

Advanced Genomics LLC 10750 Hammerly Blvd, STE 120, Houston, TX 77043 T: 281-888-5158 CLIA: 45D0292474

PLEASE SUBMIT THE FOLLOWING WITH REQUISITION FOR	R٨
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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 IMMUNODEFICIENCY TESTING REQUISITION FORM

PATIENT INFORMATION										
Patient First Name	Patient	Last Name	Biological Sex F M							
Date of Birth (MM/DD/YYYY) Phone						Email Address				
Address		City		State		Zip				
Ethnicity: African American Asian Caucasian Hispanic Jewish(Ashkenazi) Portuguese Other										
PATIENT INSURA	NCE INI	ORMATIC	ON		SPEC	IMEN INFORM	ATION			
☐ Insurance ☐ Self-Pay ☐ C		Date Sample Collected (mm/dd/yy) (required)								
Name of the insurance Secondary Insurance, If				Medical Rec						
Insurance Policy/ID number Name of the insured			ed	☐ Buccal Swab						
Insurance Group number	sured	☐ Other (specify source)								
ORDERIN	G PHYS	ICIAN/SEI	NDING FACII	LITY (Each Listed	person will r	eceive a copy of the re	port)			
Facility Name (Facility Code):			Address	:		City:				
State/Country:	Zip:			Phone:						
Ordering Licensed Provider Name (L	ast, First)(0	Code)	NPI#		Phone		Fax/Email			
		STATE	MENT OF ME	DICAL NECE	SSITY					
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:							Date:			
INDICATIONS FOR TESTING (CHECK ALL THAT APPLY)										
☐ Diagnostic ☐ Family history ☐ Po	ositive or n	ormal control	Other							
Will Patient management be change	d dependi	na on the test	results? ☐ Yes☐	No						

CLINICAL PRESENTATION

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

may be relavant to genetic testing:
- Behavior - Phenotypes

- Bellavioi Fileliotyp
- 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.

Custom Ir	nmunc	odefic	ciency NGS Tes	ting	(Select the g	enes below) or	Co	mpreh	ensive Im	mı	unodeficiency NO	GS To	esting Pane	l (Te	st Al	l Genes)	
□ BLM			G6PD		NRAS	□ TERT		IFNG	iR1 □		ATM		MEFV		C	DX1	
 □ BRC	42		G6PC		PMS2	□ F13B		IFNO	GR2 □]	RFXANK		CYBB		P	IK3CD	
│ │ □ CFTF	2	□.	JAK2		PLCG2	□ F7		RAG	1 🗆]	PTPRC		JAGN1] N	1SH2	
 □ F9			MSH6		PTEN	□ FGB		RAG	2 🗆		NCF1		STK4		V	PS13B	
 □ F5			MYD88		RUNX1	□ STAT1		SPIN	lK5 □]	TNFRSF13B		CYBA		В	RCA1	
 □ FANG	CC		PALB2		MPL	□ STAT3		BTK]	ITGB2		NFKB2				
INDICATION (S) FOR TESTING ICD-1																	
INFECTIO							1		ERS INVO	LV	ING THE IMMUNI	F MF	CHANISM	,			
1	Descri	-					DISORDERS INVOLVING THE IMMUNE MECHANISM ICD Description										
1			unodeficiency	virus	s [HIV] disease		□ D80.0 Hereditary hypogammaglobulinemia										
	Pneum	locyst	.0313				□ D80.1 Nonfamilial hypogammaglobulinemia□ D80.2 Selective deficiency of immunoglobulin A [IgA]										
1			ASMS OF LYMP		•			080.3			eficiency of immu				bcla	sses	
1	Descri		D RELATED TIS	SUE	1			080.4 080.5			eficiency of immur				n M	[laM]	
1		•	eoplasm associa	ated	l with transpla	nted organ		080.6	, , ,								
1		_	nant immunopi					080.7			mmunoglobuline ypogammaglobul		sia afinfancu				
1	Acute pachieve		yelosis with my mission	elof	ıbrosis not hav	ving	l .	080.7			unodeficiencies w				tibo	dy defects	
1			yelosis with my	elof	ibrosis in remi	ssion		080.9			ficiency with pred	omii	nantly antibo	ody o	lefe	cts	
1	-		yelosis with my astic disease no		-	se		081.0	unspecifi Severe co		ı bined immunode	ficie	ncy [SCID] w	ith r	eticu	ılar	
				Cla	3311160			081.1	dysgenesis Severe combined immunodeficiency [SCID] with low T- and								
1	YSPLAS Descri		SYNDROMES					201.2	B-cell nur	mk	oers						
1		•	nemia with exc	ess c	of blasts 2		L L	081.2			bined immunode ell numbers	псіе	ncy [SCID] w	ith ic	ow o	r	
□ D47.1	Chroni	c mye	eloproliferative (dise	ase			081.4	Nezelof's	sy	ndrome						
☐ D47.9 Neoplasm of uncertain behavior of lymphoid hematopoietic and related tissue unspecified						081.6 081.7	-		compatibility com compatibility com	-							
1			ant lymphoprol			(PTLD)		081.89	Other co	mk	oined immunodefi	cien	cies	.icric	y		
1						vior of lymphoid		081.9 082.0			immunodeficiency Irich syndrome	/ un	specified				
	hemato	opoie	tic and related	tissu	ie			082.0			syndrome						
APLASTI	C AND	OTHE	R ANEMIAS AI	ND (OTHER BONE			082.2	Immunodeficiency with short-limbed stature Immunodeficiency following hereditary defective response to								
1			YNDROMES				U L	082.3	Epstein-B			nere	editary defec	tive	resp	onse to	
1	Descri Other o	-	tutional aplasti	c an	emia		l .	082.4	Hyperimi	mι	ınoglobulin E [lgE						
□ D61.810	Antine	oplas [,]	tic chemothera	py ir	nduced pancy	topenia)82.8)82.9			ficiency associated ficiency associated						
1		_	induced pancyt	ope	nia			083.0	Common	١Va	ariable immunode	ficie	ncy with pre				
□ D61.818	Other p	Jancy	тореніа				 r	083.1			ies of B-cell numbe ariable immunode			don	ninai	nt	
OTHER D BLOOD-F			OF BLOOD AND				'	705.1			gulatory T-cell diso			·uon	miai		
1	Descri							083.2	Common to B- or T-		ariable immunode	ficie	ncy with aut	:oan	tibo	dies	
			ngranulocytosis					083.8			non variable imm	uno	deficiencies				
1	-	-	osis secondary Induced agranu			nerapy		083.9			ariable immunode						
□ D70.4	Cyclic r	neutro	openia	,			l .	084.0 084.1			e function antiger he complement sy			i			
	Other r		openia unspecified					084.8	Other spe	eci	fied immunodefic	ienc					
□ D71	Functio	onal d	lisorders of poly			eutrophils	l .	084.9 089.3			ficiency unspecific constitution syndr		.				
1			malies of leuko	cyte	S		l .				-versus-host disea						
□ D72.810 □ D72.818		-	openia ased white bloc	od ce	ell count			089.811	Chronic g	gra	ft-versus-host dise	ease					
□ D72.819	Decrea	sed w	hite blood cell	cou							nronic graft-versus s-host disease uns						
1	Neutro Myelof	-	splenomegaly s					089.82	Autoimm	nur	ne lymphoprolifera	ative	syndrome [
□ D76.1	Hemop	hago	cytic lymphohi					089.89			fied disorders invo ere classified	olvin	g the immur	าe m	ech	anism	
1	-	_	cytic syndrome cytosis syndrom		ection-associa	ted		089.9			volving the immur	ne m	echanism ui	nspe	cifie	d	

	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	ı	E43	Unspecified severe protein-calorie malnutrition			
□ T86.03	Bone marrow transplant infection			<u> </u>			
□ T86.09	Other complications of bone marrow transplant		HYPERTI	ENSIVE & KIDNEY RELATED DISEASES			
□ T86.10	Unspecified complication of kidney transplant						
□ T86.11	Kidney transplant rejection	_	ICD	Description			
□ T86.12	Kidney transplant failure	╽╙	I12.0	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	╽╙	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	Ιп	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	l		Encounter for aftercare following bone marrow transplant			
□ T86.5	Complications of stem cell transplant	l					
	Lung transplant rejection	╽╙	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	Ιп	Z49.01	Encounter for fitting and adjustment of extracorporeal			
	Bone graft rejection	_	217.01	dialysis catheter			
	Bone graft failure	۱_	740.00	•			
	Bone graft infection	╽╙	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	l	Z94.81	Bone marrow transplant status			
☐ T86.90	Unspecified complication of unspecified transplanted organ and tissue	l	Z94.82	Intestine transplant status			
☐ T86.91	Unspecified transplanted organ and tissue rejection	l		·			
☐ 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 that becomes available may supplement the information.

Healthcare providers can contact Advanced Genomics 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 Advanced Genomics 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 arelative 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. Advanced Genomics 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. Advanced Genomics 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. Advanced Genomics shares this type of information with healthcare providers, scientists, and healthcare databases. Advanced Genomics 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. Advanced Genomics 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

 $Applicable\ Only\ for\ Full\ Exome\ Sequencing\ and\ Genome\ Sequencing\ Tests.\quad \bullet\ Does\ not\ pertain\ to\ Xpanded\ ^\circ\ or\ Slice\ tests$

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 authoriz eAdvanced Genomics 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 **Advanced Genomics** 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 **Advanced Genomics** on my behalf, I agree to endorse the insurance check and forward it to **Advanced Genomics** within 30 days of receipt as payment towards **Advanced Genomics** 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, Advanced Genomics 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 pur pose of Advanced Genomics 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, Advanced Genomics 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 tur n, Advanced Genomics 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 **Advanced Genomics** its assigned affiliates and authorized representatives for laboratory services furnished to me by **Advanced Genomics** irrevocably designate, authorize and appoint **Advanced Genomics** 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 **Advanced Genomics** immediately upon receipt. I hereby authorize **Advanced Genomics**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 **Advanced Genomics** in compliance with federal and state laws . **Advanced Genomics** 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 **Advanced Genomics** 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:

STOP ORDERING PHYSICIAN SIGN HERE Physician must only order tests that are medically necessory 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: