Mass General Brigham

Personalized Medicine
Laboratory for Molecular Medicine
65 Landsdowne Street • Cambridge, MA 02139
Phone: (617) 768-8500 • Fax: (617) 768-8513
The LMM is a satellite facility of Massachusetts General Hospital. • CLIA # 22D1005307

SPECIMEN INFORMATION

Specimen: ❑ Blood
❑ Saliva *(NOT accepted for panel testing, only for Familial Variant Testing.)*
❑ Cord Blood *
❑ DNA derived from (*Choose One*):
❑Whole Blood ❑ Cord Blood* ❑ CVS* ❑ Amnio* ❑ Other_____
**Maternal cell contamination studies must be completed prior to sending and report must be attached to this form.*

Date Collected: (mm/dd/yyyy) _____ / _____ / _____

PATIENT INFORMATION

First name: _____ MI: _____

Last name: _____

Date of Birth: (mm/dd/yyyy) _____ / _____ / _____

Gender: ❑ Male ❑ Female ❑ Unknown/Unspecified

Is patient pregnant? ❑ No ❑ Yes EDD:_____

Address: _____

City: _____ State: _____ Zip Code: _____

Phone: _____

Email: _____

Institution: _____

Medical Record Number: _____

Is the patient adopted? ❑ No ❑ Yes

Is the patient deceased? ❑ No ❑ Yes, date:_____

Race and Ethnicity: *Please check **ALL** that apply*

❑ White ❑ Ashkenazi Jewish ❑ Asian
❑ Hispanic ❑ Black/African American
❑ Native Hawaiian or other Pacific Islander
❑ American Indian/Native Alaskan ❑ Other _____

REFERRING PROVIDER INFORMATION

Referring Provider

Name (First, Last): _____

Phone: _____ Fax: _____

Email: _____

Institution: _____

Address: _____

_____

City: _____ State: _____

Zip Code: _____ Country: _____

Genetic Counselor / Additional Contacts

Name (First, Last): _____

Phone: _____ Fax: _____

Email: _____

Institution: ❑ Same as Referring Provider ❑ Provided below

_____

_____

Place facility sticker here

_____

_____

PAYMENT INFORMATION

Please note: *Payment information must be completed for testing to begin.*

❑ **Patient Pay** (please complete section in its entirety)**

❑ **Check** (*please attach to forms*)*

Please make checks payable to **Partners Personalized Medicine**

❑ **Credit card** (*please fill out credit card information in its entirety*)

Card type: ❑ Mastercard ❑ Visa ❑ AMEX

Name (as it appears on card): _____

Credit card number: _____

Expiration Date: _____ **3 Digit Security Code:** _____

For patient pay, please provide billing address and contact information. If same as above, please note section as such.

❑ **Referring Institution** (please complete section in its entirety)

For new referring facilities, please complete and submit the New Institution Add Form

Bill to Name/Department: _____

Address: _____

_____

City: _____ State: _____

Zip Code: _____ Country: _____

Phone: _____

Contact Person: _____

Patient Pay Billing Address: _____

City: _____ State: _____ Zip Code: _____ Country: _____

Home: _____ Cell/Work: _____ Email: _____

Patient Name: _____ Date of Birth: _____/_____/_____ (MM/DD/YYYY)

SPECIMEN & SHIPPING REQUIREMENTS

The preferred blood specimen is a 7 ml blood sample (3-5ml for infants) collected in a lavender top (K_2EDTA or K_3EDTA) blood tube. Smaller blood samples or other tissue specimens may also be acceptable for certain tests. All samples must have two patient identifiers, preferably the patient's name and date of birth. Please contact the laboratory for more details.

Each sample must be accompanied by a requisition form (available at Partners.org/PersonalizedMedicine/Laboratory-For-Molecular-Medicine/Ordering). The ordering provider must sign the declaration below.

The blood sample (with forms) should be shipped overnight at room temperature to:

Laboratory for Molecular Medicine
65 Landsdowne Street
Cambridge, MA 02139

For more detailed information about shipping requirements and procedures, see our website Partners.org/PersonalizedMedicine/Laboratory-For-Molecular-Medicine/Ordering/Sample-Requirements-Payment-Shipping.

LABORATORY FOR MOLECULAR MEDICINE POLICIES

By requesting testing from the Laboratory for Molecular Medicine (LMM), the ordering provider indicates that he/she understands AND accepts the policies of the LMM, as noted below, and has communicated these policies to the patient.

