otogenetics® corporation

Deafness Gene Testing Requisition

Patient Information

First name _____ Last name_____

Gender ☐Male ☐Female Date of birth (mm/dd/yy)_____

Ancestry:

☐Caucasian ☐Eastern European ☐Hispanic
☐Western European ☐Native American ☐Northern European
☐African American ☐Asian ☐Middle Eastern
☐Caribbean ☐Central/South American ☐Pacific Islander
☐Ashkenazi-Jewish ☐Other:_____

Mailing address_____

City _____ State_____Postal code_____

Home phone _____Work phone_____

Clinical Reporting Information

Reporting Preference: ☐EMR ☐Fax ☐Email

Physician_____NPI #_____

Genetic Counselor _____

Street address 1 _____

Street address 2 _____

City _____State _____Postal code_____

Phone _____ Fax _____

Email_____

Send Additional Report Copies To:

Physician or GC/Acct # _____

Fax #/Email/CE #_____

Physician or GC/Acct # _____

Fax #/Email/CE #_____

Sample Information

Medical record # _____ Specimen ID _____

Date sample obtained (mm/dd/yy)_____

Specimen Type:

☐ Blood in BD Vacutainer® Collection Tube (4ml tube, 2mL blood)

☐ Saliva in DNAGenotek Oragene Tube (OG-510) (1 mL sample volume)

☐ Swab collected with DNAGenotek ORAcollect (OCR-100) device

☐ Blood spots collected on GE 903 Snap-Apart Card (4 blood spots)

☐ Other _____(Call lab before sending sample)

Patient has had an allogeneic bone marrow transplant ☐Yes ☐No

Date of last transfusion ____/____/____
(must be at least 2 weeks prior to blood draw for testing)

Statement of Medical Necessity

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 tests(s) requested herein. I confirm that I have provided genetic testing information to the patient and they have consented to genetic testing.

Medical Professional
Signature (required)_____Date_____

Patient Consent:

I have read the Informed Consent document (page 3), and I give permission to Otogenetics to perform genetic testing as described. I also give permission for my specimen and clinical information to be used in anonymized studies at Otogenetics and for publication, if appropriate. My name or other personal identifying information will not be used in or linked to the results of any studies and publications.

☐Check this box if you wish to opt out of research studies.

Patient Signature_____Date_____

Please Choose a Payment Option

☐ **Institutional Bill**

Account # _____

Hospital/Lab Name_____

Contact Name_____

Address_____

City_____State_____ Zip Code_____

Phone_____Fax_____

☐Please send a duplicate report to this address

☐ **Patient Bill**

I understand that my credit card will be charged the full amount for the testing.

Please bill my credit card (all major cards accepted)

☐MasterCard ☐Visa ☐Discover ☐American Express

Name on card_____Postal Code_____

Account #_____Exp. Date_____CVC_____

Signature _____Date_____

☐Please attach a copy of both sides of insurance cards for Otogenetics to request insurance reimbursement for your payment whenever applies

Disease Panel (All panels provide 100x average on-target coverage)	**Cat.#**	**Price**	**Select Test**
Human Deafness Genes DA4 (167 genes, 412kb capture)	Oto-DA	$1,245	
Human Usher Genes (10 genes, 70kb capture)	Oto-Usher	$1,245	

Do not write in this field. FOR LAB USE ONLY

Patient ID#_____

01062017

Clinical Information NOTE: DETAILED MEDICAL RECORDS MUST BE ATTACHED

Clinical Diagnosis:_____

ICD-9/10 Codes: _____Diagnosis Age(s): _____

Please check all that apply.

General Clincial History

- ☐ Amyotrophic Lateral Sclerosis
- ☐ Ataxia
- ☐ Autism
- ☐ Autoimmune Disorders
- ☐ Bleeding / Thrombotic Disorders
- ☐ Brain Malformation
- ☐ Cancer Susceptibility
- ☐ Cardiac Arrhythmia
- ☐ Cardiomyopathy
- ☐ Congenital Heart Defect
- ☐ Connective Tissue Disorders
- ☐ Craniofacial Abnormalities
- ☐ Deafness
- ☐ Developmental Delay
- ☐ Diarrheal Disorders
- ☐ Endocrine Disorders
- ☐ Epilepsy
- ☐ Eye Disorders, unspecified
- ☐ Kidney Abnormalities
- ☐ Liver Disease
- ☐ Metabolic Disorders
- ☐ Multiple Congenital Anomalies
- ☐ Muscular Dystrophy
- ☐ Neurologic Disorders, unspecified
- ☐ Primary Immunodeficiency
- ☐ Retinal Disorders
- ☐ Sexual Development Disorders
- ☐ Skeletal Dysplasia
- ☐ Skin Disorders
- ☐ Sudden Infant Death
- ☐ Sudden Unexplained Death
- ☐ Vascular Abnormalities
- ☐ Other:_____

