The Lantern Project™ Requisition Form

Lighting the way to rare disease diagnosis

This test requisition form can be used to submit a specimen as part of The Lantern Project testing program. This program is brought to you at no additional charge by Sanofi.
The Lantern Project is for diagnostic testing only. The testing options below are not appropriate for carrier testing.
Please complete every field and tick box clearly.

STEP 1: PATIENT INFORMATION

Patient's First Name | Middle Initial | Patient's Last Name

MM/ DD /YYYY
Patient's Date of Birth | Patient ID/MR Number/External Sample Number

Biological Sex: ○ Male ○ Female ○ Unknown
Gender Identity (if different from above):_____

Patient's Street Address | City / Town

State | Zip Code | Country | Patient's Preferred Phone | Patient's Email

Ethnicity (check all that apply): ○ African-American ○ Asian (China, Japan, Korea) ○ Caucasian/N. European/S. European ○ Finnish ○ French Canadian ○ Hispanic
○ Jewish - Ashkenazi ○ Jewish - Sephardic ○ Mediterranean ○ Middle Eastern (Saudi Arabia, Qatar, Iraq, Turkey) ○ Native American ○ E. Indian
○ Southeast Asian (Vietnam, Cambodia, Thailand) ○ South Asian (India, Pakistan) ○ Other (specify)_____

PATIENT SAMPLE INFORMATION

SAMPLE TYPE: ○ Saliva Swab (acceptable for DNA testing only) ○ Whole Blood ○ Dried Blood Spots Collection Date: MM/DD/YY Age of Onset:_____

Patient has previously had a blood transfusion: ○ Yes ○ No Was this sample collected in the State of NV, NY or OR?: ○ Yes ○ No

INDICATION FOR TESTING (MORE THAN ONE SELECTION MAY APPLY)

○ Clinical Suspicion ○ Family History ○ Newborn Screening Confirmation (please include previous testing results)

INCLUSION OF MEDICAL RECORDS, CLINICAL SUMMARY, PICTURES AND FAMILY HISTORY IS RECOMMENDED. CLINICAL INFORMATION IS CRUCIAL FOR ACCURATE INTERPRETATION OF RESULTS.

For general questions on the collection and return of samples, please call: Revvity at +1(866) 354-2910 or by emailing Genomics@revvity.com

MOBILE PHLEBOTOMY SAMPLE COLLECTION REQUEST*

* Only to be requested if patient cannot have sample collected at provider's office. For patient's 13 years and older.

KIT TYPE REQUESTED: ○ DBS Pack ○ Whole Blood Pack **VISIT TYPE:** ○ ExamOne Office ○ Home

Patient Name | Requested Date | Patient Primary Phone Number | Patient Secondary Phone Number

Special Instructions

! To request mobile phlebotomy services, submit completed requisition form via the Online Order Submission Tool or Client Portal found at www.revvity.com

For samples that are collected not utilizing the Revvity test packs, ship sample, test requisition form, and informed consent form by preferred shipping method to Revvity at: **Revvity, 250 Industry Dr. Suite 400, Pittsburgh, PA 15275**

STEP 2: PROVIDER

Provider's First and Last Name | Ordering Provider Account Number | NPI

Clinic/Hospital/Institution Name | Provider's Email

Provider's Street Address | City / Town | State | Zip Code | Country

Provider's Phone | Provider's Fax

PROVIDER SPECIALTY

○ Biochemical Genetics
○ Cardiology
○ Gastroenterology
○ Genetics
○ Hematology
○ Nephrology
○ Neurology
○ Neuromuscular or Rehab Med
○ Ophthalmology
○ Orthopedics/Metabolic Bone
○ Primary Care
○ Pulmonology
○ Rheumatology
○ Other (Please list): _____

○ Please check here if Pediatrics in above Specialties

ADDITIONAL PROVIDER/GENETIC COUNSELOR (IF APPLICABLE)

Provider/Genetic Counselor's Name | Provider /Genetic Counselor's Account # | Provider/Genetic Counselor's Phone

Provider/Genetic Counselor's Email | Provider/Genetic Counselor's Fax

FOR INTERNAL USE ONLY				
Date Rec'd_____ Rec'd _____				
TEMP	SPEC	COL	#TUBES	VOL
R/C/F				
R/C/F				
R/C/F				

revvity

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Please complete every field and tick box clearly

the lantern project

STEP 3: [X] INSTITUTIONAL BILLING

Sanofi	B0100
Institution/Organization Name	Provider /Genetic Counselor's Account #

