AT THE FOREFRONT UChicago Medicine | Medical Laboratories

Endocrinology Requisition Form

The University of Chicago Genetic Services Laboratories
5841 South Maryland Avenue, Room G701/MC0077, Chicago, IL 60637
Toll Free: 888.824.3637 | Local: 773.834.0555 | Fax: 773.702.9130
ucglabs@bsd.uchicago.edu | dnatesting.uchicago.edu | CLIA#: 14D0671659 | CAP#: 18827-01

Patient and Sample Information

Name: *Last* _____ *First* _____ **Date of Birth (mm/dd/yyyy):** _____

Sex assigned at birth: ☐ Male ☐ Female **MRN:** _____

Ethnicity: ☐ Caucasian ☐ African-American ☐ Hispanic ☐ Asian ☐ Ashkenazi Jewish ☐ Other _____

Date Sample Drawn: _____ **Specimen Type:**

☐ Peripheral Blood (3-10 cc in EDTA (purple) top tube ☐ DNA (DNA samples are only accepted if the DNA extraction or isolation was performed at a CLIA-certified laboratory.)

Ordering Physician Information

☐ **Referring Physician:** _____

Phone: _____ Fax: _____

Email: _____

☐ **Genetic Counselor:** _____

Phone: _____ Fax: _____

Email: _____

☐ **Referring Lab:** _____

Phone: _____ Fax: _____

Email: _____

Indication for Testing - REQUIRED

ICD-10: _____

☐ **Asymptomatic**

☐ **Symptomatic (please describe):** _____ Age of onset: _____

Clinical findings for patients with Diabetes (please check all that apply):

☐ Hyperglycemia ☐ On Insulin therapy Responsive to sulfonylureas? ☐ YES ☐ NO ☐ UNKNOWN

Clinical findings for patients with Hyperinsulinism (please check all that apply):

☐ Hypoglycemia ☐ Elevated plasma insulin concentration Diazoxide Responsive? ☐ YES ☐ NO ☐ UNKNOWN

Results of F-Dopa PET (if available): _____

☐ **Related family history (please specify):** _____ ☐ **No family history**

Parental Samples for Tier 1: Diazoxide Unresponsive Hyperinsulinism Panel only

Parental samples are highly recommended for interpretation of proband results. Send 3-10ccc in EDTA. Please label parental sample with full name and DOB. There is no charge if parental testing, if performed.

MOTHER **Date Sample Drawn:** _____ ☐ Not Available ☐ To be sent later

Name: *Last* _____ *First* _____ **Date of Birth:** _____ **MRN:** _____

☐ **Asymptomatic** ☐ **Symptomatic (hyperinsulinism) – please specify** _____ ☐ **Unknown**

FATHER **Date Sample Drawn:** _____ ☐ Not Available ☐ To be sent later

Name: *Last* _____ *First* _____ **Date of Birth:** _____ **MRN:** _____

☐ **Asymptomatic** ☐ **Symptomatic (hyperinsulinism) – please specify** _____ ☐ **Unknown**

Ordering Checklist

☐ Test Requisition Form *(required)*
☐ Completed Indication for Testing/ICD-10 study code *(required)*
☐ Completed Billing Information *(required)*
☐ Completed Research Consent Form *(recommended)*

Note: All samples should be shipped via overnight delivery at room temperature to the address at the top of this page. No weekend or holiday deliveries. Label each specimen with the patient's name, date of birth and date sample collected.

For Office Use Only

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ALL NEXT GENERATION SEQUENCING TESTS INCLUDE BOTH SEQUENCING AND DELETION/DUPLICATION ANALYSIS

Congenital Hyperinsulinism testing

☐ Tier 1 Panel: Diazoxide Unresponsive Hyperinsulinism Panel (KCNJ11, ABCC8, GCK sequencing, ABCC8 deletion/duplication; turnaround time 7 days). Please alert lab when sending sample.

☐ Hyperinsulinism Panel

☐ Concurrent: run Tier1 panel **and** Hyperinsulinism panel at the **same** time.

