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

AUTISM 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

Biological 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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ETHNICITY

- ◯ African American
- ◯ Ashkenazi Jewish
- ◯ East Asian (China, Japan, Korea)
- ◯ Finnish
- ◯ French Canadian
- ◯ Hispanic American
- ◯ Mennonite
- ◯ Middle Eastern (Saudi Arabia, Qatar, Iraq, Turkey)
- ◯ Native American
- ◯ Northern European Caucasian (Scandinavian, UK, Germany)
- ◯ Pacific Islander (Philippines, Micronesia, Malaysia, Indonesia)
- ◯ South Asian (India, Pakistan)
- ◯ Southeast Asian (Vietnam, Cambodia, Thailand)
- ◯ Southern European Caucasian (Spain, Italy, Greece)
- ◯ Other (Specify): _____

SAMPLE

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

SAMPLE TYPE

- ◯ Blood in EDTA Tube (Purple-Top)
- ◯ Blood in Sodium Heparin Tube (Green-Top)
- ◯ DNA, Extracted
- ◯ Liver
- ◯ Plasma (From Heparin)
- ◯ Skeletal Muscle
- ◯ Skin Fibroblast Culture
- ◯ Tissue
- ◯ Urine

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.

INDICATION FOR TESTING (REQUIRED)

ICD10 Diagnosis Code(s):

AUTISM TESTS

AUTISM PANELS

TEST CODE	TEST NAME	SAMPLE TYPE *
☐ 8100	Male Specific Comprehensive Autism Panel *Acylcarnitine Analysis (TC 4300), Amino Acid Analysis (TC 4100), CMA - HR + SNP Screen (TC 8665), Plasma and Urine Creatine/Guanidinoacetate Determination (TC 4130 & 4260), FMR1 CGG Repeat (TC 6573), Organic Acid Screen (TC 4200)*	BE + BH + PH + U
☐ 8110	Female Specific Comprehensive Panel *Acylcarnitine Analysis (TC 4300), Amino Acid Analysis (TC 4100), CMA - HR + SNP Screen (TC 8665), Plasma and Urine Creatine/Guanidinoacetate Determination (TC 4130 & 4260), FMR1 CGG Repeat (TC 6573), MECP2 Sequence Analysis (TC 6068), MECP2 Deletion/Duplication Analysis (TC 6069), Organic Acid Screen (TC 4200)*	BE + BH + PH + U
☐ 4000	Biochemistry 5-Plex *Acylcarnitine Analysis (TC 4300), Amino Acid Analysis (TC 4100), Creatine/Guanidinoacetate Determination (PH) (TC 4130), 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 (PH) (TC 4130)*	PH

AUTISM-RELATED INDIVIDUAL TESTS

BIOCHEMICAL TESTING

TEST CODE	TEST NAME	SAMPLE TYPE *
☐ 4100	Amino Acid Analysis	PH
☐ 4300	Acylcarnitine Analysis	PH
☐ 4135	Carnitine Biosynthesis Panel - Urine	U
☐ 4130	Creatine/Guanidinoacetate Determination	PH
☐ 4260	Creatine/Guanidinoacetate Determination	U
☐ 4200	Organic Acid Screen	U

MITOCHONDRIAL TESTING

TEST CODE	TEST NAME	SAMPLE TYPE *
☐ 2010	Advanced mtDNA Point Mutations & Deletions (BCM-MitomeNGSSM)	BE, SM, T
☐ 2055	Comprehensive mtDNA Analysis (BCMMtomeNGSSM)	BE, T, L, DNA, SM
☐ 2130	mtDNA Depletion/Integrity Panel (BCMMtomeNGSSM)	BE, DNA
☐ 3700	mtDNA Content (qPCR) Analysis - Skeletal Muscle	SM
☐ 3720	mtDNA Content (qPCR) Analysis - Liver	L
☐ 3200	Mitochondrial Respiratory Chain Enzyme Analysis (ETC) - Skeletal Muscle	SM
☐ 3210	Mitochondrial Respiratory Chain Enzyme Analysis (ETC) - Skin Fibroblast Culture	SFC
☐ 2000	MitoMet®Plus aCGH	BE
☐ 2086	Nuclear Panel by Massively Parallel Sequencing (BCM-MitomeNGSSM)	BE, SFC, SM, DNA
☐ 2085	Dual Genome Panel by Massively Parallel Sequencing (BCM-MitomeNGSSM)	BE, SFC, SM, DNA

For a complete list of tests offered in each autism panel, please visit BMGL.com. To order Global Metabolomic Assisted Pathway Screen (Global MAPS®), please send sample with Global MAPS® requisition, which can be found at BMGL.com.

* Refer to Sample Specifications Table (page 3)

Testing options continued on next page

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AUTISM TESTING REQUISITION

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AUTISM TESTS - CONTINUED

AUTISM-RELATED INDIVIDUAL TESTS

MITOCHONDRIAL TESTING

TEST CODE	TEST NAME	SAMPLE TYPE *	SPECIFY GENE OF INTEREST
☐ 2001	Oligonucleotide Targeted Array Analysis (Single Target Gene)	BE	
☐ 2003	Oligonucleotide Targeted Array Analysis (Up to 5 Target Genes)	BE	

CYTOGENETIC TESTING

TEST CODE	TEST NAME	SAMPLE TYPE *	SPECIFY GENE OF INTEREST
☐ 8665	CMA - HR + SNP Screen (Comprehensive)	BE + BH	
☐ 8600	Chromosome Analysis	BH	

DNA TESTING

TEST CODE	TEST NAME	SAMPLE TYPE *
☐ 6006	Angelman Syndrome Methylation Analysis	BE, DNA
☐ 6007	Angelman Syndrome (*UBE3A* Sequence Analysis)	BE, DNA
☐ 6067	ARX-Related Disorders Sequence Analysis	BE, DNA
☐ 6126	CDKL5-Related Disorders Sequence Analysis	BE, DNA
☐ 6165	CHARGE Syndrome (*CHD7*) Sequence Analysis	BE, DNA
☐ 6573	*FMR1* CGG Repeat Expansion Analysis	BE, DNA
☐ 6240	Lesch-Nyhan Syndrome (*HPRT*) Sequence Analysis	BE, DNA
☐ 6068	*MECP2* Sequence Analysis	BE, DNA

TEST CODE	TEST NAME	SAMPLE TYPE *
☐ 6069	MECP2 Deletion/Duplication Analysis	BE, DNA
☐ 6065	Noonan Syndrome (*PTPN11*) Sequence Analysis	BE, DNA
☐ 6475	Noonan Syndrome (*RAF1*) Sequence Analysis	BE, DNA
☐ 6460	Noonan Syndrome (*SOS1*) Sequence Analysis	BE, DNA
☐ 6127	*PLP1* Sequence Analysis	BE, DNA
☐ 6505	*PTEN* Sequence Analysis	BE, DNA
☐ 6121	*RECQL4* Sequence Analysis	BE, DNA
☐ 2510	*TMLHE* Sequence Analysis	BE, DNA

SAMPLE SPECIFICATIONS TABLE

ABBREVIATION	SAMPLE NAME	RECOMMENDED AMOUNT (2 YRS - ADULT)	RECOMMENDED AMOUNT (NEWBORN - 2YRS)	SHIPPING INSTRUCTIONS	SPECIAL NOTES
BE	Blood in EDTA tube (purple-top)	3 - 5 cc	2 -3 cc	Ship at room temperature in an insulated container by overnight courier. 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.	
DNA	DNA, Extracted	10 - 15 ug	10 - 15 ug	Ship at room temperature in an insulated container by overnight courier. Do not heat or freeze.	Minimal concentration of 50ng/uL; A260/A280 of ~1.7
L	Liver	25 - 50 mg	25 - 50 mg	Ship frozen sample in insulated container, with 3 -5 lbs dry ice, by overnight courier.	Liver should be flash frozen in liquid nitrogen at collection with no media added and stored at -80°C.
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.
SFC	Skin Fibroblast Culture	Two T-25 flasks	Two T-25 flasks	Ship at ambient temperature in an insulated container by overnight courier.	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.
T	Tissue	50 mg	50 mg	Ship frozen sample in insulated container, with 3 -5 lbs dry ice, by overnight courier.	Tissue should be flash frozen in liquid nitrogen at collection with no media added, and stored at -80°C.
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.

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INFORMED CONSENT FOR AUTISM TESTING

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

INFORMED CONSENT FOR GENETIC TESTING

TEST INFORMATION

This consent form will provide you with information regarding genetic testing, which you should discuss with your healthcare provider or a genetic counselor. In order to ensure that you have understood the purpose and significance of genetic testing, we have provided information about the testing process and potential results below.

The purpose of genetic testing is to identify the cause of a suspected disease in you or your family. The testing analyzes your genetic material (DNA) for an abnormal change (variant) that could explain the disease you or members of your family are experiencing. Genetic testing can be a diagnostic test, which is used to identify or rule out a specific genetic condition. Genetic screening tests are used to assess the chance for a person to develop or have a child with a genetic condition. Genetic screening tests are not typically diagnostic, and results may require additional testing.