4. TEST MENU (Review Specimen Requirements prior to Submitting Sample. If appropriate testing option is not listed, please call to discuss)

	Test Requested	Indication for Testing	Sample Type
Acid Sphingomyelinase Deficiency (ASMD, Niemann-Pick Type A and B)			
○	SAN012 > SAN013 Acid sphingomyelinase enzyme assay with reflex to *SMPD1* sequencing	• Clinical suspicion of acid sphingomyelinase disease • Follow-up of presumptive positive newborn screen	DBS, Whole Blood (EDTA)
○	SAN013 *SMPD1* sequencing	• Molecular confirmation of genetic status following low ASM enzyme activity (provide enzyme results from outside lab)	DBS, Whole Blood (EDTA), Saliva
○	SAN600 *SMPD1* known familial variant testing (fill out section on top of next page)	• Family history of acid phingomyelinase disease	DBS, Whole Blood (EDTA), Saliva
Gaucher Disease			
○	SAN008, SAN012 > SAN009 + SAN004 or SAN013 Glucocerebrosidase enzyme assay (includes ASM enzyme assay in parallel) with reflex to *GBA* and Lyso-GL1 or *SMPD1* sequencing as appropriate	• Clinical suspicion of Gaucher disease or ASMD • Follow-up of presumptive positive newborn screen	DBS
○	SAN009 > SAN004 *GBA* sequencing with reflex to Lyso-*GL1*	• Molecular confirmation of genetic status following low glucocerebrosidase enzyme activity (provide enzyme results from outside lab)	DBS
○	SAN600 > SAN004 *GBA* known familial variant testing (fill out section on top of next page) with reflex to Lyso-*GL1*	• Family history of Gaucher disease	DBS
Fabry Disease			
○	SAN006 > SAN007 + SAN005 Alpha-galactosidase A enzyme assay with reflex to *GLA* sequencing and Lyso-*GL3* (*GLA* sequencing will be run on all samples from female patients)	• Clinical suspicion of Fabry disease • Follow-up of presumptive positive newborn screen	DBS, Whole Blood (EDTA)
○	SAN007 > SAN005 *GLA* sequencing with reflex to Lyso-*GL3*	• Clinical suspicion of Fabry disease • Follow-up of presumptive positive newborn screen	DBS, Whole Blood (EDTA)
○	SAN600 > SAN005 *GLA* known familial variant testing (fill out section on top of next page) with reflex to Lyso-*GL3*	• Family history of Fabry disease	DBS, Whole Blood (EDTA)
Mucopolysaccharidosis Type I (Hurler, Hurler/Sheie, Sheie Syndromes)			
○	SAN010 > SAN011 Alpha-iduronidase enzyme assay with reflex to *IDUA* sequencing	• Clinical suspicion of MPS I • Follow-up of presumptive positive newborn screen	DBS, Whole Blood (EDTA)
○	SAN011 *IDUA* sequencing	• Molecular confirmation of genetic status following low alpha-iduronidase enzyme activity (provide enzyme results from outside lab)	DBS, Whole Blood (EDTA), Saliva
○	SAN600 *IDUA* known familial variant testing (fill out section on top of next page)	• Family history of MPS I	DBS, Whole Blood (EDTA), Saliva
Mucopolysaccharidosis – Unspecified			
○	SAN001 > SAN011 MPS enzyme panel (MPS I, II, IIIB, IVA, IVB, VI, VII) (with *IDUA* sequencing reflex if MPS I enzyme deficient)	• Clinical suspicion of an MPS condition	DBS, Whole Blood (EDTA)
Pompe Disease			
○	SAN014 > SAN015 Acid alpha-glucosidase enzyme assay with reflex to *GAA* sequencing	• Clinical suspicion of Pompe disease • Follow-up of presumptive positive newborn screen	DBS, Whole Blood (EDTA)
○	SAN015 *GAA* sequencing	• Molecular confirmation of genetic status following low acid alpha-glucosidase enzyme activity (provide enzyme results from outside lab)	DBS, Whole Blood (EDTA), Saliva
○	SAN003 **STAT:** acid alpha-glucosidase enzyme with reflex to rapid *GAA* sequencing (for suspected infantile- onset disease and newborn screening confirmation only)	• Suspected infantile-onset disease • Follow-up of presumptive positive newborn screen	DBS, Whole Blood (EDTA)
○	SAN600 *GAA* known familial variant testing (fill out section on top of next page)	• Family history of Pompe disease	DBS, Whole Blood (EDTA), Saliva
Focused Neuromuscular Disease Panel (Do NOT select this panel if you have also selected single gene *GAA* sequencing test) ○			
○	SAN200 > SAN014 multigene panel (*GAA* positives will reflex to acid alpha-glucosidase enzyme assay (DBS or blood required for enzyme)	• Clinical suspicion of a limb girdle muscular dystrophy. If Pompe disease is strongly suspected, suggest ordering alpha-glucosidase enzyme assay instead or in parallel.	DBS, Whole Blood (EDTA), Saliva
Enzyme Only Test Requested			