☐ Reflex: run Tier1 panel first. If negative, run Hyperinsulinism panel

Monogenic Diabetes testing

☐ Monogenic Diabetes Panel

☐ Wolfram Syndrome Panel

☐ Type A Insulin Resistant Diabetes with Acanthosis Nigricans (INSR Mutation Analysis)

Disorders of Sex Development (DSD) testing

☐ Abnormal/Ambiguous Genitalia Panel

☐ 46,XX Disorder of Sex Development/Complete Gonadal Dysgenesis Panel

☐ 46,XY Disorder of Sex Development/Complete Gonadal Dysgenesis Panel

Dyslipidemia testing

☐ Dyslipidemia Panel

☐ Hypercholesterolemia Panel

Hypogonadotropic Hypogonadism

☐ Hypogonadotropic Hypogonadism/ Kallmann Syndrome Panel

Maturity-Onset Diabetes of the Young (MODY) testing

☐ MODY Panel

☐ Monogenic Diabetes Panel

☐ *GCK* (MODY2) Mutation Analysis

Neonatal Diabetes testing

☐ Comprehensive Neonatal Diabetes Mutation Analysis

☐ 6q24 Methylation-Specific MLPA

☐ Neonatal Diabetes Panel

☐ UPD6 (requires sample from both parents also)

Lipodystrophy testing

☐ Lipodystrophy Panel

MCT8 (Allan-Herndon-Dudley syndrome) testing

☐ Tier 1 (*SLC16A2 (MCT8)* Thyroid panel) followed by Tier 2 (*SLC16A2 (MCT8)* sequencing) if Tier 1 abnormal.
**3-10cc blood in an EDTA tube and 3-10cc blood in a red top tube required.

Monogenic Obesity testing

☐ Monogenic Obesity Panel

☐ Non-Syndromic Monogenic Obesity Panel

☐ Bardet Biedl Panel

Pancreatic Agenesis testing

☐ Pancreatic Agenesis panel

Infertility Testing

☐ Male infertility panel

☐ Female Infertility panel

☐ Premature Ovarian Failure Panel

Rickets testing

☐ Hypophosphatemic Rickets Panel

Thyroid Disorders testing

☐ Hypothyroidism Panel

☐ Hyperparathyroidism Panel

☐ Hypoparathyroidism panel

Aniridia Testing

☐ *PAX6* Mutation Analysis

Currarino syndrome

☐ *MNX1* Mutation Analysis

Hereditary Hemorrhagic Telangiectasia (HHT)

☐ Hereditary Hemorrhagic Telangiectasia (HHT) panel

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Targeted Mutation Analysis

(Testing for a previously detected mutation or sequence change)
Requires prior approval by UCGS Lab Staff if this is a gene for which we do not offer full sequencing.

Gene: _____

Change: _____

Name of Proband / U of C lab number: _____

Relationship to proband: _____

Single Gene Mutation Analysis (Sequencing and Deletion/Duplication Analysis)

Any gene included in one of our sequencing panels can also be ordered individually. Please contact UCGS Lab Staff for prior approval before ordering.

Gene Requested: _____

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BILLING OPTIONS

There are some tests for which we do not offer insurance billing. Please consult our website and quick guide (list of tests, costs, TAT and CPT codes) or contact us for more information.
All samples received with incomplete billing information will delay processing time.
Test canceled while "in progress" will be billed for the amount of work completed up to that point.
Please forward all billing questions to: venessa.gamboa@uchospitals.edu or call 312-213-5441.

Patient Name: *Last* _____ *First* _____ (MI): _____ Date of Birth: _____

1.) Institutional Billing *(Pre-payment is required for all samples referred from outside the US or Canada.)*

Billing Institution: _____ PO#: _____

Financial Contact: _____ Phone: _____ Fax: _____

Address: _____ City: _____ State: _____ Zip: _____

Email (required): _____

2.) Self-Pay

Please provide address and contact information for the entity or individual to be invoiced.

Name: _____

Address: _____

City : _____ ***State:*** _____ ***Zip/Postal Code:*** _____

Phone: _____ ***Email:*** _____

3.) Insurance Billing *(We do NOT accept Illinois or any out-of-state Medicaid. Please note we do not bill insurance for all our testing options. Please see our website for more details. Prices listed on our website are not applicable for insurance billing, please contact us for insurance pricing information.)* *A legible photocopy of the front and back of the insurance card and insurance authorization must be included.*

ICD-10 Diagnosis Code(s): _____ ***(Must be provided or insurance cannot be filed.)***

Policyholder Name: _____ Date of Birth: ____/____/_____ Sex: ☐ Male ☐ Female

Policyholder Address: _____ City: _____ State: _____ Zip: _____

Relationship to the Patient: ☐ Self ☐ Spouse ☐ Dependent ☐ Other Preauthorization # (*if applicable*): _____

Name of Primary Insurance: _____ Policy No. _____ Group No.: _____

Insurance Address: _____ City: _____ State: _____ Zip: _____

PCP/Referring Physician Name: _____ NPI #: _____

Name of Secondary Insurance: _____ Policy No.: _____ Group No.: _____

Insurance Address: _____ City: _____ State: _____ Zip: _____

The policy holder's signature to the following statement: I hereby authorize any physician who treated or attended to me or my dependent(s) to furnish any medical information requested. In consideration of services rendered, I hereby transfer and assign to the University of Chicago Genetic Services Laboratories any benefits of insurance I may have. I assume responsibility for the balance of the cost of testing not paid by my insurance company. A photocopy of this authorization shall be considered as effective and valid as original.

Authorized Signature: _____ Date: ____/____/_____

CONSENT/AUTHORIZATION BY SUBJECT FOR PARTICIPATION IN A RESEARCH PROTOCOL FOR THE BETTER UNDERSTANDING OF THEIR GENETIC CONDITION

Protocol Number: 11-0151

Name of Subject :_____

Date of Birth: _____

STUDY TITLE: Molecular Genetic Studies of Rare Orphan Genetic Disease

Research Team: Soma Das, Ph.D.
5841 S. Maryland Ave. Room L-155 MC 0077, Chicago, IL 60637
773-834-0555

You are being asked to allow your child to participate in a research study that may help us learn more about the genetic condition for which you are being tested. This consent form describes the study, the risks and benefits of participation, as well as how your confidentiality will be maintained. Please take your time to contact us with questions and feel comfortable making a decision whether to participate or not. If you decide to participate in this study, please sign this form**. Throughout this consent form, "you" will refer to you or your child, as appropriate.**

WHY IS THIS STUDY BEING DONE?

You have already consented to clinical genetic testing. We are asking you to also participate in further studies. The purpose of these studies is to learn more about the genetic cause of diseases tested for in our lab, gather more information about these disorders, and experiment with new methods that may be better for testing.

WHAT IS INVOLVED IN THE STUDY?

During this study, Dr. Das and her team will collect information about you for this research. We may contact your doctor to request additional Protected Health Information (PHI), which consists of any health information related to your diagnosis (such as date of birth, medical record number, primary diagnosis, clinical features, relevant and family history, outcome). The data collected will be used to develop a database of patients being tested for genetic diseases and will be kept for the duration of the database. This study will look at how often different genetic mutations happen and clinical information related to the mutation.

When our lab is researching new genes or testing methods that are related to your diagnosis, we may include your sample, with others from similar patients in a small study before offering this new test. This data will help in directing doctors about the likelihood of a positive or negative test result in their patient. We may also use your sample to set up new methods that will improve the clinical testing in our laboratory. Your clinical information and sample, without any identifiers, may also be shared with other researchers that are interested in this specific condition.

HOW LONG WILL I BE IN THE STUDY?

