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## CARDIOPULMONARY DISORDERS RISK TESTING REQUISITION FORM

INSTRUCTIONS					C	Ordering Physician Information							
	Physician Name NPI			NPI#		FAX#							
<ul> <li>Patient and Physician must sign the consent form</li> <li>All items identified as '<i>Required</i>' must be</li> </ul>			Office/Practice/Institution Name				Physician's Email						
provided/attached to the requisition form.													
SUBMISSION CHECKLIST			Street Address										
SOAP notes and progress notes			City State					Zip Code					
Patient insurance ID card or face sheet			Office Contact Name						Con	Contact Email			
Physician and Patient Signature			Office Contact Name Contact Phor			. FIIONE	one Con						
	e select one	one physician per order)											
Physician name: P			hysician NPI: Physician name:					Physician NPI:					
Physician name: I			hysician NPI: Physician name:						Physician NPI:				
PATIENT INFORMATION									REQUIRED				
Patient First Name Patient Last Name			D			Date of Birth (mm/dd/yyyy)				Phone Number			
Address				State			State			Zip			
Gender Identity			Sexual Orientation				Ancestry						
<ul> <li>Male</li> <li>Female</li> <li>Female-to-Male</li> <li>Male-to-Female</li> <li>Genderqueer</li> <li>Other (Specify)</li> <li>Other (Specif</li></ul>			Lesbian, gay, or homosexual Straight or heterosexual				□ White/Caucasian			Middle Eastern			
			Bisexual				<ul> <li>Native American</li> <li>Hispanic</li> </ul>			an Indian			
			Something else (Describe)								ہ e Hawaiian and Other		
			<ul> <li>Choose not to disclose</li> </ul>				□ Ashkenazi Jewish Pacific Islander				ific Islander		
PAYMENT OPTIONS (SELECT ONE) REQUIRED													
			Primary Insurance			Insurance Policy/ID#					Group		
Self-Pay (Please provide credit card details or mail the check to the laboratory address)			Primary Policy Holder Name				Date of Birth						
			Secondary Insurance			Insurance Policy/ID#				Group			
Client Billing / Institutional Billing							Data of Data						
			Secondary Policy Holder Name					Date	Date of Birth				
SPECIMEN INFORMATION REQUIRED							REQUIRED						
		Sh	ipping Instructio	ons									
Sample Type			Label each specimen tube with the patient's full name and						Send completed Requisition form with collected sample to:				
Buccal Swab Extracted DNA Sample Draw Date (mm/dd/yyyy)			date of birth or patient's full name and collection date.						1203 South White Chapel STE 150,				
/	yyy)	•	<ul> <li>To receive the specimen requirements and shipping guidelines, please send an email to -</li> </ul>					Sout	Southlake,Texas 76092				
CLINICAL HISTORY													
Indications for Testing Diagnostic Presymptomatic Family History Family Variant Other:													
Previous genetic tests:  Yes No													
(If Yes, please specify the test and results)													
Will Patient management be changed depending on the test results?  Yes  No													
FAMILY HISTORY													
No Known Family History     Pedigree Attached			ed 🗆 Adopted										
Relationship	Maternal	Paterna	l Relavant Hist	ory					Age at Disgnosis				
1			]										
2													

#### **Family History and Genetic Predisposition**

## 1. Do you have a family history of heart diseases?

□ Yes, immediate family (parents, siblings, children)

- □ Yes, extended family (grandparents, aunts, uncles, cousins)
- □ No □Unsure
- 2. Are there any known genetic conditions in your family? Yes (please specify) \_\_\_\_\_

□ No □Unsure

### Personal Health History

# 3. Have you been diagnosed with any of the following conditions?

- □ Coronary artery disease
- □ Hypertension (high blood pressure)
- □ Heart failure
- □ Arrhythmias
- □ Peripheral artery disease
- □ Cardiomyopathy
- Valvular heart disease
- Congenital heart defects
- □ High cholesterol (hyperlipidemia)
- Diabetes mellitus
- None of the above

### 4. Have you experienced any of the following symptoms?

- □ Chest pain or discomfort
- Shortness of breath
- Palpitations
- □ Fainting or near-fainting episodes
- □ Swelling in the legs, ankles, or feet
- □ Fatigue or weakness during physical activity
- □ None of the above

#### PULMONARY QUESTIONNAIRE

#### Family History and Genetic Predisposition

## 1. Do you have a family history of lung diseases?

- □ Yes, immediate family (parents, siblings, children)
- □ Yes, extended family (grandparents, aunts, uncles, cousins) □ No □ Unsure
- □ No □ Unsure

