PREVENTION GENETICS part of EXACT SCIENCES

Test information is available on our website:
PreventionGenetics.com

PREVENTIONGENETICS USE ONLY

All testing must be ordered by a qualified Healthcare Provider

THIS FORM MUST ACCOMPANY ALL SPECIMENS

SPECIAL PROJECT - TEST REQUISITION FORM
SP249 - REGENERON PHARMACEUTICALS AMPLIFY™ SPONSORED TESTING PROGRAM

PERSON COMPLETING FORM	CONTACT (PHONE AND EMAIL)	DATE OF REQUEST (MM/DD/YYYY)

PATIENT INFORMATION

LAST (FAMILY) NAME	FIRST NAME	MI	DATE OF BIRTH (MM/DD/YYYY)

PATIENT ID	MEDICAL RECORD NUMBER (MRN)	SPECIMEN COLLECTION DATE (MM/DD/YYYY) *If no collection date is provided, date of receipt will be used.*	GEOANCESTRY / ETHNICITY
			☐ Asian ☐ Black/African American ☐ White/Caucasian ☐ Ashkenazi Jewish ☐ Hispanic ☐ Native American ☐ Pacific Islander ☐ French Canadian ☐ Sephardic Jewish ☐ Mediterranean ☐ Other: _____

HAS PATIENT BEEN TESTED PREVIOUSLY AT PREVENTIONGENETICS?
☐ NO
☐ YES, PG ID# _____

SPECIMEN SOURCE
☐ Blood ☐ Saliva
☐ Buccal ☐ Other _____

BIOLOGICAL SEX
☐ Male ☐ Female
☐ Other _____ *SPECIFY KARYOTYPE*

HAS PATIENT'S RELATIVE BEEN TESTED AT PREVENTIONGENETICS?
☐ NO ☐ YES, provide
_____ *NAME* _____ *DATE OF BIRTH*
_____ *RELATIONSHIP TO PATIENT* _____ *or PreventionGenetics ID NUMBER*

BLOOD TRANSFUSION
☐ NO ☐ Within last 30 days, provide
_____ *MM/DD/YYYY*
_____ *TYPE*

BONE MARROW TRANSPLANT
☐ NO ☐ YES
_____ *MM/DD/YYYY*

CLINICAL HISTORY

Family History

Is there a family history of hearing loss? ☐ Yes ☐ No If yes, describe below and attach pedigree and/or clinical notes.

RELATIONSHIP TO PATIENT	SELECT	DIAGNOSED CONDITION	AGE AT DIAGNOSIS
	☐ Maternal ☐ Paternal		
	☐ Maternal ☐ Paternal		
	☐ Maternal ☐ Paternal		
	☐ Maternal ☐ Paternal		
	☐ Maternal ☐ Paternal		

Required Personal History

This is information is required to enter the program and we need the clinician to document.

	RIGHT EAR	LEFT EAR
Hearing loss severity *SELECT ALL THAT APPLY*	☐ Mild (26-40 dB) ☐ Moderate (41-55 dB) ☐ Moderately-Severe (56-70 dB) ☐ Severe (71-90 dB) ☐ Profound (>90 dB)	☐ Mild (26-40 dB) ☐ Moderate (41-55 dB) ☐ Moderately-Severe (56-70 dB) ☐ Severe (71-90 dB) ☐ Profound (>90 dB)
Does patient have cochlear implant?	☐ Yes ☐ No	☐ Yes ☐ No

Required Clinical History

Other Clinical Features:

☐ None
☐ Skeletal abnormalities
☐ Optic atrophy
☐ Renal abnormalities
☐ Other visual disturbances
☐ Charcot-Marie-Tooth disease
☐ Developmental delay
☐ Ataxia and/or dystonia
☐ Other clinical features(s) (please specify): _____

Environmental Factors:

Is this patient known to have experienced any of the following? ☐ Premature birth ☐ Kernicterus ☐ Perinatal hypoxia

ELIGIBILITY CRITERIA

This program is available to patients in the U.S. (BOTH OPTIONS MUST BE SELECTED FOR THE PATIENT TO BE ELIGIBLE):

☐ Patient is less than 18 years of age
☐ Medical history consistent with auditory neuropathy diagnosis:
- Absent or highly abnormal ABR
- Presence of OAEs and/or cochlear microphonic (CM)

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TEST SELECTION

TEST CODE	DESCRIPTION	SPECIAL INSTRUCTIONS
15747	Amplify Hearing Loss Panel*	**SP249**

ADDITIONAL INFORMATION OR SPECIAL INSTRUCTIONS REGARDING TEST ORDER

☐ **SPECIMEN COLLECTED IN NEW YORK STATE**
Include Genetic Testing Healthcare Provider Statement and New York State Non-Permitted Laboratory Test Request approval letter if test is not NY state approved. For a list of NY state approved tests, see website.

*Genes: *A2ML1, ABHD12, ABHD5, ACOX1, ACTB, ACTG1, ADCY1, ADGRV1, AIFM1, ALMS1, ANLN, AP1B1, ARSB, ARSG, ASIC5, ATOH1, ATP1A3, ATP2B2, ATP6V1B1, BCAP31, BCS1L, BDP1, BSND, BTD, CABP2, CACNA1D, CATSPER2, CCDC50, CD151, CD164, CDC14A, CDH23, CEACAM16, CEP250, CEP78, CHD7, CIB2, CISD2, CLDN14, CLDN9, CLIC5, CLPP, CLRN1, CLRN2, COCH, COL11A1, COL11A2, COL1A1, COL2A1, COL4A3, COL4A4, COL4A5, COL4A6, COL9A1, COL9A2, COL9A3, CRYM, DBH, DCAF17, DCDC2, DIABLO, DIAPH1, DIAPH3, DMXL2, DNAJC3, DNMT1, DSPP, DTNA, EDN3, EDNRA, EDNRB, EFTUD2, ELMOD3, EPS8, EPS8L2, ERAL1, ESPN, ESRRB, EYA1, EYA4, FDXR, FGF3, FGFR3, FITM2, FOXC1, FOXI1, GALNS, GATA3, GDF6, GIPC3, GJA1, GJB1, GJB2, GJB3, GJB6, GLB1, GNS, GPRASP2, GPSM2, GRAP, GREB1L, GRHL2, GRXCR1, GRXCR2, GSDME, GUSB, HARS1, HARS2, HGF, HGSNAT, HOMER2, HOXA2, HSD17B4, HYAL1, IDS, IDUA, IFNLR1, ILDR1, JAG1, KARS1, KCNE1, KCNJ10, KCNQ1, KCNQ4, KITLG, LARS2, LHFPL5, LHX3, LMX1A, LOXHD1, LOXL3, LRP2, LRTOMT, MAFB, MAN2B1, MAP1B, MARVELD2, MCM2, MEOX1, MEPE, MET, MIR96, MITF, MPZ, MPZL2, MRPS2, MSRB3, MYH14, MYH7B, MYH9, MYO15A, MYO18B, MYO3A, MYO6, MYO7A, NAGLU, NARS2, NDP, NDRG1, NF2, NLRP3, NOG, OPA1, OSBPL2, OTOA, OTOF, OTOG, OTOGL, P2RX2, PAX3, PCDH15, PCGF2, PDE1C, PDZD7, PEX1, PEX10, PEX11B, PEX12, PEX13, PEX14, PEX16, PEX19, PEX2, PEX26, PEX3, PEX5, PEX6, PEX7, PHYH, PJVK, PLS1, PLS3, PMP22, PNPT1, POLR1C, POLR1D, POU3F4, POU4F3, PRKCB, PRPS1, PTPRQ, RAI1, RDX, REEP6, REST, RIPOR2, RMND1, ROR1, RPS6KA3, S1PR2, SCP2, SEMA3E, SERAC1, SERPINB6, SGSH, SH3TC2, SIX1, SIX2, SIX5, SLC12A2, SLC17A8, SLC22A4, SLC26A4, SLC26A5, SLC29A3, SLC44A4, SLC4A11, SLC52A2, SLC52A3, SLC9A1, SLITRK6, SMPX, SNAI2, SOX10, SPNS2, STRC, SYNE4, TBC1D24, TBX1, TCOF1, TECTA, TFAP2A, TIMM8A, TJP2, TMC1, TMEM126A, TMEM132E, TMEM43, TMIE, TMPRSS3, TNC, TPRN, TRIOBP, TRMT10C, TRRAP, TSHZ1, TSPEAR, TUBB4B, TWNK, UBR1, USH1C, USH1G, USH2A, VCAN, WBP2, WFS1, WHRN, XYLT2, ZNF469*

GENETIC COUNSELING

Telehealth genetic counseling with Genome Medical, a national telegenetics care provider, is available at no cost to patients through this sponsored testing program. Genetic counseling via telephone appointment is available for patients to provide information, education, support and address questions related to sponsored genetic testing and results..

By checking the box below, my patient has agreed to allow PreventionGenetics to facilitate the provision of post-test genetic counseling services by Genome Medical.

