



# PSG + MSU + YOU:

## Your Role in the World of Diagnostics

Presented by: Plasma Services Group  
5/2018

# Overview:

- ▶ Plasma Services Group introduction
- ▶ Why your diagnosis makes you important as a specialty plasma donor
- ▶ Specialty plasma donation vs. other standard blood donations
- ▶ Test kits explained
- ▶ The benefits of donating plasma for PSG
  - ▶ Doctor Donor Alliance Program
  - ▶ Myositis donor success story
- ▶ Qualification process
- ▶ Q&A

# Plasma Services Group

- ▶ Who we are:
  - ▶ The link between those diagnosed with autoimmune conditions and the medical diagnostic community
  - ▶ An essential source of disease-state human plasma for diagnostic, test kit manufacturers and researchers across the globe
- ▶ What we do:
  - ▶ Specialize in specialty plasma donor recruitment
  - ▶ Focus on recruiting donors with autoimmune and infectious disease diagnoses
  - ▶ Recruit across the USA

# Why Myositis? Why You?

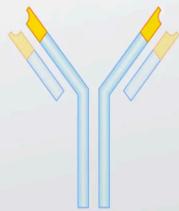
- ▶ Myositis is a rare condition with only 5-10 out of every 1 million people developing the disease\*
- ▶ New antibodies associated with Myositis and overlap syndromes are being researched and new detection methods being developed
- ▶ A huge need exists within the medical diagnostic community and industry for specialty plasma donors with rare antibodies so that:
  - ▶ test kits can be made
  - ▶ new and better diagnostic methods can be researched, developed, compared, and made available for labs and clinicians worldwide



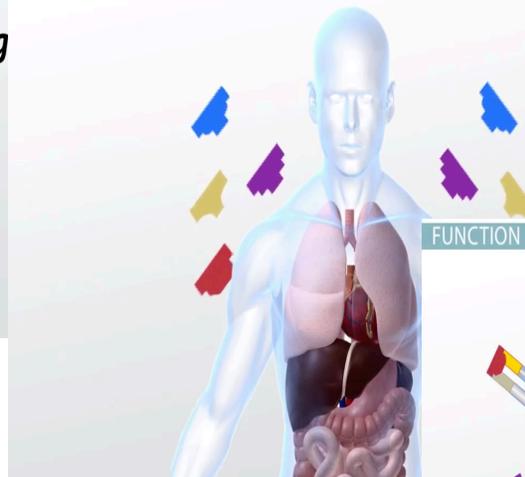
# Antibodies and Antigenes

WHAT ARE ANTIBODIES?

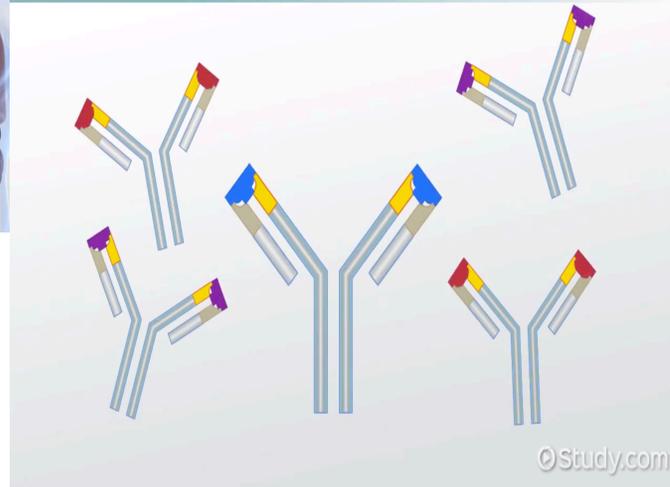
**antibodies**  
**immunoglobulin**  
*help stop intruders from harming*



HOW ANTIBODIES FIGHT ANTIGENS



FUNCTION



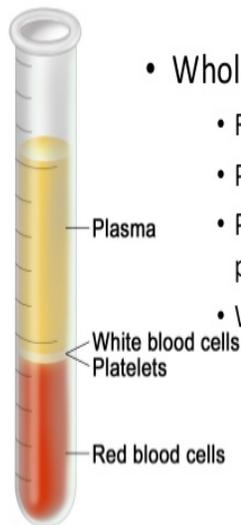
# Standard Donations vs. Specialty Plasma Collections

	Whole Blood	Plasma	Specialty Plasma
Frequency of Donation	Once every 56 days	Up to 2x per week (with 24 hours in between)	Up to 2x per week (with 24 hours in between)
Uses	Transfusions (in vivo)	Therapies, Drug manufacturing (in vivo)	Research & Diagnostics, Manufacture Test Kits (in vitro)
Reasons for Deferral (medical)	Diagnoses/ Medications	Diagnoses/ Medications	<del>Diagnoses/ Medications</del>
Reasons for Deferral (lifestyle)	tattoos, piercings, sexual activity, travel	tattoos, piercings, sexual activity, travel	<del>tattoos, piercings, sexual activity, travel</del>

# Standard Blood Donations

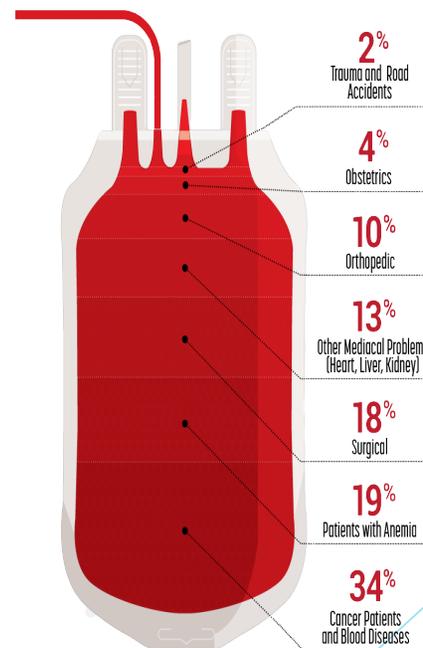
- ▶ Whole blood (red cells / white cells / plasma containing antibodies) is collected with nothing returned to donor
- ▶ No automated machine used during donation
- ▶ The blood and blood components make up the normal “donor blood pool” and will be used for transfusions and other “in vivo” (for use within human) purposes

## Components of Blood



- Whole blood contains 4 main elements:
  - Red blood cells – carry oxygen to tissue
  - Platelets – used in coagulation (clotting)
  - Plasma – maintains blood volume and blood pressure, and prevents excessive bleeding
  - White blood cells – fight infection

## What is Donated Blood Used For?



2%  
Trauma and Road  
Accidents

4%  
Obstetrics

10%  
Orthopedic

13%  
Other Medical Problems  
(Heart, Liver, Kidney)

