EXPRESS GENE MOLECULAR DIAGNOSTICS LABORATORY
EXPRESS GENE expressgene.us

Hearing Impairment (Hearing) Genetic Test Requisition & Consent Form

9000 SW 152 Street Ste. 209
Miami • FL • 33157
Tel: 786.250.3419 • Fax: 786.250.3074
Email: info@expressgene.us

CLIA ID # 10D2178891

1. PATIENT INFORMATION

Last Name:	First Name:	Gender: ☐ M ☐ F	DOB:
Address:	City:	State:	Zip:
Email:	MRN:		Phone:
Ethnicity: ☐ African American ☐ Ashkenazi ☐ East Asian ☐ Hispanic ☐ White ☐ Middle Eastern ☐ Other			

2. INSURANCE INFORMATION (Include copy of both sides of insurance card)

Insurance Name:	Policy #:	☐ HMO	Auto#
Relation: ☐ Self ☐ Spouse ☐ Child	Name, DOB of Policy Holder (If not self):		

3. ORDERING PHYSICIAN INFORMATION & FACILITY CONTACTS

Provider Name:	NPI:	Provider Phone:	Fax:
Provider Address:	City:	State:	Zip:
Facility Name:	Contact Person:	Email:	

Confirmation of Informed Consent and Medical Necessity for Genetic Testing:

My signature below certifies that I am a licensed medical professional or his/her representative or a genetic counselor authorized to order genetic testing. My signature further acknowledges the patient has been supplied information regarding genetic testing and has been informed about the purpose, limitations, and possible risks. The patient has been given the opportunity to ask questions about this consent and seek outside genetic counseling. The patient has given consent for genetic testing to be performed and the signed consent form is on file. I confirm that this testing is medically necessary for the specified patient, and that these results will be used in the medical management and treatment decisions for this patient. I confirm that the patient has been informed and hereby authorizes (i) Express Gene Molecular Diagnostics to release information concerning their testing to their insurer to obtain reimbursement for the testing services; (ii) Express Gene Molecular Diagnostics to be paid directly by the insurer for services rendered; and/or if applicable (iii) Express Gene Molecular Diagnostics or its affiliates to be the patient's designated representative for the purpose of appealing any denial of insurance benefits. I confirm the patient fully understands they are legally responsible for sending Express Gene Molecular Diagnostics any and all of the money that they receive directly from their insurance company in payment for this testing.

Medical Professional Signature_____DATE_____

4. SPECIMEN COLLECTION INFORMTION:

Specimen Collection Type: ☐ Blood ☐ Buccal Smear ☐ Other (specify)_____	Collection Date/Time:
Collector Name:	Collection Place: ☐ Office ☐ Lab ☐ Home ☐ Outpatient ☐ Other____

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5. TESTING PANELS:

☐ **Express Gene™ Hearing Impairment (Hearing) Genetic Testing Panel**

The Hearing Impairment (Hearing) Genetic Testing Panel is a cutting-edge genetic testing panel meticulously designed to identify various forms of hearing impairment. Comprising 184 carefully selected genes, this panel is designed to identify variations associated with both syndromic and non-syndromic forms of hearing impairment. Also, different inheritance pattern, such as dominant, recessive, X-Linked are covered. List of 216 genes on our website: www.expressgene.us

VARIOUS SUB-PANELS:

☐ Express Gene™ Usher Syndrome (21 genes)

☐ Express Gene™ Syndromic Hearing loss panel (62 genes)

☐ Express Gene™ Congenital Hearing panel (92 genes)

For further details, please visit www.expressgene.us

6. INDICATIONS FOR TESTING (CHECK ALL THAT APPLY):

Diagnostics ☐ Family History ☐ Recurrent or unexplained infections ☐ Patient Management ☐

Relevant ICD-10 codes:

7. CLINICAL INFORMATION

Other Relevant ICD-10 Codes:

List Relevant family history of disease: Affected Family Member and Relationship to Patient:

Previous Genetic Testing: ☐ No ☐ Yes
If Yes reason_____ Date of Previous Test_____

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8. INFORMED CONSENT & PATIENT SIGNATURE

Informed Consent:

Consent to Testing and Use of Results: The specimen identified on this form is my own. I have not contaminated it in any way. I am voluntarily submitting this specimen for analysis by my physician and/or Express Gene Molecular Diagnostics Laboratory. I authorize Express Gene Molecular Diagnostics Laboratory to release the test results to the ordering practitioner. I further authorize the lab and my healthcare provider to release to my insurance provider any medical information necessary to process the claim.

Consent for Genetic Testing: Your doctor has ordered the Genetics Test. This is a test for variations in genes that affect your overall health and wellbeing or response to treatment. If variant(s) are present, it may indicate a higher-than-average risk for developing diseases. It will help in evaluating the risk of having or being a carrier of a heritable disease. A lack of the mutation does not completely rule out the disease, since some variations are still unknown, and their significance have not been investigated. Additionally, there is a limitation on NGS sequencing methodology, that certain variation might not being captured or identified with this method. Results from this test(s) are treated with complete confidentiality and reports rendered only to the patient and his/her physician. Patient samples will be saved for 30 days and then destroyed after testing. I have read this consent or have had it read to me. I have been given a copy of this form. I have been given the chance to ask questions before I sign this form. I have been told that I can ask other questions at any time. I want to have this genetic test done.

Consent use of sample or data for research: To improve genetic testing results and solve unexplored genetic diseases, I understand and agree that my leftover specimen, genetic data, and/or clinical information may be used anonymously for research, education, and other business purposes. I hereby authorize Express Gene Molecular Diagnostics Laboratory to contact me in future regarding disease symptoms, recently discovered genes, mutations or to follow up on disease outcomes**. To opt out on this section you can cross out this paragraph and sign below, without affecting processing of your tests**.

Consent / Insurance Release: By signing this form, I hereby authorize Express Gene Molecular Diagnostics to submit the medical information regarding this testing to my designated insurance carrier for reimbursement if necessary. I also authorize benefits to be payable to Express Gene Molecular Diagnostics. I understand that I am responsible for any amounts not paid by insurance for reasons, but not limited to non-covered and non-authorized services. I permit a copy of this authorization to be used in place of the original.

Patient Signature_____DATE_____

Print Name: _____

Medical Professional Signature_____DATE_____

Print Name: _____

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6. DIAGNOSIS ICD-10 CODE (List is only provided as a guide, no limitation to these codes)

ICD-10 Code for Hearing Loss:

Sensorineural Hearing Loss: H90.3
Conductive Hearing Loss: H90.0
Mixed Hearing Loss: H90.6
Unspecified Hearing Loss: H90.9

Genetic Disorders that also include hearing loss:

Disorders of Bone Density and Structure and hearing impairment: Q78.9
Other Disorders of the Nervous System and hearing impairment: G99.8
Other Specified Congenital Anomalies and hearing impairment: Q89.8
Other Disorders of Kidney and Ureter and hearing impairment: Q63.8
Congenital Anomalies of Integument and hearing impairment: Q82.8

7. ELIGIBILITY CRITERIA

Eligibility criteria for Hearing Impairment Genetic Testing panel.

1- Clinical Symptoms or Family History:

Individuals with a family history of hearing impairment.
Individuals exhibiting clinical symptoms of hearing loss, speech delay, or other related issues.

2- Age Considerations:

Testing might be recommended at different ages, depending on the specific genes being assessed. For example, genetic testing for adult-onset hearing impairment, would be at the age of onset, while congenital hearing loss may be recommended in infancy.

3- Referral by Healthcare Professionals:

Typically, individuals are referred for genetic testing by healthcare professionals, based on their symptoms, medical necessity, and treatment plan.

4- Diagnostic Uncertainty:

When there is uncertainty about the cause of hearing impairment, genetic testing may be recommended to identify specific genetic factors.

5- Syndromic Hearing Loss:

Individuals with syndromic forms of hearing loss, where hearing impairment is associated with other medical conditions or abnormalities.

6- Pre-conception or Prenatal Testing:

For individuals planning to start a family or during pregnancy, genetic testing may be offered to assess the risk of passing on genetic conditions related to hearing impairment.