Enzyme only Test Name	Test Code

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STEP 4: TEST MENU (CONT.)

KNOWN FAMILIAL VARIANT TESTING* (*SMPD1, GBA, GLA, IDUA, GAA* ONLY)

Gene/Disease

Name of Family Member

Variant Name (c.)

Variant Name (c.)

Relationship of Family Member to Patient

Original Accession#

*Please provide copy of the family member's report, if available.

For sample collection requirements and/ or to order a sample collection it, please nagivate to Lanternprojectdx.com

STEP 5: PHYSICIAN STATEMENT

Confirmation of informed and medical necessity for genetic testing

I, the undersigned person (or representative thereof), attest that I am a licensed medical professional authorized to order genetic testing and confirm that the patient has given appropriate informed consent for the testing ordered, including a discussion of the benefits and limitations. I confirm that testing is medically necessary and that test results may impact medical management for the patient. Furthermore, all information on this TRF is true to the best of my knowledge. I also will ensure I am not also billing Medicare or other insurance for the laboratory analysis of these tests. My signature applies to the informed consent and/or attached letter of medical necessity, if applicable (unless this box is checked). ❑

Signature_____ Date_____

The Lantern Project is not intended to and should not interfere in any way with a healthcare professional's or patient's independent judgement and freedom of choice in the treatment options for these diseases. Healthcare professionals and patients should always consider the full range of treatment options and select those most appropriate for the individual patient.

Healthcare providers who use this program will ensure they are not also billing for the performance/laboratory analysis of these laboratory tests.

6. ADDITIONAL OPTIONAL PHENOTYPE / PATIENT HISTORY SECTION (Check all that apply)

Clinical diagnosis: _____

Age of manifestation: _____ ICD-10 Codes: _____

INCLUSION OF MEDICAL RECORDS, CLINICAL SUMMARY, PICTURES AND FAMILY HISTORY IS RECOMMENDED. CLINICAL INFORMATION IS CRUCIAL FOR ACCURATE INTERPRETATION OF RESULTS.

A. NEUROLOGY

1. Brain Imaging

- O 1.1 Abnormal myelination
- O 1.2 Brain atrophy
- O 1.3 Cerebellar abnormalities
- O 1.4 Hydrocephalus
- O 1.5 White matter lesions/hyperintensities
- O 1.6 Leukodystrophy
- O 1.7 Cerebrovascular abnormalities

2. Cognitive Dysfunction

- O 2.1 Delayed motor development
- O 2.2 Delayed language development
- O 2.3 Developmental regression
- O 2.4 Intellectual disability
- O 2.5 Autism
- O 2.6 ADHD/Depression
- O 2.7 Psychiatric Disorder
- O 2.8 Executive function issues
- O 2.9 Lewy Body dementia
- O 2.10 Learning disabilities
- O 2.11 Bipolar/schizophrenia

3. Movement Abnormality

- O 3.1 Ataxia
- O 3.2 Balance issues
- O 3.3 Dexterity/fine motor abnormalities
- O 3.4 Dystonia
- O 3.5 Parkinsonism

4. Neuromuscular

- O 4.1 Hypotonia
- O 4.2 Hypertonia
- O 4.3 Hyperreflexia
- O 4.4 Spasticity
- O 4.5 Muscle pain
- O 4.6 Muscle weakness - proximal
- O 4.7 Muscle weakness - distal

5. Others

- O 5.1 Encephalopathy
- O 5.2 Headache/migraine
- O 5.3 Macrocephaly
- O 5.4 Neuropathy (with or without acroparesthesia)
- O 5.5 Tia/stroke
- O 5.6 Abnormal EMG
- O 5.7 Abnormal NCV
- O 5.8 Abnormal muscle biopsy

B. CONSTITUTIONAL/LABORATORY

- O 1 Elevated creatine kinase
- O 2 AST, ALT, GGT, and/or bilirubin
- O 3 Elevated ferritin
- O 4 Elevated LDL
- O 5 Decreased HDL
- O 6 Elevated triglycerides
- O 7 Anemia
- O 8 Thrombocytopenia
- O 9 Elevated BUN
- O 10 Elevated creatinine
- O 11 Elevated urinary GAGs
- O 12 Exercise intolerance
- O 13 Hypo/anhidrosis
- O 14 Hyperhidrosis
- O 15 Elevated Hex4
- O Other _____

C. EYE

- O 1 Cataract
- O 2 Ophthalmoplegia (including gaze palsy)
- O 3 Ptosis
- O 4 Strabismus
- O 5 Visual impairment
- O 6 Corneal verticillata
- O 7 Retinal vessel abn
- O 8 Corneal clouding
- O 9 Retinal degeneration
- O 10 Cherry red spot
- O 11 Saccadic movements
- O Other _____

D. PULMONARY

- O 1 Reduced vital capacity
- O 2 Diaphragmatic weakness
- O 3 Sleep apnea
- O 4 Interstitial lung disease
- O 5 Reduced pulmonary function
- O 6 Stridor
- O 7 Reduced DL_{CO}
- O Other _____

E. MOUTH,THROAT, EAR

- O 1 Conductive hearing loss
- O 2 Sensorineural hearing loss
- O 3 Enlarged tongue
- O 4 Tinnitus
- O 5 Recurrent otitis media
- O 6 Obstructive airway disease
- O 7 Chronic rhinitis
- O 8 Enlarged tonsils, adenoids
- O 9 Vertigo
- O Other _____

F. SKIN

- O 1 Angiokeratoma
- O Other _____

G. SKELETAL

- O 1 Short stature
- O 2 Pathologic fractures
- O 3 Scoliosis
- O 4 Kyphosis
- O 5 Dysostosis multiplex
- O 6 Osteopenia/osteoporosis
- O 7 Osteonecrosis
- O 8 Erlenmeyer flask deformity
- O 9 Bone pain
- O 10 Joint contractures/joint stiffness
- O 11 Carpal tunnel syndrome
- O 12 Genu valgum
- O 13 Hip dysplasia
- O 14 Vertebral beaking
- O 15 Cervical stenosis
- O 16 Odontoid hypoplasia
- O 17 Phalangeal tapering
- O 18 Platyspondyly
- O 19 Epiphyseal flaring
- O Other _____

H. CARDIAC

- O 1 Angioedema
- O 3 Arrythmia
- O 4 Coronary artery disease
- O 5 Wolff-Parkinson-White
- O 6 Dilated cardiomyopathy
- O 7 Hypertrophic cardiomyopathy
- O 8 Hypertension
- O 9 Hypotension
- O 10 Lymphedema
- O 11 Myocardial infarction
- O 12 Pulmonary hypertension
- O 13 Atrial/mitral valve abnormalities
- O 14 Left ventricular hypertrophy
- O 15 Atrial fibrillation
- O Other _____

I. GASTROINTESTINAL

- O 1 Abdominal pain
- O 2 Diarrhea
- O 3 Constipation
- O 4 Nausea/vomiting
- O 5 Liver failure
- O 6 Hepatosplenomegaly
- O 7 Umbilical/inguinal hernia
- O 8 Liver cirrhosis/fibrosis
- O Other _____

J. RENAL

- O 1 Renal cyst
- O 2 Renal Bx findings: _____
- O 3 Glomerulosclerosis
- O 4 Proteinuria
- O 5 Albuminuria/proteinuria
- O 6 CKD/ESRD
- O Other _____