The purpose of this test is to see if you or your child may have a genetic variant or chromosome rearrangement. This may cause a genetic disorder or may determine the chance that you or your child will develop or pass on a genetic disorder in the future. "Your child" can also mean your unborn child, for the purposes of this consent.

In a genetic test, depending on the case, you can be tested for:

- A single gene/variant responsible for a specific, suspected genetic disease.
- Multiple genes in parallel.

The sample/specimen that is needed to perform the genetic test is stated in the test order form and is typically blood or purified DNA, but may also be tissue, saliva or buccal swab.

RESULTS

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

- **Positive:** Positive or "abnormal" results mean there is a change in the genetic material found that is related to your/your child's medical issues or that you/your child are at an increased risk of developing the disorder in the future. It is possible to test positive for more than one genetic variant.
- **Negative:** Negative or "normal" results mean no relevant genetic change related to your/your child's medical issues was detected. This does not mean there is no genetic change, but it may mean that the type of testing performed could not detect it.
- **Results of Unclear Significance:** Testing can detect change(s) in DNA which we do not yet fully understand. These alterations are also referred to as variants of uncertain significance (VUS). Additional studies may be recommended if a VUS is identified in a gene that may be associated with your/your child's medical concerns.
- **Secondary / Incidental Findings:** Testing can sometimes detect a change in a person's DNA unrelated to the reason for testing. If this change has medical or reproductive significance, it is called a secondary or incidental finding.

CONSIDERATIONS AND LIMITATIONS

- Results may indicate affected status, increased risk to someday be affected with, and/or reproductive risk for a genetic disorder. It is important to understand that genetic tests, even if negative, are not exhaustive. It is not possible to exclude risks for all possible genetic diseases for yourself and your family members.
- A positive test result is an indication that the individual(s) being tested may be predisposed to or have the specific disease or condition which prompted testing. You might consider additional independent testing, consult a personal physician, or pursue genetic counseling.
- It is possible that the knowledge of the test results may result in psychological stress for you and your family. It is always recommended to discuss the results with your healthcare provider or genetic counselor.
- If several family members are tested, the correct interpretation of the results depends on the provided relationships between 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 discrepancy is identified, it may be necessary to report this to the physician who ordered the testing.
- Genetic testing is highly accurate. Rarely, inaccurate results may occur for various reasons. These reasons 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 sample(s) tested, you can contact your physician to cancel the test. If testing is complete, but you have not received your results yet, you can inform your physician that you no longer wish to receive the results. If you withdraw consent for testing after 5pm CST the next business day following sample receipt by the laboratory, you will be charged for the full cost of the test.

PATIENT CONFIDENTIALITY AND SPECIMEN RETENTION

- Results will only be released to a licensed healthcare provider, to those allowed access to test results by law, and to those authorized in writing.
- 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 heath care providers unless specific prior arrangements have been made.

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INFORMED CONSENT FOR AUTISM TESTING

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INFORMED CONSENT FOR GENETIC TESTING

PATIENT CONFIDENTIALITY AND SPECIMEN RETENTION (CONT.)

- Samples from residents of New York State will not be included in the de-identified research studies described in this authorization and will not be retained for more than 60 days after test completion, unless specifically authorized by your selection. No tests other than those authorized shall be performed on the biological sample.
- Information including results, indications for testing and clinical status obtained from this testing may be shared with healthcare providers, scientists and healthcare databases or used in scientific publications or presentations, but the personal identifying information of all persons studied will not be revealed in such data sharing or publications/presentations.

RESEARCH & RECONTACT CONSENT

For more information on research at Baylor Genetics, please visit baylorgenetics.com. Please read the below statements carefully and check the appropriate box.

Note: If left blank, consent is interpreted as "NO."

☐ I agree to use of my de-identified specimen for research to improve genetic testing for all patients and contribute to scientific research.

☐ I am a New York State Resident, and I give Baylor Genetics permission to store my specimen in accordance to the laboratory retention policy for internal quality assurance and possible research studies.

☐ In addition to agreeing above, I agree to be contacted by Baylor Genetics regarding research opportunities.

PATIENT AUTHORIZATION

By signing this statement of consent, I acknowledge that I have read and understand the informed consent for genetic testing. I have received appropriate explanations from my physician regarding the purpose, scope, type and significance of the planned genetic testing and achievable results. All my questions have been answered and I have had the necessary time to make an informed decision about the genetic test.

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

Patient Signature | Date (DD/MM/YYYY)

Printed Name