



MINERVA LABS

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PRIMARY IMMUNODEFICIENCY TESTING REQUISITION FORM

INSTRUCTIONS

- Patient and Physician must sign the consent form
- All items identified as '**Required**' must be provided/attached to the requisition form.

SUBMISSION CHECKLIST

- ☐ SOAP notes and progress notes
- ☐ Patient insurance ID card or face sheet
- ☐ Physician and Patient Signature

Ordering Physician Information

Physician Name	NPI#	FAX#
Office/Practice/Institution Name	Physician's Email	
Street Address		
City	State	Zip Code
Office Contact Name	Contact Phone	Contact Email

Ordering Provider (Please select one physician per order)

Physician name:	Physician NPI:	Physician name:	Physician NPI:
Physician name:	Physician NPI:	Physician name:	Physician NPI:

PATIENT INFORMATION

REQUIRED

Patient First Name	Patient Last Name	Date of Birth (mm/dd/yyyy)	Phone Number
Address		City	State
			Zip

Gender Identity

- ☐ Male
- ☐ Female
- ☐ Female-to-Male
- ☐ Male-to-Female
- ☐ Genderqueer
- ☐ Other (Specify)
- ☐ Choose not to Disclose

Sexual Orientation

- ☐ Lesbian, gay, or homosexual
- ☐ Straight or heterosexual
- ☐ Bisexual
- ☐ Something else (Describe)
- ☐ Choose not to disclose

Ancestry

- ☐ White/Caucasian
- ☐ Native American
- ☐ Hispanic
- ☐ African American
- ☐ Ashkenazi Jewish
- ☐ Middle Eastern
- ☐ American Indian
- ☐ Asian
- ☐ Native Hawaiian and Other Pacific Islander

PAYMENT OPTIONS (SELECT ONE)

REQUIRED

☐ Insurance Billing (Please provide the insurance information)	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	
☐ Client Billing / Institutional Billing	Secondary Insurance	Insurance Policy/ID#	Group
	Secondary Policy Holder Name	Date of Birth	

SPECIMEN INFORMATION

REQUIRED

Sample Type

- ☐ Buccal Swab
- ☐ Extracted DNA

Sample Draw Date (mm/dd/yyyy)

...../...../.....

Shipping Instructions

- Label each specimen tube with the patient's full name and date of birth or patient's full name and collection date.
- To receive the specimen requirements and shipping guidelines, please send an email to - **info@minervalabs.health**

Send completed Requisition form with collected sample to:
1203 South White Chapel STE 150,
Southlake, Texas 76092

CLINICAL HISTORY

Indications for Testing ☐ Diagnostic ☐ Presymptomatic ☐ Family History ☐ Family Variant ☐ Other:

Age of Primary Diagnosis:

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

Has patient received a bone marrow transplant? ☐ Yes ☐ No

If yes, date of bone marrow transplant

Percent engraftment

General

- ☐ Acute liver failure
- ☐ Fever(s)
- ☐ Failure to thrive
- ☐ (Hepato)splenomegaly
- ☐ Lethargy
- ☐ Respiratory insufficiency/failure
- ☐ Sudden unexplained coma/death
- ☐ Other; specify _____

Head and Neck

- ☐ Abnormal CT/MRI of brain; specifyspecify
- ☐ Dysmorphic facies
- ☐ Enlarged lymph nodes
- ☐ Microcephaly
- ☐ Oral leukoplakia
- ☐ Small lymph nodes and/or tonsils
- ☐ Thymic hypoplasia
- ☐ Other; specify _____

Skin

- ☐ Alopecia
- ☐ Eczema
- ☐ Hypopigmentation/ hyperpigmentation
- ☐ Rash/dermatitis
- ☐ Telangiectasia of eyes or skin
- ☐ Dysplastic nails
- ☐ Other skin lesions; specify _____

Hematologic History

- ☐ Bone marrow failure
- ☐ Cytopenias (2 of 3 cell lineages)
- ☐ Leukopenia/neutropenia
- ☐ Red cell anemia
- ☐ Thrombocytopenia/small platelets
- ☐ Other; specify _____

Oncologic History

- ☐ Lymphoma; specify type
- ☐ Myelodysplasia/AML
- ☐ Other leukemia; specify type
- ☐ Recurrent primary tumors; specify types
- ☐ Solid tumor; specify type
- ☐ Other; specify _____

Infectious Disease History

- ☐ Recurrent, unusual or difficult to treat infections

_____ viral

_____ bacterial

_____ fungal
- ☐ Recurrent pneumonia, ear infections or sinusitis
- ☐ Recurrent deep abscesses of the organs or skin

VMultiple courses of antibiotics or IV antibiotics necessary to clear infections
- ☐ Other; specify _____