1. Our testing process includes highly skilled technicians and advanced technology. As in any laboratory, there is a small possibility that the test will not work properly, or an error may occur.
2. Listed turn around times (TATs) represent the typical TAT for a test, but are not guaranteed.
3. If the requisition form is incomplete, and the healthcare provider cannot provide the required information, lab staff may need to contact patients directly to obtain or verify the information needed to complete the form.
4. Test results, as well as any updates to those results, may become part of a patient's permanent medical record (electronically or otherwise) or be made available (electronically or otherwise) to the ordering healthcare institution and its healthcare team.
5. Results will only be released to the ordering provider and other providers listed on the requisition form. The ordering provider assumes the responsibility to disclose the test results and direct care as appropriate.
6. The ordering provider can obtain access to your genomic sequence files for the purpose of your clinical care.
7. Test results and submitted clinical information may be shared with other clinical laboratories for the purpose of improving our understanding of the relationship between genetic changes and clinical symptoms. Sharing data in this manner may enable us to provide better interpretations of your genetic findings as well as assist other patients with similar results. We will protect your prvacy/confidentiality by removing your name and other direct identifiers, such as SSN or medical record number, from data shared with other laboratories.

RESEARCH POLICIES & OPPORTUNITIES

Blood or other samples sent to the LMM may be used by Partners Healthcare System (PHS), by medical organizations connected to PHS, or by educational or business organizations approved by PHS, for IRB approved research, education and other activities that support PHS's mission, without your/the patient's specific consent. Other types of research performed in association with the Laboratory for Molecular Medicine require that we obtain consent from the patient (see below).

PATIENTS - Please check off and initial below whether we can contact you to let you know about research studies in which you/your child may be able to participate. These research studies may include:

- A request for additional clinical records about your condition
- Studies to find new causes for your condition
- Studies to evaluate newly developed treatments for your condition

Please check one option: _____ Yes, you can contact me _____ (patient initials)
If yes, please provide your contact information on the first page
_____ No, please do not contact me _____ (patient initials)

ORDERING PROVIDER SIGNATURE

I, _____ (print name), as ordering provider, certify that the patient being tested and/or their legal guardian have been informed of the risks, benefits, and limitations of the testing ordered, as well as the policies of the LMM listed above. I have obtained informed consent, as required by my own state and/or federal laws. In addition, I assume responsibility for returning the results of genetic testing to my patient and/or their legal guardian and for ensuring that my patient receives appropriate genetic counseling to understand the implications of their test results.

_____

Signature (Ordering Provider) Date

Please Note: A patient consent form is available on our website (Partners.org/PersonalizedMedicine/Laboratory-For-Molecular-Medicine/Ordering/Policies) for your convenience and DOES NOT need to be returned to the LMM.

HEARING LOSS REQUISITION FORM

Patient Name: _____ Date of Birth: _____/_____/_____ (MM/DD/YYYY)

TESTING TO BE PERFORMED

Check box(es) to order test(s). For reflex testing, indicate order of testing in space provided (i.e. 1, 2, 3).

Otogenome Test

____ ❑ OtoGenome™ Test for Hearing Loss and Related Syndromes (110 Genes)*

OtoGenome Test is performed via next-generation sequencing (NGS) and includes CNV analysis when NGS data meets necessary quality standards. Includes Usher, Pendred, Jervell and Lange-Nielsen, Branchio-Oto-Renal, Waardenburg, Alport, Alstrom, Muckle-Wells, Deafness Infertility syndromes. This test also encompasses the Connexin Test, Comprehensive DFNB1 and STRC Panel, and STRC only tests listed below.

____ ❑ **REFLEX** to OtoGenome™ Test for Hearing Loss (110 Genes)*

Common Autosomal Recessive Hearing Loss Test

____ ❑ Connexin Test: GJB2 Sequencing and DFNB1 (GJB6) Deletion

Pendred Syndrome or Hearing Loss with EVA

____ ❑ *SLC26A4* (PDS) Gene Sequencing Test

Low Frequency Nonsyndromic Hearing Loss and Wolfram Syndrome

____ ❑ *WFS1* Gene Sequencing Test

X-linked Hearing Loss with Perilymphatic Gusher

____ ❑ *POU3F4* Gene Sequencing Test

FAMILIAL VARIANT TEST

Familial Variant Testing

(*First 3 variants, $500; each additional variant, $50.)*

____ ❑ Familial Variant(s) OR ❑ Research Confirmation

(If proband testing was performed elsewhere, please attach a copy of the original result and send positive control sample, if available.)

