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PLEASE SUBMIT THE FOLLOWING WITH REQUISITION FORM

 \square 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

PULMONARY GENETIC TESTING REQUISITION FORM

COMPLE	TE ENTIF	RE FORM	AND SUI	BMIT P	EDIGRE	E/C	LINIC NOT	ES TO AVOID	DELA	/S		
PATIEN	T INFORI	MATION	IMPORTAN two s	T - Include sections b	e a current me elow and incl	edica ude	ation list AND a pa photocopy of ins	atient face sheet OR of urance card (front ar	complete nd back).	next		
First Name			La	Last Name					Gender F ☐ M ☐			
Date of Birth (MM/DD/YYYY					Email							
Address				City			State		Zip			
Ethnicity: African Am	Caucasiar	an 🗌 Hispanic 🔲 Jewish(Ashkenazi) 🗌 Portugu			Portuguese 🗌	ese Other						
PATIENT INS						SPECIMEN INFORMATION*						
- Attach patient demographics and copy of insurance card Insurance Self-Pay Client Bill					Date 9	Date Sample Collected (mm/dd/yy) (required)						
Primary Insurance	cial Security Number			Medic	Medical Record#							
Primary Insurance ID#	rimary Insurance Group				☐ Buccal Swab ☐ Other (specify source)							
ORE	DERING F	PHYSICIA	AN/SENDI	NG FA	CILITY (E	ach	Listed person will	receive a copy of the	e report)			
Facility Name (Facility Code)				Address	5							
City	State/Country			Zip			Phone	Phone				
Ordering Provider Name (Last, First)			NPI#			Phone/Fax/Email						
		S	TATEMEN	IT OF	MEDICAI	L N	ECESSITY					
By submission of this test rec as the ordering provider is a requisition form are reason disorder; (iv) the test results (v) have obtained this patien appropriate diagnosis code(uthorized by able and mo will determi at's and relati	y law to ord edically nec ne my patie ives', when a	er the test(s) essary for th ent's medical r applicable, wr	requeste e diagno nanagen itten info	d; (iii) certify sis and/or t nent and tre rmed conse	tha reat	at any custom p tment of a dise ent decisions of	anel and/or ordere ase, illness, impair f this patient's cond	d test(s) ment, sy lition on	requested on this test mptom, syndrome or this date of service;		
Signature of Provider (required)						Date:						
		INDIC	CATIONS I	OR TE	STING (C	HEC	CK ALL THAT AP	PLY)				
☐ Diagnostic ☐ Family histo	ory 🗌 Positiv	ve or normal	l control 🔲 C	Other		•••••						
Will Patient management be	changed de	pending on	the test resul	ts? □Ye	es 🗆 No 🗀	STAT	T TEST : Date res	ults needed (if kno	wn):			
	CLIN	IICAL HI	STORY At	tach any a	available deta	iled	medical records a	and clinical notes				
Please indicate any clinical presentation	ons and/or Endir	ngs that may be	relevant to genet	ic testing:				which may not seem like a		ciation for disease. Please list rds and/or pedigree.		

