PREVENTION GENETICS part of EXACT SCIENCES

PREVENTIONGENETICS USE ONLY

All testing must be ordered by a qualified Healthcare Provider

THIS FORM MUST ACCOMPANY ALL SPECIMENS

Test information is available on our website PreventionGenetics.com

SPECIAL PROJECT - TEST REQUISITION FORM - CANADA

SP194 - IONIS ALS SPONSORED TESTING

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

PATIENT INFORMATION

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

PATIENT ID	**SPECIMEN COLLECTION DATE** (MM/DD/YYYY) If no collection date is provided, date of receipt will be used.	**SPECIMEN SOURCE** ☐ Blood ☐ Buccal ☐ Saliva ☐ DNA, Source_____

HAS PATIENT BEEN TESTED PREVIOUSLY AT PreventionGenetics?

☐ NO ☐ YES, PG ID# _____

GEOANCESTRY / ETHNICITY

☐ White/Caucasian ☐ Middle Eastern ☐ Native American
☐ French Canadian ☐ Ashkenazi Jewish ☐ Asian
☐ Black/African American ☐ Pacific Islander ☐ Southeast Asian
☐ Hispanic ☐ Other: _____

BIOLOGICAL SEX

☐ Male ☐ Female

☐ Other _____ SPECIFY KARYOTYPE

BLOOD TRANSFUSION

☐ NO ☐ Within last 30 days

_____ MM/DD/YYYY

_____ TYPE

BONE MARROW TRANSPLANT

☐ NO ☐ Yes, include date

_____ MM/DD/YYYY

CLINICAL INFORMATION

Age of onset of first ALS symptom _____

Site of onset: ☐ Limb ☐ Bulbar ☐ Respiratory ☐ Cognitive

PEDIGREE Either include pedigree below or attach to this Test Requisition Form.

ELIGIBILITY FOR TESTING PROGRAM - PROVIDER CONSENT

To be eligible for this program, patient must meet one criteria below. I attest this patient has the following clinical diagnosis or family history, as indicated. Asymptomatic patients with a family history of ALS must be 18 years or older to qualify for testing. Symptomatic patients under the age of 18 must have clinical information provided to determine eligibility.

CHECK ALL THAT APPLY

☐ **Suspected diagnosis or diagnosis of ALS**

☐ **Presymptomatic**

☐ **Family history of ALS in relative.** If yes, select relative(s).

FIRST DEGREE: ☐ Parent(s) ☐ Sibling(s) ☐ Child(ren)

SECOND DEGREE: ☐ Grandparent(s) ☐ Grandchild(ren) ☐ Aunt(s) / Uncle(s) ☐ Niece(s) / Nephew(s)

The undersigned person (or representative thereof) ensures he/she is a licensed medical professional authorized to order genetic testing and confirms that the patient has given appropriate informed consent for genetic testing. I confirm testing is medically necessary, and test results may impact medical management for the patient. All information on this ordering form is true to the best of my knowledge. In connection with the ALS Genetic testing program, I have informed the patient that PreventionGenetics may notify me, the ordering medical professional, of clinical updates related to genetic test results. I have also informed the patient that de-identified patient data may be used and shared with third parties, including Ionis Pharmaceuticals, Inc., and third parties such as the ALS Association, in order to support research to improve the diagnosis and treatment of genetic diseases. No personal identifying information will be shared. I warrant that I will not seek reimbursement for this sponsored test from any third party, including but not limited to U.S. federal healthcare programs. I also acknowledge that organization and clinician contact information provided in the order may be shared with third parties, including Ionis Pharmaceuticals, Inc., and I hereby consent that such parties may contact me directly in connection with the ALS Genetic Testing program, Ionis Pharmaceuticals, Inc. products, or on-going or potential clinical trials sponsored by Ionis Pharmaceuticals, Inc. I understand that the use of this sponsored test is not intended to be, nor should it be construed as, either express or implied, an obligation or inducement for me to recommend, purchase, order, prescribe, promote, administer or otherwise support any Ionis Pharmaceuticals Inc.'s product or any other PreventionGenetics product or service.

HEALTHCARE PROVIDER SIGNATURE _____ PRINTED NAME _____ DATE _____

TEST SELECTION

TEST CODE	TEST NAME	DESCRIPTION	SPECIAL INSTRUCTIONS
☐ 15479	Amyotrophic Lateral Sclerosis (ALS) Panel	*C9orf72* and *ATXN2* repeat expansions are reported separately	**SP194 CANADA**
☐ 8949	*SOD1* Sequencing with CNV Detection		
☐ 6927	*FUS* Sequencing with CNV Detection		
☐ 151	*C9orf72* repeat expansion		
☐ 12976	*ATXN2* repeat expansion		
☐ 100	Family follow-up targeted testing	Gene(s): Variant(s) or comments: Proband Info:	

ADDITIONAL INFORMATION

PREVENTION GENETICS part of EXACT SCIENCES

Test information is available on our website:
PreventionGenetics.com

PREVENTIONGENETICS USE ONLY

GENETIC COUNSELING

Genetic counseling, via telehealth visits, is available to all patients who participate in this sponsored testing program through Genome Medical, a third party genetic counseling service. Pre and/or post test genetic counseling via telephone appointment is available to patients to provide information, education, support and address questions related to genetic testing and results.

By checking the following boxes, I agree to allow PreventionGenetics to facilitate the provision of pre-test and/or post-test genetic counseling services by Genome Medical, a third party genetic counseling provider.

Check all that apply:

- ☐ Refer to Genome Medical for pre-test genetic counseling.
- ☐ Refer to Genome Medical for post-test genetic counseling.
  - ☐ If results are negative, no referral to Genome Medical is needed.

Genome Medical will contact the patient for scheduling. Please provide the patient's phone number and email address.

PATIENT PHONE NUMBER

PROVINCE/TERRITORY OF CANADA (REQUIRED)

☐ Patient is French speaking

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

Genetic counseling is typically provided by telephone.

☐ Patient needs accommodations for communication

Patients who are not able to provide verbal authorization to speak with relatives and/or caregivers will need to provide Power of Attorney (POA) documentation to Genome Medical prior to their Genetic counseling visit. POA can be sent to: clinical@genomemedical.com

☐ Video consult requested (via Zoom)

PROVIDER CONTACT 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	EMAIL ADDRESS

PHONE NUMBER	NPI#	PHONE NUMBER	NPI#

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

ADDITIONAL ACCESS TO REPORTS

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

BILLING INSTITUTION

BILLING INSTITUTION	PO NUMBER	SPECIAL PROJECT NUMBER
Ionis Pharmaceuticals		**SP194**

SPECIMEN REQUIREMENTS

WHOLE BLOOD
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.

SALIVA
Saliva collection kit used according to manufacturer instructions.

OCD-100 BUCCAL SWAB
OCD-100 Buccal Swab used according to manufacturer instructions. Buccal swabs are most appropriate for targeted, known variant testing.

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. Holiday schedules will be posted on our website at least one week prior to major holidays.

BLOOD
DO NOT FREEZE. During hot weather, include a frozen ice pack in the shipping container. Place a paper towel or other thin material between the ice pack and the blood tube. In cold weather include an unfrozen ice pack in the shipping container as insulation. At room temperature, blood specimen is stable for up to 48 hours. If refrigerated, blood specimen is stable for up to one week.

SALIVA, AND BUCCAL
Specimens may be shipped at room temperature.

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

CONTACT US
For additional questions or concerns, contact a Client Service Representatives at (715) 387-0484, ext. 0, or our Genetic Counseling Team at option 2, or email: support@preventiongenetics.com.

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

REFERENCE SP194 - CANADA

PATIENT CONSENT

By signing this document, I authorize PreventionGenetics, a CLIA and CAP accredited clinical genetic testing laboratory, to analyze a sample of my (my child's/ward's) DNA for the purpose of determining if I (my child/my ward) have a genetic change in the DNA, called a variant, that may cause or increase the risk of the genetic condition, Amyotrophic Lateral Sclerosis (ALS). ALS Genetic testing looks for changes in a specified predefined gene list that causes or increases the risk of ALS.

