CLIFFSIDE LABS
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Immunodeficiency NGS Test Requisition Form

PATIENT INFORMATION

Patient's First Name	Patient's Last Name	M.I.	Sex
			☐ Male ☐ Female

Date of Birth (MM/DD/YYYY)	Patient's Address	City, State, and Zip

Patient's Email Address (required)	Patient's Phone Number	Patient's Cell Phone (required)

Ancestry (Select all that apply)

☐ Asian ☐ African American ☐ Ashkenazi Jewish ☐ Caucasian ☐ French Canadian ☐ Hispanic
☐ Indian ☐ Middle Eastern ☐ Native American ☐ Pacific Islander ☐ Other: _____

▼ BARCODE ▼

REQUIRED BARCODE STICKER
Attach barcode for the kit your patient used.

Sample Collection Date (MM/DD/YYYY)

PATIENT INSURANCE INFORMATION

Insurance Company Name	Member ID	Relationship to Patient
		☐ Self ☐ Spouse/Partner ☐ Child ☐ Other _____
Policy Holder's First Name (if not self)	**Policy Holder's Last Name** (if not self)	**Please attach a copy of front and back of insurance card and ID**

ORDERING PROVIDER

Provider Facility	Provider Name	Phone Number	Fax Number	NPI Number

Email Address	Address	City, State, and Zip

GENES PANEL

☐ **Primary Immunodeficiency Plus (Ref Lab 19 genes)** (Sequencing and Deletion/Duplication)
BLM, BRCA2, CFTR, F5, F9, FANCC, G6PC, G6PD, JAK2, MPL, MSH6, MYD88, NRAS, PALB2, PLCG2, PMS2, PTEN, RUNX1, TERT

☐ **Periodic Fever and Autoinflammatory Disorders (54 genes)** (Sequencing and Deletion/Duplication)
ACP5, ADA2, ADAM17, ADAR, AP1S3, ASAH1, CARD14, COPA, DDX58, ELANE, HAX1, HTR1A, IFIH1, IL10RA, IL10RB, IL1RN, IL36RN, ISG15, LPIN2, MEFV, MVK, NLRC4, NLRP1, NLRP12, NLRP3, NOD2, OTULIN, PLCG2, POLA1, POMP, PRG4, PRKCD, PSENEN, PSMA3, PSMB4, PSMB8, PSMG2, PSTPIP1, RBCK1, RIPK1, RNASEH2A, RNASEH2B, RNASEH2C, SAMHD1, SH3BP2, SLC29A3, TMEM173, TNFAIP3, TNFRSF11A, TNFRSF1A, TREX1, TRNT1, USP18, WDR1

ICD-10 Code(s) for the PRIMARY GENES: (1) _____ (2) _____ (3) _____ (4) _____ (5) _____

PERSONAL HISTORY

Diagnosed Condition(s)	Age at Dx	Diagnosed Condition(s)	Age at Dx

FAMILY HISTORY

Relationship to Patient	Maternal (M) Paternal (P)	Diagnosed Condition(s)	Age at Dx	Living or Deceased (Please provide age at death)
	☐ M ☐ P			
	☐ M ☐ P			
	☐ M ☐ P			

PATIENT INFORMED CONSENT (Please sign below)

I confirm that I have been informed about the details of Cliffside Labs LLC Genetics Tests ordered for me by my provider. I understand the risks, benefits and limitations of testing and I voluntarily consent to testing. I give permission to Cliffside Labs LLC to perform the genetic tests described. I understand I am financially responsible for services performed and for sending Cliffside Labs LLC all of the money I receive directly from my health plan for this test. I authorize Cliffside Labs LLC to submit claims to my medical insurance on my behalf, to give my health plan my health information on this form and other information provided by my healthcare provider that is necessary for reimbursement, to inform my health plan of my test result only if required for preauthorization or payment of additional reflex testing, for plan benefits to be payable to Cliffside Labs LLC, for Cliffside Labs LLC to contact me about my out of pocket responsibility. I affirm that I have given consent to my treating physician, to communicate with a specialist about the results of my genetic test, and I am aware of the applicable cost-sharing for such consultation.