Once enrolled, you will likely remain in this study as long as your DNA sample remains in our laboratory. If you want your sample, to be removed from the study at any time, please contact us, and the sample will not be used for further studies. Existing results will remain in our database until the study ends.

WHAT ARE THE RISKS OF THE STUDY?

There are no known added risks of the research. No additional information will be obtained from you, as all of the information has already been collected as part of clinical genetic testing or evaluation by your doctor.

ARE THERE ANY BENEFITS TO TAKING PART IN THE STUDY?

If you agree to take part in this study, there may be direct medical benefit to your family. We may identify a cause for the genetic disease in your family. If a mutation is identified in your DNA, through our testing, your referring doctor will be notified and will receive a clinical report. Our study may also be helpful in finding the genetic causes of disease and will benefit doctors and patients as a group.

WHAT OTHER OPTIONS ARE THERE?

You may choose not to participate.

WHAT ARE THE COSTS?

There will be no additional costs to you or your insurance company resulting from this research study. However, you or your insurance company will be responsible for costs related to your usual medical care.

WILL I BE PAID FOR MY PARTICIPATION?

You and your child will not be paid to participate.

WHAT ABOUT PRIVACY?

Study records that identify you will be kept private. All of your personal information will be entered into a password-protected database to prevent access to non-authorized personnel. If your data is shared with other researchers, all patient identifiers will be removed. Data from this study may be used in medical journals or presentations. If results from this study or related studies are made public in a medical journal, individual patients will not be identified. If we wish to use a patient's identity in a medical journal, we will ask for your permission at that time.

As part of the study, Dr. Das and her team will report any positive results of further testing to your referring doctor and/or genetic counselor. Dr. Das may also share these results, without your name or date of birth, with other researchers.

People from the University of Chicago, including the Institutional Review Board (IRB), a committee that oversees research at the University of Chicago, may also view the records of the research. If health information is shared outside the University of Chicago, the same laws that the University of Chicago must obey may not protect your health information. Dr. Das does not have to give you any results that are not are not important to your health or your family's health at that time.

This consent form will be kept by the research team for at least six years. The study results will be kept in your child's research record and be used by the research team indefinitely. When the study ends, your personal information will be removed from all results. Any information shared with your doctor may be included in your medical record and kept forever.

The Genetic Information Nondiscrimination Act (GINA) is a federal law that may help protect you from health insurance or employment discrimination based on genetic information. GINA is a federal law that will protect you in the following ways:

- Health insurance companies and group plans may not request genetic information from this research;
- Health insurance companies and group plans may not use your genetic information when making decisions regarding your eligibility or premiums;
- Employers with 15 or more employees may not use your genetic information when making a decision to hire, promote, or fire you or when setting the terms of your employment.

GINA does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. GINA also does not protect you against discrimination based on an already-diagnosed genetic condition or disease.

WHAT ARE MY RIGHTS AS A PARTICIPANT?

Taking part in this study is optional. You may choose not to participate at any time during the study. Choosing not to participate or leaving the study will not affect your child's testing at the University of Chicago.

If you choose to leave the study and you do not want any of your child's future health information to be used, you must inform Dr. Das in writing at the address on the first page. Dr. Das may still use your child's information that was collected before to your written notice. You will be given a signed copy of this form. This consent form does not have an expiration date.

WHO DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

If you have further questions about the study, please call 773-834-0555.

If you have any questions about your rights in this research study you may contact the IRB, which protects participants in research projects. You may reach the Committee office between 8:30 am and 5:00 pm, Monday through Friday, by calling (773) 702-6505 or by writing: University of Chicago, Institutional Review Board, 5841 S. Maryland Ave., MC7132, I-625, Chicago, IL 60637.

Consent

I have received information about this research project and the procedures. No guarantee has been given about possible results. I will receive a signed copy of this consent form for my records.

I give my permission to participate in the above research project.

Signature of Subject:_____

Date: _____

I give my permission for my child/relative/the person I represent to participate in the above research project.

Signature of Parent / Legal Guardian / Legally Authorized Representative:

_____

Date: _____