# 2. Are there any known genetic conditions a ecting the lungs in your family?

□ Yes (please specify) □ No □ Unsure

#### Personal Health History

# 3. Have you been diagnosed with any of the following respiratory conditions?

- □ Asthma
- □ Chronic obstructive pulmonary disease (COPD)
- Cystic fibrosis
- □ Alpha-1 antitrypsin deficiency
- Pulmonary fibrosis
- Pulmonary hypertension
- Bronchiectasis
- Sarcoidosis
- Lung cancer
- None of the above

# 4. Have you experienced any of the following symptoms?

- Persistent cough
- □ Shortness of breath Wheezing
- □ Chest tightness
- □ Recurrent respiratory infections
- Coughing up blood
- Excessive mucus production
- □ None of the above

#### 5. Have you had any previous cardiac events?

□ Heart attack □ Stroke □ Transient ischemic attack (TIA) □ None of the above

#### Lifestyle Factors

## 6. Do you currently smoke or have you ever smoked?

□ Current smoker □ Former smoker □ Never smoked

#### 7. How would you describe your current exercise routine?

- □ Sedentary (little to no exercise)
- □ Light exercise (1-2 times per week)
- □ Moderate exercise (3-4 times per week)
- □ Vigorous exercise (5 or more times per week)

#### **Additional Risk Factors**

#### 8. What is your current age?

□ Under 40 □ 40-50 □ 51-60 □ Over 60

#### 9. What is your body mass index (BMI)?

- □ Under 18.5 (underweight) □ 18.5-24.9 (normal weight) □ 25-29.9 (overweight)
- □ 30 or above (obese)

#### 10. Have you ever been told you have sleep apnea?

□ Yes □ No □ Unsure

# 5. Have you had any of the following respiratory-related events?

- Pneumothorax (collapsed lung)
- □ Hospitalization for respiratory issues
- □ Respiratory failure requiring ventilation
- None of the above

#### **Lifestyle Factors**

□ Radon

### 6. Do you currently smoke or have you ever smoked?

□ Current smoker □ Former smoker □ Never smoked

### 7. Have you been exposed to any of the following

## environmental factors?

- Secondhand smoke Occupational dust or chemicals
- □ Air pollution □ Asbestos
  - None of the above

#### How would you describe your current exercise capacity?

- □ No limitations in physical activity
- □ Slight limitation in physical activity
- □ Marked limitation in physical activity
- □ Unable to carry out any physical activity without discomfort

#### Additional Risk Factors

#### 9. What is your body mass index (BMI)?

□ Under 18.5 (underweight) □ 18.5-24.9 (normal weight) □ 25-29.9 (overweight) □ 30 or above (obese)

# 10. Do you have a history of frequent respiratory infections?

Yes, more than 3 per year
Yes, 1-2 per year
No, rarely get respiratory infections

### CUSTOM PANEL (SELECT GENES) OR COMPREHENSIVE PANEL

				CardioGenomics Genes						
□ ABCC9 □ ABCG5 □ ABCG8 □ ACTA1 □ ACTA2 □ ACA3 □ AC	□ BRAF □ CACNA1C □ CACNA2D1 □ CACNB2 □ CALM1 □ CALR3 □ CASQ2 □ CAV3 □ CAVIN4 □ CBL □ CBS □ CETP □ COL3A1 □ COL5A1 □ COL5A1	<ul> <li>CRELD1</li> <li>CRYAB</li> <li>CSRP3</li> <li>CTF1</li> <li>DES</li> <li>DMD</li> <li>DNAJC19</li> <li>DOLK</li> <li>DPP6</li> <li>DSC2</li> <li>DSG2</li> <li>DSP</li> <li>DTNA</li> <li>EFEMP2</li> <li>ELN</li> </ul>	□ FBN1 □ FBN2 □ FHL1 □ FHL2 □ FKRP □ FKRP □ FKTN □ GAA □ GATAD1 □ GCKR □ GJA5 □ GLA □ GPD1L □ GPIHBP1 □ HADHA	CardioG HRAS HSPB8 JLK JAG1 JPH2 JUP KCNA5 KCND3 KCNE1 KCNE2 KCNE3 KCNH2 KCNJ2 KCNJ5 KCNJ8	<ul> <li>KRAS</li> <li>LAMA2</li> <li>LAMA4</li> <li>LAMP2</li> <li>LDB3</li> <li>LDLR</li> <li>LDLRAP1</li> <li>LMF1</li> <li>LMNA</li> <li>LPL</li> <li>LTBP2</li> <li>MAP2K1</li> <li>MAP2K2</li> <li>MIB1</li> <li>MYBPC3</li> </ul>	MYH7           MYL2           MYL3           MYL4           MYL6           MY06           MY06           MY0722           MYPN           NEXN           NKX2-5           NODAL           NPPA           NRAS           PCSK9	🗆 SALL4	2 □ SGCB A □ SGCD □ SGCG □ SHOC2	□ TGFB3 □ TGFBR1 □ TGFBR2 □ TMEM43 □ TMPO	□ VCL □ ZBTB17 □ ZHX3 □ ZIC3
	COX15		HCN4	C KCNQ1	D MYH11	D PDLIM3				
D BAG3	CREB3L	🗆 EYA4	D HFE	C KLF10	D MYH6	D PKP2	□ SCO2	□ TBX5	□ TXNRD2	
				Pulm	ionary Gene	5				
□ ABCA3 □ CCDC39 □ CCDC40 □ CFTR □ CHAT □ CHRNA1 □ CHRNB1	□ CHRND □ CHRNE □ COLQ □ CSF2RA □ CSF2RB □ DKC1 □ DNAAF1	<ul> <li>DNAAF2</li> <li>DNAH1</li> <li>DNAH5</li> <li>DNAH11</li> <li>DNAI1</li> <li>DNAI2</li> <li>DNAL1</li> </ul>	EDN3     EFEMP2     ELMOD2     ELN     FBLN5     FLCN     FOXF1	☐ GAS8 ☐ GLRA1 ☐ HPS1 ☐ HPS4 ☐ ITGA3 ☐ LTBP4 ☐ MECP2	D NKX NME PARI	2-1 8 N X2B	RAPSN  RET  RSPH3  RSPH4A  RSPH9  RTEL1  SCN4A	□ SCNN1A □ SCNN1B □ SERPINA1 □ SFTPA1 □ SFTPA2 □ SFTPB □ SFTPC	□ SLC6A5 □ SLC7A7 □ SLC34A2 □ SMAD4 □ SMPD1 □ STAT3 □ TERC	□ TERT □ TINF2 □ TSC1 □ TSC2 □ ZEB2

#### COMMONLY USED ICD10 (DIAGNOSIS) CODES

please note, the icd-10 codes herein are solely for informational use. it is incumbent upon order practitioners to the diagnosis code that precisely justifies test conduct, regardless of its presence in the subsequent list.

#### CARDIOGENOMICS DISEASE

□ R60.9 - Edema, unspecified □ **I35.9** - Nonrheumatic aortic valve disorder, unspecified E78.4 - Other Hyperlipidemia □ R00.2 - Palpitations П 142.0 - Dilated Cardiovascular E78.5 - Hyperlipidemia, unspecified R06.02 - Shortness of breath □ **142.5** - Other restrictive Cardiovascular E87.1 - Hypo - osmolality and / or hypernatremia □ R06.00 - Dyspnea, unspecified 142.9 - Supraventricular tachycardia G89.29 - Other Chronic Pain R06.09 - Other forms of dyspnea 149.2 - Junctional premature depolarization □ **110** - Essential (Primary) Hypertension П □ R06.3 - Periodic breathing I25.10 - Atherosclerotic heart disease of native 148.0 - Paroxysmal atrial fibrillation □ **R06.83** - Snoring coronary artery without angina pectoris □ 148.2 - Chronic atrial fibrillation R06.89 - Other abnormalities of breathing I25.5 - Ischemic Cardiovascular 149.91 - Unspecified atrial fibrillation R07.9 - Chest pain, unspecified I25.6 - Silent Myocardial Ischemia 149.8 - Other speci ed cardiac arrhythmias **R07.2** - Precordial pain □ **125.89** - Other forms of chronic ischemic heart disease □ R00.1 - Bradycardia, unspecified R07.82 - Intercostal pain □ 125.9 - Chronic ischemic heart disease, unspecified I50.9 - Heart Failure, unspecified **R07.89** - Other chest pain □ **I34.1** - Nonrheumatic mitral (valve) insuiency □ **I50.21** - Acute systolic (congestive) heart failure R94.31 - Nonspecific abnormal □ **I34.1** - Nonrheumatic mitral (valve) prolapse □ **I50.22** - Chronic systolic(congestive) heart failure electrocardiogram (ECG)(EKG) □ **I34.2** - Nonrheumatic mitral (valve) stenosis □ 150.32 - Chronic diastolic (congestive) heart failure Z79.01 - Long term (current) use of □ **I35.8** - Other nonrheumatic mitral valve disorders 150.33 - Acute on chronic diastolic (congestive) heart failure anticoagulants I34.9 - Nonrheumatic mitral valve disorder, unspecified 151.9 - Heart disease, unspecified □ **I35.0** - Nonrheumatic aortic (Valve) stenosis **Z01.810** - Encounter for preprocedural □ 152 - Other heart diseases classi ed elsewhere □ I35.1 - Nonrheumatic aortic (Valve) Insuciency cardiovascular examination R55 - Syncope and Collapse □ **I35.2** - Nonrheumatic aortic (valve) stenosis with **Z01.812** - Encounter for preprocedural R60.0 - Localized edema insufficiency laboratory examination E78.01 - Familial hypercholesterolemia □ **I35.8** - Other Nonrheumatic aortic (valve) disorders D Z01.818 - Encounter for other R60.1 - Generalized edema 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
- □ **127.0**-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 in uenzae
- □ J20.3-Acute bronchitis due to coxsackievirus
- □ J20.4-Acute bronchitis due to Parain uenxa 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 unspecied
- 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
- □ J20.7-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
- J45.30-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