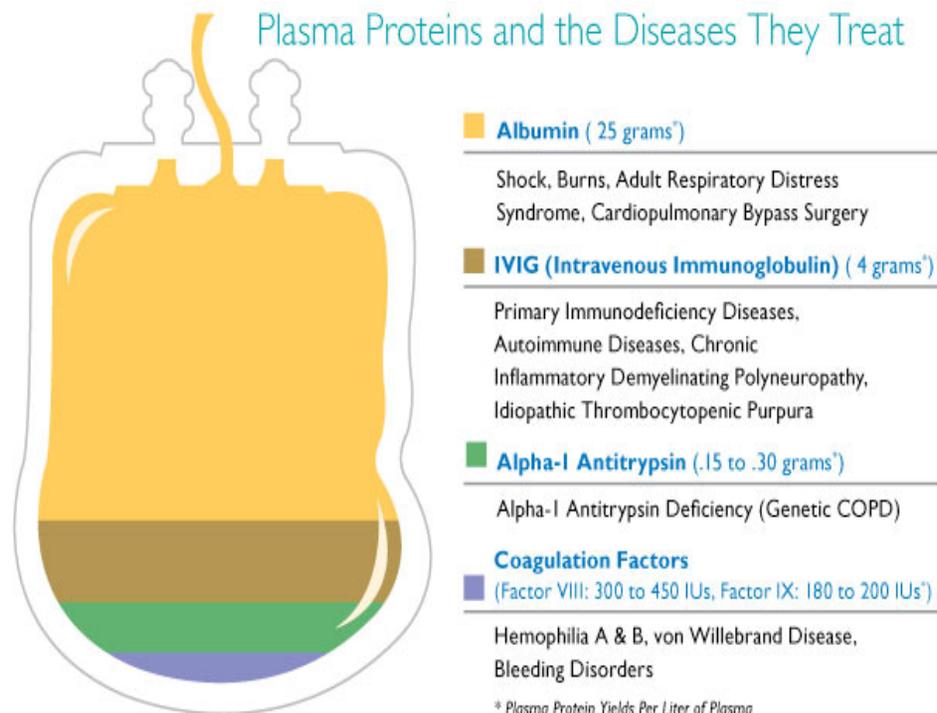
18%  
Surgical

19%  
Patients with Anemia

34%  
Cancer Patients  
and Blood Diseases

# Standard Plasma Donations

- ▶ As with standard whole blood donation, the donor must pass stringent screening questions but once accepted can donate safely twice within a 7 day period.
- ▶ An automated machine is used to collect a portion of whole blood and separate red cells from plasma. The red cells are returned to the donor, and the plasma is collected in a bag attached to the machine.
- ▶ Standard plasma donations are used for transfusions and for making therapies and treatments that go into people “in vivo”



\* Plasma Protein Yields Per Liter of Plasma

# How is Specialty Plasma Donation different?

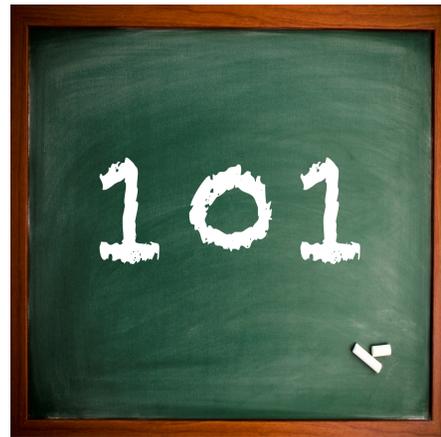
- ▶ As with standard plasma donation, an automated machine is used, and red cells are returned to the donor making it safe to donate twice within a 7 day period with at least one full day of rest between donations.
- ▶ Donors are NOT deferred because of diagnoses, medications, lifestyle choices and/or travel history. \*
- ▶ PSG plasma donations are only used “in vitro” (outside of the human body) to make diagnostic test kits, help advance research and develop better diagnostic methods. They are NEVER used as part of a therapy or to make anything that goes inside of a human.

## In Short...

- ▶ PSG needs you as a specialty plasma donor because of your myositis diagnosis
- ▶ You will not be deferred as a result of your autoimmune diagnosis
- ▶ YOU are the essential link in manufacturing and developing better diagnostics



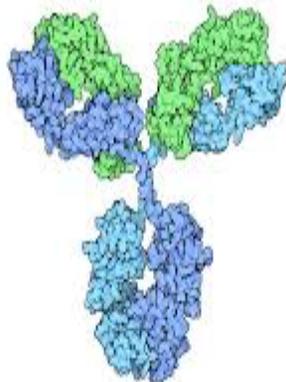
# Test Kits:



How YOU and PSG form a missing link

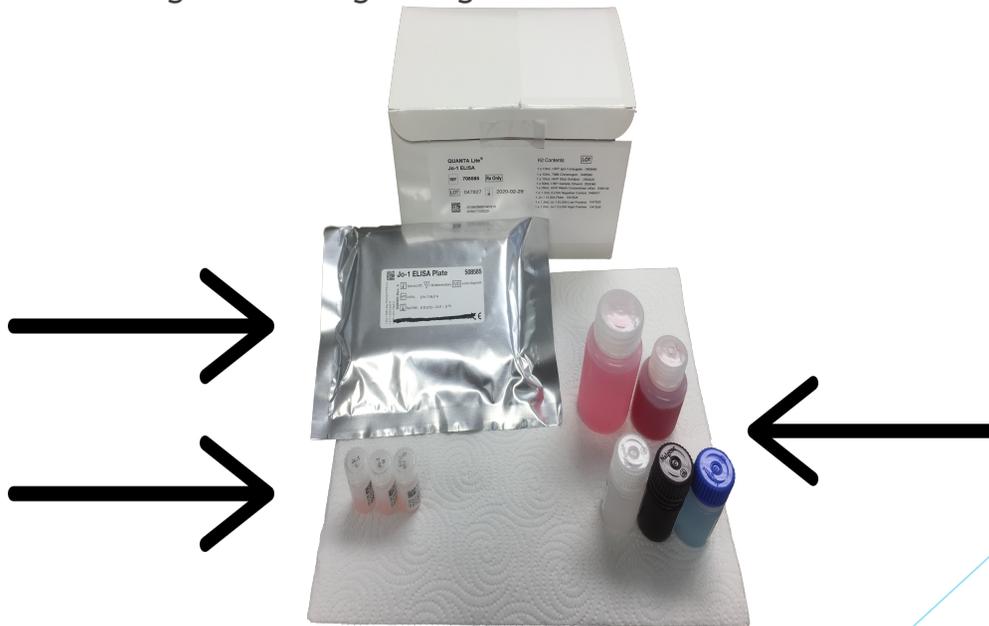
# How diagnostic test kits work?

- ▶ Many tests work by detecting the presence of antibodies.
  - ▶ The type of antibodies present can help identify the type of autoimmune disease (i.e. Myositis vs Lupus) and the sub class of disease (i.e. statin induced myositis vs inclusion body myositis)
  - ▶ The type of antibodies present can also help determine best treatments
  - ▶ For some autoimmune conditions, testing the concentration or levels of antibodies in the bloodstream can help monitor disease progression and response to treatments



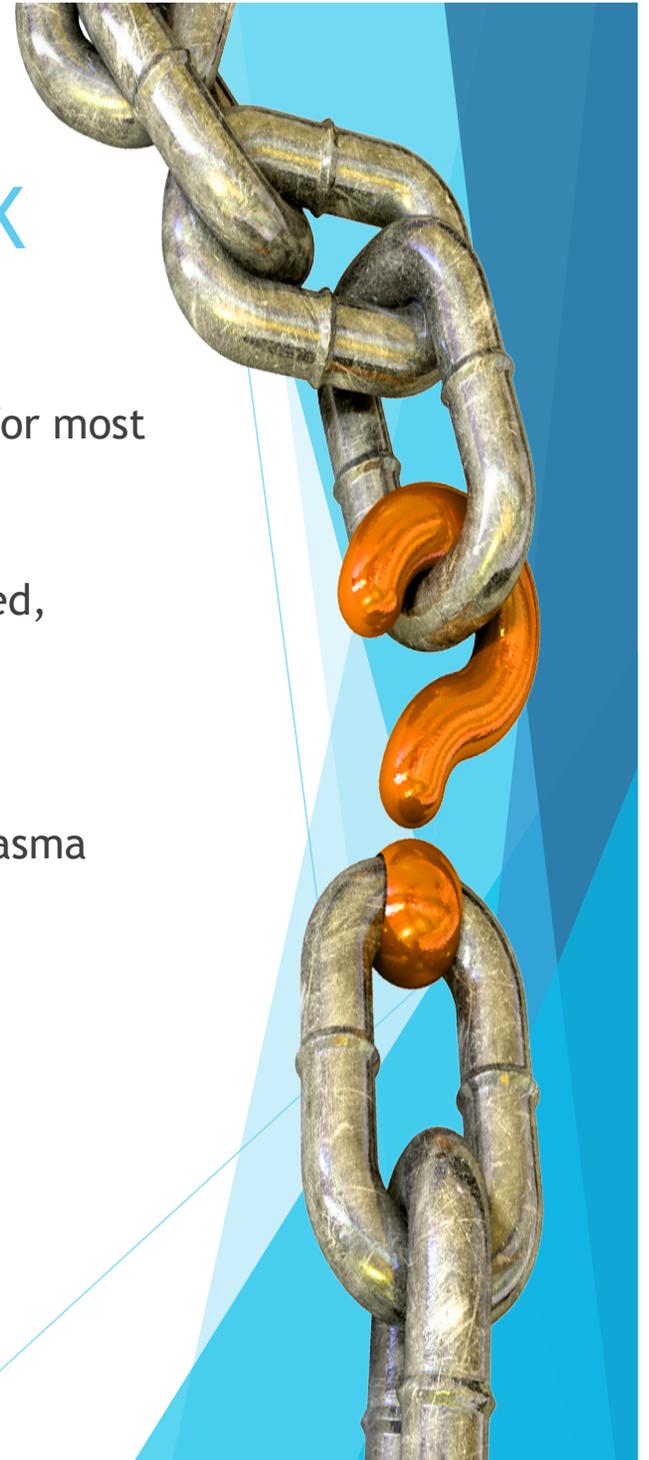
# How are diagnostic test kits made?

- ▶ Test kits that detect antibodies typically have the following components:
  - ▶ Antigen: antibody binding.
  - ▶ Reagents: produce a color change or other measurable reaction.
  - ▶ Calibrators and Controls: **human serum or plasma** that has known antibody levels to compare patient samples against.
    - ▶ Calibrators establish the normal, high and low ranges for test results
    - ▶ Positive and negative controls must be run with every test to ensure nothing went wrong during the test



# PSG + MSU + YOU = THE LINK

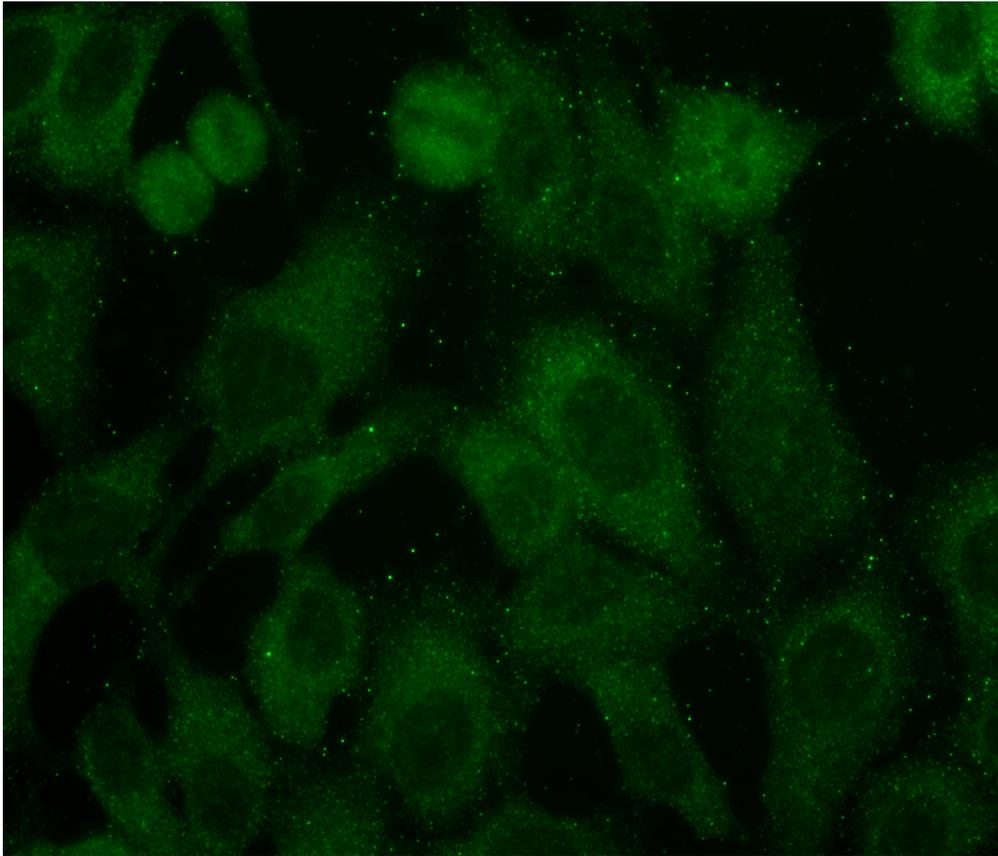
- ▶ Specialty plasma donors are currently the only source for most autoimmune calibrators and controls.
- ▶ Without donors, kits could not be manufactured, studied, compared or developed.
- ▶ PSG forms the vital link between YOU, the specialty plasma donor, and the companies that research, develop and manufacture Myositis diagnostic tests.



# Examples of Myositis Specific Antibody Tests

- ▶ Immunofluorescence Assay (IFA): antibodies found in patient serum and plasma samples bind to different cell structures and reagents make the bound antibodies fluoresce so a technician can see and interpret the antibody patterns.
- ▶ Enzyme-linked Immuno-assay (ELISA): antibodies found in patient plasma bind to antigen coated on plastic wells, and reagents produce a yellow color that is more intense with higher antibody levels.
- ▶ Line Immuno-Assay (LIA): patient antibodies bind to antigen coated on a strip and reagents produce a line or band that is darker or more intense with higher antibody levels

# Immunofluorescence Assay (IFA):



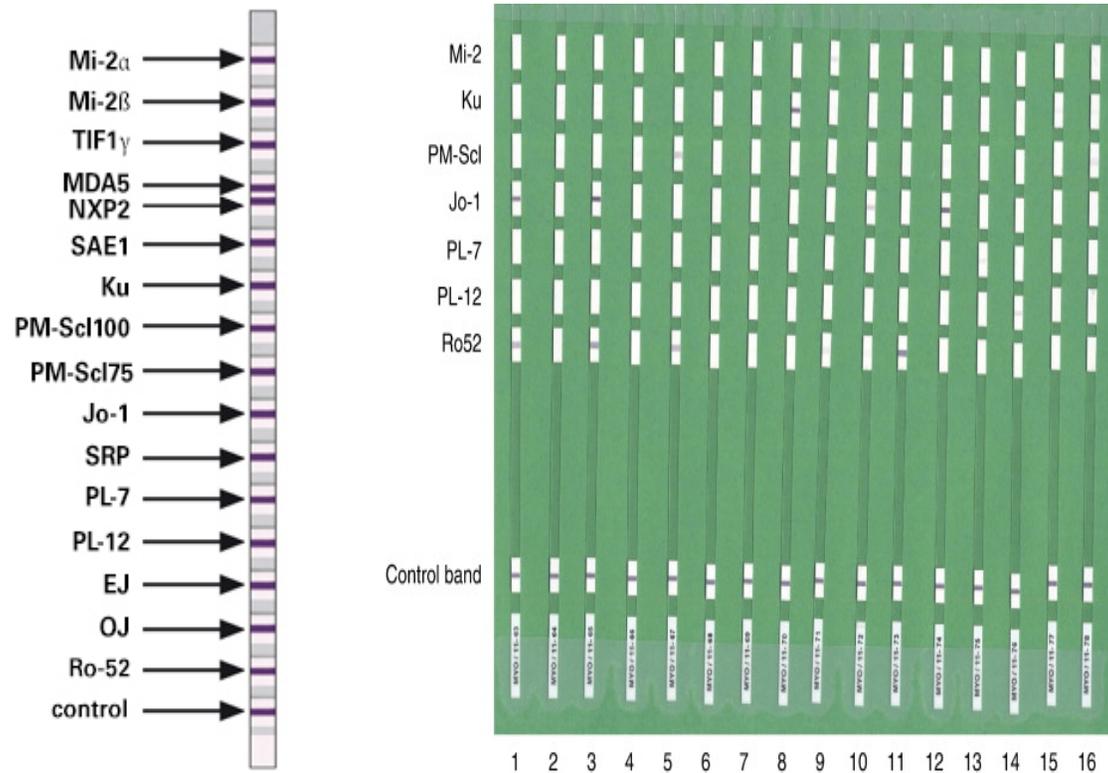
Jo-1 antibodies in patient plasma bind to structures in cell cytoplasm, and reagents produce a specific fluorescence pattern that is read and interpreted by a lab specialist

# Enzyme-linked Immuno-assay (ELISA):



Anti-HMGCR antibodies in patient plasma bind to antigen coated on a plate, and reagents produce a yellow color change. The darker or more intense the yellow, the higher the anti-HMGCR antibody levels.

# Line Immuno-Assay (LIA):



Patient antibodies bind to antigens coated on a strip, and reagents produce a line or band that is darker or more intense with higher antibody levels

# Validation and Antibody Discovery

- ▶ Your plasma donation could also be used by companies to validate that a test kit is working properly or that a lab is performing the test correctly
  - ▶ Samples are sent to labs within the US and around the world to ensure that kits and labs are reporting accurate results
- ▶ The samples PSG collects are stored in our Biobank
  - ▶ The samples may be tested on new tests and testing platforms
  - ▶ Research and development (R&D) departments around the world use PSG samples to develop new and better tests, including new antibody discovery





+



+

You:

How everyone  
benefits

# Donor Benefits:

- ▶ Donors are highly compensated for your time and effort for each plasma donation
  - ▶ Donors receive a min. of \$200/ per donation
  - ▶ Eligible donors approved for 2 donations over 72 hrs. receive \$400 !
  - ▶ Flexible donation dates based on your availability
  - ▶ extra money helps offset medical expenses
- ▶ Eligible to participate in future paid draws and projects



# Medical Diagnostic Benefits:

- ▶ PSG procures a reliable source of vital specialty plasma so test kits can continue to be manufactured
- ▶ R&D teams around the world discover and compare new and more accurate test systems, including emerging anti-bodies and tools for early detection



# Myositis Community Benefits:

- ▶ The more readily available materials are to make test kits, the more affordable testing becomes
- ▶ Access to more myositis donor samples results in:
  - ▶ better research cohorts
  - ▶ precise diagnostics and treatments
  - ▶ successful outcomes for those diagnosed with Myositis



# DDAP: Doctor, Donor Alliance Program



- ▶ By Talking to your Doctor about the PSG Specialty Plasma Donor Program, you give her/him the chance to join in the benefits.
- ▶ PSG routinely works with physicians to distribute our literature and educate the autoimmune community about the need for specialty plasma donation



# Anti-HMGCR:

## A critical link created in the nick of time

**A newly discovered antibody marker against HMG-CoA reductase (HMGCR) is associated with necrotizing autoimmune-myopathy and can be detected in up to 25% of these patients. ... The discovery of HMG-CoA reductase inhibitors, also known as statins, was a breakthrough in the treatment of high cholesterol**

“Statin Induced Myositis “ or Anti-HMGCR-associated myositis can be associated with statins in some cases



# The Need:

- ▶ A research and manufacturing leader in the myositis and autoimmune diagnostic industry reached out to PSG because they had developed a test kit for anti-HMGCR but could not source plasma with high enough anti-HMGCR levels to make the calibrators and controls for the kit.
- ▶ The kit was going to be pulled from the market the following year if anti-HMGCR plasma could not be found



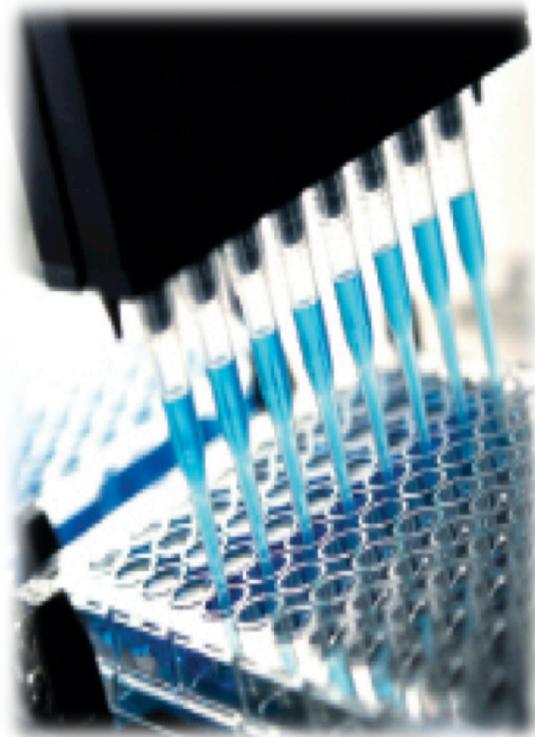
# The Solution:

- ▶ The company partnered with PSG to recruit and test for an anti-HMGCR donor
- ▶ After several months of recruitment, PSG identified a donor located in Texas
- ▶ PSG communicated with donor's physician and created a steady donation schedule that spanned a year



# The Outcome:

- ▶ Because of this one donor and PSG's efforts, the company is still manufacturing the kits and creating new test systems to detect anti-HMGCR antibodies



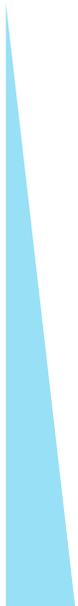


Since you know you  
can make a  
**DIFFERENCE...**

let's discuss HOW...

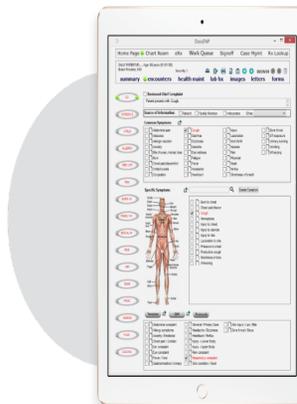
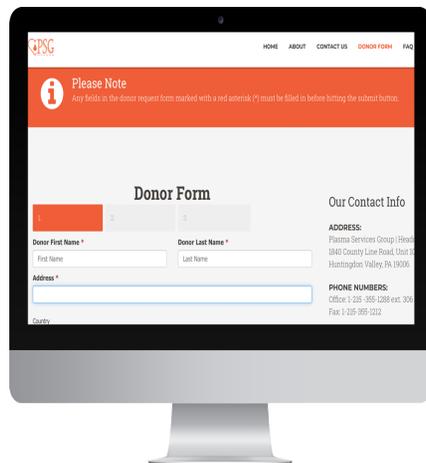
Watch the video below:

<https://vimeo.com/327304247>



# First steps to qualify as a specialty plasma Donor:

- ✓ Fill out our online donor form as thoroughly as possible at: <https://www.psgdonors.com/donor-form/>
- ✓ When contacted by our donor liaison, be ready to share any available labs
- ✓ Once our team reviews the labs, we will reach out to let you know if we would like to collect a blood sample to test in our lab at PSG
- ✓ You will also be e-mailed an Informed Consent to read and sign before we collect a sample.



# Sample Collection

- ▶ PSG sends Sample Kit
- ▶ A Phlebotomist will come to you to draw your sample
- ▶ Your Phlebotomist will send back your sample to PSG for testing
- ▶ Testing usually takes about 4-6 weeks
- ▶ Once testing is complete, you will be notified about your qualification



# Approved for Plasma Donation

- ✓ If you qualify for plasma donation, you will read and sign another Informed Consent for Plasma Donation
- ✓ We will reach out to your doctor to obtain a signed Physician's Approval for plasma donation
- ✓ If you do not have a doctor, we may ask that you receive a physical from the MD of the donation center
- ✓ We will help arrange and pay for any travel that may be required



# Not Approved for Plasma Donation?

## DON'T WORRY!

- ▶ If you do not qualify for plasma donation, we will retain your sample in our Biobank to test as future projects emerge
- ▶ We may contact you in the future to participate in a paid Biobank sample collection or even plasma donation



# Closing

- ▶ PSG would like to thank everyone for their time and attention today
- ▶ We would like to extend a special THANK YOU to MSU for the chance to host this webinar and for all their collaboration and efforts to “empower the Myositis community through education, support, awareness, advocacy and access to research:”



- ▶ We look forward to answering any questions you may have.



thank  
you!