K. HEME/ONC AND IMMUNOLOGY

- O 1 Anemia
- O 2 Renal Bx findings: _____
- O 3 Thrombocytopenia
- O 4 Hypercoagulation
- O 5 Hypocoagulation
- O 6 Splenomegaly
- O 7 Neutropenia
- O 8 MGUS
- O 9 Other malignancy _____
- O 10 Polyclonal gammopathy
- O 10 Hematologic malignancy
- O Other _____

L. PPRENATAL AND DEVELOPMENTAL HISTORY AND MORPHOLOGY

- O 1 Dysmorphic/coarse features
- O 2 Hydrops fetalis
- O 3 IUGR
- O 4 Oligohydramnios
- O 5 Polyhydramnios
- O 6 Macrocephaly
- O Other _____

INFORMED CONSENT FORM

Revvity Omics, Inc., ("Revvity") requires a completed Patient's Informed Consent Form (ICF) for testing to be performed. The ICF must be completed by the patient, or a legally authorized representative of the patient (or by the healthcare provider where permitted under applicable law or regulation). For any patient below the age of majority, the ICF must be completed by the patient's legally authorized representative.

The purpose of this ICF is to provide you with a description of the Test ordered, known risks and benefits of the Test, anonymization of personal health information ("PHI"), sample and data retention, research opportunities, and the reporting of secondary findings, if applicable. Given the complexity of the type of the Test, it is recommended that you and/or your child receive genetic counseling by a trained genetics professional before and after the testing is performed. There is no cost to you for the Test(s) in the Lantern Project and the test(s) are paid for you by Sanofi Genzyme. If you receive a diagnosis after using this testing program, you are in no way obligated to be treated with a medication Sanofi Genzyme manufactures.

TEST INFORMATION

Your healthcare provider ("HCP") has recommended that you or your child, receive enzymatic, biochemical or molecular genetics clinical testing ("Test") indicated on the submitted Test Requisition Form ("Requisition"). For more information on the reasons your HCP has ordered the Test, and the disorders your HCP is having you tested for, please consult with your HCP. You are free to decide if you want this Test performed or not. Providing a Sample and undergoing the Test is voluntary and you may withdraw your consent without penalty at any time.

Enzyme/Biomarker Test: This type of test measures the presence or absence of enzymes/biomarkers and/or their level of activity in an individual. Only the enzymes/biomarkers identified on the requisition will be tested. Results from this type of Test may indicate the presence of a specific condition or conditions, and follow-up confirmatory testing may be recommended.

Genetic/Genomic Test: This type of Test looks at the genes in your DNA. This Test is used to identify what, if any, DNA variant(s) you or your child is carrying which is causing the specific disease or condition you are being tested for. Identifying the mutation may be useful for diagnostic and treatment purposes, and allows at-risk family members to be tested. Only the genes identified on the Requisition will be analyzed. In some cases, we may not be able to determine with certainty which gene is actually causing the disease.

TEST METHOD

If you consent to the Test, your HCP will take a sample of your and/or your child's blood, saliva, body fluid, tissue or other sample type. Your Sample will be sent to Revvity's laboratories in the United States for the Test; the enzyme activity, biomarker tests, and select genetic testing assays will be conducted in Pennsylvania, USA, and all other genetic testing will be conducted in Connecticut, USA.

Under some circumstances, including inadequate or poor quality sample, an additional Sample may be required for Tests to be performed.

TEST RESULTS

Your treating HCP has sole responsibility for all decisions concerning the possible management of your diagnosis and disease; Revvity will not provide a diagnosis. Revvity will report Test results only to your HCP via secure email, a secure internet portal, or fax. Your HCP is responsible for communicating with you regarding the results of the Test and may refer you or your child to a specialist for further clinical evaluation and confirmation of diagnosis, if applicable. Possible results include:

1. *Positive:* A result indicates the enzyme/biomarker results are below normal ranges. A positive genetic test result may indicate that you are a carrier of, predisposed to, or have the specific disease or condition being tested for. A positive genetic test may limit your access to health insurance or life assurance coverage; for example, a life insurance company might ask you to provide genetic information indicating a disorder if this information is available to you.
2. *Negative:* A negative result indicates that the enzyme/biomarker results were within normal ranges, or that no disease-causing variant was identified in the Test performed. No Test can rule out all genetic diseases or conditions. A negative result does not guarantee that you are free from genetic disorders or other medical conditions.
3. *Inconclusive/Variant of Uncertain Significance:* A variant of uncertain significance (VOUS) result indicates that a variant outside of the normal range was detected, but it is currently unknown if the variant is associated with a genetic disorder. A VOUS is not the same as a positive result and does not clarify whether there is an increased risk to develop a genetic disorder. The variant could be a benign change or it could be indicative of disease/disease-causing.
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. This information would be disclosed to your HCP if it potentially impacts medical care, and you have consented to receive this type of result. The Focused Neuromuscular Disease Panel tests 99 genes, some of which lead to symptoms only in adulthood. Children undergoing this test may receive results that will not impact their health for many years.

TEST REPORT

Reported disease-causing variants are described as pathogenic variant(s), likely pathogenic variants(s), or variant(s) of uncertain significance in genes interpreted to be responsible for, or potentially contributing to, a disease or condition. In addition, variants in genes not known to be associated with disease but for which there is evidence to suggest an association with disease may also be reported. Your/your child's symptoms can be an integral part of interpreting test results. Please ensure your HCP has filled out the Patient History section of the requisition.

INFORMATION ABOUT PARENTAL AND FAMILIAL SAMPLES

In some circumstances, it may be helpful for additional family members to undergo testing in order to provide information that can aid in the interpretation of the test results. These Tests could be part of a TRIO Test or as stand-alone targeted testing. Revvity, in consultation with the HCP, will decide if other family members need to be tested. If the HCP recommends testing for additional family members, only the Test performed will be reported. If undergoing a TRIO test (WES or WGS), parents will have the option of receiving a full parental report. If selected, the respective parental consent section must be completed below.

TEST LIMITATIONS

Due to current limitations in technology and incomplete knowledge of diseases and genes, some variants may not be detected by the Test ordered. There is a possibility that the Test result that is uninterpretable or of unknown significance may require further testing when more information is gained. In rare circumstances, Test results may be suggestive of a condition different from that which was originally considered for the purpose of consenting to this Test. The Test may also find variants or genes that lead to conditions for which you currently do not have symptoms or may not be related to your current condition.

TEST RISKS

Patients and family members may experience anxiety before, during, and/or after testing. Testing multiple family members may reveal that familial relationships are not biologically what they were assumed to be. For example, the Test may indicate non-paternity (the stated father of an individual is not the biological father) or consanguinity (the parents of an individual are closely related by blood). These biological relationships may need to be reported to the HCP who ordered the test. Genetic testing can also reveal unexpected differences in the genetic makeup of an individual (e.g., a male with two copies of an x-linked gene rather than the expected one).

Taking a blood or tissue sample from you and/or your child may lead to mild pain, bruising, swelling, redness, and a slight risk of infection. Light-headedness, fainting or nausea may occur if your HCP collects blood or tissue samples. These side-effects are typically brief and transient, but you should contact your HCP if you and/or your child require treatment. Under some circumstances an additional sample may be required for Tests to be performed.

A positive test result may limit your access to health insurance or life assurance coverage; for example, a life insurance company might ask you to provide genetic information indicating a disorder if this information is available to you. Please refer to information on the Genetic Information Nondiscrimination Act (GINA) and applicable local laws for more information.

CONFIDENTIALITY

You have the right to confidential treatment of the Sample and your PHI. Your HCP will provide Revvity with Personal Health Information ("PHI") such as your name, date of birth, gender and clinical symptoms to help track your sample and report results. To maintain confidentiality, the test results will only be released to the referring health care provider, to the ordering laboratory, to the patient/guardian, to other health care providers involved in your diagnosis and treatment, or as otherwise required by law or regulation. Unless required by law, Revvity will not disclose your PHI to any person or entity except with your written consent. No identifying information will be disclosed to Sanofi Genzyme, the sponsor of this testing program.

You and your HCP can control how your Sample and PHI are processed. You have the right to request access to your PHI, request corrections of any errors in recorded PHI, or where PHI may be missing or incomplete ask that it be completed. You also have the right to ask that your PHI be erased, subject to law or regulation. You can contact your HCP for such requests and your HCP will contact Revvity, or you can contact Revvity directly by visiting www.revvity.com. If requests for access, correction, completion, or erasure cannot be fulfilled, you will be informed and provided with the reasons why your requests cannot be fulfilled.

SAMPLE AND DATA RETENTION

Pursuant to laboratory best practices, your DNA sample will be retained by Revvity for a minimum of two years and then destroyed. Additionally, your PHI, the data from the Tests (including those performed before any withdrawal of consent) and the related reports will be retained by Revvity for a minimum of two years and then destroyed. In some instances, it may be beneficial to you for Revvity to retain your sample for a longer period of time in order to conduct additional testing, and Revvity will do so with appropriate documentation from you or your HCP.

Revvity is requesting consent to keep you and/or your child's anonymized sample and data indefinitely. This consent is optional, and the Test will be performed whether or not you provide consent to the following:

- Revvity will anonymize and retain your Sample indefinitely for internal quality control, test validation, assay development and improvement. By allowing Revvity to retain your Sample, you understand and agree that you give up any property rights you may have in the Sample and are donating it to Revvity Omics, Inc. If you withdraw your consent, no additional tests or anonymization will be carried out on your Sample; no results will be reported and your sample, reports and data that have not been anonymized will be destroyed.
  - ❑ Check here if you would like to opt out of anonymized sample retention. Note, if not checked, this is interpreted as "consent given"
- Revvity will anonymize your data and retain the anonymized data and related anonymized reports from your Tests indefinitely for internal statistical, quality analysis, research, scientific and technical development, and market research.Revvity may also share your anonymized data and anonymized report with third parties including your anonymized data and anonymized report with third parties.
  - ❑ Check here if you would like to opt out of anonymized data retention. Note, if not checked, this is interpreted as "consent given"

For residents of the State of NV, NY or OR:

❑ By checking here I give Revvity permission to store my sample for longer than 60 days. Note, if not checked, this is interpreted as "consent not given"

RESEARCH OPTIONS

Revvity may collaborate with scientists, researchers and drug developers to advance knowledge of genetic diseases. If there are opportunities to participate in future research relevant to the disease in you and/or your child, Revvity may contact you or your HCP about the development of new testing, drug development, or other treatments. No identifying information will be disclosed to Sanofi Genzyme, the sponsor of this testing program.

WITHDRAWAL OF CONSENT

I understand this consent is voluntary and is valid until I withdraw my consent. I understand I may withdraw my consent to sample and data retention, and to the Test at any time, that Revvity will not perform the Test unless I provide consent to the Test. If I withdraw any consent, it will not affect actions taken before I withdrew my consent, including any anonymization of data or of my Sample. I understand that if I wish to withdraw my consent I should contact Revvity via email at: genomics@revvity.com or toll-free by telephone +1-866-354-2910 to request withdrawal.

PATIENT CONSENT TO TESTING

❑ By checking this box I attest:

I have read and understood the Informed Consent Form in its entirety, including the explanation of why my sample is being tested, how genetic testing is performed and the risks associated with genetic testing. I have had the opportunity to ask my HCP questions about the information contained herein, and understand that I am entitled to a copy of this ICF. My signature below acknowledges my free consent to the Test, and to any additional consents indicated above, and such testing in no way guarantees my health, the health of an unborn child, or the health of other family members.

Patient Signature (or Parent/Guardian if patient is minor) _____ Date _____

Patient Name _____ Name and Relationship (Parent/Guardian if patient is minor) _____

FAMILY MEMBER CONSENT TO TESTING (if applicable)

❑ By checking this box I attest:

I have read and understood the Informed Consent Form in its entirety, including the explanation of why my sample is being tested, how genetic testing is performed and the risks associated with genetic testing. I have had the opportunity to ask my HCP questions about the information contained herein, and understand that I am entitled to a copy of this ICF. My signature below acknowledges my free consent to the Test, and to any additional consents indicated above, and such testing in no way guarantees my health, the health of an unborn child, or the health of other family members.

Family Member Signature _____ Date _____

Family Member Name _____ Relationship to Patient _____

FAMILY MEMBER CONSENT TO TESTING (if applicable)

❑ By checking this box I attest:

I have read and understood the Informed Consent Form in its entirety, including the explanation of why my sample is being tested, how genetic testing is performed and the risks associated with genetic testing. I have had the opportunity to ask my HCP questions about the information contained herein, and understand that I am entitled to a copy of this ICF. My signature below acknowledges my free consent to the Test, and to any additional consents indicated above, and such testing in no way guarantees my health, the health of an unborn child, or the health of other family members.

Family Member Signature _____ Date _____

Family Member Name _____ Relationship to Patient _____