

Medex Laboratories Inc. CLIA # 45D2222222

Lab Director: Rodolfo J Nudelman Lab Address: 9525 Bissonnet Street, Suite # 250, Houston TX 77036 Tel: 832 476 8089 | Fax: 832 786 5133

PLEASE SUBMIT	THE EOLI OWII	NC WITH DEA	HISITION EOD
LEASE SUBMIT	THE FOLLOWII	NG WITH REQ	DISTITION FOR

☐ Statement 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

PRIMARY	' IMMUNOD	EFICIENCY	TESTING REC	QUISITION FORM
---------	-----------	-----------	-------------	-----------------------

PATIENT INFORMATION									
Patient First Name	Patient	Last Name	Biological Sex F M						
Date of Birth (MM/DD/YYYY)		I	Phone Number			Email Address			
Address	Address City					ate Zip			
Ethnicity: African American	☐ Asia	an 🗌 Cauc	asian 🗌 Hispar	nic	hkenazi) 🗌	Portuguese 🔲	Other		
PATIENT INSURA	NCE INI	ORMATIC	ON		SPEC	IMEN INFORM	IATION		
☐ Insurance ☐ Self-Pay ☐ Client Bill			Date Sample Collected (mm/dd/yy) (required)						
Name of the insurance Secondary Insurance			Medical Record#			#			
nsurance Policy/ID number Name of the insured			ed	☐ Buccal Swab					
nsurance Group number Date of Birth of Insured				☐ Other (specify source)					
ORDERIN	G PHYS	ICIAN/SEI	NDING FACII	LITY (Each Listed	person will r	eceive a copy of the r	eport)		
Facility Name (Facility Code):			Address	:		City:			
State/Country:						Phone:			
Ordering Licensed Provider Name (Last, First)(Code)					Fax/Email				
		STATE	MENT OF ME	DICAL NECE	SSITY				
By submission of this test requisition as the ordering provider is authorize requisition form are reasonable and disorder; (iv) the test results will dete (v) have obtained this patient's and rappropriate diagnosis code(s) are income.	ed by law t d medicall ermine my elatives', w	o order the te y necessary fo patient's med hen applicabl	st(s) requested; (i or the diagnosis lical managemen e, written informe	ii) certify that any and/or treatmen t and treatment d	custom pa t of a disea ecisions of t	nel and/or ordered se, illness, impairm this patient's condit	test(s) requested on this test ent, symptom, syndrome or ion on this date of service;		
Signature of Provider (required)							Date:		
	IND	ICATIONS	FOR TESTIN	IG (CHECK ALL T	HAT APPLY)			
☐ Diagnostic ☐ Family history ☐ Po	ositive or n	ormal control	☐ Other						

CLINICAL PRESENTATION

Please indicate any clinical presentations and /or findings that may be relavant to genetic testing:

- Behavior
- Phenotypes

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

- Conditions
- Physical
- Pedigree/Family History Symptoms

There are many presentations which may not seem like a direct association for disease. Please List the most suspected presentations and attach detailed medical records and/or pedigree.

