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

CONNECT

BIOCHEMICAL TESTING 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

Accession # | Hospital / Medical Record #

Patient discharged from the hospital/facility: ◯ Yes ◯ No

Genetic Sex: ◯ Female ◯ Male ◯ Unknown

Gender identity (if different from above):

REPORTING RECIPIENTS

Ordering Physician | Institution Name

Email (Required for International Clients) | Phone | Fax

ADDITIONAL RECIPIENTS

Name | Email | Fax

Name | Email | Fax

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

Name of Insured | Insured Date of Birth (MM / DD / YYYY)

Patient's Relationship to Insured | Phone of Insured

Address of Insured

City | State | Zip

Primary Insurance Co. Name | Primary Insurance Co. Phone

Primary Member Policy # | Primary Member Group #

Name of Insured | Insured Date of Birth (MM / DD / YYYY)

Patient's Relationship to Insured | Phone of Insured

Address of Insured

City | State | Zip

Secondary Insurance Co. Name | Secondary Insurance Co. Phone

Secondary Member Policy # | Secondary Member Group #

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, as well as any amounts not paid by my insurance carrier for reasons including, but not limited to, non-covered and non-authorized services. 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 that Medicare does not cover routine screening tests.

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

STATEMENT OF MEDICAL NECESSITY (REQUIRED)

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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			____ / ____ / ____	

SAMPLE

SAMPLE TYPE

- ◯ Blood in ACD (Yellow-top)
- ◯ Blood in Sodium Heparin (Green-top)
- ◯ Blood in EDTA (Purple-top)
- ◯ Cerebrospinal Fluid
- ◯ Cultured Skin Fibroblast
- ◯ Plasma from Sodium Heparin
- ◯ Serum (including marble-top, red-top, etc.)
- ◯ Skeletal Muscle
- ◯ Urine

DATE OF COLLECTION (MM/DD/YYYY)

____ / ____ / ____

INDICATION FOR TESTING (REQUIRED)

ICD10 Diagnosis Code(s):

☐ Clinical management of known diagnosis - Please specify:

☐ Clinical History - Please describe:

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BIOCHEMICAL TESTS

Note: To order Global MAPS® (Metabolomic Assisted Pathway Screen), please visit baylorgenetics.com/reqs

BIOCHEMICAL PANELS

	TEST CODE	TEST NAME	SAMPLE TYPE
☐	4000	Biochemistry 5-Plex *Acylcarnitine Analysis (TC 4300), Amino Acid Analysis (TC 4100), Plasma and Urine Creatine/Guanidinoacetate Determination (TC 4130 & 4260), Organic Acid Screen (TC 4200)*	PH + U
☐	4175	Biochemistry 3-Plex *Acylcarnitine Analysis (TC 4300), Amino Acid Analysis (TC 4100), Creatine/Guanidinoacetate Determination (TC 4130)*	PH
☐	4015	Creatine Deficiency Syndromes Panel *Creatine Deficiency Syndromes Panel - Plasma and Urine Creatine/Guanidinoacetate Determination (TC 4130 & 4260)*	PH + U
☐	4400	Neonatal and Infantile Seizures Panel *Acylcarnitine Analysis (TC 4300), Plasma and CSF Amino Acid Analysis (TC 4100 & 4160), Biotidinase Deficiency (TC 4555), Creatine/Guanidinoacetate Determination (TC 4130), Organic Acid Screen (TC 4200), Pyridoxine-Dependent Seizures Panel (TC 4811), Sulfocysteine Determination (TC 4225)*	PH + CSF + SE + U

ANALYTE ANALYSIS

	TEST CODE	TEST NAME	SAMPLE TYPE
☐	4300	Acylcarnitine Analysis	PH
☐	4100	Amino Acid Analysis	PH
☐	4160	Amino Acid Analysis	CSF
☐	4240	Amino Acid Analysis	U
☐	4310	Carnitine Determination	PH
☐	4130	Creatine/Guanidinoacetate Determination	PH
☐	4260	Creatine/Guanidinoacetate Determination	U
☐	4627	Cystine Determination	WBC
☐	3210	ETC	SFC

	TEST CODE	TEST NAME	SAMPLE TYPE
☐	3200	ETC	SM
☐	4150	Methylmalonic Acid	PH
☐	4200	Organic Acid Screen	U
☐	4650	Phenylbutyrate Metabolite Analysis	PH
☐	4651	Phenylbutyrate Metabolite Analysis	U
☐	4811	Pyridoxine-Dependent Seizures Panel	PH
☐	4250	Succinylacetone Determination	U
☐	4225	Sulfocysteine Determination	U
☐	4330	Thymidine Determination	PH

ENZYME ANALYSIS

	TEST CODE	TEST NAME	SAMPLE TYPE
☐	4536	Argininemia / Arginase Deficiency	RBC
☐	4555	Biotidinase Deficiency	SE

	TEST CODE	TEST NAME	SAMPLE TYPE
☐	4569	Tay-Sachs Disease & Sandhoff Disease/ Hexosaminidase A and B	SE
☐	4617	Tay-Sachs Disease Carrier Testing Hexosaminidase A	SE
☐	4620	Tay-Sachs Disease Carrier Testing Hexosaminidase A	WBC

SAMPLE TYPE KEY:

BA Blood in ACD tube
BH Blood in Sodium Heparin
BE Blood in EDTA tube
CSF Cerebrospinal Fluid
PH Plasma (From Heparin)
RBC Red Blood Cells
SE Serum
SFC Cultured Skin Fibroblast
SM Skeletal Muscle
U Urine
WBC White Blood Cells

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BIOCHEMICAL TESTING REQUISITION

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SAMPLE SPECIFICATIONS TABLE

ABBREVIATION	SAMPLE NAME	RECOMMENDED AMOUNT		SHIPPING INSTRUCTIONS	SPECIAL NOTES
		(2 YRS - ADULT)	(NEWBORN - 2 YRS)		
BA	Blood in ACD tube (yellow-top)	3 - 5 cc	3 - 5 cc	Ship at room temperature in an insulated container by overnight courier to arrive within 36 hours of collection. Do not heat or freeze.	
BH	Blood in Sodium Heparin tube (green-top)	3 - 5 cc	1 - 2 cc	Ship at room temperature in an insulated container by overnight courier. Do not heat or freeze.	
CSF	Cerebrospinal Fluid	1 - 2 cc	1 - 2 cc	Ship frozen sample in insulated container, with 3 -5 lbs dry ice, by overnight courier.	Store the specimen frozen at -20°C. Specimen may be stored frozen for up to 7 days.
PH	Plasma (From Heparin)	2 cc	2 cc	Ship frozen sample in insulated container, with 3 -5 lbs dry ice, by overnight courier.	Draw blood in heparin (green-top) tube(s) and separate them as soon as possible. Store the specimen frozen at -20°C. Specimen may be stored frozen for up to 7 days.
RBC	Red Blood Cell	3 - 5 cc	3 - 5 cc	Ship at room temperature in an insulated container by overnight courier to arrive within 36 hours of collection. Do not heat or freeze	Draw blood in an ACD (yellow-top) tube(s).
SE	Serum	1 - 2 cc	1 - 2 cc	Ship frozen sample in insulated container, with 3 -5 lbs dry ice, by overnight courier.	Draw blood in a no-additive (red-top) or serum gel (red/gray-top) tube(s) and separate as soon as possible. Store the specimen at -20°C.
SFC	Skin Fibroblast Culture	Two T-25 flasks	Two T-25 flasks	Ship at ambient temperature in an insulated container by overnight courier. Do not heat or freeze.	Send two T-25 flasks at approximately 60-80% confluence.
SM	Skeletal Muscle	150 mg	150 mg	Ship frozen sample in insulated container, with 3 -5 lbs dry ice, by overnight courier.	Skeletal muscle should be flash frozen in liquid nitrogen at collection with no media added, and stored at -80°C. Surgical pathology report required. If a pathology report is not available at this time, please send a clinical summary and the results of any pertinent ancillary testing.
U	Urine	3 - 5 cc	2 - 4 cc	Ship frozen sample in insulated container, with 3 -5 lbs dry ice, by overnight courier.	Collect random urine. Do not add preservatives. Store the specimen frozen at -20°C.
WBC	White Blood Cell	7 - 10 cc	3 - 5 cc	Ship at room temperature in an insulated container by overnight courier to arrive within 36 hours of collection. Do not heat or freeze	Draw blood in an ACD (yellow-top) tube(s).