Gene #1_____Variant #1_____

Gene #2_____Variant #2_____

Gene #3_____Variant #3_____

Gene #4_____Variant #4_____

Proband Name_____ Relationship to Proband_____

LMM Accession #: PM-_____

PLEASE PROCEED TO PAGE 4 TO COMPLETE THE FAMILY HISTORY

HEARING LOSS REQUISITION FORM

Patient Name: _____ Date of Birth: _____/_____/_____ (MM/DD/YYYY)

CLINICAL INFORMATION

Clinical status: ❑ Affected ❑ Unknown (no screening/evaluation) ❑ Unaffected (all screening/evaluation(s) normal)
Purpose of study: ❑ Diagnostic ❑ Carrier testing ❑ Other: _____

Age at onset of hearing loss: _____ **ICD-10 Codes:** ❑ H90.5 (unspecified sensorineural hearing loss)
❑ Other _____

Type of hearing loss: ❑ Sensorineural ❑ Conductive ❑ Auditory neuropathy/dys-synchrony ❑ Mixed
Laterality: ❑ Bilateral ❑ Unilateral
Progression: ❑ Stable ❑ Progressive ❑ Fluctuating ❑ Unknown

Severity (PTA): **Please attach audiogram if available**
Left Ear: ❑ Mild (15-30dB) ❑ Moderate (31-50dB) ❑ Moderately-severe (51-70dB) ❑ Severe (71-90dB) ❑ Profound (>90db)
Right Ear: ❑ Mild (15-30dB) ❑ Moderate (31-50dB) ❑ Moderately-severe (51-70dB) ❑ Severe (71-90dB) ❑ Profound (>90db)

Audiogram shape/frequencies:
Left Ear: ❑ Flat (all frequencies) ❑ Sloping (high frequency) ❑ Saucer-shaped (mid frequency) ❑ Rising (low frequency)
Right Ear: ❑ Flat (all frequencies) ❑ Sloping (high frequency) ❑ Saucer-shaped (mid frequency) ❑ Rising (low frequency)

Exposure to aminoglycoside antibiotics (e.g gentamicin, neomycin, tobramycin, amikacin): ❑ Yes ❑ No ❑ Unknown

Auditory neuropathy/dys-synchrony:
- ❑ No
- ❑ Present OAEs
- ❑ Absent ABR w/ cochlear microphonic
- ❑ Unknown

BOR features:
- ❑ None
- ❑ Ear tags
- ❑ Ear abnormalities
- ❑ Branchial arch abnormality
- ❑ Renal abnormality
- ❑ Other (explain):_____

Electrocardiogram (ECG) finding:
- ❑ None
- ❑ Long QT
- ❑ Unknown
- ❑ Other (explain): _____

Eye finding:
- ❑ None
- ❑ Unknown
- ❑ Retinitis pigmentosa - Age of onset:_____
- ❑ Other (explain): _____

Temporal bone abnormalities on CT/MRI:
- ❑ None
- ❑ EVA (enlarged vestibular aqueducts)
- ❑ Mondini dysplasis
- ❑ Stapes fixation
- ❑ Perilymphatic gusher
- ❑ Unknown
- ❑ Other (explain):_____

CAPS/Muckle Wells features:
- ❑ Uticaria-like rash
- ❑ Conjunctivitis
- ❑ Nephritis
- ❑ Amyloidosis

Vestibular problems:
- ❑ None
- ❑ Delayed walking
- ❑ Dizziness/Vertigo
- ❑ Balance problems
- ❑ Unknown

Waardenburg features:
- ❑ None
- ❑ White forelock
- ❑ Heterochromia
- ❑ Hypoplastic/vivd blue irises
- ❑ Dystopia canthorum
- ❑ Musculoskeletal abnl.
- ❑ Hirschsprung

Alport features:
- ❑ Hematuria
- ❑ Proteinuria
- ❑ ESRD

Previous genetic testing: ❑ No ❑ Yes - Test/Results:_____

Other relevant medical problems: ❑ None ❑ Yes (explain): _____
Has another family member already had genetic testing for this disease? ❑ No ❑ Yes
If yes, please describe and attach a copy of the genetic test lab report and pedigree.

FAMILY HISTORY

Sibling with or other family history of similar hearing loss? ❑ Yes ❑ No
List affected individuals and the nature of their hearing loss (Sketch below or attach pedigree if appropriate):_____
_____
_____

Paternal Ancestry:_____
Maternal Ancestry:_____
Consanguinity: ❑ Yes ❑ No

○ = Female □ = Male ◇ = Gender Unspecified
● ■ ◆ = Affected Individual ⊙= Carrier

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