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

INHERITED EYE DISORDERS 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): _____

INDICATION FOR TESTING (REQUIRED)

☐ Symptomatic (Summarize below) ☐ Symptomatic with Family History

_____

☐ Asymptomatic

◯ Population Screening ◯ Positive Family History

Disease | Gene | Variant

ICD10 Diagnosis Code(s): _____

SAMPLE

SAMPLE TYPE

- ◯ Blood in EDTA-tube (purple-top)
- ◯ Blood in Heparin-tube (green-top)
- ◯ Cultured Skin Fibroblast
- ◯ Other (Specify) _____
- ◯ DNA
- ◯ Saliva
- ◯ Skin Biopsy
- ◯ Tissue

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.

Blood should not be sent from patients who have had a bone marrow transplant or recent blood transfusion

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

TESTING OPTIONS

☐ Targeted Sequencing for Known Familial Mutation (If selected, specify test code and gene below and complete section to the right)

Test Code | Gene

☐ Full Gene Sequencing

☐ Deletion/ Duplication Analysis

FOR TARGETED TESTING SELECTION ONLY

Proband Last Name | Proband First Name

_____ / _____ / _____
Date of Birth (MM/DD/YY)

Relationship of Proband to Patient

Proband testing location (Select one)

☐ Baylor Genetics Lab# Family#

☐ Another laboratory

1. Attach a copy of the Proband test results
2. A positive control sample of the Proband is requested. Please provide, if available.

INHERITED EYE DISORDERS TESTS

CYTOGENETIC TESTS

TEST CODE	TEST NAME	SAMPLE TYPE*	SPECIFY GENE OF INTEREST	SPECIFY REGION OF INTEREST
☐ 8665	Chromosomal Microarray Analysis (CMA) - HR + SNP Screen (Comprehensive)	BE, DNA, CF, SB, BUC		
☐ 8655	Chromosomal Microarray Analysis (CMA) - HR	BE, DNA, CF, SB, BUC		

MITOCHONDRIAL DNA (MTDNA) MUTATION SCREENS

TEST CODE	TEST NAME	SAMPLE TYPE*
☐ 2010	Advanced mtDNA Point Mutations and Deletions by Massively Parallel Sequencing (BCM-MitomeNGSSM)	BE, DNA, CF, T
☐ 2055	Comprehensive mtDNA Analysis by Massively Parallel Sequencing (BCM-MitomeNGSSM)	BE, DNA, CF, T

* Refer to Sample Specifications Table (page 5)

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FISH STUDIES

MASSIVELY PARALLEL SEQUENCING (BCM-MITOMENGSSM) PANELS

TEST CODE	TEST NAME	SAMPLE TYPE*	TEST CODE	TEST NAME	SAMPLE TYPE*
☐ 20100	Albinism Panel (13 genes)	BE, DNA, CF, SA, BUC	☐ 5255	Primary Open Angle Glaucoma Panel (MYOC, OPTN)	BE, DNA, CF, SA, BUC
☐ 5260	Developmental Glaucoma Panel (8 genes)	BE, DNA, CF, SA, BUC	☐ 2140	Progressive External Ophthalmoplegia Panel (10 genes)	BE, DNA, CF, SA, BUC
☐ 5250	Familial Exudative Vitreoretinopathy Panel (FZD4, LRP5, NDP, and TSPAN12)	BE, DNA, CF, SA, BUC	☐ 2190	Retinitis Pigmentosa + RPGR orf15 by NGS (66 genes)	BE, DNA, CF, SA, BUC
☐ 5090	Leber Congential Amaurosis Panel (19 genes)	BE, DNA, CF, SA, BUC	☐ 2195	Usher Syndrome Panel (9 genes)	BE, DNA, CF, SA, BUC

DNA COPY NUMBER ANALYSIS

TEST CODE	TEST NAME	SAMPLE TYPE*	SPECIFY GENE OF INTEREST				
☐ 2000	MitoMet®Plus aCGH Analysis	BE					
☐ 2001	Oligonucleotide Targeted Array Analysis (Single Target Gene)	BE					
☐ 2003	Oligonucleotide Targeted Array Analysis (Up to 5 Target Genes)	BE					

SINGLE GENE ANALYSIS

If a test is not found on this form, please obtain the test code from our website (www.BMGL.com) and write in the below space(s).

Test Code | Gene | Test Code | Gene | Test Code | Gene

Test Name | Test Name | Test Name

TEST CODE	TEST NAME	DISORDER	SAMPLE TYPE*
☐ 6603	ABCA4 Comprehensive (Seq. & Del/Dup Analysis)	ABCA4-Related Disorders	BE, DNA
☐ 2924	BEST1 Comprehensive (Seq. & Del/Dup Analysis)	BEST1-Related Disorders	BE, DNA
☐ 2419	CEP290 Comprehensive (Seq. & Del/Dup Analysis) CEP290	CEP290-Related Disorders	BE, DNA
☐ 6655	CDH23 Sequence Analysis	CDH23-Related Disorders	BE, DNA
☐ 6660	CLRN1 Sequence Analysis	CLRN1-Related Disorders	BE, DNA
☐ 7521	COL2A1 Comprehensive (Seq. & Del/Dup Analysis)	COL2A1-Related Disorders	BE, DNA
☐ 2389	CDHR1 Comprehensive (Seq. & Del/Dup Analysis)	Cone-Rod Dystrophy 15	BE, DNA
☐ 2849	CRB1 Comprehensive (Seq. & Del/Dup Analysis)	CRB1-Related Disorders	BE, DNA
☐ 5280	OAT Sequence Analysis	Gyrate Atrophy of Choroid and Retina	BE, DNA
☐ 2789	IMPDH1 Comprehensive (Seq. & Del/Dup Analysis)	IMPDH1-Related Disorders	BE, DNA
☐ 2394	LCA5 Comprehensive (Seq. & Del/Dup Analysis)	LCA5-Related Disorders	BE, DNA