PATIENT VISIT HISTORY				Date of the Previous Patient Visit				Date of the Last Genetic Testing, if any			
Reasons for Testing											
☐ Positive newborn screen ☐ Infections:mmol/L				☐ Pancreatic insufficiency IRT level:							
☐ Sweat chloride: ☐ <40 ☐ 40-60 ☐ <60 ☐ CBACD				☐ Ultrasound findings:							
☐ Meaconium ileus ☐ Pancreatic insufficiency IRT level:				Relevant lab results (include copies if possible)							
Respiratory distress, explain:											
Other:											
TARGETED SINGLE GENE TESTING PANEL											
☐ ABCA3 ☐ CCDC39 ☐ CCDC40 ☐ CFTR ☐ CHAT		CSF2RA CSF2RB DKC1 DNAAF1 DNAAF2		ELN	PS4 [GA3 [FBP4 [IECP2 [□ PIH □ RA □ RE □ RS	PH3	☐ SCNN1B☐ SERPINA1☐ SFTPA1☐ SFTPA2☐ SFTPB	☐ SMPD1 ☐ STAT3 ☐ TERC ☐ TERT ☐ TINF2		
☐ CHRNA1 ☐ CHRNB1 ☐ CHRND ☐ CHRNE ☐ COLQ		DNAH1 DNAH5 DNAH11 DNAI1 DNAI2		FLCN □ N FOXF1 □ N	F1 [KX2-1 [ME8 [□ RS □ RT □ SC	PH4A PH9 EL1 N4A NN1A	□ SFTPC □ SLC6A5 □ SLC7A7 □ SLC34A2 □ SMAD4	□ TSC1 □ TSC2 □ ZEB2		
			11	NDICATION (S) FOR	TESTING (I	CD-10 C	Codes)				
□ C34.1-Malignant Neoplasm of upper lobe, right bronchus or lung □ C34.2-Malignant Neoplasm of upper lobe, left bronchus or lung □ C34.3-Malignant Neoplasm of lower lobe, right bronchus or lung □ C34.3-Malignant Neoplasm of lower lobe, left bronchus or lung □ C34.3-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 □ J44.1-Chronic Obstructive Pulmonary disease NOS □ J20.0- Acute bronchitis due to Mycoplasma pneumoniae □ J20.1-Acute bronchitis due to Mycoplasma pneumoniae □ J20.1-Acute bronchitis due to Parainfluenxa virus □ J20.3-Acute bronchitis due to Parainfluenxa virus □ J20.5-Acute bronchitis due to Parainfluenxa virus □ J20.5-Acute bronchitis due to respiratory syncytial virus □ J20.5-Acute bronchitis due to echovirus □ J20.8-Acute bronchitis due to echovirus □ J20.9-Acute bronchitis due to other specified organisms □ J20.9-Acute bronchitis due to other specified organisms □ J20.9-Acute bronchitis due to other specified □ J28.0-Acute pulmonary Edema □ R06.02-Shortness of Breath □ R06.02-Shortness of Breath □ R06.2-Sweezing R05-Cough □ R07.1-Chest pain on breathing □ R07.81-Pleurodynia □ J45.20 Mild Intermittent Asthma □ J45.23-Mild Intermittent Asthma with status asthmaticus □ J45.31-Mild Persistent Asthma □ J45.40-Moderate persistent Asthma □ J45.30-Mild Persistent Asthma □ J45.30-Mild Persistent Asthma with satus asthmaticus □ J45.31-Mild Persistent Asthma with status asthmaticus □ J45.31-Mild Persistent Asthma with status asthmaticus □ J45.30-Mild Persistent Asthma with status asthmaticus □ J45.41-Moderate persistent Asthma with status asthmaticus □ J45.51-Servere persistent Asthma with scute exacerbation □ J45.50-Servere persistent Asthma with acute exacerbation □ R22.2-Localized swelling, mass and lump, trunk □ R09.0-2 Hypoxemia □					ecified bronchus or lunus or lung in the control of	chus or luction tric) utte corpuleumoniae eumoniae eumoniae eumoniae luenzae rus sytial virus organism cious orga ic ute) exace ethe) exace ethenaticu erbation s asthmaticus e exacerbatic exacerbatic cacerbatic	ulmonale e e s s anisms erbation erbation us ticus on ation us	□ 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 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 □ R07.1- Chest pain on breathing □ R07.1- Solitary explicit of chest) □ 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			
☐Yes☐No ☐STATTE	ST: Da	ate result Needed (if Kr	nown)								

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 **Medex Laboratories Inc.** used to interpret my results.

Healthcare providers can contact Medex Laboratories Inc. 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 **Medex Laboratories Inc.** 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 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. **Medex Laboratories Inc.** 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. **Medex Laboratories Inc.** 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. **Medex Laboratories Inc.** shares this type of information with healthcare providers, scientists, and healthcare databases. **Medex Laboratories Inc.** 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. **Medex Laboratories Inc.** 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 **Medex Laboratories Inc.** 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 **Medex Laboratories Inc.** 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 **Medex Laboratories Inc.** on my behalf, I agree to endorse the insurance check and forward it to **Medex Laboratories Inc.** within 30 days of receipt as payment towards **Medex Laboratories Inc.** 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, **Medex Laboratories Inc.** 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 **Medex Laboratories Inc.** 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, **Medex Laboratories Inc.** 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, **v** 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 **Medex Laboratories Inc.** its assigned affiliates and authorized representatives for laboratory services furnished to me by **Medex Laboratories Inc.** lirrevocably designate, authorize and appoint **Medex Laboratories Inc.** 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 **Medex Laboratories Inc.** immediately upon receipt. I hereby authorize **Medex Laboratories Inc.** in mediately upon receipt. I hereby authorized **Medex Laboratories Inc.** in sassigned 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 **Medex Laboratories Inc.**, in compliance with federal and state laws. **Medex Laboratories Inc.**, its assigned affiliates and their authorized representatives may release to my health plan administrator, my employer, and my authorized representatives my personal health information for the purpose of procuring payment of **Medex Laboratories Inc.** and for all the laboratory services. I understand the acceptance 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 SIGNATURE 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: