INVITAE ALSIdentified™

ORDER ID
For Invitae internal use only

Requisition Form

ALS Identified Sponsored Testing
Requisition Form TRF865-2

This requisition form can be used to submit an order for the **ALS Identified program**, a sponsored genetic testing program brought to you by **Biogen**.

INSTRUCTIONS: Review the ordering options and then complete all sections of this form. Your ordering option will be indicated in the Test Selection section.

ORDERING OPTIONS

1. ALS IDENTIFIED SPONSORED TESTING PROGRAM BY BIOGEN

For individuals that meet the eligibility criteria below and wish to receive the program-specific genetic testing panels.

REQUIRED: You must select below the appropriate eligibility criteria for this patient.

This program is available to individuals 18 or older living in the U.S. and Puerto Rico diagnosed with ALS or asymptomatic individuals with a family history of ALS (must select one):

- ◯ Symptomatic individual with clinical diagnosis of amyotrophic lateral sclerosis (ALS)
  - **Required:** Age of symptom onset: _____ years
  - Age of diagnosis: _____ years
- ◯ Asymptomatic individual with family history of early (<65 years of age) onset diagnosis of amyotrophic lateral sclerosis (ALS)

2. GENE-SPECIFIC FAMILY FOLLOW-UP TESTING BY INVITAE

For relatives of program participants who received a Pathogenic/Likely Pathogenic result or approved VUS who want to receive gene-specific family follow-up testing at no additional charge. Relatives do not need to meet the eligibility criteria listed above. Learn more at www.invitae.com/family.

PATIENT INFORMATION

First name	MI	Last name
Date of birth (MM/DD/YYYY)	Biological sex ◯ M ◯ F	MRN (medical record number)

Ancestry ◯ Asian ◯ Black/African American ◯ White/Caucasian ◯ Ashkenazi Jewish ◯ Hispanic ◯ Native American ◯ Pacific Islander ◯ French Canadian ◯ Sephardic Jewish ◯ Mediterranean ◯ Other: _____

Phone	Email address (report access after clinician releases)	
Address		City
State	ZIP/Postal code	Country

Ship a kit to this patient (optional) by faxing or emailing this completed form to Invitae
Kit type: ◯ Buccal swab kit ◯ Saliva kit
Ship to: ◯ Address above ◯ Alternate address: _____

SPECIMEN INFORMATION

Specimen type: Blood (3-mL purple EDTA) -OR- Buccal Swabs (OCD-100, 2 devices) -OR- Saliva (Oragene™) -OR- DNA source: _____

We are unable to accept blood/buccal/saliva from patients with:
- *Allogeneic bone marrow transplants*
- *Blood transfusion <2 weeks prior to specimen collection*

Specimen collection date (MM/DD/YYYY): _____
If not provided, the day before specimen receipt will be used

Special cases: ◯ History of/current hematologic malignancy in patient

INVITAE PARTNER CODE

ALS

CLINICIAN INFORMATION

Organization name		
Phone	Fax	
Address	City	
State	ZIP/Postal code	Country

Primary clinical contact name (if different from ordering provider)	NPI
Primary clinical contact email address (for report access)	

Ordering provider (select one ordering provider by marking the checkbox before the name)

	Name	NPI	Email address (for report access)
◯			
◯			
◯			
◯			
◯			
◯			

Additional clinical or laboratory contacts (optional, to share access to order online)

◯ **Share this order with the primary clinical contact's default clinical team, manage at invitae.com**

Name	Email address (for report access)
Name	Email address (for report access)

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CLINICAL HISTORY

FAMILY HISTORY

Is there a family history of disease for which the patient is being tested? ◯ Yes ◯ No If yes, describe below and attach pedigree and/or clinical notes.

Family history of:	Yes/No	Relatedness	Age of onset of family member(s)	Family history of:	Yes/No	Relatedness	Age of onset of family member(s)
ALS				**ALS**			
Frontotemporal dementia (FTD)				**Frontotemporal dementia (FTD)**			
Other/unspecified dementia				**Other/unspecified dementia**			

PERSONAL HISTORY

Is/was this patient affected or symptomatic?† ◯ Yes ◯ No

Provide details in the required clinical history questions (if applicable).

† Symptomatic means this patient has features or signs known or suspected to be related to the genetic testing being ordered and could include findings on physical examination, laboratory tests, or imaging.

CLINICAL HISTORY FOR SYMPTOMATIC INDIVIDUALS

Motor Features	YES	NO	UNKNOWN
Most recent ALSFRS-r score, if available_____	◯	◯	◯
Region of symptom onset:			
Bulbar	◯	◯	◯
Limb	◯	◯	◯
Respiratory	◯	◯	◯
Cognitive	◯	◯	◯
Progressive muscle weakness and/or atrophy	◯	◯	◯
Muscle fasciculations and/or cramps	◯	◯	◯
Dysarthria (difficulty speaking)	◯	◯	◯
Dysphagia (swallowing difficulties)	◯	◯	◯
Increased muscle tone and/or increased extremity deep-tendon reflexes/hyperreflexia (jaw jerk, Hoffman sign, positive Babinski sign, crossed adductors, extensor plantor response)	◯	◯	◯
Spasticity	◯	◯	◯
Hyporeflexia and/or decreased or absent deep tendon reflexes	◯	◯	◯
Pseudobulbar affect (inappropriate laughing/crying/forced yawning)	◯	◯	◯

Cognitive Features	YES	NO	UNKNOWN
Progressive cognitive decline	◯	◯	◯
Behavioral changes	◯	◯	◯
Psychiatric illness	◯	◯	◯
Other: _____	◯	◯	◯

Other relevant clinical features or previous findings: _____

_____

OPTIONAL - REQUESTED VARIANTS FOR THIS PATIENT'S REPORT, IF KNOWN

*To have the presence or absence of specific variants commented on in this patient's report, provide the details below. For gene-specific family follow-up see **Note** under Test Selection.*

Was the proband (individual with variant) tested at Invitae? ◯ Yes, Invitae Order ID: RQ# _____ ◯ No: Attach copy of lab results (*required*)

Variant(s) *(e.g. GENE c.2200A>T (p.Thr734Ser) NM_00012345) If left blank, all variants identified in the proband will be commented on.*		**This patient's relationship to proband:**
		◯ Parent ◯ Sibling ◯ Grandchild
		◯ Child ◯ Self ◯ Other: _____

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TEST SELECTION – Select test(s) from either option 1 or 2 below (No re-requisitions available for this panel):

1. ALS IDENTIFIED SPONSORED TESTING PROGRAM BY BIOGEN – Indicate test(s) to be performed below:

Test code	Test name	# of genes	Gene list
○ 444002	Invitae Hereditary Amyotrophic Lateral Sclerosis	22	ALS2, ANG, ANXA11, CHCHD10, C9ORF72, DCTN1, ERBB4, FUS, HEXA, KIF5A, OPTN, PFN1, SETX, SOD1, SPG11, SQSTM1, TARDBP, TBK1, TFG, UBQLN2, VAPB, VCP
	○ 444002.1 Add-on preliminary-evidence genes	9	ATP13A2, CHMP2B, DDHD1, ERLIN1, FIG4, MATR3, NEFH, SIGMAR1, TIA1

2. GENE-SPECIFIC FAMILY FOLLOW-UP TESTING BY INVITAE *For relatives of a program participant ('proband') who received a Pathogenic/Likely Pathogenic result or approved VUS.*

○ Family follow-up testing for Proband's Invitae Order ID: RQ#_____	**This patient's relationship to proband:** ○ Parent ○ Sibling ○ Grandchild ○ Child ○ Other: _____	**Gene(s) to be tested in this patient:**

***NOTE**: The presence or absence of all variants identified in the proband for the gene(s) ordered for gene-specific family follow-up will be commented on in this patient's report unless a limited selection is specified in the **Requested Variants** section above. Invitae will report any Pathogenic/Likely Pathogenic variants found in this patient for the gene(s) ordered.*

Invitae continually updates its panels based on the most recent evidence. If an order is placed using an outdated test requisition form, Invitae reserves the right to upgrade ordered tests to their current versions. Test IDs containing add-on codes will include the original panel as well as the add-on.

By signing this form, the medical professional acknowledges that the individual/family member authorized to make decisions for the individual (collectively, the "Patient") has been supplied information regarding and consented to undergo genetic testing, substantially as set forth in Invitae's Informed Consent for Genetic Testing (www.invitae.com/forms). The medical professional will retain evidence that the patient consented to genetic testing. The Patient has been informed that Invitae may notify them of clinical updates related to genetic test results (in consultation with the ordering medical professional as indicated) and has been informed that deidentified (also referred to as pseudonymized) patient data may be used and shared with third parties in connection with the Program, for research and commercial purposes. For orders originating outside the United States, the Patient has been informed that their personal information and specimen will be transferred to and processed in the United States. The medical professional warrants that (i) he/she will not seek reimbursement for this no-charge test from any third party, including but not limited to government healthcare programs; (ii) participation in the Program will not influence his/her medical decisions; (iii) he/she is not obligated to purchase or prescribe any product or service offered by a sponsor of the Program; (iv) he/she is not obligated to participate in or to encourage patients to participate in any clinical trial or other research program conducted by a sponsor; and (v) he/she will participate in the Program in accordance with applicable laws. The medical professional consents to the sharing of organization and clinician contact information with third parties, including commercial organizations, who may contact the medical professional directly in connection with the Program. A list of third party partners will be provided upon request. I attest that I am authorized under applicable law to order this test.

Medical professional signature (required)	**Date (MM/DD/YYYY)**

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