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INFORMED CONSENT FOR BIOCHEMICAL TESTING

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 biochemical testing, 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.

The purpose of biochemical testing is to determine if a disease may be present or if there is an increased risk for a disease to occur in a patient or their family. The purpose of this testing is usually, but not always, to identify a genetic disease. 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 body. Each person has a unique set of DNA and most of the differences in our DNA do not impact our health. Biochemical testing analyzes analytes such as proteins and metabolites to look for abnormal changes in their amount and/or function which may indicate the presence of a genetic disease. Genetic testing, which analyzes DNA to find any abnormal changes (mutations also called variants) that might cause disease, make it more likely to develop disease, and/or increase the chance of having a child affected by disease, is often performed at the same time as biochemical testing.

The testing ordered by your healthcare provider can determine if you or your child have results which are associated with a genetic disease.

Depending on why biochemical testing is needed, you or your child might be tested for:

- A single disease that has already been found in your family.
- A single disease that causes a specific, suspected set of symptoms.
- Multiple diseases at the same time. These might be similar diseases or diseases that are unrelated to each other.
- Biochemical and genetic testing, where each test can provide specific information about a single or multiple genetic diseases.

RESULTS

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

- **Positive:** Positive or "abnormal" results mean there is a change in the analytes found 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 disease. Positive results might include significantly elevated or significantly reduced levels of analytes.
- **Negative:** Negative or "normal" results mean none of the analytes tested indicate a cause for your/your child's medical issues or that you/your child are not expected to be at an increased risk for developing a disease in the future. This might indicate that there are no analytes that are significantly different than what would be seen in a healthy person. Biochemical testing, while highly accurate, might not detect changes in analytes which would indicate a disease is present. This can be due to limitations of the information available about the analytes being tested, limitations of the testing technology, or fluctuations that may occur in analytes due to diet, medications taken, or other reasons.

CONSIDERATIONS AND LIMITATIONS

- This consent form can only be used for biochemical testing. Consent forms for other tests are located at https://www.baylorgenetics.com/consent/.
- Results may indicate you 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 biochemical tests, even if negative, cannot always determine if someone will be affected by a disease. This can be due to limitations of the information available about the disease(s) being tested, or limitations of the testing technology. It is not possible to exclude risks for all diseases for you and your family members.
- In some instances, additional genetic testing or other testing may be needed to fully understand the likelihood of your 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.
- It is recommended that you discuss biochemical 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 is too old to complete testing, is affected by external conditions, 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 amongst family members.
- Biochemical 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.

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			/ /	

PATIENT CONFIDENTIALITY AND SPECIMEN RETENTION (CONT.)

- If you sign this consent form, but you no longer wish to have your 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 begun testing. 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 any test results directly from Baylor Genetics by providing a written request. I also understand that laboratory raw data, while not routinely released as part of the testing process, 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. Specimens are not returned to individuals or to referring heath care providers unless specific prior arrangements have been made.
- Samples from residents of New York State will not be included in research studies without your written consent and will not be retained for more than 60 days after receipt of the sample. No tests other than those authorized shall be performed on the biological sample.
- 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 personally.
- 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.

FINANCIAL AGREEMENT AND GUARANTEE

By signing this consent form, I accept full and complete financial responsibility for all biochemical 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 biochemical testing that was ordered by my healthcare provider and billed to me by Baylor Genetics.

I understand that a completed Advance Beneficiary Notice (ABN) is required for Medicare patients if the service is deemed not medically necessary.

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 or their provider(s) directly as part of this research. I agree to allow Baylor Genetics to contact me or my provider(s) 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 will be made via secure email if possible):

☐ Email ☐ Phone ☐ Mail

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			____ / ____ / ____	

PATIENT AUTHORIZATION

By signing this statement of consent, I acknowledge that I have read, understand, and hereby grant my informed consent for biochemical testing. I have received appropriate explanations from my healthcare provider about the planned biochemical 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 biochemical test(s).

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

Patient's Printed Name	Patient's Signature	Date (MM / DD / YYYY)
		____ / ____ / ____

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

Relationship of Personal Representative to the Patient	Ordering Provider's Signature	Date (MM / DD / YYYY)
		____ / ____ / ____

*If you are signing as a person with legal authority to act on behalf of the patient, you may be required to provide evidence of your authority.

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