Test Specific History

- ☐ Hearing Loss: Onset Age _____

Degree of Hearing Loss:

- ☐ Mild
- ☐ Moderate
- ☐ Severe
- ☐ Unilateral
- ☐ Bilateral
- ☐ Antibiotic Use Related Hearing Loss
- ☐ Conductive hearing loss
- ☐ Sensorineural hearing loss
- ☐ Congenital hearing loss
- ☐ Usher Syndrome
- ☐ Pendred Syndrome
- ☐ Hearing loss with EVA
- ☐ Branchio-Oto-Renal (BOR) syndrome
- ☐ Waardenburg Syndrome
- ☐ Stickler Syndrome
- ☐ Alport Syndrome
- ☐ Charcot-Marie-Tooth Disease
- ☐ Enlarged Vestibular Aqueduct
- ☐ Neurofibromatosis 2 (NF2)
- ☐ Recurring otitis media
- ☐ Recusrring otitis media with effusion
- ☐ Other:_____
- ☐ Refsum Disease
- ☐ Chudley-McCullough Syndrome

Additional History/Comments

Additional Description: _____

Differential Diagnosis: _____

Additional Suspected Gene(s): _____

Reference gene symbols from HGNC (HUGO Gene Nomenclature Committee http://www.genenames,org)

Family History

☐ Congenital Anomalies ☐ Mental Retardation ☐ Multiple Miscarriages ☐ Parental Consanguinty / degree of relation:_____

☐ Hearing Loss - Please detail below ☐ Other:_____

Family History of Clinical Conditions

☐ No Known Family History ☐ Pedigree Attached ☐ Adopted

Relationship	Maternal	Paternal	Condition / Symptoms	ICD 09 / 10
_____	☐	☐	_____	_____
_____	☐	☐	_____	_____
_____	☐	☐	_____	_____
_____	☐	☐	_____	_____
_____	☐	☐	_____	_____
_____	☐	☐	_____	_____

Family Member Testing

☐ Testing for a previously identified variant

Gene: _____ Variant: _____

Proband Name:_____Relationship to proband: _____

☐ Positive control included/will be sent - Positive control is recommended if previous test was performed at another lab.

☐ Positive control not available. Please initial to acknowledge acceptance of caveat language on a negative report_____

☐ Family Member Test Report included - A clear copy of the test report on the positive family member is recommended if previous test was performed at another lab.

Shipping the sample to:

Sample Receiving
Otogenetics Corporation
4553 Winters Chapel Rd, Suite 100
Atlanta, GA 30360
ph: 855-686-43632 email: support@otogenetikcs.com sample tracking information

General information about genetic testing for hereditary disorders:

1. Genetic disorders may be caused by variants (changes) in the DNA sequence of a gene. Genetic disorders may also be due to a deletion (loss) or duplication (gain) of genetic material. The deletion or duplication may include part of a gene, an entire gene, or multiple genes.

2. The purpose of genetic testing is to evaluate for changes in the DNA sequence of a gene and when clinically indicated, may look for deletions or duplications of gene(s). This test may help determine if I am affected with, or am at risk to someday develop a form of a hereditary disorder.

3. The genes included on this test are associated with several different types of disorders and with varying levels of abnormal phenotype.

4. This test cannot identify all types of variants, deletions, or duplications causing genetic disorders. Specifically, this test cannot identify any genetic changes involving genes not included in the specific test(s) ordered by my health care provider. In rare instances, the Next Generation Sequencing (NGS) may identify a clinically significant genetic variant in a gene not included on the panel ordered. These findings may be disclosed to the ordering healthcare provider on a case-by-case basis.

5. I understand that this test is not the only way to look for genetic abnormalities. My health care provider may recommend this test before or after ordering other genetic or laboratory tests.