Patient Signature _____ **Date** _____

CONFIRMATION OF INFORMED CONSENT AND MEDICAL NECESSITY

By ordering testing, the undersigned person represents that he/she is a licensed medical professional authorized to order genetic testing OR is a representative of a licensed medical professional authorized to order genetic testing; acknowledges the patient has been supplied information regarding genetic testing and the patient has given informed consent for genetic testing to be performed and the signed consent form is on file; and acknowledges that all genetic tests are done through genetic sequencing and deletion duplication to assure accuracy of the test results. I confirm that this is medically necessary for the diagnosis or detection of a disease, illness, impairment, syndrome or disorder, and that these results will be used in the medical management and treatment decisions for this patient. In addition, by signing below you confirm that you: (a) have an on-going relationship with the patient, (b) will use the results in the management of the patient's medical condition, (c) will follow up with the patient once the test results are received to render additional treatment decisions based on the test results, (d) will maintain a detailed chart with SOAP notes specifying how the test results impacted the medical care and treatment of the patient in follow-up visits, (e) that you understand that if the patient is a Medicare beneficiary that Medicare does not cover routine screening tests, (f) the test ordered is not a screening test, and that all local and national CMS coverage guidelines to determine medical necessity of the ordered test have been met, and (g) I choose to have an independent medical geneticist review and provide advice on my patients genetic test results "interprofessional consultation" (99451 & 99452).

Ordering Physician Signature _____ **Date** _____

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Informed Consent for Immunodeficiency Genetic Testing

This Informed Consent Form is to be filled out and signed by the patient. This form reviews the benefits, risks and limitations of genetic testing that is ordered by your healthcare provider to assess your risk for developing Immunodeficiency. **Genetic testing is confidential and voluntary and you are not required to have the test. You may wish to obtain genetic counseling prior to signing this consent form. If so, a request should be made to your healthcare provider.** Please read carefully and discuss any questions you may have with your healthcare provider before signing the consent below.

Purpose of Testing: Genetic changes or mutations can occur in certain gene(s) that are associated with Immunodeficiency. This test analyses these particular gene(s) to determine if there are genetic changes present in your test sample that significantly increase your risk for developing Immunodeficiency. Genetic testing provides a more precise estimate of a person's risk for Immunodeficiency than using your personal and family history alone. In some cases, the results of this test may also provide information about risks for medical conditions that are not related to Immunodeficiency.

Test Procedure: Your healthcare provider typically obtains an oral buccal or cheek swab or a saliva sample and sends it to Cliffside Labs LLC for analysis. Cliffside Labs LLC will analyze the DNA of the specific gene(s) to check for genetic changes related to Immunodeficiency.

Test Results and Interpretation: Your test results should be explained in support with your personal and family health history, results of your physical examination, other laboratory and hospital tests, and the clinical expertise of your healthcare provider. There are three possible results from this test: - positive, negative, or uncertain.

> **A Positive Result:** A mutation(s) was identified in your DNA that is associated with an increased risk for Immunodeficiency. This means you are at increased risk for Immunodeficiency. Knowing that you have a mutation in one or more of the genes analyzed may help you make more informed choices with your doctor about your medical care. You and your healthcare provider can use this information to make a personalized screening and prevention plan. Following your plan may lower your chance of developing Immunodeficiency or may increase the chance that any Immunodeficiency detected will be diagnosed when it is at an earlier and more treatable stage. Screening for family members may be recommended. A positive result does not mean that you have Immunodeficiency or that you will definitely develop Immunodeficiency in your lifetime.
>
> **A Negative Result:** No mutations were identified in any of the genes that were tested using the test method specified. This result greatly reduces the likelihood that you have a mutation in the genes that were tested and known Immunodeficiency risk associated with these genes. If you are the first person in your family being tested, a negative result means that you still have at least the same risk for Immunodeficiency as a person in the general population. You may still be at a greater than average risk for Immunodeficiency due to a genetic predisposition that cannot be detected by this test. If you test negative for a mutation that is known to be in your family, then you may be considered to have the same risk for Immunodeficiency as a person in the general population.

If you are found to carry a mutation in any of the genes analyzed, this may be informative for your blood relatives.

The results of your Immunodeficiency Test will be sent to your ordering physician and may be sent to a third-party genetics counseling service, to provide genetics counseling services, as selected by Cliffside Labs LLC, and will become part of your medical record. All other parties can only obtain results by submitting an Authorization for Release of Information Form.

Benefits of the Test: Your genetic test results may help you make more informed decisions with your healthcare provider about your health such as screening and prevention medication therapies. If a gene mutation is identified, blood relatives may choose to be tested to determine whether or not they share the same risks for Immunodeficiency. If you get a positive result, you should discuss with your healthcare provider how Immunodeficiency is inherited and learn about the likelihood that your children or blood relatives may have to inherit the same mutation(s) in the gene(s) tested. If you test negative for a known mutation in your family, then you cannot pass that mutation onto your children and you may be considered as having the same risk as a person in the general population.

