PREVENTION GENETICS
part of EXACT SCIENCES

FA IDENTIFIED

PREVENTIONGENETICS USE ONLY

Test information is available on our website:
PreventionGenetics.com

All testing must be ordered by a qualified Healthcare Provider

THIS FORM MUST ACCOMPANY ALL SPECIMENS

FOR PATIENT SELF COLLECTING A SAMPLE, CHOOSE ONE:
☐ Ship one Saliva GeneFiX™ Saliva Collection kit to patient's address.
☐ Ship one Buccal OCD-100 kit to patient's address.

GENETIC TESTING FOR FRIEDREICH ATAXIA
TEST REQUISITION FORM - SP320

ELIGIBILITY CRITERIA

FOR INDIVIDUALS WHO MEET THE ELIGIBILITY CRITERIA BELOW AND WISH TO RECEIVE THE PROGRAM SPECIFIC GENETIC TESTS.

☐ Patient must reside within US & Puerto Rico
☐ Patient must be suspected of or have a clinical diagnosis of Friedreich Ataxia.
☐ Patient must be 16 years of age or older.

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)

ADDRESS	CITY	STATE/PROV	ZIP/POSTAL CODE

PHONE	EMAIL ADDRESS

MEDICAL RECORD NUMBER (MRN)

SPECIMEN COLLECTION DATE (MM/DD/YYYY)
If no collection date is provided, date of receipt will be used.

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,
_____ MM/DD/YYYY
_____ TYPE

BONE MARROW TRANSPLANT
☐ NO ☐ Yes, include date
_____ MM/DD/YYYY

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

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.

Relative's relationship to this patient	Maternal or Paternal	Diagnosed condition	Age at diagnosis

PERSONAL HISTORY

Is/was this patient affected or symptomatic?* ☐ Yes ☐ No
Provide details in the required clinical history questions (if applicable).
If yes, age of symptom onset: _____

* 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.

REQUIRED CLINICAL HISTORY

Patient is presenting the following symptoms:
☐ Absent reflexes
☐ Ataxia
☐ Bladder dysfunction
☐ Cardiomyopathy
☐ Decreased proprioception
☐ Diabetes mellitus
☐ Dysarthria
☐ Hearing loss
☐ Muscle weakness
☐ Pes cavus
☐ Reduced visual acuity
☐ Scoliosis
☐ Spasticity
☐ Other: _____

Does the patient currently have a clinical diagnosis:
☐ Friedreich Ataxia (G11.11)
☐ Early-onset cerebellar ataxia (G11.1)
☐ Later-onset cerebellar ataxia (G11.2)
☐ Hereditary ataxia (G11.8)
☐ Charcot-Marie-Tooth (G60.0)
☐ Cerebral Palsy (G80.9)
☐ Other: _____

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PATIENT

LAST NAME

FIRST NAME | MI

TEST SELECTION

TEST CODE	TEST NAME	DESCRIPTION	SPECIAL INSTRUCTIONS
☑ 20060	**Friedreich Ataxia Genetic Evaluation**	FXN GAA repeat expansion. If single GAA repeat expansion, autoreflex to FXN gene sequencing 16047.	**SP320**

COMMENTS OR ADDITIONAL ORDER INFORMATION

☐ **SPECIMEN COLLECTED IN NEW YORK STATE**
Include New York State 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.

GENETIC COUNSELING

Refer your patients and caregivers to a genetic counselor for additional information about the implications of their test. Genetic counselors in your area can be identified by visiting the website of the National Society of Genetic Counselors at https://findageneticcounselor.nsgc.org.

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 Biogen Pharmaceuticals, and consent to Biogen Pharmaceuticals contacting you.

HEALTHCARE PROVIDER SIGNATURE | PRINTED NAME | DATE

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 **BIOGEN10320**

SPECIAL PROJECT NUMBER **SP320**

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NOTE: This page does not need to be returned with completed TRF.

Test information is available on our website:
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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. 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).

Shipping: At room temperature or refrigerated, a blood specimen is stable for up to 3-4 weeks. Specimens and gel packs may be shipped at ambient (room temperature). Fresh blood specimens are preferred.

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. Though saliva specimens are typically stable for up to 1 year, specimens should be sent to PreventionGenetics for testing as soon as possible, post-collection.

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 accommodate. Default instructions are in 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

Requirements: Send in a screw cap tube at least 5 µg -10 µg of purified DNA at a concentration of at least 100 ng/uL, minimum 2 µg for limited specimens. Indicate concentration on tube label. For requests requiring more than one test, send an additional 5 µg DNA per test ordered when possible. For rapid tests, good DNA quality is of utmost importance.

Shipping: Specimens may be shipped at room temperature. Label the tube with the composition of the solute and DNA concentration along with the patient's name, date of birth, and/or ID number. We only accept genomic DNA for testing; we do not accept products of whole genome amplification reactions or other amplification reactions. DNA must be extracted from a CLIA-certified laboratory or a laboratory meeting equivalent requirements as determined by CAP and/or CMS.

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.

SHIPPING ADDRESS

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

COMMENT SP320