BAYLOR GENETICS

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2450 HOLCOMBE BLVD.
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HOUSTON, TX 77021-2024

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**FAX**
1.800.434.9850

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# WHOLE GENOME SEQUENCING (WGS) REQUISITION

## PATIENT INFORMATION (COMPLETE ONE FORM FOR EACH PERSON TESTED)

Patient Last Name | Patient First Name | MI | Date of Birth (MM / DD / YYYY)

Address | City | State | Zip | Phone

Genetic Sex: ◯ Female ◯ Male ◯ Unknown

Accession # | Hospital / Medical Record #

Gender identity (if different from above):

**Note:** All reports will be sent via fax except for international recipients.

## ORDERING PHYSICIAN

Ordering Physician | Institution Code

Institution Name

Email (Required for International Clients)

Phone | Fax

## ADDITIONAL REPORTS

Name | Email | Phone | Fax

Name | Email | Phone | Fax

**Note:** Reports will be sent by FAX except for international recipients

## PAYMENT (FILL OUT ONE OF THE OPTIONS BELOW)

◯ **SELF PAYMENT**

☐ Pay With Sample ☐ Bill To Patient

◯ **INSTITUTIONAL BILLING**

Institution Name | Institution Code | Institution Contact Name | Institution Phone | Institution Contact Email

◯ **INSURANCE**

☐ Do Not Perform Test Until Patient is Aware of Out-Of-Pocket Costs (excludes prenatal testing)

REQUIRED ITEMS
1. Copy of the Front/Back of Insurance Card(s)
2. ICD10 Diagnosis Code(s)
3. Name of Ordering Physician
4. Insured Signature of Authorization

ICD10 Diagnosis Code(s) (Required)

| | |
|---|---|
| Primary Insurance Co. Name | Secondary Insurance Co. Name |
| Primary Insurance Co. Phone | Secondary Insurance Co. Phone |
| Primary Member Policy # | Secondary Member Policy # |
| Primary Member Group # | Secondary Member Group # |
| Name of Insured | Name of Insured |
| Insured Date of Birth (MM / DD / YYYY) | Insured Date of Birth (MM / DD / YYYY) |
| Patient's Relationship to Insured | Patient's Relationship to Insured |
| Phone of Insured | Phone of Insured |
| Address of Insured | Address of Insured |
| City / State / Zip | City / State / Zip |

By signing below, I hereby authorize Baylor Genetics to provide my insurance carrier any information necessary, including test results, for processing my insurance claim. I understand that I am responsible for any co-pay, co-insurance, and unmet deductible that the insurance policy dictates. If self-pay is selected, I agree to pay for the cost of testing ordered and billed by Baylor Genetics as outlined in the Good Faith Estimate I received. I understand that I am responsible for sending Baylor Genetics any and all payments that I receive directly from my insurance company in payment for this test. Please note, Medicare may not cover certain screening tests.

Patient / Guardian Printed Name | Patient / Guardian Signature | Date (MM / DD / YYYY)

## STATEMENT OF MEDICAL NECESSITY AND CONSENT TO TERMS & CONDITIONS FOR TEST ORDER (REQUIRED)

This requisition hereby incorporates the Terms and Conditions of the Laboratory Services found at https://www.baylorgenetics.com/lab-terms-conditions/ or, in the case of international entities, https://www.baylorgenetics.com/terms-conditions-of-the-laboratory-services-international/. This test is medically necessary for the risk assessment, diagnosis, or detection of a disease, illness, impairment, symptom, syndrome, or disorder. The results will determine my patient's medical management and treatment decisions. The person listed as the Ordering Physician is authorized by law to order the test(s) requested herein. I confirm that I have provided genetic testing information to the patient, and they have consented to genetic testing.

Physician's Printed Name | Physician's Signature | Date (MM / DD / YYYY)

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# WHOLE GENOME SEQUENCING (WGS) REQUISITION

Patient Last Name | Patient First Name | MI | Date of Birth (MM / DD / YYYY) | Genetic Sex

## INSTRUCTIONS FOR ORDERING

Global MAPS® can be ordered along with a genome test, however the turnaround time for results will differ from genome sequencing. Parental samples are required for Trio WGS and Duo WGS, and optional for Proband WGS.

Please contact the laboratory if placing test orders for different members of the family other than the proband or their parents.

## TRIO WGS TEST OPTIONS

- ☐ 1800 Trio Whole Genome Sequencing
- ☐ 1822 Rapid Trio Whole Genome Sequencing

CORRESPONDING PARENTAL TESTS
(Both Biological Parents Are Required)

- ☐ 1850 Parental WGS - Maternal
- ☐ 1550 Parental WGS - Paternal

## DUO WGS TEST OPTIONS

- ☐ 1803 Duo Whole Genome Sequencing
- ☐ 1823 Rapid Duo Whole Genome Sequencing

CORRESPONDING PARENTAL TESTS
(One Parent Is Required)

- ☐ 1850 Parental WGS - Maternal
- ☐ 1550 Parental WGS - Paternal

## PROBAND WGS TEST

- ☐ 1810 Proband Whole Genome Sequencing
- ☐ 1829 Rapid Proband Whole Genome Sequencing

CORRESPONDING PARENTAL TESTS

- ☐ 6997 Parental Control

## OPT-IN TESTING OPTIONS

Opt-In for RNA Sequencing (RNAseq) as reflex to WGS

☐ If WGS identifies a qualified variant that might be reclassified through RNA sequencing, please reflex to RNAseq if possible.

