



Informed Consent for Molecular Genetic Testing

Patient		CSC ID number	
Address			
City		State	Zip code
Telephone		Birthdate	
Spouse			
Father		Mother	
Paternal grandparents			
Maternal grandparents			
Genetic test(s) requested (see list):	Disease		
	Gene		
	Mutation		

The diagnosis of a genetic disease or the identification of people at risk for having a child with a genetic disease requires the testing of DNA for the presence of an abnormal gene. You and/or your physician are requesting the Clinic for Special Children (CSC) to perform a genetic test on you or your child. The purpose and accuracy of this test has been explained to you and your questions have been satisfactorily answered.

Development and performance of this testing was determined by the CSC. This clinical testing has not been approved by the FDA; however, the FDA has determined that such approval is not necessary. Some reagents used in this testing are produced for research purposes only. There is always a chance that an error may occur (including, but not limited to, sample contamination and sample misidentification). A negative test result does not necessarily exclude a genetic disease. Results of genetic testing should be considered with the results of other laboratory testing as well as clinical evaluation. The results of these tests will be handled in the standard medically confidential manner.

You and/or your physician acknowledge permission to (1) obtain about 3 mls of blood from a vein in your arm, (2) isolate DNA from this sample, (3) perform the requested diagnostic tests (if any), and (4) store the DNA sample at the Clinic for Special Children. By signing this form, you acknowledge that your DNA sample remaining after diagnostic testing may be used further for quality-control purposes. Your name or other personal identifying information will not be used in or linked to the results of any studies or medical publications. However, you have the right to learn of any medically significant findings identified in the course of that process. Please select your preference below:

I DO or I DO NOT agree to be re-contacted for future research studies relevant to the CSC's mission. I understand that my decision to opt-out of such follow-up contacts will not affect my ability to obtain testing or receive medical care at CSC.

I DO or I DO NOT want to be informed of incidental findings (medically actionable findings not related to the indication for testing).

Patient or Parent/legal guardian

Date

Alternate consent: I, the health care provider requesting the above testing, have explained the benefits and limitations of genetic testing to the patient and/or their legal guardian and have received verbal consent to order genetic testing.

Healthcare provider

Date

Laboratory Requisition



Clinic for Special Children

535 Bunker Hill Road, PO Box 126, Strasburg, PA 17579 T 717.687.9407 F 717.687.9237

Patient

Name

Date of Birth

Address

Phone number

Sample

Peripheral blood

Cord blood

Filter card

Testing Requested

Targeted mutation testing (*Please see test list at <http://www.clinicforspecialchildren.org>*)

Disease (e.g., MSUD)

Gene (e.g., BCKDHA)

Variant (e.g., c.1312T>A)

Disease

Gene

Variant

Disease

Gene

Variant

Indication for testing

Carrier testing

Clinically normal individual with no family history

Family history of the condition

Diagnostic testing

Clinical indication _____

Spouse with family history of condition

Spouse is a known carrier for the condition

Chromosomal microarray (*Peripheral or cord blood only*)

Clinical indication _____

Reporting

Requesting physician/ midwife/ counselor

Institution

Address

Phone number

Fax number *

Email *

Billing

Name

Institution

Address

Phone number

Fax number

Email

These items are REQUIRED. Failure to provide proper documentation may result in delayed testing or rejection of sample.

***POSITIVE diagnostic results will be reported by phone to requesting provider. Please indicate preference for reporting NEGATIVE results by checking the appropriate box (fax or email).**