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REQUIRED

REQUIRED

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

Additional ICD Codes:

### **PATIENT CONSENT**

By signing this form, I acknowledge that the information provided by me is true and correct. I have read or have had read to me the **Minerva** Labs Informed Consent document at the end of this test requisition form, and understand the information regarding molecular genetics testing. For direct insurance billing: I authorize my insurance benefits to be paid directly to **Minerva Labs** and their affiliates, authorize **Minerva Labs** to release medical information concerning my testing to my insurer, to be my designated representative for purposes of appealing any denial of benefits as needed and to request additional medical records for this purpose. I understand that I am financially responsible for any amounts not covered by my insurer and responsible for sending **Minerva Labs** and their affiliates, money received from my health insurance company. I also give permission for my specimen and clinical information to be used in de-identified studies at **Minerva Labs** and their affiliates for publication, if appropriate. I have had the opportunity to ask questions about the testing, the procedure, the risks, and the alternatives. I authorize **Minerva Labs** and their affiliates to perform the testing as ordered.

Signature

Date

#### Certificate of medical necessity, Consent, Test Authorization and Physician Signature

The individual signing this form, or their representative, hereby confirms their status as a licensed medical professional authorized to order genetic testing and confirms that the patient has provided informed consent for the testing and that it is medically necessary. They 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. They acknowledge that the test results may have an impact on the patient's medical management. The information provided on this form is accurate to the best of their knowledge. The signature on this form applies to the attached letter of medical necessity. If the insurance provider requests the laboratory to gather the medical necessity for any reason, the signer agrees to provide the Care Plan notes and Letter of Intent for this order.

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 pass on 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 **Minerva Labs** used to interpret my results. Healthcare providers can contact **Minerva Labs** 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 **Minerva Labs** 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 about a 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

## **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. **Minerva Labs** 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 **Minerva Labs** 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. **Minerva Labs** 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 deidentified information helps healthcare providers to provide better care for their patients and researchers to make new discoveries. **Minerva Labs** shares this type of information with healthcare providers, scientists, and healthcare databases. **Minerva Labs** 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 Lab/Valgen Labs** 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.

**EXOME/GENOME SEQUENCING SECONDARY FINDINGS** • Applicable only for full exome sequencing and genome sequencing tests • Does not pertain to Xpanded<sup>®</sup> 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 nor 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 **Minerva Labs** 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 **Minerva Labs**.

I understand that my out-of-pocket costs may be different than the estimated amount indicated to me by **Minerva Labs** 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 **Minerva Labs** on my behalf, I agree to endorse the insurance check and forward it to **Minerva Labs** within 30 days of receipt as payment towards **Minerva Labs** claim for services rendered.

If I do not have health insurance, I agree to pay for the full cost of the genetic testing that was ordered by my healthcare provider and billed to me by **Minerva Labs**. I further understand and agree that, if I fail to make payment for genetic testing, in accordance with the payment policies of **Minerva Labs**, my account may be turned over to an external collection agency for non-payment. I agree to pay any associated collection costs, including attorney fees. By my signature on the **Minerva Labs** Test Requisition Form or at the bottom of this form, I accept full and complete financial responsibility for all genetic testing ordered by my healthcare provider.