## GLOBAL MAPS® TESTS

- ☐ 4900 Global Metabolomic Assisted Pathway Screen - Plasma from EDTA
- ☐ 4901 Global Metabolomic Assisted Pathway Screen - Urine

Was plasma extracted from EDTA? ◯ Yes ◯ No

## ADDITIONAL REPORTING OPTIONS

If a box is not checked the lab will default to No / Not Report.

**Option for Reporting of Incidental Findings**

Pathogenic and likely pathogenic variants in genes covered under Category II of the Incidental Findings section of the consent form will be reported.

☐ Please report pathogenic and likely pathogenic variants in genes associated with Incidental Findings.

**Trio Orders Only – Option for Reporting of Research Findings**

For variants in genes with no known disease association, these variants will be reported if biallelic or de novo.

☐ Please report biallelic and de novo variants in genes with no known disease association.

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# WHOLE GENOME SEQUENCING (WGS) REQUISITION

Patient Last Name _____ Patient First Name _____ MI _____ Date of Birth (MM / DD / YYYY) ____ / ____ / ____ Genetic Sex _____

## PROBAND SAMPLE(S)

Please refer to www.baylorgenetics.com for full sample requirements.

- ◯ Blood in EDTA (preferred)
- ◯ Buccal Swab
- ◯ Saliva
- ◯ Cord Blood
- ◯ Cultured Skin Fibroblast
- ◯ Extracted DNA from _____

Global MAPS® only

- ◯ Plasma from EDTA
- ◯ Urine

____ / ____ / _____
Date of Collection
(MM / DD / YYYY)

**NOTE:** Extracted DNA/RNA will only be accepted if the isolation of nucleic acids for clinical testing occurs in a CLIA-certified laboratory or a laboratory meeting equivalent requirements as determined by the CAP and/or the CMS.

## BIOLOGICAL PARENTS INFORMATION

BIOLOGICAL PARENTS SAMPLES ARE REQUIRED FOR TRIO WGS; Other family members cannot be substituted for either parent. Be sure to label parental samples with full name and date of birth - DO NOT LABEL WITH CHILD'S NAME. Parent(s) must sign the parental testing authorization on consent.

### MATERNAL INFORMATION

☐ Asymptomatic ☐ Symptomatic (Attach summary of findings)

Maternal Last Name _____ Maternal First Name _____ MI _____

Maternal Date of Birth (MM / DD / YYYY) ____ / ____ / ____

Date of Collection (MM / DD / YYYY) ____ / ____ / ____

Sample Type:

- ◯ Blood in EDTA (preferred)
- ◯ Buccal Swab
- ◯ Saliva

### PATERNAL INFORMATION

☐ Asymptomatic ☐ Symptomatic (Attach summary of findings)

Paternal Last Name _____ Paternal First Name _____ MI _____

Paternal Date of Birth (MM / DD / YYYY) ____ / ____ / ____

Date of Collection (MM / DD / YYYY) ____ / ____ / ____

Sample Type:

- ◯ Blood in EDTA (preferred)
- ◯ Buccal Swab
- ◯ Saliva

## ITEM CHECKLIST FOR TESTING

- ☐ Proband Sample (Required)
- ☐ Maternal Sample (Required for Trio)
- ☐ Paternal Sample (Required for Trio)
- ☐ Signed WGS Consent Form
- ☐ Clinical Note/Summary
- ☐ Requisition
- ☐ Indication for Study
- ☐ Pedigree (optional)

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# WHOLE GENOME SEQUENCING (WGS) REQUISITION

Patient Last Name | Patient First Name | MI | Date of Birth (MM / DD / YYYY) | Genetic Sex

## INDICATION FOR TESTING (REQUIRED)

Please provide the following clinical information regarding the patient to be tested. Please also submit a clinic note and pedigree, if available. Phenotypes listed are in HPO terms with the corresponding HPO number (http://human-phenotype-ontology.github.io/). This information is needed to facilitate interpretation of whole genome sequencing results. If the laboratory requires additional information, please indicate the health care provider to be contacted:

### PRE/PERINATAL HISTORY

- ☐ 0001622 Prematurity - GA at birth _____
- ☐ 0001511 Intrauterine Growth Restrictions
- ☐ 0001562 Oligohydramnios
- ☐ 0001561 Polyhydramnios
- ☐ 0000476 Cystic Hygroma
- ☐ 0000776 Congenital Diaphragmatic Hernia
- ☐ 0001508 Failure to Thrive
- ☐ 0001539 Omphalocele
- ☐ 0002084 Encephalocele
- ☐ 0010880 Increased Nuchal Translucency
- ☐ _____

### EYE DEFECTS & VISION

- ☐ 0000505 Visual Impairment
- ☐ 0000618 Blindness
- ☐ 0000589 Coloboma
- ☐ 0000526 Aniridia
- ☐ 0000528 Anophthalmia
- ☐ 0000568 Microphthalmia
- ☐ 0000508 Ptosis
- ☐ 0000486 Strabismus
- ☐ 0000519 Cataract Congenital Bilateral
- ☐ _____
- ☐ _____