* Refer to Sample Specifications Table (page 5)

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SINGLE GENE ANALYSIS CONTINUED

TEST CODE	TEST NAME	DISORDER	SAMPLE TYPE*
☐ 6039	OCRL Sequence Analysis	Lowe Syndrome	BE, DNA
☐ 2839	LRAT Comprehensive (Seq. & Del/Dup Analysis)	LRAT-Related Disorders	BE, DNA
☐ 6083	X-Linked, GPR143 Comprehensive (Seq. & Del/Dup Analysis)	Oculocutaneous Albinism	BE, DNA
☐ 3529	Type 3, OPA3 Comprehensive (Seq. & Del/Dup Analysis)	Optic Atrophy	BE, DNA
☐ 2414	ABHD12 Comprehensive (Seq. & Del/Dup Analysis)	Polyneuropathy, Hearing Loss, Ataxia, Retinitis Pigmentosa, and Cataract Disorder	BE, DNA
☐ 2959	RDH12 Comprehensive (Seq. & Del/Dup Analysis)	RDH12-Related Disorders	BE, DNA
☐ 2974	EYS Comprehensive (Seq. & Del/Dup Analysis)	Retinitis Pigmentosa	BE, DNA
☐ 2994	FAM161A Comprehensive (Seq. & Del/Dup Analysis)	Retinitis Pigmentosa	BE, DNA
☐ 2984	MERTK Comprehensive (Seq. & Del/Dup Analysis)	Retinitis Pigmentosa	BE, DNA
☐ 2459	PDE6B Comprehensive (Seq. & Del/Dup Analysis)	Retinitis Pigmentosa	BE, DNA
☐ 2399	PROM1 Comprehensive (Seq. & Del/Dup Analysis)	Retinitis Pigmentosa	BE, DNA
☐ 2939	PRPH2 Comprehensive (Seq. & Del/Dup Analysis)	Retinitis Pigmentosa	BE, DNA
☐ 2479	RGR Comprehensive (Seq. & Del/Dup Analysis)	Retinitis Pigmentosa	BE, DNA
☐ 2449	RP2 Comprehensive (Seq. & Del/Dup Analysis)	Retinitis Pigmentosa	BE, DNA
☐ 2359	RPGR Comprehensive (Seq. & Del/Dup Analysis)	Retinitis Pigmentosa	BE, DNA

* Refer to Sample Specifications Table (page 5)

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SINGLE GENE ANALYSIS CONTINUED

TEST CODE	TEST NAME	DISORDER	SAMPLE TYPE*
☐ 2934	RPE65 Comprehensive (Seq. & Del/Dup Analysis)	RPE65-Related Disorders	BE, DNA
☐ 2899	PRKCG Comprehensive (Seq. & Del/Dup Analysis)	Spinocerebellar Ataxia 14 (SCA)	BE, DNA
☐ 6650	USH2A Sequence Analysis	USH2A-Related Disorders	BE, DNA

* Refer to Sample Specifications Table below

SAMPLE SPECIFICATIONS TABLE

ABBREVIATION	SAMPLE NAME	RECOMMENDED AMOUNT		SHIPPING INSTRUCTIONS	SPECIAL NOTES
		(2 YRS - ADULT)	(NEWBORN - 2 YRS)		
BE	Blood in EDTA tube (purple-top)	3 - 5 cc	3 cc	Ship at room temperature in an insulated container by overnight courier. Do not heat or freeze.	For clarification or follow-up of CMA results, sodium heparin (green top) tubes are highly recommended. Send 3 - 5 cc (adults/children) and 1 - 2 cc (infant<2 years).
CF	Cultured Skin Fibroblast	2 T25 flasks		Ship at room temperature in an insulated container by overnight courier. Do not heat or freeze.	Send 2 T25 flasks at 80 - 100% confluence
DNA	DNA, Extracted	At least 20 ug of purified DNA		Ship at room temperature in an insulated container by overnight courier. Do not heat or freeze.	Minimal concentration of 50 ng / uL; A260 / A280 of ~1.7 - 2.0
SA	Saliva	See Special Notes		Ship at room temperature in an insulated container by overnight courier. Do not heat or freeze.	Collected with Oragene•DX DNA Self-Collection Kit
T	Tissue	50 mg		Ship frozen sample in insulated container with 3 - 5 lbs. of dry ice by overnight courier.	Tissue should be flash frozen in liquid nitrogen at collection with no media added, and stored at -80° C.
SB	Skin Biopsy	$5mm^3$		Ship at ambient temperature (18-25° C / 64-77° F). Protect paraffin tissue from excessive heat. Ship in cooled container during summer months.	Collect skin from a central location (e.g., buttock or upper thigh) rather than from a distal location (e.g., foot) to enhance cell viability. Place sample in a separate sterile container with RPMI media. In the absence of RPMI media, place sample in a sterile container with a small amount of sterile saline. Unacceptable Conditions: Specimens placed in formalin or other fixatives.

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INFORMED CONSENT FOR INHERITED EYE DISORDERS 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 INHERITED EYE DISORDERS TESTING

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

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