	P	ane	l ID: FT-TP0	130	66 - COMP	REHENSIVE	PRI	MAR	Y IMMU	JN	ODEFICIENC	Y - 4	49 GENES	5
 □ BLM	١		G6PD		NRAS	□ TERT		IFN	GR1		ATM		MEFV	□ CDX1
 □ BRC	A2		G6PC		PMS2	□ F13B		IFN	GR2		RFXANK		CYBB	□ PIK3CD
□ CFT			JAK2		PLCG2	□ F7		RAG	i1 [PTPRC		JAGN1	□ MST1
□ F9	•		MSH6		PTEN	□ FGB		RAC			NCF1		STK4	□ VPS13B
									_				CYBA	□ VF313D
□ F5			MYD88		RUNX1	□ STAT1					TNFRSF13B			
□ FAN			PALB2		MPL	□ STAT3					ITGB2		NFKB2	
			OR TESTING			ICD-1	0 C	odes						
INFECTION ICD	OUS DI Descri						1				/ING THE IMMUNI	E ME	CHANISM	
□ B20		-	nunodeficiency	viru	s [HIV] disease		ICD Description □ D80.0 Hereditary hypogammaglobulinemia							
□ B59	Pneun	ocy	stosis					080.1			l hypogammaglob			.1
MALIGN	ANT N	OPL	ASMS OF LYMP	НО	ID,		l	080.2 080.3			eficiency of immur eficiency of immur	_	_	
1			ND RELATED TIS	SUE				080.4	Selective	e d	eficiency of immur	nogl	obulin M [lg/	M]
ICD □ C80.2	Descri Malign		n neoplasm associ	atec	l with transnla	nted organ	1	080.5 080.6			ficiency with incre leficiency with nea		•	•
□ C88.8			gnant immunop					00.0	with hyp	ber	immunoglobuline	mia		
□ C94.40			nyelosis with my	elof	ibrosis not hav	ving	l	080.7 080.8			ypogammaglobul			<i>y</i> ly antibody defects
□ C94.41			emission nyelosis with my	olof	ibrosis in romi	ccion	1	080.9			ficiency with pred			
□ C94.41			nyelosis with my					201.0	unspeci			c _: _	[CCID]	:4h4: ala
□ C94.6	Myelo	dysp	lastic disease no	t cla	ssified			081.0	dysgene		nbined immunode	iicie	ncy [SCID] w	ith reticular
MYELOD	OYSPLA	STIC	SYNDROMES					081.1			nbined immunode	ficie	ncy [SCID] w	ith low T- and
ICD	Descri							081.2	B-cell nu Severe c		pers nbined immunode	ficie	ncy [SCID] w	ith low or
□ D46.22		-	anemia with exc						normal l	В-с	ell numbers		,	
□ D47.1 □ D47.9		-	eloproliferative of uncertain beh			homatonoiotic	1	081.4 081.6			yndrome ocompatibility com	nlev	class I defici	iency
□ D47.9	-		l tissue unspecifi		n or tyrripriola	петтагорогенс	l	081.7			compatibility com			
□ D47.Z1	Post-tr	ansp	lant lymphopro	lifera				081.89 081.9			bined immunodefi			
☐ D47.Z9 Other specified neoplasms of uncertain behavior of lymphoid hematopoietic and related tissue				vior of lymphoid	1	082.0		Combined immunodeficiency unspecified Wiskott-Aldrich syndrome						
							I	082.1			s syndrome	. 1	le e al esta secono	
1			IER ANEMIAS AI SYNDROMES	ND (OTHER BONE		1)82.2)82.3			ficiency with short ficiency following			tive response to
ICD	Descri								Epstein-	Baı	rr virus		ŕ	•
□ D61.09			titutional aplasti				1	082.4 082.8			unoglobulin E [lgE] ficiency associated			ified major defects
1		-	stic chemothera -induced pancyt			topenia		082.9	Immuno	ode	ficiency associated	d wit	h major defe	ect unspecified
□ D61.818		_		.ope	illa			083.0			ariable immunode ies of B-cell numb			dominant
OTHER	OISORD	FRS	OF BLOOD AND	<u> </u>				083.1	Commo	n v	ariable immunode	ficie	ncy with pre	dominant
BLOOD-								083.2			gulatory T-cell diso ariable immunode			roantibodios
ICD	Descri							763.2	to B- or			iicie	incy with aut	oantibodies
□ D70.0 □ D70.1			agranulocytosis tosis secondary		ancer chemot	herapy	1	083.8			mon variable imm			C 1
□ D70.2		_	-induced agranu	ılocy	ytosis		1	083.9 084.0			ariable immunode te function antiger			
□ D70.4 □ D70.8			ropenia ropenia					084.1	Defects	in t	the complement sy	/ster	m	
□ D70.9	Neutro	pen	ia unspecified				1)84.8)84.9	-		ified immunodefic ficiency unspecific		ies	
□ D71 □ D72.0			disorders of poly omalies of leuko		-	eutrophils		089.3	Immune	e re	constitution syndr	ome	2	
□ D72.810	Lymph	ocyt	openia								:-versus-host disea aft-versus-host dise			
1			eased white bloo			I					hronic graft-versus			
□ D72.819 □ D73.81			white blood cell ic splenomegaly		пт инѕрестео	I		089.813	Graft-ve	rsu	s-host disease uns	peci	fied	A I DC1
□ D75.81	Myelo	fibro	sis				l	089.82			ne lymphoprolifera ified disorders invo		•	
□ D76.1 □ D76.2			ocytic lymphohi ocytic syndrome			ted			not else	wh	ere classified		_	
□ D76.3		_	ocytosis syndron					089.9	Disorde	r in	volving the immur	ne m	iechanism ur	nspecified