### MOTOR/COGNITIVE DEVELOPMENT

- ☐ 0000750 Delayed Speech & Language Development
- ☐ 0001270 Delayed Motor Milestones
- ☐ 0002376 Developmental Regression
- ☐ Intellectual Disability
  - ☐ 0001256 Mild
  - ☐ 0002342 Moderate
  - ☐ 0010864 Severe
- ☐ 0000729 Autistic Spectrum Disorder
- ☐ _____
- ☐ _____

### STRUCTURAL BRAIN ABNORMALITIES

- ☐ 0001360 Holoprosencephaly
- ☐ 0001339 Lissencephaly
- ☐ 0002084 Encephalocele
- ☐ 0000238 Hydrocephalus
- ☐ 0002119 Ventriculomegaly
- ☐ 0001273 Abnormality of Corpus Callosum
- ☐ 0002539 Cortical Dysplasia
- ☐ 0012444 Brain Atrophy
- ☐ 0002352 Leukoencephalopathy
- ☐ 0002269 Abnormality of Neuronal Migration
- ☐ 0002126 Polymicrogyria
- ☐ 0001302 Pachgyria
- ☐ 0002500 Abnormality of Cerebral White Matter
- ☐ 0007266 Cerebral Dysmyelination
- ☐ 0006808 Cerebral Hypomyelination
- ☐ 0002134 Abnormality of the Basal Ganglia
- ☐ 0002363 Abnormality of the Brainstem
- ☐ 0007360 Aplasia/Hypoplasia of the Cerebellum
- ☐ 0006817 Aplasia/Hypoplasia of the Cerebellar Vermis
- ☐ _____

### NEUROLOGICAL

- ☐ 0001284 Areflexia
- ☐ 0200134 Epileptic Encephalopathy
- ☐ 0001250 Seizures
  - ☐ 0002373 Febrile Seizures
  - ☐ 0012469 Infantile Spasms
  - ☐ 0002123 Generalized Myoclonic Seizures
  - ☐ 0002069 Generalized Tonic-clonic Seizures
  - ☐ 0010818 Generalized Tonic Seizures
  - ☐ 0010819 Atonic Seizures
  - ☐ 0002121 Absence Seizures
  - ☐ 0011169 Generalized Clonic Seizures
  - ☐ 0001251 Ataxia
  - ☐ 0001332 Dystonia
  - ☐ 0002072 Chorea
  - ☐ 0001257 Spasticity
  - ☐ 0009830 Neuropathy
- ☐ _____
- ☐ _____

### CRANIOFACIAL

- ☐ 0000256 Macrocephaly
- ☐ 0000252 Microcephaly
- ☐ 0001363 Craniosynostosis
- ☐ 0000204 Cleft Upper Lip
- ☐ 0000175 Cleft Palate
- ☐ 0000316 Hypertelorism
- ☐ 0000601 Hypotelorism
- ☐ 0008050 Abnormality of the Palpebral Fissures
- ☐ 0000286 Epicanthal Folds
- ☐ 0000288 Abnormality of the Philtrum
- ☐ 0010938 Abnormality of the External Nose
- ☐ _____
- ☐ _____

Indications continued on next page

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**INDICATION FOR TESTING (REQUIRED) - CONTINUED**

### HAIR & SKIN

- ☐ 0000957 Cafe-Au-Lait Spots
- ☐ 0001034 Hypermelanotic Macule
- ☐ 0001010 Hypopigmentation of the Skin
- ☐ 0008066 Abnormal Blistering of the Skin
- ☐ 0008064 Ichthyosis
- ☐ 0000988 Skin Rash
- ☐ 0001581 Recurrent Skin Infections
- ☐ 0005306 Capillary Hemangiomas
- ☐ 0001597 Abnormality of the Nail
- ☐ 0004554 Generalized Hypertrichosis
- ☐ 0001596 Alopecia
- ☐ 0002208 Coarse Hair
- ☐ 0002299 Brittle Hair
- ☐ _____
- ☐ _____

### CARDIAC

- ☐ 0001631 Atrial Septal Defect
- ☐ 0001629 Ventricular Septal Defect
- ☐ 0001655 Patent Foramen Ovale
- ☐ 0001713 Abnormality of Cardiac Ventricle
- ☐ 0001636 Tetralogy of Fallot
- ☐ 0001680 Coarctation of Aorta
- ☐ 0001647 Bicuspid Aortic Valve
- ☐ 0002616 Aortic Root Dilatation
- ☐ 0001638 Cardiomyopathy
- ☐ 0011675 Arrhythmia
- ☐ _____
- ☐ _____

### GENITOURINARY

- ☐ 0000113 Polycystic Kidney Dysplasia
- ☐ 0000107 Renal Cyst
- ☐ 0008738 Partially Duplicated Kidney
- ☐ 0000104 Renal Agenesis
- ☐ 0000085 Horseshoe Kidney
- ☐ 0000069 Abnormality of the Ureter
- ☐ 0000795 Abnormality of the Urethra
- ☐ 0000047 Hypospadias
- ☐ 0000028 Cryptorchidism
- ☐ 0000035 Abnormality of the Testis
- ☐ 0000062 Ambiguous Genitalia
- ☐ _____
- ☐ _____