Laboratory findings

- ☐ Anemia
- ☐ Decreased telomere length
- ☐ Neutropenia/leukopenia
- ☐ Thrombocytopenia
- ☐ Abnormal ALPS panel
- ☐ Abnormal mitogen stimulation
- ☐ Abnormal lymphocyte subsets
- ☐ Abnormal TREC assay
- ☐ Abnormal B cell function; specify
- ☐ Abnormal T cell function; specify
- ☐ Low or absent NK function
- ☐ Complementation group correction (specify)
- ☐ Increased chromosome breakage
- ☐ ↑ ferritin
- ☐ ↑ soluble IL2Rα
- ☐ ↑ triglycerides and/or ↓ fibrinogens
- ☐ Abnormal protein assay by flow cytometry; specify
- ☐ Other; specify _____

Congenital abnormalities/malformations/dysmorphic features (Please specify)

Other Symptoms (Please specify)

FAMILY HISTORY

- ☐ No Known Family History
- ☐ Pedigree Attached
- ☐ Adopted

Relationship	Maternal	Paternal	Relavant History	Age at Disgnosis
1		☐		
2		☐		
3		☐		

CUSTOM PANEL (SELECT GENES) OR ☐ COMPREHENSIVE PANEL

REQUIRED

- ☐ ATM

☐ BLM

☐ BRCA1

☐ BRCA2

☐ BTK

☐ CDX1

☐ CFTR

☐ CYBA

☐ CYBB

☐ F13B

☐ F5

☐ F7

☐ F9

☐ FANCC

☐ FGB

☐ G6PC

☐ G6PD

☐ IFNGR1

☐ IFNGR2

☐ ITGB2

☐ AK2

☐ JAGN1

☐ MEFV

☐ MPL
- ☐ MSH2

☐ MSH6

☐ MYD88

☐ NCF1

☐ NFKB2

☐ NRAS

☐ PALB2

☐ PIK3CD

☐ PLCG2

☐ PMS2

☐ PTPRC

☐ RAG1

☐ RAG2

☐ RFXANK

☐ RUNX1

☐ SPINK5

☐ STAT1

☐ STAT3

☐ STK4

☐ TERT

☐ TNFRSF13B

☐ VPS13B

☐ PTEN

REQUIRED

	B20	Human immunodeficiency virus [HIV] disease.		D82.8	Other specified immunodeficiencies Various other specified immunodeficiencies
	B37.9	Candidiasis, unspecified A fungal infection caused by Candida species, not specified by site.		D82.9	Immunodeficiency, unspecified An unspecified condition affecting the immune system.
	C81.0	Nodular lymphocyte predominant Hodgkin lymphoma.		D83.0	Common variable immunodeficiency with predominant abnormalities of B-cell numbers and function.
	C81.43	Other Hodgkin lymphoma, mixed cellularity, spleen.		D83.1	Common variable immunodeficiency with predominant immuno regulatory A disorder with T-cell disorders dysfunction and variable
	C85.90	Non-Hodgkin lymphoma, unspecified, unspecified site A type of cancer that starts in cells called lymphocytes, which are part of the body's immune system. The specific type of lymphocyte and the site are not specified.		D83.2	Common variable immunodeficiency with autoantibodies to B-cell dysfunction and variable antibody deficiencies.
	C88.8	Other malignant immunoproliferative diseases This includes other specified malignant disorders where the immune system produces excessive amount of abnormal cells.		D83.8	Other common variable immunodeficiencies Various other types of common variable immunodeficiencies.
	C90.00	Multiple myeloma having achieved remission A cancer of plasma cells that has not yet responded to treatment.		D83.9	Common variable immunodeficiency, unspecified Unspecified common variable immunodeficiency.
	C94.41	Acute erythroid leukemia A rare and aggressive type of leukemia that primarily affects red blood cell precursors.		D84.0	Lymphocyte function antigen-1 (LFA-1) defect.
	C94.6	Myelodysplastic disease, unspecified A group of disorders caused by poorly formed or dysfunctional blood cells, not otherwise specified.		D84.821	Immunodeficiency due to drugs and external causes Immune deficiency resulting from medications or external factors.
	D46.9	Myelodysplastic syndrome, unspecified.		D84.821	Immunodeficiency due to drugs and external causes Immune deficiency resulting from medications or external factors.
	D47.2	Monoclonal gammopathy A condition where an abnormal protein (monoclonal protein or M protein) is found in the blood.		D84.89	Other immunodeficiencies Various other specified immunodeficiencies.
	D52.9	Dietary vitamin B12 deficiency anemia, unspecified.		D84.9	Immunodeficiency, unspecified Unspecified immunodeficiency condition.
	D59.9	Acquired hemolytic anemia, unspecified.		D89.89	Other specified disorders involving the immune mechanism, not elsewhere classified Various other immune disorders not classified elsewhere.
	D60.0	Constitutional aplastic anemia.		D89.9	Disorder involving the immune mechanism, unspecified An unspecified immune disorder.
	D60.9	Acquired pure red cell aplasia, unspecified A rare disorder where the bone marrow stops producing red blood cells.		E03.8	Other specified hypothyroidism.
	D61.3	Idiopathic aplastic anemia A condition where the body stops producing enough new blood cells, without a known cause.		E05.0	Thyrotoxicosis with diffuse goiter.
	D61.818	Other pancytopenia A condition characterized by a deficiency of all types of blood cells (red, white, and platelets).		E05.90	Thyrotoxicosis, unspecified without thyrotoxic crisis or storm.
	D64.0	Hereditary sideroblastic anemia.		E06.0	Acute thyroiditis.
	D64.81	Anemia due to antineoplastic chemotherapy Anemia caused by cancer treatment drugs.		E06.1	Subacute thyroiditis.
	D69.3	Immune thrombocytopenic purpura A disorder that can lead to easy or excessive bruising and bleeding, resulting from unusually low levels of platelets.		E11.618	Type 2 diabetes mellitus with other diabetic arthropathy.
	D69.9	Hemorrhagic condition, unspecified.		E29.0	Testicular hypofunction.
	D70.8	Other neutropenia A condition involving an abnormally low count of neutrophils, a type of white blood cell.		E43	Unspecified severe protein-calorie malnutrition A severe deficiency of protein and calories, unspecified
	D71	Functional disorders of polymorphonuclear neutrophils.		E46	Unspecified protein-calorie malnutrition.
	D72.810	Lymphocytopenia A condition involving a lower-than-normal count of lymphocytes, a type of white blood cell.		E78.0	Pure hypercholesterolemia.
	D72.818	Other decreased white blood cell count Conditions where white blood cell count is abnormally low.		E88.81	Metabolic syndrome.
	D72.819	Decreased white blood cell count, unspecified A condition with an unspecified low white blood cell count.		G35	Multiple sclerosis.
	D72.820	Lymphocytopenia.		L08.1	Erythrasma.
	D80.0	Hereditary hypogammaglobulinemia A genetic disorder where the body produces very low levels of immunoglobulin G (IgG).		L08.9	Local infection of the skin and subcutaneous tissue, unspecified.
	D80.1	Nonfamilial hypogammaglobulinemia A non-genetic disorder where the body produces low levels of immunoglobulins		M05.79	Rheumatoid arthritis with rheumatoid factor of multiple sites without organ or systems involvement Rheumatoid arthritis affecting multiple sites.
	D80.4	Selective deficiency of immunoglobulin M [IgM] A condition where the body produces low levels of IgM.		M05.79	Rheumatoid arthritis with rheumatoid factor of multiple sites without organ or systems involvement Rheumatoid arthritis affecting multiple sites.
	D80.6	Antibody deficiency with near-normal immunoglobulins or with hyperimmunoglobulinemia An immune deficiency where antibody levels are near normal or elevated.		M05.79	Rheumatoid arthritis with rheumatoid factor of multiple sites without organ or systems involvement Rheumatoid arthritis affecting multiple sites.
	D80.8	Other immunodeficiencies with predominantly antibody defects Various other conditions primarily affecting antibody production.		M05.9	Rheumatoid arthritis with rheumatoid factor, unspecified Rheumatoid arthritis with rheumatoid factor, unspecified.
	D80.9	Immunodeficiency with predominantly antibody defects, unspecified Unspecified conditions affecting antibody production.		M06.9	Rheumatoid arthritis, unspecified Unspecified rheumatoid arthritis.
	D81.89	Other combined immunodeficiencies Various combined immune deficiencies not otherwise specified.		M32.10	Drug-induced systemic lupus erythematosus Lupus caused by drug reactions.
	D81.9	Combined immunodeficiency, unspecified An unspecified disorder affecting multiple parts of the immune system.		M32.9	Systemic lupus erythematosus, unspecified A chronic autoimmune disease that can affect any part of the body, unspecified.
	D82.4	Hyperimmunoglobulin E [IgE] syndrome A disorder characterized by high levels of IgE and recurrent infections.		M45.0	Ankylosing spondylitis of multiple sites in spine A type of arthritis affecting multiple sites in the spine.
				M45.6	Ankylosing spondylitis of lumbar spine Arthritis affecting the lumbar spine.
				M45.9	Ankylosing spondylitis of unspecified sites in spine Arthritis affecting unspecified sites in the spine.
				R53.0	Neoplastic (malignant) related fatigue.
				T86.40	Unspecified complications of bone marrow transplant Complications arising from bone marrow transplants, unspecified.
				Z83.2	Family history of diseases of the blood and blood-forming organs and certain disorders involving the immune mechanism Family history of blood and immune system disorders.
				Z85.71	Personal history of Hodgkin lymphoma History of having Hodgkin lymphoma.
				Z85.72	Personal history of non-Hodgkin lymphoma History of having non-Hodgkin lymphoma.
				Z86.2	Personal history of diseases of the blood and blood-forming organs and certain disorders involving the immune mechanism History of blood and immune system disorders.

PATIENT CONSENT

Date _____

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.

Date _____

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. **Minerva 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® 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.

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