Risks of the Test: Genetic testing is done on DNA most often obtained from a blood, oral buccal or saliva sample. Side effects from having blood drawn are uncommon, but may include dizziness, fainting, soreness, bleeding, bruising and rarely, infection. Saliva and oral buccal swab collection is not invasive. Genetic screening test may cause you to discover sensitive information about your health or disease risks, including disease risks other than the one you are testing for, or for diseases that currently have no treatment.

The US Genetic Information Discrimination Act-GINA of 2008 prohibits discrimination on the basis of genetic information in regard to health insurance and employment. The results of genetic testing are considered Protected Health Information, PHI, as described in the Health Insurance Portability and Accountability Act, HIPPA of 1996 (Public Law 104.191). Federal legislation prohibits unauthorized disclosure of confidential personal information.

Limitations of the Test: This test only analyzes for certain specific genetic changes that are associated with an increased risk for developing Immunodeficiency. Genetic testing provides a risk assessment only for those Immunodeficiency gene(s) being analyzed. If your test results are positive, there may be differing opinions amongst physicians as to which treatment option is best to take. Your course of treatment and medical care is best determined by you in consultation with your doctor or healthcare provider.

Financial Responsibility: Genetic testing of appropriate persons is generally reimbursed by health insurance. You are responsible for any cost of the genetic test that is not reimbursed by your health insurance.

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Sample Retention: After testing is complete, your de-identified submitted specimen may be used for test development and improvement, internal validation, quality assurance, and training purposes. DNA specimens are not returned to individuals or to referring health care providers unless specific prior arrangements have been made. Samples from residents of New York State will not be included in the de-identified research studies described in this authorization and will not be retained for more than 60 days after test completion, unless specifically authorized by your selection below. The authorization is optional, and testing will be unaffected if you do not check the box for the New York authorization language.

Participation in Research: You have the option of consenting to the use of your anonymized sample, genetic information and results in research to develop new tests for all patients. Participation in research is voluntary. If you consent to participating in research and later change your decision, Cliffside Labs LLC will destroy any remaining portion of your test sample that was stored and remove your information from the research database.

Patient Consent Statement

By signing below, I, the patient acknowledge that

- Immunodeficiency Genetics testing is done to determine a person's increased risk of developing Immunodeficiency.
- This test is not done to diagnose whether I have or will get a certain disease in the future. This test is intended to tell me about my hereditary risk related to Immunodeficiency as discussed with my healthcare provider and selected on my test order form.
- I have been offered the opportunity to ask questions and discuss with my healthcare provider the benefits and limitations of the genetics test(s) to be performed as indicated on the test requisition form and ordered by my healthcare provider.
- I have discussed with the healthcare provider ordering this test the reliability of positive and negative test results and the level of accuracy that a positive result has for a specific disease or condition and serves as a predictor of such a disease.
- I understand that I should not make any medical decisions based on my results without speaking with my healthcare provider first. I understand that I should discuss my results and appropriate medical management with my healthcare provider.
- I have not been offered anything of value to induce me to provide my genetic sample.
- I understand that I am the owner of my medical history and test results. My healthcare provider cannot discuss nor disclose my test results and associated medical history to a third party unless related to treatment or payment for treatment, without my written authorization.
- I understand it is entirely my decision to have or not to have any genetic testing.
- I have read this document in its entirety and understand that I can keep a copy of the signed document for my records.

I have read and fully understand the above. **Please initial** _____

☐ I **consent** to being tested for predisposition to Immunodeficiency and I will discuss my test results and appropriate medical management with my healthcare provider.

I understand the following information regarding use of my test sample for research:
Cliffside Labs LLC is committed to improving genetic testing for all patients and contributing to scientific research. For more information on research please visit www.cliffsidelab.com. **Please NOTE: If left blank, the consent for research is interpreted as "NO".**

☐ **Optional:** I consent to use of my de-identified test samples for research.

☐ **Optional:** In addition to the above, I consent to be contacted by Cliffside Labs LLC regarding research opportunities.

☐ **Optional:** I am a New York State resident and I consent to storing my test samples at Cliffside Labs LLC beyond 60 days for future use or testing.

Signature of Patient or Legal Guardian: _____ **Date:** _____