This test includes sequencing of the coding regions of almost all genes, called Whole Exome Sequencing (WES). Although WES will be done, a specified predefined gene list will be analyzed and reported. Any other genetic changes will not be analyzed or reported as part of this ALS genetic testing program.

I understand that I may have a disease-causing or risk variant in a gene that will not be analyzed or reported. I understand that no genetic test can detect every change in the DNA, and that a negative test does not eliminate the possibility of having a genetic form of ALS or another genetic condition. I also understand that I cannot be identified from the genetic data alone.

Genetic health and family information unrelated to ALS may be learned from genetic testing. Genetic counselling is recommended. Genetic counsellors explain the genetics of the condition, the genetic testing results and implications to patients and their family members. My ordering healthcare provider will receive the ALS genetic test results. If I speak with a genetic counsellor, he or she will also receive the genetic test results in order to provide genetic counselling.

If ALS genetic testing is done before symptom onset, I understand that there may be a risk of insurance discrimination or employment discrimination. Therefore, it is advisable to secure insurance coverage before genetic testing or genetic counselling for predictive ALS genetic testing, and to keep results confidential, other than with family members, who may also be at risk of developing ALS or to provide support, trusted individuals and your healthcare provider. Predictive genetic testing is not offered to children under 18 years of age, unless there is a known family history of childhood onset ALS in a gene with a therapeutic intervention commercially available or through a research study.

There is no cost or payment to me for the genetic testing, through the Ionis program.

By participating in the Ionis Sponsored ALS Genetic Testing Program, I authorize PreventionGenetics laboratory to use and share my de-identified genetic variant data and personal information, including age of ALS onset, site of onset, age at genetic testing, ancestry and presence or absence of ALS family history for research, possible publications and therapeutic development purposes to Ionis. I also authorize PreventionGenetics to disclose whole exome sequencing data, to Ionis Pharmaceuticals, with no personal identifying information (called pseudonymised data) for research purposes, in order to help scientists improve understanding, diagnosis and treatment for rare genetic conditions, including for possible scientific publications. Other clinical information, including symptom onset may also be shared with Ionis Pharmaceuticals.

All information shared with Ionis Pharmaceuticals will be identified only by an ID number; this is called pseudonymised data. Names and other personal identifying information will not be used or connected to the results in any analyses, educational materials, presentations, or publications. Personal identifying information is confidential, will not be shared, and participants' privacy will be protected to the greatest extent under applicable laws.

Ionis and PreventionGenetics make important decisions about the use of my data. I understand that my data may be sent to the USA, I further understand the laws in the USA may be different then the laws in my country. I have the right to access, through my doctor, all the data collected about me and, if applicable, ask for corrections. I have the additional rights to object to how my information is being handled. If I would like to make any such requests, I understand that I should contact my doctor, who will then contact PreventionGenetics laboratory at support@preventiongenetics.com. I may also contact the Data Protection Agency in my applicable State or Province. After deidentified variant data is published in aggregate analyses, it will no longer be able to be retracted or omitted.

_____ INITIAL HERE
I consent to PreventionGenetics storing and to Ionis processing (analyzing) my genomic information indefinitely for clinical or research analyses to help improve understanding of the genetics of ALS, and in case new information about the genetics of the condition tested becomes available.

_____ INITIAL HERE
I do not consent to PreventionGenetics storing and to Ionis processing (analyzing) my genomic information indefinitely for research analyses to help improve understanding of the genetics of ALS, and in case new information about the genetics of the condition tested becomes available.

PATIENT SIGNATURE (OR LEGAL GUARDIAN)	PATIENT OR LEGAL GUARDIAN PRINTED NAME	DATE
WITNESS SIGNATURE	WITNESS PRINTED NAME	DATE