### RESPIRATORY

- ☐ 0002093 Respiratory Insufficiency
- ☐ 0002878 Respiratory Failure
- ☐ 0002104 Apnea
- ☐ 0002791 Hypoventilation
- ☐ 0002883 Hyperventilation
- ☐ 0002788 Recurrent Upper Respiratory Tract Infections
- ☐ _____
- ☐ _____

### METABOLIC

- ☐ 0001946 Ketosis
- ☐ 0003074 Hyperglycemia
- ☐ 0001943 Hypoglycemia
- ☐ 0001941 Acidosis
- ☐ 0003128 Lactic Acidosis
- ☐ 0003215 Dicarboxylic Aciduria
- ☐ 0002490 Increased CSF lactate
- ☐ 0001992 Organic Aciduria
- ☐ 0030085 Abnormal CSF Lactate Level
- ☐ 00003542 Increased Serum Pyruvate
- ☐ 0003535 3-Methylglutaconic aciduria
- ☐ 0001942 Metabolic acidosis
- ☐ 0100493 Hypoammonemia
- ☐ 0001987 Hyperammonemia
- ☐ 0004923 Hyperphenylalaninemia
- ☐ 0003234 Decreased Plasma Carnitine
- ☐ 0003236 Elevated Serum Creatine Phosphokinase
- ☐ Abnormal Newborn Screen
- ☐ Unusual Color/Odor
- ☐ _____
- ☐ _____

### MUSCULOSKELETAL

- ☐ 0011398 Hypotonia
- ☐ 0001276 Hypertonia
- ☐ 0000098 Tall Stature
- ☐ 0004322 Short Stature
- ☐ 0001382 Joint Hypermobility
- ☐ 0001371 Flexion Contracture
- ☐ 0002804 Arthrogryposis Multiplex Congenita
- ☐ 0001161 Hand Polydactyly
- ☐ 0001829 Foot Polydactyly
- ☐ 0006101 Finger Syndactyly
- ☐ 0001770 Toe Syndactyly
- ☐ 0100490 Camptodactyly of Finger
- ☐ 0012165 Oligodactyly
- ☐ 0001762 Talipes Equinovarus
- ☐ 0002757 Recurrent Fractures
- ☐ 0002650 Scoliosis
- ☐ 0002808 Kyphosis
- ☐ 0003307 Hyperlordosis
- ☐ 0001528 Hemihypertrophy
- ☐ 0001513 Obesity
- ☐ 0001548 Overgrowth
- ☐ 0002652 Skeletal Dysplasia
- ☐ _____
- ☐ _____

### GASTROINTESTINAL

- ☐ 0002021 Pyloric Stenosis
- ☐ 0002575 Tracheoesophogeal Fistula
- ☐ 0002032 Esophageal Atresia
- ☐ 0002020 Gastroesophageal Reflux
- ☐ 0001733 Pancreatitis
- ☐ 0002014 Diarrhea
- ☐ 0002019 Constipation
- ☐ 0002037 Inflammatory Bowel Disease
- ☐ 0004389 Intestinal Pseudo-Obstruction
- ☐ 0001399 Hepatic Failure
- ☐ 0002572 Episodic Vomiting
- ☐ 0001744 Splenomegaly
- ☐ 0002240 Hepatomegaly
- ☐ 0001508 Postnatal Failure to Thrive
- ☐ 0002578 Gastroparesis
- ☐ _____
- ☐ _____

Indications continued on next page

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## WHOLE GENOME SEQUENCING (WGS) REQUISITION

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### INDICATION FOR TESTING (REQUIRED) - CONTINUED

#### ENDOCRINE

- ☐ 0000819 Diabetes Mellitus
- ☐ 0000873 Diabetes Insipidus
- ☐ 0000821 Hypothyroidism
- ☐ 0000829 Hypoparathyroidism
- ☐ 0000834 Abnormality of the Adrenal Glands
- ☐ 0001738 Exocrine Pancreatic Insufficiency
- ☐ 0002721 Immunodeficiency
- ☐ _____
- ☐ _____

#### EAR DEFECTS & HEARING

- ☐ 0000407 Sensorineural Hearing Impairment
  - ☐ 0008619 Bilateral
- ☐ 0000405 Conductive Hearing Impairment
- ☐ 0000410 Mixed Hearing Impairment
- ☐ 0004467 Preauricular Pit
- ☐ 0000384 Preauricular Skin Tag
- ☐ 0000369 Low-set Ears
- ☐ 000037 Abnormality of the Pinna
- ☐ _____
- ☐ _____

#### HEMATOLOGY

- ☐ 0001875 Neutropenia
  - ☐ 0005549 Congenital
  - ☐ Chronic
  - ☐ Cyclic
- ☐ 0001873 Thrombocytopenia
- ☐ 0040185 Macrothrombocytopenia
- ☐ 0005537 Decreased Mean Platelet Volume
- ☐ 0005518 Erythrocyte Macrocytosis
- ☐ 0004444 Spherocytosis
- ☐ 0012410 Pure Red Cell Aplasia
  - ☐ Aplastic
  - ☐ Hypoplastic
- ☐ 0001903 Anemia
- ☐ 0005528 Bone Marrow Hypocellularity
- ☐ _____
- ☐ _____

#### CANCER

- ☐ Type of Cancer _____
- ☐ Age of Diagnosis _____
- ☐ Family History of Cancer and Affected Relatives

_____

_____

#### OTHER

- ☐ Organomegaly
- ☐ Chronic Infections
- ☐ 0004311 Abnormality of Macrophages
- ☐ 0001954 Episodic Fever
- ☐ 0004313 Hypogammaglobulinemia
- ☐ 0010701 Abnormal Immunoglobulins
- ☐ 0002721 Immunodeficiency
- ☐ 0012088 Abnormal urinary odor
- ☐ 0012537 Food intolerance
- ☐ 0008067 Abnormally lax or hyperextensible skin
- ☐ Abnormal Movements
- ☐ Family History of Similar Disorder
- ☐ 0001254 Lethargy
- ☐ 0002415 Leukodystrophy
- ☐ _____
- ☐ _____

#### GENES OF INTEREST

_____

_____

_____

_____

### ADDITIONAL CLINICAL INFORMATION

### DIFFERENTIAL DIAGNOSIS

Consent on next page

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# WHOLE GENOME SEQUENCING (WGS) CONSENT

| Patient Last Name | Patient First Name | MI | Date of Birth (MM / DD / YYYY) | Genetic Sex |
|---|---|---|---|---|
| | | | / / | |

## TEST INFORMATION

This consent form will provide you with information regarding Whole Genome Sequencing (WGS), which you should discuss with your healthcare provider or a genetic counselor. To assist you in understanding the reason for this testing, we have provided information about the testing process and potential results below. This testing can be performed on you or your child.

The WGS test may identify changes, called variants, in a person's DNA that cause genetic diseases or medical conditions. DNA is the genetic material that we receive from our parents. Genes are made of DNA and are the instructions for maintaining the health of our bodies. The WGS test provides a comprehensive analysis of the human genome. Based on the symptoms that are known for you/your child, genes with changes associated with these symptoms will be reported. It is possible that even if WGS identifies the underlying genetic cause for a disease in a family this information may not help in predicting medical outcomes or changing medical management or treatment of disease. In addition, WGS testing may also identify information about genes and diseases that have a clear and immediate medical significance to your health or the health of your family members, even if that information is not related to the currently known symptoms. After you have received your results, you should discuss the significance of these results with your healthcare provider or genetic counselor.

## RESULTS

There are several types of test results that may be reported including:

- **Positive:** Positive or "abnormal" results mean a variant in the DNA was detected that is related to your/your child's medical issues or that you/your child are at an increased risk of developing a disease in the future. It is possible to test positive for more than one variant. Positive results might include pathogenic variants (variants known to be associated with disease) and likely pathogenic variants (variants that are likely to be associated with disease).
- **Negative:** Negative or "normal" results mean that no relevant variants were detected that are related to your/your child's medical issues or that would increase your/your child's risk for developing a disease in the future. This might indicate that there are no variants associated with disease in the genes tested. Genetic testing, while highly accurate, might not detect a variant present in the genes tested. This can be due to limitations of the information available about the genes being tested, or limitations of the testing technology.
- **Variant of Uncertain Clinical Significance:** Testing can detect variant(s) in DNA which we do not yet fully understand. These are also referred to as variants of uncertain clinical significance (VUS). Additional testing may be recommended for you/your child or your family if a VUS is identified in a gene that may be associated with your/your child's medical condition.
- **Secondary / Incidental Findings:** Testing can sometimes detect a variant in a person's DNA unrelated to the reason for testing. If this variant is expected to have medical or reproductive significance, it is called a secondary or incidental finding.

## INCIDENTAL FINDINGS

This test may find changes in genes that cause symptoms or diseases not related to the reason for having the test. These are called Secondary or Incidental Findings, and are associated with a clear and immediate medical significance to your/your child's health or the health of your family members.

### CATEGORY I: ACMG SECONDARY FINDINGS

The American College of Medical Genetics (ACMG) has published a series of guidelines for the reporting of these types of medically actionable or secondary findings (including PMID: 34012068). These guidelines include a list of genes, which are updated occasionally, that are considered medically actionable and indicate laboratories should report pathogenic (disease-causing) and likely pathogenic findings in these genes. In accordance with an update to this policy statement (PMID: 25356965), you and your provider may choose to opt-in to have these findings reported — please indicate this selection in the Patient Reporting Options and Release of Updated Results section below.

### CATEGORY II: OTHER INCIDENTAL FINDINGS

Medically actionable variants are changes found in genes known to be associated with disease but not associated with your/your child's current symptoms or clinical presentation. These variants are reported as they may cause severe, early-onset disease or may have implications for treatment and prognosis. You and your provider may choose to opt-in to have these findings reported — this selection is on page 2 of the test requisition form.

## ADDITIONAL REPORTING INFORMATION

The report will NOT include findings in genes causing adult-onset neurodegenerative syndromes for which there is presently no prevention or cure unless directly related to the phenotype. If specific genes causing adult-onset neurodegenerative syndromes should be considered for reporting, these genes should be marked in the Genes of Interest section on the requisition. For each gene, please indicate whether findings should be reported for only the proband (patient) or both the proband and their parents.

Additional reporting for Proband WGS: Samples from biological parents may help facilitate interpretation of Proband (patient-only) WGS results. After the proband report is issued, parental samples can be tested by WGS or targeted testing for the variants detected in the proband's genome data, at an additional charge. Free testing for variants of uncertain clinical significance for immediate family members is available with prior written approval.

Additional considerations for Duo/Trio WGS: As part of the Duo/Trio WGS test, a sample from one (for Duo) or both (for Trio) biological parent(s) is required. WGS will be performed on the proband (patient) and parental sample(s) at the same time and the sequence data will be analyzed in the context of the family relationships. The parental data will be used to help interpret the proband's data. Follow up testing is available for other family members at an additional charge. Free testing for variants of unknown significance is available with prior written approval. A separate parental report will be issued regarding ACMG secondary findings.

Your physician may order a test that includes WGS in combination with another type of testing. These tests include other methodologies which may help identify changes that the WGS alone cannot. Testing of parents with other methodologies may or may not be necessary to interpret the proband's results. Any results obtained from these additional tests will be included in a separate report from the WGS report. Please visit the Baylor Genetics website for further information about these tests and their associated consent forms.

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**FAX**
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# WHOLE GENOME SEQUENCING (WGS) CONSENT

| Patient Last Name | Patient First Name | MI | Date of Birth (MM / DD / YYYY) | Genetic Sex |
|---|---|---|---|---|
| | | | / / | |

## RNASEQ INFORMATION

For variants that meet certain criteria ("qualified variants"), a comprehensive analysis of the RNA can be performed by RNAseq. RNA is made from DNA and is used by the body to create many different proteins. RNAseq can help clarify the clinical significance of the qualified variant(s) being assessed. It is possible that even if RNAseq identifies additional information it may not be enough to clarify the clinical significance of any or all qualified variants.

The results of RNAseq may help to clarify the clinical significance of one or more variant(s) identified via WGS. An updated version of your WGS report may be issued with information obtained from RNAseq. Possible test results may include:

- Reclassification of the variant to pathogenic/likely pathogenic ("upgrade"): One or more previously identified variant(s) are now classified as pathogenic or likely pathogenic. These variants are now considered to be related to your/your child's medical issues or indicate that you/your child are at an increased risk of developing a disease in the future.
- Reclassification of the variant to benign ("downgrade"): One or more previously identified variants are now classified as benign (unlikely to be associated with disease). These variants are now considered unrelated to your/your child's medical issues and not expected to be associated with an increased risk of developing a disease in the future.
- Classification of the variant remains the same: One or more previously identified variant(s) was not able to be upgraded or downgraded. These variants still have the same classification. Additional testing may be recommended to further clarify the clinical significance of these variants.

## CONSIDERATIONS AND LIMITATIONS

- This consent form can only be used for WGS. Consent forms for other tests are located at Baylor Genetics' website (https://www.baylorgenetics.com/consent/).
- Results may indicate you/your child have a genetic disease, are at increased risk to develop a genetic disease, and/or be at an increased risk to have a child with a genetic disease. It is important to understand that genetic tests, even if negative, cannot rule out every variant. Genetic testing, while highly accurate, might not detect a variant present in the gene(s) tested. This can be due to limitations of the information available about the gene(s) being tested, or limitations of the testing technology. It is not possible to exclude risks for all genetic diseases for you/your child and your family members.
- It is possible that even if the test identifies the underlying genetic cause for the disease in your family, this information may not help in predicting the progression of disease or change management or treatment of disease.
- Depending on the type of genetic testing performed and the results, additional genetic testing or other testing may be needed to fully understand the likelihood of you/your child developing the disease or the severity of the disease. This additional testing might be needed for you/your child or other members of your family. This information will be discussed by your healthcare provider and additional consent obtained as required.
- In many instances, WGS will not identify a qualified variant. If no qualified variant is identified by WGS, RNAseq will not be performed.
- It is recommended that you discuss genetic testing with your healthcare provider or genetic counselor before signing this consent and again after results are made available.
- It may not always be possible to complete testing as sometimes the sample does not have enough DNA/RNA to perform testing or other reasons. In these cases, another sample may need to be sent to the laboratory to perform testing.

## PATIENT CONFIDENTIALITY AND SPECIMEN RETENTION

- If several family members are tested, the correct interpretation of the results depends on the information provided about the relationships among family members. In rare cases, genetic testing can reveal that the true biological relationships in a family are not as they were reported. If a difference is identified, it may be necessary to share this information with the healthcare provider who ordered the testing.
- Genetic testing is highly accurate, however in rare cases, inaccurate results may occur. Reasons for this include, but are not limited to, mislabeled samples, inaccurate reporting of clinical/medical information, or rare technical errors.
- If you sign this consent form, but you no longer wish to have your/your child's sample(s) tested, you can contact the healthcare provider who ordered the test to cancel the test. If you wish to cancel testing, the laboratory must be notified of the cancellation request before 5 PM CST the business day after the sample has been received by Baylor Genetics. If the laboratory is not notified of your cancellation request until after this time, you will be charged for the full cost of the test.
- Only Baylor Genetics and Baylor Genetics contracted partners will have access to the sample(s) provided to conduct the requested testing. Results will only be released to the following person(s): (i) a licensed healthcare provider, (ii) those authorized in writing, (iii) the patient or their personal representative, and (iv) those allowed access to test results by law. I understand that I have the right to access my test results directly from Baylor Genetics by providing a written request. I also understand that laboratory raw data can be requested by providing a written request or HIPAA Authorization Form.
- In rare cases, persons with genetic diagnoses have experienced problems with insurance coverage and employment. The U.S. Federal Government has enacted several laws that prohibit discrimination based on genetic test results by health insurance companies and employers. In addition, these laws prohibit unauthorized disclosure of this information. For more information, you can visit www.genome.gov/10002077.
- Samples will be retained in the laboratory in accordance with the laboratory retention policy.
- After testing is complete, the 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 healthcare providers unless specific prior arrangements have been made.
- Samples from residents of New York State will not be included in general research studies without your written consent and will not be retained for more than 60 days after receipt of the sample, unless specifically authorized by your selection below. No tests other than those authorized shall be performed on the biological sample.

BAYLOR GENETICS

**BAYLOR GENETICS**
2450 HOLCOMBE BLVD.
GRAND BLVD. RECEIVING DOCK
HOUSTON, TX 77021-2024

**PHONE**
1.800.411.4363
**FAX**
1.800.434.9850

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### PATIENT CONFIDENTIALITY AND SPECIMEN RETENTION CONTINUED

**FOR SAMPLES SUBMITTED FROM NEW YORK STATE**

Initial

I understand that no genetic test other than those I have authorized shall be performed on my biological sample, and the sample will be destroyed at the end of testing or not more than 60 days after the sample was taken. However, by initiating here, I hereby authorize the lab to retain my sample(s) for longer retention in accordance with the laboratory retention policy for internal laboratory quality assurance studies and possible research testing.

- By signing this Consent form, I understand and agree that information identified may also be submitted to public databases, such as ClinVar. Such submission serves to contribute knowledge to the medical community. I understand that limited clinical information is also required for the submission of information to ClinVar's database and further that the contents of this limited clinical information may, although unlikely, include information that may identify me or members of my family.

### PATIENT REPORTING OPTIONS AND RELEASE OF UPDATED RESULTS

Please read the statements below carefully and check the appropriate box. Due to the nature of the methodology of this testing we are unable to guarantee that all pathogenic (disease-causing) variants in each option will be detected by WGS.

For all options below: If no selection is made, this will default to the NO option.

**FOR ALL WGS:**

**REPORTING OF CATEGORY I (ACMG) SECONDARY FINDINGS FOR THE PATIENT**

Pathogenic and likely pathogenic variants in genes included in the ACMG policy statement regarding recommendations for reporting of secondary findings will be reported as medically actionable on the WGS report.

☐ YES - Please report pathogenic and likely pathogenic variants in genes determined to be medically actionable by the ACMG policy statement.

☐ NO - Please do NOT report pathogenic and likely pathogenic variants in genes included in the ACMG policy statement.

**OPTION TO ALLOW RELEASE OF UPDATED RESULT**

If a possible diagnosis can be made with new information, we would like to issue an updated report to the physician who ordered your WGS. This updated report will NOT include a complete review of all of you/your child's data.

☐ YES - If new information regarding the clinical significance of changes in my/my child's WGS becomes known, I would like Baylor Genetics to issue an updated report which includes this information to my physician who ordered this WGS testing.

☐ NO - Please do NOT issue an updated report if there is new information regarding the clinical significance of my/my child's WGS that becomes known.

**FOR DUO AND TRIO WGS ONLY:**

We understand that our samples will be utilized for Duo or Trio WGS as ordered by our healthcare provider. This will be analyzed to help interpret the sequence data of our child. A separate parental report will be issued regarding the below category of secondary findings. Testing of parental status for this category of results will be initiated independently of our child's data. It may be possible to infer information about a family member's results based on our child's or other family member's results.

**REPORTING OF MATERNAL CATEGORY I (ACMG) SECONDARY FINDINGS**

Pathogenic and likely pathogenic variants in genes included in the ACMG policy statement regarding recommendations for reporting of incidental findings will be reported as medically actionable on the maternal WGS report.

☐ YES - Please report pathogenic and likely pathogenic variants in genes determined to be medically actionable by the ACMG policy statement.

☐ NO - Please do NOT report pathogenic or likely pathogenic variants in genes included in the ACMG policy statement.

**REPORTING OF PATERNAL CATEGORY I (ACMG) SECONDARY FINDINGS**

Pathogenic and likely pathogenic variants in genes included in the ACMG policy statement regarding recommendations for reporting of incidental findings will be reported as medically actionable on the paternal WGS report.

☐ YES - Please report pathogenic and likely pathogenic variants in genes determined to be medically actionable by the ACMG policy statement.

☐ NO - Please do NOT report pathogenic or likely pathogenic variants in genes included in the ACMG policy statement.

**FOR WGS PERFORMED ON ANOTHER FAMILY MEMBER BESIDES THE PROBAND OR PARENTS ONLY:**

We understand that our samples will be utilized for WGS as ordered by our healthcare provider. This will be analyzed to help interpret the sequence data of my other family members being tested. A separate report will be issued regarding the below category of secondary findings. Testing of familial status for these categories of results will be initiated independently of my family member's data. It may be possible to infer information about a family member's results based on the results obtained.

**REPORTING OF CATEGORY I (ACMG) SECONDARY FINDINGS FOR OTHER FAMILY MEMBER**

Pathogenic and likely pathogenic variants in genes included in the ACMG policy statement regarding recommendations for reporting of incidental findings will be reported as medically actionable on the family member's WGS report.

☐ YES - Please report pathogenic and likely pathogenic variants in genes determined to be medically actionable by the ACMG policy statement.

☐ NO - Please do NOT report pathogenic or likely pathogenic variants in genes included in the ACMG policy statement.

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## FINANCIAL AGREEMENT AND GUARANTEE

By signing this consent form, I accept full and complete financial responsibility for all genetic testing ordered by my healthcare provider. For insurance billing, I hereby authorize Baylor Genetics to bill my health insurance plan on my behalf, and further authorize Baylor Genetics to release any information to my insurance carrier which is reasonably required for billing. I additionally designate Baylor Genetics as my designated representative for purposes of appealing any denial of benefits by my insurance carrier. I irrevocably assign associated payment to Baylor Genetics, and direct that payment be made directly to Baylor Genetics. I understand that my out-of-pocket costs may be different than the estimated amount indicated to me by Baylor Genetics as part of a verification of benefits investigation. I agree to be financially responsible for all amounts as indicated on the explanation of benefits issued by my health insurance plan. If my insurance provider sends a payment directly to me for unpaid services performed by Baylor Genetics on my behalf, I agree to endorse the insurance check as appropriate and forward such check to Baylor Genetics within thirty (30) days of receipt thereof, as payment towards Baylor Genetics' claim for services rendered. If I do not have health insurance, I agree to pay for the full cost of the genetic testing that was ordered by my healthcare provider and billed to me by Baylor Genetics.

If my health insurer does not cover the test or I do not have health insurance, I have received a good faith estimate of the cost for the genetic testing ordered by my provider and agree to pay for the cost of the genetic testing billed to me by Baylor Genetics based on that good faith estimate. More information is available in Baylor Genetics' No Surprises Act and Good Faith Estimate Notice located at: https://www.baylorgenetics.com/no-surprises-act/.

I understand that a completed Advance Beneficiary Notice (ABN) is required for Medicare fee for service patients if the service is not payable by Medicare as not medically necessary or reasonable.

## RECONTACT FOR RESEARCH CONSENT

Baylor Genetics participates in research relating to health, disease prevention, drug development, and other scientific purposes. Baylor Genetics may contact patients directly as part of this research. I agree to allow Baylor Genetics to contact me about possible research involving the sample(s) and/or information associated with this testing. I understand that patients generally receive no compensation for this participation in research. For more information on research at Baylor Genetics, please visit baylorgenetics.com.

If I wish to opt out of being recontacted for research purposes by Baylor Genetics, I understand that I may check the box below:

☐ Please do not contact me regarding any research that uses information obtained from this testing.

For any research I may be contacted about, I prefer contact through the following methods (please check all that apply – if no choices are selected, contact via secure email will be made if an email address is provided):

☐ Email ☐ Phone ☐ Mail

## PATIENT AUTHORIZATION

By signing this statement of consent, I acknowledge that I have read, understand, and hereby grant my informed consent for genetic testing. I have received appropriate explanations from my healthcare provider about the planned genetic test(s) and possible results. I have been informed by my healthcare provider about the availability and importance of genetic counseling and have been provided with written information identifying a genetic counselor or medical geneticist who can provide such counseling services. All my questions have been answered and I have had the necessary time to make an informed decision about the genetic test(s).

I hereby give permission to Baylor Genetics to conduct genetic testing as recommended by my physician.

Patient Name | Patient's Signature | Date Signed (MM / DD / YYYY)

Patient's Parent / Personal Representative* Name | Patient's Parent / Personal Representative Signature | Date Signed (MM / DD / YYYY)

Relationship of Personal Representative* to the Patient

Ordering Provider's Signature | Date Signed (MM / DD / YYYY)

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### PATIENT AUTHORIZATION

**FOR DUO AND TRIO WGS ONLY**

| | | |
|---|---|---|
| Maternal Name | Maternal Signature | Date Signed (MM / DD / YYYY) |
| Paternal Name | Paternal Signature | Date Signed (MM / DD / YYYY) |
| Maternal Personal Representative* Name | Maternal Personal Representative* Signature | Date Signed (MM / DD / YYYY) |
| Relationship of Maternal Personal Representative* | | Date Signed (MM / DD / YYYY) |
| Paternal Personal Representative* Name | Paternal Personal Representative* Signature | Date Signed (MM / DD / YYYY) |
| Relationship of Paternal Personal Representative* | | Date Signed (MM / DD / YYYY) |

**FOR AFFECTED SIBLING OR OTHER FAMILY MEMBER WGS ONLY**

| | | |
|---|---|---|
| Affected Sibling/Other Family Member Name | Affected Sibling/Other Family Member Signature | Date Signed (MM / DD / YYYY) |
| Affected Sibling/Other Family Member Parent / Personal Representative* Name | Affected Sibling/Other Family Member Parent / Personal Representative* Signature | Date Signed (MM / DD / YYYY) |
| Relationship of Personal Representative* to Affected Sibling / Other Family Member | | Date Signed (MM / DD / YYYY) |