely pathogenic variants that may be present in a relative, but are not present in the proband, will not be identified, or reported. Only changes at the sequence level will be reported in the secondary findings report. Larger deletions/duplications, abnormal methylation, triplet repeat or other expansion variants, or other variants not routinely identified by clinical exome and genome sequencing will not be reported.

FINANCIAL AGREEMENT AND GUARANTEE - For insurance billing, I understand and authorize **Elite Clinical Laboratory** to bill my health insurance plan on my behalf, to release any information required for billing, and to be my designated representative for purposes of appealing any denial of benefits. I irrevocably assign to and direct that payment be made directly to I understand that my out-of-pocket costs may be different than the estimated amount indicated to me by **Elite Clinical Laboratory** as part of a benefit investigation. I agree to be financially responsible for any and all amounts as indicated on the explanation of benefits issued by my health insurance plan. If my insurance provider sends a payment directly to me for services performed by **Elite Clinical Laboratory** on my behalf, I agree to endorse the insurance check and forward it to **Elite Clinical Laboratory** within 30 days of receipt as payment towards **Elite Clinical Laboratory** claim for services rendered.

MEDICARE

A completed Advance Beneficiary Notice (ABN) is required for Medicare patients.

DIGITAL PATIENT LETTER CONSENT

• Applicable Only for Commercial Insurance

• Estimate is provided by your health insurance company and therefore NO estimate will be sent for any orders placed with federal or state-funded insurance plans (e.g. Medicare, Medicaid, Tricare, etc.), institutional bill, or patient bill (self-pay).

To provide you with the estimated out-of-pocket expenses related to your test, **Elite Clinical Laboratory** will send you an email and/or text with the link to access your personalized Digital Patient Letter.

In order to send this information, we need your consent and agreement to the following items:

1. can use your email address or mobile phone number solely for the purpose of **Elite Clinical Laboratory** sending your estimated financial obligation. Text message data rates may apply. is not responsible for undelivered messages due to incorrect or illegible contact information.

2. will send you an email and/or text message containing a link to view your personalized Patient Letter that includes the test out-of-pocket estimate. The link is time-sensitive and will only be available for 72 hours from the time the message is sent. In order to view the estimate, you must click the link in the message.

3. If you take no action, **Elite Clinical Laboratory** will assume that you agree to move ahead with testing and will bill your health insurance. You can approve testing with insurance, switch to self-pay, or cancel the test via the link within the given 72-hour window. In turn, **Elite Clinical Laboratory** if receives your sample(s) and the billing method hasn't been changed, or the test hasn't been cancelled, we will move ahead with testing as ordered, and you will be responsible for any out-of-pocket costs for the completion of the test(s).

Patient Signature

I hereby assign all rights and benefits under my health plan and all rights and obligations that I and my dependents have under my health plan to **Elite Clinical Laboratory** its assigned affiliates and authorized representatives for laboratory services furnished to me by **Elite Clinical Laboratory** I irrevocably designate, authorize and appoint **Elite Clinical Laboratory** or its assigned affiliates and their authorized representatives as my true and lawful attorney-in-fact for the purpose of submitting my claims, obtain a copy of my health plan document, Summary Plan Description, disclosure, appeal, litigation or other remedies in accordance with the benefits and rights under my health plan and in accordance with federal or state laws. If my health plan fails to abide by my authorization and makes payment directly to me, I agree to endorse the insurance check and forward it to **Elite Clinical Laboratory** immediately upon receipt. I hereby authorize **Elite Clinical Laboratory** its assigned affiliates and authorized representatives to contact me or my health Plan/administrator for billing or payment purposes by phone, text message, or email with the contact information that I have provided to **Elite Clinical Laboratory**, in compliance with federal and state laws. **Elite Clinical Laboratory**, its assigned affiliates and their authorized representatives may release to my health plan administrator, my employer, and my authorized representative my personal health information for the purpose of procuring payment of **Elite Clinical Laboratory** and for all the laboratory services. I understand the acceptance of insurance does not relieve me from any responsibility concerning payment for laboratory services and that I am financially responsible for all charges whether or not they are covered by my insurance.

Signature of Patient or Patient Representative / Relationship to Patient Date:

ORDERING PHYSICIAN SIGN HERE

Physician must only order tests that are medically necessary for the diagnosis or treatment of a patient

I attest that this test is medically necessary for the diagnosis or detection of a disease or disorder and that the results will be used in medical management and care decisions for the patient. Furthermore, all information on this Requisition Form is true to the best of my knowledge. I agree to provide the Care Plan notes and Letter of Intent for this order if the insurance requests the lab to gather the medical necessity for any reason

Ordering Physician Signature Date: