Immunology Diagnostic Laboratory
Troy R. Torgerson, MD PhD - Director / Hans D. Ochs, MD – Co-Director
CLIA (Washington) #50D1056266
www.seattlechildrens.org/IDL

1900 Ninth Avenue, CS9-7
Seattle, WA 98101-1304
Phone: 206-987-7IDL (7435)
Fax: 206-987-7310
Email: idl@seattlechildrens.org

SAMPLE SUBMISSION FORM

Patient Information

Name _____
Last, First MI

DOB _____
mm / dd / yyyy

Gender ☐ M ☐ F

Ethnicity
☐ African American
☐ Asian
☐ Caucasian
☐ Hispanic
☐ Other, Specify: _____

_____
Address Apt#

_____
City/State/Zip

Email _____

Phone _____

Patient label

Patient Informed Consent

My signature below indicates that I have read (or had read to me) the Patient Informed Consent on page 2 of this form. I understand this information and agree to have the testing performed.

_____
Signature of Patient/Parent or Legal Guardian Date

Referring Physician Information

Name _____
First Last Title

Email _____

Phone _____

Fax _____

Pertinent Clinical Information

Suspected Diagnosis _____

Indication for testing
☐ Carrier Screen ☐ Diagnostic ☐ Family History ☐ Other _____

History

Physical findings

Family history

Lab findings

☐ Bone Marrow Transplant
☐ Gene Therapy
> Date _____
mm / dd / yyyy

Institutional Billing

Institution _____

Billing Contact _____

Institutional Billing Address Stamp or Address/City/State/Zip

Sample Specifications

Date Collected _____ MRN _____
mm / dd / yyyy

Test(s) Requested
1. _____
2. _____
3. _____
4. _____

Sample Type
☐ Blood
☐ Buccal swab
☐ Skin fibroblasts
☐ CVS/Amniocytes
☐ Isolated DNA
☐ Other, Specify: _____

Special Instructions

Carrier Analysis or Prenatal Diagnosis

Family Mutation

_____ _____
Gene (eg. *FOXP3*) Variant

Index patient name _____

Patient's relation to index _____

☐ Copy of the mutation report attached

Other information

IMMUNOLOGY DIAGNOSIC LABORATORY USE ONLY				
DATE RECEIVED	TIME	TYPE/AMOUNT RECEIVED	HD NUMBER	INITIALS

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IDL LAB PATIENT INFORMED CONSENT

By signing this form I understand that:

1. The purpose of this test is to look for abnormalities in my immune cells or for genetic changes (called "mutations" or "variants") in one or more genes that are believed to be associated with the medical condition that I am being tested for. These tests can be used to confirm a clinical diagnosis in a person with symptoms or to determine if other family members might have the same disease.
2. In order to provide the best possible interpretation of the test results, it is helpful to obtain as much information as possible about your medical condition. By signing this consent, I give my health care provider permission to send the following to the IDL lab:
   - My blood, DNA, tissue, or other type of sample for testing
   - Medical records describing my symptoms and results of other testing performed
   - Information about my family history
3. Even though the methods used by the IDL lab to test my immune cells and to look for genetic changes in my DNA are very accurate, they may not detect every possible change that is associated with disease. There is also a very small chance that an error in the testing could occur.
4. Sometimes a new genetic change (variant) is identified but there is not enough information in the medical literature to determine if that change causes the disease that I have. In this case, the IDL lab will offer an interpretation based on experience and the best evidence available in the scientific literature. If new information affects the interpretation of previously reported test results, the IDL lab may contact my physician. If a genetic change is identified, the IDL lab recommends that this be discussed in detail with my doctor, a specialist in genetics, or a genetic counselor.
5. Unless otherwise required by law, the IDL lab will release test results only to the ordering health care provider or to persons that I specifically designate in writing.
6. When DNA testing is performed on multiple family members, there is a chance that the test may uncover unexpected information about family relationships including determining that the presumed father is not the biological father or that an individual is adopted.
7. Unless indicated below, samples left over after testing is complete will be stored for 25 years or more in case re-testing is necessary. Additional testing on stored samples can be ordered by my health care provider after they obtain my informed consent and send a written request to the IDL lab.

   ☐ **Do not retain my sample for more than 60 days after testing is completed.**
8. Dr. Torgerson, Dr. Ochs, and the IDL lab are involved in a number of ongoing research projects related to understanding immune system diseases. Depending on the outcome of the testing performed in the IDL lab, I may be eligible for enrollment in research studies that pertain to my medical condition. A representative from the lab may contact me to determine whether I would be willing to participate in a research study. I may also contact Dr. Torgerson or Dr. Ochs if I wish to participate.

   ☐ **I do not want to be contacted about potential research projects that may apply to my condition**
9. By signing above, I indicate that I have read and understand this information and my questions have been answered. If the patient is a minor or is otherwise unable to give consent, a parent, legal guardian, or other legally authorized person should sign on the patient's behalf.

IDL USE ONLY
HD NUMBER

Patient Information	
Name	
DOB	MRN

Patient Label

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AVAILABLE TESTS, CPT CODES & PRICES

Agammaglobulinemia, X-Linked (XLA)		
☐ BTK Gene	$2,125	81479
☐ BTK Protein Flow	$565	88184(1), 88185(1), 88187(1)

Autoimmune Polyglandular Syndrome Type 1 (APECED)		
☐ AIRE Gene	$1750	81479

Chronic Mucocutaneous Candidiasis (CMC)		
☐ STAT1 Gene	$1725	81479

Common Variable Immunodeficiency (CVID)		
☐ ICOS Gene	$1000	81479
☐ ICOS Protein Flow	$585	88184(1), 88185(2), 88187(1)

Hyper IgE Syndrome (HIES)		
☐ STAT3 Gene (AD-HIES)	$1725	81405
☐ DOCK8 Gene	$3775	81479
☐ DOCK8 Protein Flow	$500	88184(1), 88185(2), 88187(1)
☐ HIES Screen by Flow (Th17 cells & pSTAT3)	$670	86353(2), 88184(1), 88185(4), 88187(1)

Hyper IgM Syndrome (HIGM)		
☐ CD40 Ligand Gene	$950	81404
☐ CD40 Gene	$1400	81479
☐ AID Gene	$1000	81479
☐ UNG Gene	$1200	81479
☐ CD40 Ligand Protein Flow	$690	86353(2), 88184(1), 88185(5), 88187(1)
☐ CD40 Protein Flow	$485	88184(1), 88185(2), 88187(1)

IL-10 Receptor Defects		
☐ IL-10 Receptor Gene (IL10RA/IL10RB)	$1875	81479
☐ IL-10 Receptor Function Screen by Flow	$565	86353(2), 88184(1), 88185(1), 88187(1)

Immune dysregulation, Polyendocrinopathy, Enteropathy, X-linked Syndrome (IPEX & IPEX-Like)		
☐ FOXP3 Gene	$1300	81479
☐ CD25 Gene	$1300	81479
☐ STAT5B Gene	$2175	81479
☐ FOXP3 Protein Flow/T_{REG} Flow	$605	88184(1), 88185(4), 88187(1)

Leukocyte Adhesion Deficiency Type I (LADI)		
☐ CD18 Gene	$1950	81479
☐ CD18 Protein Flow	$550	88353(1), 88184(1), 88185(1), 88187(1)

Mammalian Susceptibility to Mycobacterial Disease (MSMD)		
☐ GATA2 Gene	$1300	81479
☐ MSMD Screen by Flow (pSTAT1/4 in response to IFNγ, IL-12 Stimulation)	$700	86353(4), 88184(1), 88185(1), 88187(1)

Netherton Syndrome		
☐ SPINK5 Gene	$3425	81479

Severe Combined Immunodeficiency (SCID)		
☐ IL2RG (Common γ Chain) Gene	$1250	81479
☐ JAK3 Gene	$2450	81479
☐ RAG1/RAG2 Gene	$1300	81479
☐ Artemis Gene	$1800	81479
☐ IL-7 Receptor α (IL7RA) Gene	$1300	81479
☐ ZAP-70 Gene	$1650	81479
☐ X-SCID Screen by Flow (pSTAT3/5)	$600	86353(2), 88184(1), 88185(1), 88187(1)
☐ IL7RA (CD127) Protein Flow	$520	88184(1), 88184(3), 88187(1)

Wiskott-Aldrich Syndrome (WAS)		
☐ WAS Gene	$1300	81479
☐ WAS Protein Flow	$465	88184(1), 88185(1), 88187(1)

Warts, Hypogammaglobulinemia, Infections, and Myelokathexis Syndrome (WHIM)		
☐ CXCR4 Gene	$700	81479

Hypohydrotic Ectodermal Dysplasia with Immune Deficiency (EDA-ID)		
☐ NEMO Gene	$1600	81479
☐ IKBα Gene	$1100	81479
☐ IKBα Degration by Flow (Functional screen for NEMO/IKBα pathway)	$565	86353(2), 88184(1), 88185(1), 88187(1)

X-Linked Lymphoproliferative Disease (XLP) / EBV Susceptibility		
☐ SAP (SH2D1A) Gene	$800	81479
☐ XIAP (BIRC4) Gene	$1150	81479
☐ MAGT1 Gene	$1350	81479
☐ SAP Protein Flow	$465	88184(1), 88185(1), 88187(1)
☐ XIAP Protein Flow	$465	88184(1), 88185(1), 88187(1)

Immunophenotyping		
☐ B Cell Immunophenotyping (Switched/Unswitched Memory B cells & B Cell Developmental Subsets)	$765	88184(1), 88185(10), 88188(1)
☐ T Cell Immunophenotyping (CD4/CD8 Naïve, Effector, Effector Memory Subsets)	$660	88184(1), 88185(7), 88187(1)
☐ T Cell Receptor Excision Circles (TREC)	$525	81479

Carrier Analysis / Family Member Analysis / Prenatal Diagnosis (known mutation)		
☐ Carrier Analysis (known mutation)	$500	81479
☐ Family Member Analysis (known mutation)	$500	81479
☐ Prenatal Diagnosis (known mutation)	$500	81479

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INSTRUCTIONS / SAMPLE REQUIREMENTS / SHIPPING

Required paperwork

**Please have patients/parents/guardians review the "Patient Informed Consent" (page 2 of the requisition form) and sign the requisition form.

The following MUST be provided before testing can be performed:

Patient Information:
- ☐ Patient's full name
- ☐ Date of birth and sex
- ☐ Consent

Specimen Information:
- ☐ Sample type
- ☐ Tests requested
- ☐ Date sample collected
- ☐ Mutation information if sample is for Prenatal diagnosis or Carrier analysis

Reporting Information:
- ☐ Provider or institution to whom report should be sent
- ☐ Address to which paper report should be sent
- ☐ Fax number of provider and/or institution
- ☐ Telephone number of provider and/or institution
- ☐ Email address of provider listed above

Billing Information:
- ☐ Address and contact information for responsible institution

** ***We do not bill insurance directly.***
** ***We are unable to collect payment directly from patients***
The requesting institution will be billed unless other arrangements are made ahead of time.

Sample Requirements

Young Child:	DNA sequencing only 3-5cc Flow cytometry & sequencing 5-7cc
Older Child/Adult:	DNA sequencing only 5-10cc Flow cytometry & sequencing 10-20cc
	**For any flow cytometry samples that are being shipped overnight please include a sample from a normal healthy individual as a control.
Anticoagulant:	All samples should be collected in preservative-free sodium heparin anticoagulant. (Green-top Vacutainer® tubes work well).

Packaging and Shipping Instructions

Packaging Instructions: If needed, specimen packaging instructions are available as a pdf from FedEx: http://images.fedex.com/us/packaging/guides/UN3373_fxcom.pdf

Shipping Instructions:
- Ship at ambient temperature (DO NOT REFRIGERATE OR FREEZE)
- Ship via overnight courier (i.e.- FedEx, UPS, Airborne Express, etc.)
- The lab accepts samples Monday-Friday but samples should be shipped only Monday-Thursday so they do not sit over the weekend.

Shipping Address:
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Seattle Children's Research Institute
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