☐ Post-test genetic counseling referral to Genome Medical (only if an individual has identified variants classified as uncertain, likely pathogenic, or pathogenic).

Provide the patient's phone number and email address to enable Genome Medical to contact the patient to schedule their genetic counseling appointment.

PATIENT PHONE NUMBER

PATIENT EMAIL ADDRESS

U.S. STATE WHERE PATIENT RESIDES (REQUIRED)

Patients will receive a text message to schedule an appointment if they have SMS texting available on their phone.

- If Power of Attorney for medical decisions/ communication is needed, the patient/ family will need to provide documentation to Genome Medical upon scheduling their GC appointment.

PROVIDER CONSENT

By signing below, you, the Healthcare Provider, agree you have obtained the patient's (or parent/guardian's if patient is a minor) informed consent to perform this test, and confirm the patient has been appropriately counseled and understands the risks, benefits, and limitations of this genetic testing and the implications of the results. You further confirm the patient authorizes PreventionGenetics to use and disclose de-identified patient test data and results ("De-identified Data") to promote research and improve the diagnosis and treatment of the genetic diseases. The De-identified Data may be used for research purposes as well as to facilitate and improve the diagnosis of genetic changes and diseases in other patients. For these reasons, PreventionGenetics may disclose De-identified Data with external physicians, scientists, researchers and pharmaceutical companies. No protected health information will be shared. As the Healthcare Provider, you hereby authorize PreventionGenetics to share your name, institution, address, and contact information with Regeneron Pharmaceuticals, and consent to Regeneron Pharmaceuticals contacting you.

HEALTHCARE PROVIDER SIGNATURE | PRINTED NAME | DATE

3800 S. Business Park Ave., Marshfield, WI 54449 USA • PreventionGenetics.com
Phone: (715) 387-0484 · General Fax: (715) 406-4175 · Billing Fax: (715) 207-6602 · Email: support@preventiongenetics.com
CLIA 52D2065132 · CAP 7185561 · NPI 1114140571 · ISO 15189:2012 #3950.01

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PROVIDER INFORMATION AND REPORTING

Our preferred method of report transmission is uploading to our secure web portal, myPrevent.
Please provide an email address, when possible. If you have additional specific reporting requests, indicate them BELOW.

PROVIDER INFORMATION

INSTITUTION

ADDRESS	**CITY**	**STATE**	**ZIP**

REQUESTING PHYSICIAN (First, Last, Degree)	**REQUESTING GENETIC COUNSELOR OR ALLIED PROVIDER** (First, Last, Degree)
EMAIL ADDRESS (For report access via myPrevent)	**EMAIL ADDRESS** (For report access via myPrevent)

PHONE NUMBER	**NPI# (US ONLY)**	**PHONE NUMBER**	**NPI# (US ONLY)**

IF YOU REQUIRE REPORTS TO BE TRANSMITTED VIA ANOTHER SECURE METHOD, SPECIFY HERE.

LIST ADDITIONAL HEALTHCARE PROVIDERS AND THEIR EMAILS TO ALLOW ACCESS TO REPORTS

INSTITUTIONAL BILLING

BILLING ID	**SPECIAL PROJECT NUMBER**
REGENER10249	**SP249**

SPECIMEN REQUIREMENTS / SHIPPING AND HANDLING INSTRUCTIONS

Label all specimen containers with the patient's name, date of birth, and/or ID number. At least two identifiers should be listed on specimen containers. Specimen deliveries are accepted Monday-Saturday for all specimen types. However, urgent and/or sensitive specimens, such as cell cultures, direct amniotic fluid, or direct chorionic villi, are preferred to arrive Monday-Thursday. Urgent/sensitive specimens shipped on Thursday should be marked for overnight delivery; those sent Friday should be marked for overnight and Saturday delivery. Contact us to make arrangements. Holiday schedules will be posted on our website at least one week prior to major holidays.

WHOLE BLOOD
Requirements: Collect 3 ml - 5 ml of whole blood in EDTA (purple top tube) or ACD (yellow top tube), minimum 1 ml for small infants. Heparin (green top tube) is strongly discouraged.

Shipping: At room temperature or refrigerated, a blood specimen is stable for up to 8 days. Include a refrigerated gel pack in the shipping container. Fresh blood specimens are preferred. If frozen, a blood specimen is stable for up to 1 month before shipping. Frozen blood specimens should be shipped frozen (preferably on dry ice) overnight.

SALIVA
Requirements: Oragene™ or GeneFiX™ Saliva Collection kit used according to manufacturer instructions. DNA from saliva specimens is invariably contaminated with microbial and food DNA, which can impact specimen quality and may result in delayed testing and/or the need for a second specimen.