6. This test requires high-quality DNA. In some cases an additional sample may be needed if the volume, quality and/or condition of the initial specimen is not adequate.

7. Rarely, the test may reveal genetic gender information or genetic changes of clinical importance in gene(s) not included in the test, which will be disclosed to the ordering healthcare provider.

What could I learn from this genetic test?

1. Negative result - I may learn that no genetic abnormality was identified by this test. This reduces the likelihood, but does not exclude a hereditary disorder.

2. Positive result - I may learn that a genetic abnormality was identified that explains either the cause of disorder that I have and/or the risk that I have to develop an abnormal phenotype in the future. The type(s) of abnormality which I have depends on the gene involved. These results may aid my physician in making decisions about my medical management, including but not limited to screening, monitoring, or treatment and preventive strategies.

3. Variant of unknown significance (VUS) - I may learn that a VUS was identified by this test. This means that a genetic change (variant) was identified, but it is unknown whether the variant may cause a disorder. The variant could be a normal genetic difference that does not cause medical problems, or it could be a variant causing abnormality. Without further information, the effects of the variant may not be known, and an inconclusive result may be reported. Testing other affected family members may be necessary to determine the significance of the variant. The laboratory will provide additional information to my healthcare provider who is ordering this testing if this variant is determined to be benign or risk-causing.

What are the limitations and risks of this genetic test?

1. In some cases, testing may not identify an abnormality even though a genetic abnormality may exist. This may be due to limitations in current knowledge about a gene's complete structure. It may be due to the fact that some types of genetic abnormalities causing a specific hereditary disorder have not yet been identified. I understand that the methods used by Otogenetics are highly accurate. However, the chance of a false positive or false negative result, due to laboratory errors incurred during any phase of testing, or due to unusual circumstances (bone marrow transplantation, blood transfusion, presence of change(s) in such a small fraction of cells that they may not be detectable (mosaicism) or incorrect reporting of family history or relationships), cannot be completely excluded.

2. Accurate interpretation of the test results requires knowledge of the true biological relationships in a family. Failure to accurately disclose the biological relationships in a family may result in incorrect interpretation of results and/or inconclusive test results.

3. Genetic testing may reveal that the true biological relationships in a family are not as they were reported. For example, non-paternity means that the stated father of an individual is not the true biological father. It is possible that this test may detect non-paternity, and it may be necessary to report this finding to the individual(s) who requested testing.

4. You may be concerned about discrimination based on genetic test results. The federal government enacted the Genetic Nondiscrimination Act (GINA) of 2008 prohibiting this type of discrimination by health insurers and employers. Furthermore, genetic test results are deemed "Protected Health Information" per the Health Insurance Portability and Accountability Act (HIPAA) of 1996 which prohibits unauthorized disclosure of such information. These laws set a minimum standard of protection across the nation. Some states may have laws limiting the use of genetic information by other types of insurers as well. For additional information about these regulations, visit http://www.genome.gov/10002077.

5. The physical risk associated with this genetic test is that of the blood draw required in order to obtain the DNA. While the risk is low, some people may experience side effects such as soreness, bruising, dizziness, or fainting. Lower risks are associated with saliva samples.

Patient confidentiality and counseling:

1. To maintain confidentiality, I understand that results will be reported to the indicated healthcare provider or ordering laboratory and upon request copied to additional healthcare provider(s) indicated on the test requisition form (page 1). I understand that results may only be disclosed to others by my written consent and/or if demanded by an order of a court of competent jurisdiction.

2. Information obtained from the test may be used in scientific publications or presentations, but the identity of all individuals studied will not be revealed in such publications or presentations.

3. It is recommended that I receive genetic counseling before and after having this test. Further testing or additional consultations with physicians may be necessary.

Specimen retention

1. Submitted specimens will be banked at Otogenetics. DNA samples are not returned to individuals or to referring physicians unless requested.

2. In some cases, if further diagnostic tests are needed, a referring physician may request in writing that additional tests be performed on an existing DNA sample (additional costs apply). Additional testing will not be performed unless requested by an authorized healthcare professional.

3. In some cases, anonymized DNA may be used by the laboratory for new test development and/or laboratory quality assurance purposes after all identifiers have been removed.

4. NY residents: DNA sample can be retained for greater than 60 days after the completion of testing.