PREVENTION GENETICS
part of EXACT SCIENCES

NAVIGATTR
Genetic Testing sponsored by AstraZeneca

Test information is available at: **navigattr.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
SP283 - NavigATTR Sponsored Testing Program

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/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

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

HAS PATIENT'S RELATIVE BEEN TESTED AT PreventionGenetics?
- ☐ NO ☐ YES, provide

NAME _____ DATE OF BIRTH (MM/DD/YYYY) _____

RELATIONSHIP TO PATIENT _____ or PreventionGenetics ID NUMBER _____

BLOOD TRANSFUSION
- ☐ NO ☐ Within last 30 days

DATE (MM/DD/YYYY) _____

TYPE _____

BONE MARROW TRANSPLANT
- ☐ NO ☐ YES, include date

DATE (MM/DD/YYYY) _____

GEOANCESTRY / ETHNICITY
- ☐ Asian
- ☐ Black/African American
- ☐ White
- ☐ Hispanic
- ☐ Native American
- ☐ Pacific Islander
- ☐ French Canadian
- ☐ Mediterranean
- ☐ Europe
- ☐ South America
- ☐ South East Asia
- ☐ North America
- ☐ Caribbean
- ☐ Other: _____

ELIGIBILITY CRITERIA

Patients must be US residents, adults (>18 years) and meet the following criteria:

At least 1 of the following:
- ☐ Family history of hereditary ATTR amyloidosis.
  Relationship: _____
  - ☐ Is patient symptomatic?
- ☐ Myocardial radiotracer (99mTc-PYP/DPD/HMDP) uptake on bone scintgraphy and the absence of a monoclonal protein in serum or urine.
  Date: _____
- ☐ Positve biopsy for Amyloidosis.
  Date: _____

OR

At least 1 symptom from different **2 separate bolded** categories:
- ☐ **Autonomic dysfunction:**
  Date of Onset: _____
  - ☐ Bladder dysfunction
  - ☐ Early satiety
  - ☐ Erectile dysfunction
  - ☐ Orthostatic hypotension
- ☐ **Bilateral carpal tunnel syndrome:**
  Date of Onset: _____
- ☐ **Gastrointestinal:**
  Date of Onset: _____
  - ☐ Nausea and vomiting
  - ☐ Alternating bouts of diarrhea/constipation
- ☐ **Heart disease:**
  Date of Onset: _____
  - ☐ Arrhythmias
  - ☐ Heart failure or cardiomyopathy
  - ☐ Edema
  - ☐ Fatigue
  - ☐ Shortness of breath
- ☐ **Lumbar spinal stenosis:**
  Date of Onset: _____
- ☐ **Motor dysfunction:**
  Date of Onset: _____
  - ☐ Difficulty walking
  - ☐ Impaired balance
  - ☐ Muscle weakness
- ☐ **Neurological disease:**
  Date of Onset: _____
  - ☐ Numbness and tingling in feet and/or hands
  - ☐ Pain in extremities
  - ☐ Sensitivity to pain and temperature
- ☐ **Renal issues:**
  Date of Onset: _____
  - ☐ Proteinuria
  - ☐ Renal insufficiency/failure

TEST SELECTION (ONLY SELECT ONE)

	TEST CODE	TEST NAME / DESCRIPTION
☐	**15139**	***TTR* Single-Gene Analysis**
☐	**16207**	**CardioNavigATTR**
☐	**16209**	**NeuroNavigATTR**

ADDITIONAL INFORMATION

SPECIAL INSTRUCTIONS

SP283

☐ **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 our website.

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 following boxes, my patient has agreed to allow PreventionGenetics to facilitate the provision of pre-test and/or post-test genetic counseling services by Genome Medical.
- ☐ **Pre-test** genetic counseling referral to Genome Medical
- ☐ **Post-test** genetic counseling referral to Genome Medical

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

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PATIENT

LAST NAME		
FIRST NAME		MI

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.

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.

INSTITUTION

ADDRESS	CITY	STATE	ZIP

REQUESTING PROVIDER (First, Last, Degree)

EMAIL ADDRESS (For report access via myPrevent)	PHONE NUMBER	NPI#

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
ASTRAZE10283	**SP283**

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.

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: 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.

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 SP283