Additional instructions to help families collecting samples at home are included in each home saliva kit order.

Shipping: Specimens may be shipped at room temperature.

BUCCAL SWAB (OCD-100 Preferred)
Requirements: OCD-100 Buccal Swab used according to manufacturer instructions. Buccal swabs are most appropriate for targeted, known variant testing. DNA from buccal specimens is invariably contaminated with microbial and food DNA, which can impact specimen quality and may result in delayed testing and/or the need for a second specimen.

OCD-100 instructions are available in about 30 different languages. To request special instructions for patients, add a note in the Comments section of the kit order indicating which language is needed and we will do our best to accomodate. Default instructions are English.

Shipping: At room temperature, an OCD-100 buccal specimen is stable for up to 80 days. Specimens may be shipped at room temperature.

DNA GENOTYPING PANEL
For quality control purposes, the PreventionGenetics DNA Genotyping Panel is performed on all clinical specimens. Genotyping results are not included in test reports.

DNA BANKING
DNA Banking has a reduced price of $98 for patients if clinical testing is also being performed at PreventionGenetics. Visit our website at www.PreventionGenetics.com/DNABanking for information about the process and forms. For questions related to PGDNABanking, contact our DNA Banking Director at (715) 387-0484 or email: dnabanking@preventiongenetics.com.

CONTACT US
For additional questions or concerns, please contact our Client Service Representatives or our Genetic Counseling Team at (715) 387-0484, or email: support@preventiongenetics.com.

ADDRESS
PreventionGenetics - Diagnostic Lab
3800 S. Business Park Ave.
Marshfield, Wisconsin 54449
USA

TESTING KITS
Clinical testing kits with prepaid return shipping are available for U.S. Clients.

Comment SP249

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AUTHORIZATION
TO USE AND DISCLOSE HEALTH INFORMATION

I authorize the laboratory that has conducted or will conduct my genetic testing under the AMPLIFY Genetic Test Program and my physician to disclose to Sano Genetics the following:

- my name;
- contact information;
- date of birth;
- information regarding my condition and diagnoses and the results of my genetic testing (collectively, "My Information") **so that Sano Genetics may use My Information for the purposes described in this form.**

I authorize Sano Genetics to use My Information for the following purposes:

- to contact me via mail, telephone, in electronic format or otherwise, to provide or offer information or services, including genetic counseling, that it believes to be of interest to me
- to help Sano Genetics develop programs and services that may be of interest to me or others with hereditary hearing loss.
- to provide me with educational or marketing information about hereditary hearing loss and their treatments.
- to contact my healthcare provider(s) about products and services that may be relevant for me, including contacting additional laboratories for further analysis.

Sano Genetics will not sell My Information or use or disclose My Information for unauthorized purposes.

I understand that this Authorization is voluntary and that my ongoing medical care or eligibility for healthcare benefits will not be affected if I decline to sign this authorization form nor will it impact my ability to participate in Sano Genetics sponsored programs in the future.

I understand that I may revoke this Authorization at any time in writing by sending a letter to PreventionGenetics at the address listed above. Revoking this Authorization will prevent PreventionGenetics from further using My Information, but will not affect uses and disclosures of My Information that were already made in reliance on this Authorization.

To revoke this Authorization or to change your contact information, submit a written request to:

PreventionGenetics, part of Exact Sciences
3800 S Business Park Ave., Marshfield WI 54449

I understand that once My Information has been disclosed, federal privacy laws may no longer apply or protect the information from further disclosure. Unless I expressly revoke this Authorization, it shall remain in effect for ten (10) years from the date I sign below.

I may obtain a copy of this Authorization to keep for my records.

SIGNATURE OF PATIENT OR PARENT/LEGAL GUARDIAN OF PATIENT
(if under the age of 18)

DATE

PRINT NAME OF PATIENT OR PARENT/LEGAL GUARDIAN

RELATIONSHIP TO PATIENT
(if Parent/legal guardian)

TERMS AND CONDITIONS

THE AMPLIFY PROGRAM TERMS AND CONDITIONS

The AMPLIFY PROGRAM is a genetic testing program ("the Program") that tests for the presence of gene mutations related to hereditary hearing loss. The testing is supported by Sano Genetics. Your participation in the Program and use of Sano Genetics content and services is subject to the terms of the agreement between you and Sano Genetics set forth in these Program Terms and Conditions, which incorporate by reference the Sano Genetics general Terms of Use (Sano Genetics and Privacy Policy (https://www.decibeltx.com/privacy-notice/). You may accept these Program Terms and Conditions by (1) clicking to accept or agree, where this option is made available to you, or (2) by signing this form at your physician's office when you agree to participate in genetic testing and share your genetic test results with Sano Genetics.

To be eligible to participate in the Program, you must be less than 18 years of age and have a medical history consistent with auditory neuropathy diagnosis; (3) have the approval of your healthcare professional to have the genetic test; and (4) authorize in writing that your healthcare professional and the genetic testing laboratory selected by Sano Genetics may test the genetic sample you provide and share your name, contact information and information regarding your condition, diagnoses, and results of your genetic testing (collectively, "Your Information") with Sano Genetics. If you are under the age of 18, you must have the approval of your legal guardian to participate in the Program.

The genetic test provided under the Program requires you to provide a saliva, buccal swab, or whole blood sample to your healthcare professional. Your sample will be analyzed by a genetic testing company selected by Sano Genetics, and the results will be provided to your healthcare professional and to Sano Genetics. The genetic testing company or companies that perform the test are independent from Sano Genetics and has no control over or influence over how the test is conducted. Sano Genetics makes no warranty that the Program will meet your requirements, that it will be secure or error-free, that the results will be accurate or reliable, or that the quality of any of the services or information will meet your expectations. You understand and agree that by participating in the Program, Sano Genetics will process, use and disclose Your Information only as permitted by your written authorization and the Sano Genetics Privacy Policy.

The Program does not test for gene mutations other than those included in this hereditary hearing loss panel, nor are the results of the testing performed in connection with the Program intended to be comprehensive. The results of the genetic test provided to your healthcare provider by the testing company may be: (1) positive (if the gene associated with hearing loss has been identified by the test); (2) negative (if no genetic cause of the hearing losshas been identified by the test); or (3) inconclusive (if the test identified a genetic mutation, but it is unknown whether the identified mutation causes hearing loss. You should consult with your own healthcare professionals about your diagnoses, genetic testing, and genetic testing results. Sano Genetics does not provide medical advice, and the results of the Program are not intended to be used by you for any diagnostic purpose or as a substitute for professional medical advice. Sano Genetics does not endorse, warranty, or guarantee the effectiveness of any specific course of action, resources, tests, physicians or other healthcare professionals, drugs, biologics, medical devices, products, procedures, opinions, or other information that may be offered to you or become available to you through the Program. Reliance on any information provided by Sano Genetics is solely at your own risk.

Through the Program, you may be offered an optional opportunity to discuss your genetic test results by telephone with a genetic counselor, in the case of certain types of results that may not be conclusive as to your hereditary hearing loss gene mutation. If you choose this option, any advice provided by the counselor is independent of Sano Genetics.

If you choose to participate in the Program, you will not be responsible for the costs of the genetic test itself or the genetic counseling described in the previous paragraph. Please be aware, however, that you will be responsible for any other costs that may be incurred as a result of participating in the Program, including but not limited to the costs of visits or consultations with your healthcare professional in connection with the genetic test or the testing results.

By participating in the Program, you understand and agree that you acquire no rights in any research or commercial products that may be developed by Sano Genetics and/or its collaborating partners. You specifically understand that you will not receive compensation for any research or commercial products that include or result from Your Information.

DISCLAIMER OF WARRANTIES. You expressly acknowledge and agree that your participation in the Program is at your sole risk, and the Program is provided on an "as is" and "as available" basis. Sano Genetics expressly disclaims all warranties of any kind, whether express or implied, including but not limited to the implied warranties of merchantability, fitness for a particular purpose, and non-infringement.

LIMITATION OF LIABILITY. SANO GENETICSDOES NOT CONTROL OR ENDORSE ANY ACTIONS RESULTING FROM YOUR PARTICIPATION IN THE PROGRAM, AND THEREFORE, SANO GENETICS SPECIFICALLY DISCLAIMS ANY LIABILITY WITH REGARD TO ANY ACTIONS RESULTING FROM YOUR PARTICIPATION IN THE SERVICES, TO THE EXTENT PERMITTED BY APPLICABLE LAW. YOU EXPRESSLY ACKNOWLEDGE AND AGREE THAT SANO GENETICS SHALL NOT BE LIABLE FOR ANY DIRECT, INDIRECT, INCIDENTAL, SPECIAL, CONSEQUENTIAL, OR EXEMPLARY DAMAGES ARISING OUT OF OR RELATED TO YOUR PARTICIPATION IN THE SERVICES.

These Program Terms and Conditions, which incorporate by reference the Sano Genetics general Terms of Use and Privacy Policy, constitute the entire agreement between you and Sano Genetics and govern your participation in the Program.

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