ARUP LABORATORIES

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REQUIRED INFORMED CONSENT FOR AMYOTROPHIC LATERAL SCLEROSIS (ALS) DNA TESTING

Patient Last Name _____ **First Name** _____ **Birth Date**___/___/___

Does the patient have symptoms of ALS? [ ] No [ ] Yes, describe: _____

Who is the patient's closest relative with ALS? _____

Was this relative's diagnosis confirmed by DNA testing? [ ] No [ ] Yes [ ] Unknown

- Amyotrophic lateral sclerosis (ALS), also known as Lou Gehrig's disease, is a progressive, fatal, neurodegenerative movement disorder. Although treatments for symptoms are available, there is currently no cure for ALS. ALS may be considered sporadic if it occurs in only one member of a family, or may be considered familial if it occurs in more than one family member. This blood test investigates eleven genes known to be associated with familial ALS. Results of this test may support a diagnosis of ALS in symptomatic individuals, or may predict that an asymptomatic person is at increased risk for developing symptoms.

- There are three possible test results:
  1) Negative: No gene mutations were detected in the ALS-associated gene(s) tested. This does not rule out the diagnosis of ALS, nor does it guarantee you will not develop ALS in the future.
  2) Positive: One or more causative gene mutations were identified in the ALS-associated gene(s) tested. This result indicates you are at increased risk for developing ALS or that you are a carrier of ALS, but is not diagnostic for ALS by itself. Some individuals with causative gene mutations do not develop ALS. The age of onset, specific symptoms, and disease progression may or may not be predictable based on the causative gene mutation alone.
  3) Uncertain: One or more genetic variations were identified in the ALS-associated gene(s) tested. Due to limited information, the significance of the variation(s) is unknown. It is not possible to determine if your risk for developing ALS is increased over that of the general population.

- Results from this test may have implications for other family members. If a genetic mutation(s) is/are identified, this may predict other family members are at risk for developing ALS or are carriers of ALS.

- If a gene mutation is identified, insurance rates, obtaining disability or life insurance, and employability could be affected. Federal law extends some protections regarding genetic discrimination (http://www.genome.gov/10002328). It is your responsibility to consider the possible impact of these results. All test results are released to the ordering health care provider and those parties' use of them is subject to state and federal laws.

- There are psychological risks associated with ALS testing. A positive result could lead to serious psychological consequences including feelings of depression, futility, despair, and severe stress. A test result predicting an uncertain clinical outcome can be frustrating. Counseling should be provided before and after testing.

- The ordering health care provider must relay the test results in person and be available for follow-up genetic counseling, as necessary. Questions regarding result interpretation or medical management should be directed to the ordering health care provider.

- Consent may be given for allowing the sample to be used for test validation, education and stored indefinitely as long as patient privacy is maintained. Refusal to provide consent will not affect the test result. If a response is not checked below, consent is implied.

I authorize consent for the use of the above named individual's sample for test validation and education: [ ] Yes [ ] No

Patient or Legal Guardian section:
I have the legal authority to request ARUP Laboratories test this sample for genetic mutations associated with amyotrophic lateral sclerosis (ALS). I am either the above patient or his/her legal guardian. I have been counseled regarding the risks, benefits, and limitations of knowing the test results and have carefully considered the psychological impact the results may have on the patient and his/her family.

Patient/Legal Guardian:
Printed Name _____ **Signature** _____ **Date** _____

Ordering Health Care Provider:
I have explained this DNA test and its limitations to the patient or legal guardian and answered all questions.

Printed Name _____ **Signature** _____ **Date** _____

Phone number_____ **Fax** _____ **Specialty**_____