	RGICAL MALABSORPTION & CONNECTIVE		MALNUT	TRITION
	RELATED DISORDER		ICD	Description
ICD	Description		E40	Kwashiorkor
□ T86.00	Unspecified complication of bone marrow transplant		E41	Nutritional marasmus
□ T86.01	Bone marrow transplant rejection		E42	Marasmic kwashiorkor
□ T86.02	Bone marrow transplant failure		E43	Unspecified severe protein-calorie malnutrition
□ T86.03	Bone marrow transplant infection			
□ T86.09	Other complications of bone marrow transplant		HVDERTI	ENSIVE & KIDNEY RELATED DISEASES
□ T86.10	Unspecified complication of kidney transplant			
□ T86.11	Kidney transplant rejection		ICD	Description
□ T86.12	Kidney transplant failure	Ш	l12.0	Hypertensive chronic kidney disease with stage 5 chronic
□ T86.13	Kidney transplant infection			kidney disease or end stage renal disease
□ T86.19	Other complication of kidney transplant		l13.11	Hypertensive heart and chronic kidney disease without heart
□ T86.20	Unspecified complication of heart transplant			failure with stage 5 chronic kidney disease or end stage renal disease
□ T86.21	Heart transplant rejection		I13.2	Hypertensive heart and chronic kidney disease with heart failure
□ T86.22	Heart transplant failure			and with stage 5 chronic kidney disease or end stage renal disease
□ T86.23	Heart transplant infection		N18.5	Chronic kidney disease stage 5
	Cardiac allograft vasculopathy			
	Other complications of heart transplant	ш	N18.6	End stage renal disease
□ T86.30	Unspecified complication of heart-lung transplant			
□ T86.31	Heart-lung transplant rejection		ENCOUN	ITER FOR OTHER POSTPROCEDURAL AFTERCARE
□ T86.32	Heart-lung transplant failure		ICD	Description
□ T86.33	Heart-lung transplant infection	П	Z48.21	Encounter for aftercare following heart transplant
□ T86.39	Other complications of heart-lung transplant			
□ T86.40	Unspecified complication of liver transplant		Z48.22	Encounter for aftercare following kidney transplant
□ T86.41	Liver transplant rejection		Z48.23	Encounter for aftercare following liver transplant
□ T86.42	Liver transplant failure		Z48.24	Encounter for aftercare following lung transplant
□ T86.43	Liver transplant infection		Z48.280	Encounter for aftercare following heart-lung transplant
□ T86.49	Other complications of liver transplant			Encounter for aftercare following bone marrow transplant
□ T86.5	Complications of stem cell transplant			
	Lung transplant rejection	ш	Z48.298	Encounter for aftercare following other organ transplant
☐ T86.811	Lung transplant fejection			
	Lung transplant infection		ENCOUN	ITER FOR CARE INVOLVING RENAL DIALYSIS
	Other complications of lung transplant		ICD	Description
	Unspecified complication of lung transplant	П	Z49.01	Encounter for fitting and adjustment of extracorporeal
	Bone graft rejection		217.01	dialysis catheter
	Bone graft failure		740.00	•
	Bone graft infection	Ш	Z49.02	Encounter for fitting and adjustment of peritoneal
	Other complications of bone graft			dialysis catheter
	Unspecified complication of bone graft		Z49.31	Encounter for adequacy testing for hemodialysis
	Intestine transplant rejection		Z99.2	Dependence on renal dialysis
	Intestine transplant rejection Intestine transplant failure			
	·		TDANCD	LANTED ORGAN AND TISSUE STATUS
	Intestine transplant infection Other complications of intestine transplant			
	Unspecified complication of intestine transplant	_	ICD	Description
			Z94.0	Kidney transplant status
	Other transplanted tissue rejection		Z94.1	Heart transplant status
	Other transplanted tissue failure		Z94.2	Lung transplant status
	Other transplanted tissue infection		Z94.3	Heart and lungs transplant status
	Other complications of other transplanted tissue		Z94.4	Liver transplant status
	Unspecified complication of other transplanted tissue		Z94.81	Bone marrow transplant status
☐ T86.90	Unspecified complication of unspecified transplanted organ and tissue		Z94.82	Intestine transplant status
☐ T86.91	Unspecified transplanted organ and tissue rejection			·
☐ T86.92	Unspecified transplanted organ and tissue failure		Z94.83	Pancreas transplant status
□ T86.93	Unspecified transplanted organ and tissue infection		Z94.84	Stem cells transplant status
□ T86.99	Other complications of unspecified transplanted organ and tissue		Z94.89	Other transplanted organ and tissue status

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.

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, **Medex Laboratories Inc** 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).

STOP 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** I irrevocably 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** 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 **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 representative my personal health information for the purpose of procuring payment of **Medex Laboratories Inc** 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:

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

Ordering Physician Signature

Date: