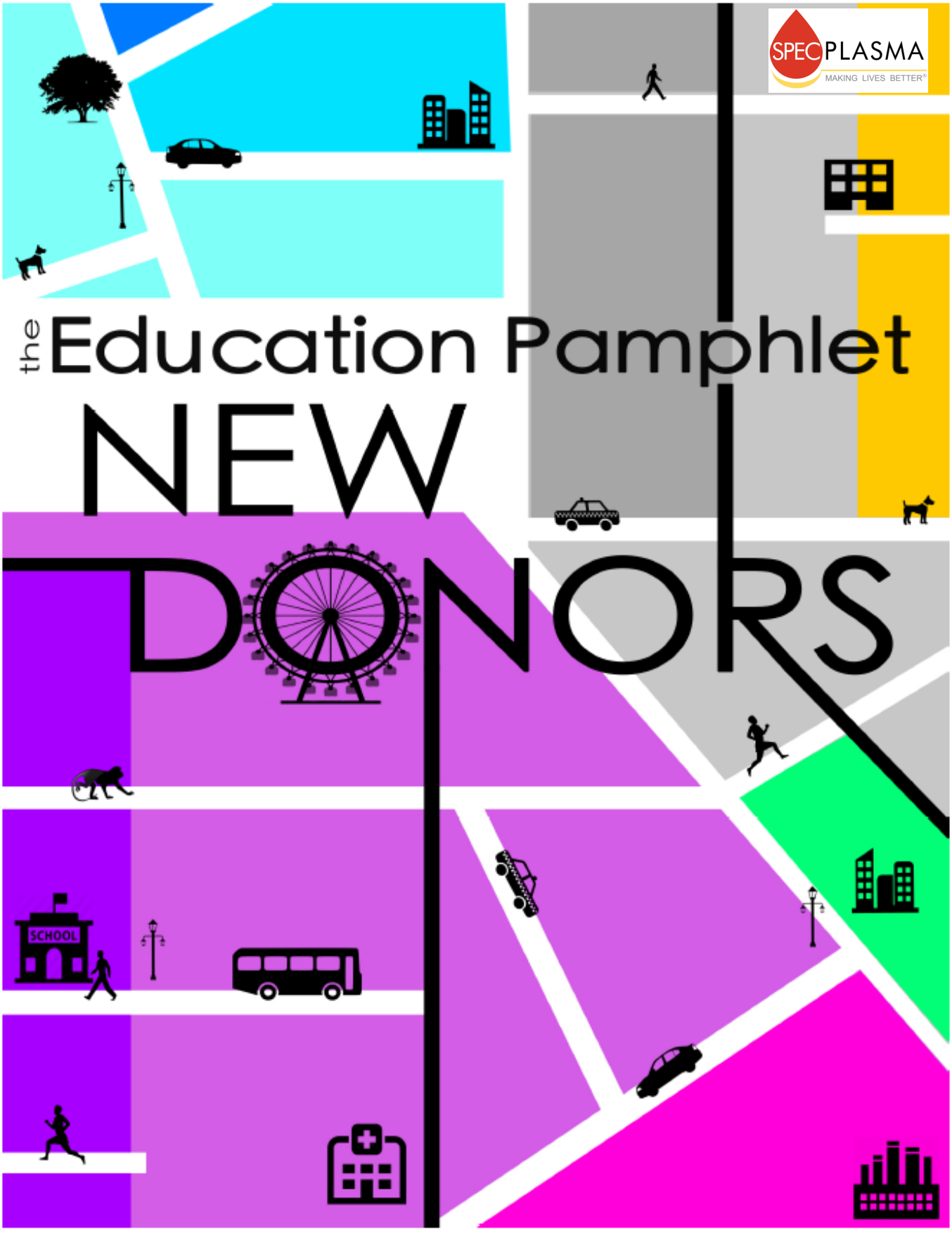


SOP 02010
Revision 2

Blood Donor Educational Material (DHQ/aDHQ v4.0)

YOU MUST READ THIS BEFORE YOU DONATE!

- **Your accurate and honest responses are critical to the safety of patients who receive blood transfusions.**
- Each question is necessary to fully evaluate the safety of your donation.
- As required by regulations, we are instructing you not to donate blood if you have a risk factor.
- If you don't understand a question, ask the blood center staff for assistance.
- YOUR RESPONSES ARE CONFIDENTIAL.

To determine if you are eligible to donate, we will:

- Ask about your health and medications you are taking or have taken.
- Ask if you have traveled to or lived in other countries.
- Ask about your risk for infections that can be transmitted by blood – especially HIV (which is the virus that causes AIDS), and viral hepatitis.
- Take your blood pressure, temperature, and pulse.
- Take a blood sample to be sure your blood count is acceptable before you donate.

If you are eligible to donate, we will:

- Clean your arm with an antiseptic (Tell us if you have any skin allergies).
- Use a sterile needle and tubing set to collect your blood.

We NEVER reuse a needle or tubing set.

WHAT HAPPENS AFTER YOUR DONATION

To protect patients, your blood is tested for hepatitis B and C, HIV, syphilis, and other infections. If your blood tests positive, it will not be given to a patient. You will be notified about any positive test result which may affect when you are eligible to donate in the future. There are times when your blood is not tested. If this occurs, you may not receive any notification. The blood center will not release your test results without your written permission unless required by law (e.g., to the Health Department).

DONOR ELIGIBILITY – SPECIFIC INFORMATION

Certain infectious diseases, such as HIV and hepatitis, can be spread through:

- Sexual contact
- Other activities that increase risk
- Blood transfusion

We will ask specific questions about sexual contact and other activities that may increase risk for these infections.

What do we mean by "sexual contact?"

The words "have sexual contact with" and "sex" are used in some of the questions we will ask you. These questions apply to all of the activities below, whether or not medications, condoms or other protection were used to prevent infection or pregnancy:

- Vaginal sex (contact between penis and vagina)
- Oral sex (mouth or tongue on someone's vagina, penis, or anus)
- Anal sex (contact between penis and anus)

A "new sexual partner" includes the following examples:

- Having sex with someone for the first time
  OR
- Having had sex with someone in a relationship that ended in the past, and having sex again with that person in the last 3 months.

HIV/Hepatitis risk factors

HIV and hepatitis are spread mainly by sexual contact with an infected person OR by sharing needles or syringes used by an infected person to inject drugs.

DO NOT DONATE if you:

- **Have EVER taken any medication to treat HIV infection.**
- **Are taking any medication to prevent HIV infection. These medications may be called: PrEP, PEP, TRUVADA, DESCOVY, APRETUDE or many other names.**

FDA-approved antiretroviral drugs are safe and effective in preventing sexual transmission of HIV. However, these antiretroviral drugs do not fully eliminate the virus from the body, and donated blood can potentially still transmit HIV infection to a transfusion recipient.

DO NOT STOP TAKING ANY PRESCRIBED MEDICATIONS IN ORDER TO DONATE BLOOD, INCLUDING PrEP and PEP MEDICATIONS.

DO NOT DONATE if you:

- Have **EVER** had a positive test for HIV infection.
- **In the past 3 months:**
  - Have had sexual contact with a new partner **and** have had anal sex.
  - Have had sexual contact with more than one partner **and** have had anal sex.
  - Have had sexual contact with anyone who has ever had a positive test for HIV infection.
  - Have received money, drugs, or other payment for sex.
  - Have used needles to inject drugs, steroids, or anything not prescribed by your doctor.
  - Have had sexual contact with anyone who has received money, drugs, or other payment for sex, **or** used needles to inject drugs, steroids, or anything not prescribed by their doctor.
  - Have had syphilis or gonorrhea or been treated for syphilis or gonorrhea.
- **In the past 12 months:**
  - Have been in juvenile detention, lockup, jail or prison for 72 hours or more consecutively.
- Have **EVER** had Ebola virus infection or disease.

DO NOT DONATE if you have these symptoms which can be present before you test positive for HIV:

- Fever
- Enlarged lymph glands
- Sore throat
- Rash

Your blood can transmit infections, including HIV, even if you feel well and all your tests are normal. Even the best tests cannot detect the virus for a period of time after you are infected.

DO NOT DONATE:

- If you think you may be at risk for HIV or other infections.
- If your purpose for donating is to obtain test results for HIV or other infections. Ask us where you can be tested for HIV and other infections.
- If your donation might harm the patient who receives your blood.

THANK YOU FOR DONATING BLOOD TODAY!

(Donor Center Name/Telephone Number)

BLOOD DONOR EDUCATIONAL MATERIAL FOR EBOLA VIRUS DISEASE OR INFECTION

This information applies following the CDC's classification of one or more countries as having "widespread transmission or cases in urban areas with uncertain control measures" at this link: http://www.cdc.gov/vhf/ebola/outbreaks/2014-west-africa/distribution-map.html.

Blood collection facilities must reduce the risk of collecting blood and blood components from a donor who may be infected with Ebola virus. It is possible that an Ebola virus infected person may not have symptoms of infection during the incubation period. In addition, anyone who has EVER had Ebola virus infection or disease may be at risk for transmitting the virus through blood donation, regardless of the length of time since recovery.

Ebola virus is transmitted from human to human by direct exposure to body fluids (such as blood, urine, stool, saliva, semen, vaginal fluids or vomit) from infected individuals. Healthcare workers, and family and friends providing care may have direct exposure to body fluids of infected patients. If direct exposure occurs, a person is at high risk of developing Ebola virus infection and must not donate blood or blood components.

DO NOT DONATE BLOOD if:

- You have **EVER** had Ebola virus disease or infection
- In the **PAST 8 WEEKS,** you have lived in, or travelled to, a country with widespread Ebola virus disease or infection.
- In the **PAST 8 WEEKS,** you have had sexual contact with a person has **EVER** had Ebola virus disease or infection, regardless of the length of time since recovery.
- In the **PAST 8 WEEKS,** you have had direct exposure to the body fluids (such as blood, urine, stool, saliva, semen, vaginal fluids or vomit) of a person with Ebola virus disease or infection, including a person under investigation.
- In the **PAST 8 WEEKS,** you have you been notified by a public health authority that you may have been exposed to a person with Ebola virus disease or infection.

PLEASE CONTACT THE DONOR CENTER, if you develop the following symptoms within the 8-week period following donation:

Fever Diarrhea
Severe Headache

followed by:

Vomiting
Muscle Pain and Weakness Abdominal Pain
Fatigue hemorrhage (bleeding or bruising)

WHAT HAPPENS AFTER YOUR DONATION

To protect patients, your blood is tested for several types of hepatitis, HIV, syphilis, and other infections. If your blood tests positive, it will not be given to a patient. There are times when your blood is not tested. If this occurs, you may not receive any notification. You will be notified about any positive test result which may disqualify you from donating in the future. The blood center will not release your test results without your written permission unless required by law (e.g. to the Health Department).

DONOR FLOW

WE REQUIRE WHEN A NEW DONOR SIGNS IN

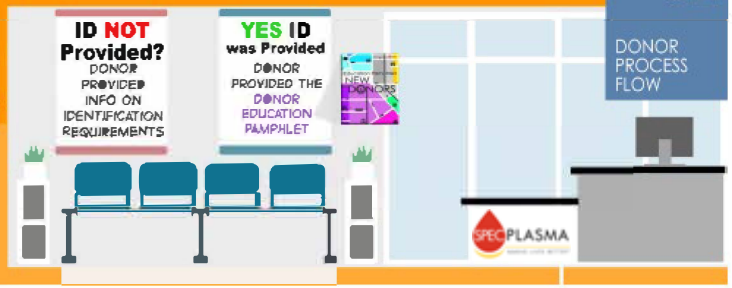
02

DONOR PROCESS FLOW

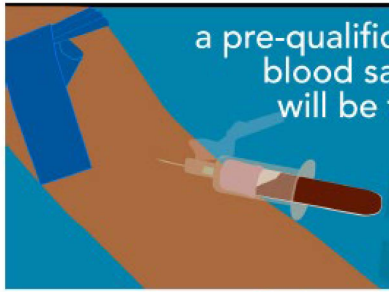
1 identification

2 social security card

3 proof of address



QUALIFICATION



a pre-qualification blood sample will be taken

a testing period of 1 - 2 days

HEALTH HISTORY QUESTIONNAIRE

Next, Donor will take a self-administered Health History Questionnaire.

You will be asked about...

1 your health history
2 your medications
3 your past donation history
4 your sexual history
5 your travel history

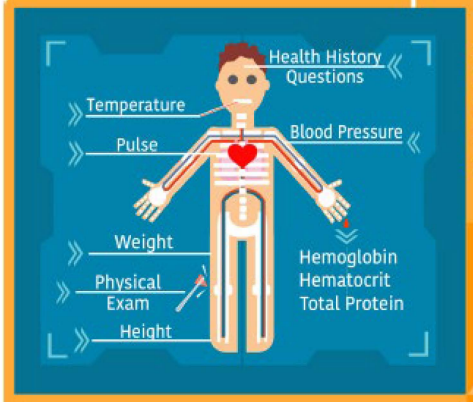
TEST RESULTS

negative	positive
1 donor appointment set	1 donor is deferred
2 donation must occur within 7 days	2 Health Department notified

AFTER DONATION

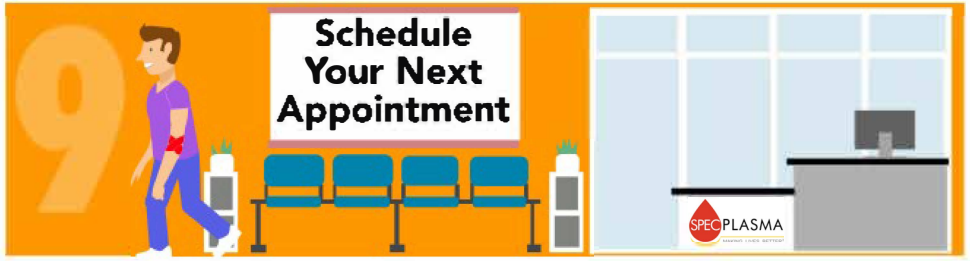
&

ASSESSMENT & CONSENTS



donor will have a physical assessment to determine suitability and safety to donate

donor will review & sign
Consent for Plasmapheresis
Consent for HIV Testing



Medication Deferral List (DHQ/aDHQ v4.0)

DO NOT STOP taking medications prescribed by your doctor in order to donate blood. Donating while taking these drugs could have a negative effect on your health or on the health of the recipient of your blood. PLEASE TELL US IF YOU:

ARE BEING TREATED WITH ANY OF THE FOLLOWING TYPES OF MEDICATIONS:	OR HAVE TAKEN:		WHICH IS ALSO CALLED:	ANYTIME IN THE LAST:
Antiplatelet agents (usually taken to prevent stroke or heart attack)	Feldene		piroxicam	**2 Days**
	Effient		prasugrel	**3 Days**
	Brilinta		ticagrelor	**7 Days**
	Plavix		clopidogrel	**14 Days**
	Ticlid		ticlopidine	
	Zontivity		vorapaxar	**1 Month**
Anticoagulants or "blood thinners" (usually taken to prevent blood clots in the legs and lungs and to prevent strokes)	Arixtra		fondaparinux	**2 Days**
	Eliquis		apixaban	
	Fragmin		dalteparin	
	Lovenox		enoxaparin	
	Pradaxa		dabigatran	
	Savaysa		edoxaban	
	Xarelto		rivaroxaban	
	Coumadin, Warfilone, Jantoven		warfarin	**7 Days**
	Heparin, low-molecular-weight heparin			
Acne treatment	Accutane Amnesteem Absorica Claravis Myorisan Sotret Zenatane		isotretinoin	**1 Month**
Multiple myeloma	Thalomid Revlimid		thalidomide lenalidomide	
Rheumatoid arthritis	Rinvoq		upadacitinib	
Hair loss remedy	Propecia		finasteride	
Prostate symptoms	Proscar		finasteride	
	Avodart Jalyn		dutasteride	**6 Months**
Immunosuppressant	Cellcept		mycophenolate mofetil	**6 Weeks**
Hepatitis exposure	Hepatitis B Immune Globulin		HBIG	**3 Months**
HIV prevention (also known as PrEP or PEP)	Any medication taken by mouth (oral) to prevent HIV.	Truvada	emtricitabine and tenofovir disoproxil fumarate	
		Descovy	emtricitabine and tenofovir alafenamide	
	Injectable HIV prevention	Apretude	cabotegravir	**2 Years**
Basal cell skin cancer	Erivedge Odomzo		vismodegib sonidegib	**2 Years**
Relapsing multiple sclerosis	Aubagio		teriflunomide	
Rheumatoid arthritis	Arava		leflunomide	
Psoriasis	Soriatane		acitretin	**3 Years**
	Tegison		etretinate	**Ever**
HIV treatment	Any medication to treat HIV. May also be called antiretroviral therapy (ART)			
Experimental medication				**As defined by the medical director**

BLOOD DHQ v4.0 FLOWCHARTS

The following information is included to assist the donor historian when providing additional information to the donor concerning their deferral:

Some medications may affect donor eligibility for the following reasons:

Antiplatelet agents affect platelet function, so people taking these drugs should not donate platelets for the indicated time. You may still be able to donate whole blood or red blood cells by apheresis.

Anticoagulants or "blood thinners" are used to treat or prevent blood clots in the legs, lungs, or other parts of the body, and to prevent strokes. These medications affect the blood's ability to clot, which might cause excessive bruising or bleeding when you donate. You may still be able to donate whole blood or red blood cells by apheresis.

Isotretinoin, finasteride, dutasteride, acitretin, and etretinate can cause birth defects. Your donated blood could contain high enough levels to damage the unborn baby if transfused to a pregnant woman.

Thalomid (thalidomide), Revlimid (lenalidomide), Erivedge (vismodegib), Odomzo (sonidegib), Aubagio (teriflunomide), and Rinvoq (upadacitinib) may cause birth defects or the death of an unborn baby if transfused to a pregnant woman.

Cellcept (mycophenolate mofetil) and Arava (leflunomide) are immunosuppressants that may cause birth defects or the death of an unborn baby if transfused to a pregnant woman.

PrEP or pre-exposure prophylaxis involves taking a specific combination of oral medicines (i.e., short-acting antiviral PrEP) or injections (i.e., long-acting antiviral PrEP) as a prevention method for people who are HIV negative and at high risk of HIV infection. FDA has determined that the available data demonstrate that the use of PrEP or PEP may delay the detection of HIV by currently licensed screening tests for blood donations, potentially resulting in false negative results in infected individuals. Although "Undetectable = Untransmittable" for sexual transmission, this **does not apply to transfusion transmission**.

PEP or post-exposure prophylaxis is a short-acting treatment started as soon as possible after a high-risk exposure to HIV to reduce the risk of infection. FDA has determined that the available data demonstrate that the use of PrEP or PEP may delay the detection of HIV by currently licensed screening tests for blood donations, potentially resulting in false negative results in infected individuals. Although "Undetectable = Untransmittable" for sexual transmission, this **does not apply to transfusion transmission**.

ART or antiretroviral therapy is the use of a combination of HIV medicines (called an HIV regimen) to treat HIV infection. HIV infection requires a permanent deferral despite treatment with ART. Antiretroviral drugs do not fully eliminate the virus from the body, and donated blood from individuals infected with HIV taking ART can potentially still transmit HIV to a transfusion recipient. Although "Undetectable = Untransmittable" for sexual transmission, this **does not apply to transfusion transmission**.

Hepatitis B Immune Globulin (HBIG) is an injected material used to prevent hepatitis B infection following a possible or known exposure to hepatitis B. HBIG does not prevent hepatitis B infection in every case; therefore, persons who have received HBIG must wait to donate blood.

Experimental medications are usually associated with a research study, and their effect on the safety of transfused blood is unknown.

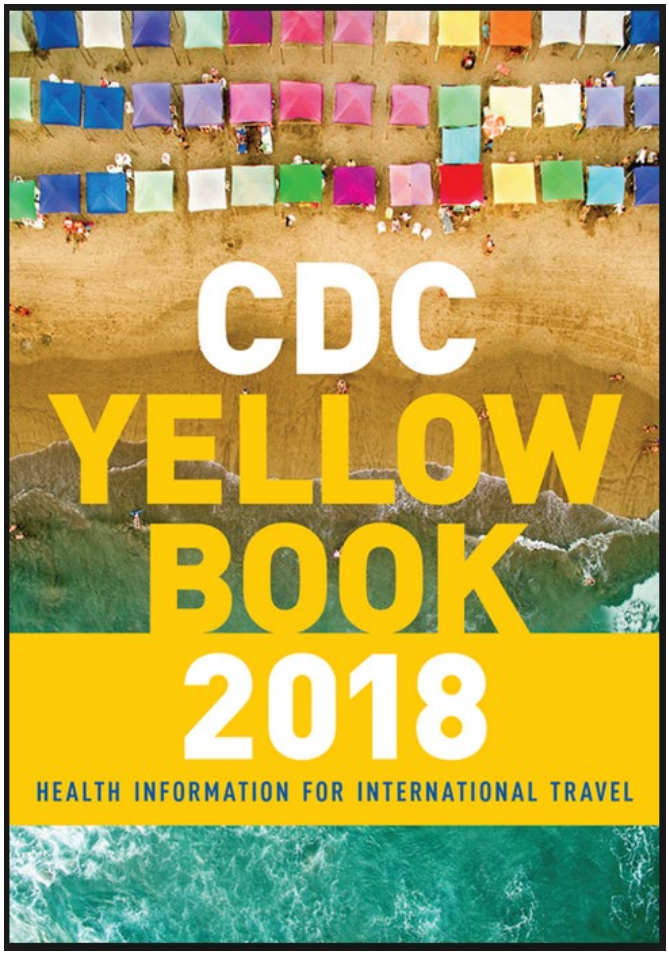
TRAVEL

In the past 3 years, have you been outside the United States or Canada?

Malaria is a serious and sometimes fatal disease that can caused by any of the following four Plasmodium species: P. falciparum; P. malariae; P. ovale; or P. vivax. About 1,500 cases of malaria are diagnosed in the United States each year, the vast majority of which are found among travelers and immigrants returning from countries where malaria transmission occurs, such as sub-Saharan Africa and South Asia. People who contract malaria typically become very sick with high fevers, shaking chills and flu-like illness. Although malaria can be fatal, illness and death from this disease usually can be prevented.

Check the CDC Yellow Book to see if you traveled to a malaria endemic area.

https://www.cdc.gov/malaria/travelers/country_table




UNITED STATES
BERMUDA
THE BAHAMAS
MEXICO
CUBA
DOMINICAN REPUBLIC
US VIRGIN ISLANDS
BELIZE
JAMAICA
HAITI
PUERTO RICO
GUATEMALA
HONDURAS
EL SALVADOR
NICARAGUA
ARUBA
TRINIDAD & TOBAGO
COSTA RICA
VENEZUELA
PANAMA
GUYANA
FRENCH GUIANA
SURINAME
COLOMBIA
ECUADOR
GALÁPAGOS ISLANDS
PERU
BRAZIL
BOLIVIA
PARAGUAY
EASTER ISLAND
ARGENTINA
CHILE
URUGUAY
Endemic
Non-endemic
Boundary representation is not necessarily authoritative.


RUSSIA
KAZAKHSTAN
UZBEKISTAN
TURKMENISTAN
AZORES
PORTUGAL
SPAIN
ITALY
GREECE
TURKEY
MADEIRA ISLANDS
CANARY ISLANDS
MOROCCO
TUNISIA
ALGERIA
LIBYA
EGYPT
SYRIA
IRAQ
IRAN
ISRAEL
JORDAN
KUWAIT
AFGHANISTAN
PAKISTAN
BAHRAIN
UAE
SAUDI ARABIA
OMAN
YEMEN
MAURITANIA
CAPE VERDE
MALI
NIGER
CHAD
SUDAN
ERITREA
DJIBOUTI
SOMALIA
SENEGAL
THE GAMBIA
GUINEA-BISSAU
GUINEA
BURKINA FASO
BENIN
NIGERIA
CÔTE D'IVOIRE
SIERRA LEONE
LIBERIA
GHANA
TOGO
CAMEROON
CENTRAL AFRICAN REPUBLIC
SOUTH SUDAN
ETHIOPIA
EQUATORIAL GUINEA
SÃO TOMÉ AND PRÍNCIPE
UGANDA
KENYA
GABON
REP. OF THE CONGO
RWANDA
BURUNDI
DEM. REP. OF THE CONGO
TANZANIA
SEYCHELLES
COMOROS
ANGOLA
MALAWI
MAYOTTE
ZAMBIA
ST. HELENA
MOZAMBIQUE
ZIMBABWE
MAURITIUS
NAMIBIA
MADAGASCAR
RÉUNION
BOTSWANA
ESWATINI
LESOTHO
SOUTH AFRICA
Endemic
Non-endemic


RUSSIA
KAZAKHSTAN
MONGOLIA
KYRGYZSTAN
TAJIKISTAN
AFG.
PAKISTAN
CHINA
NORTH KOREA
SOUTH KOREA
JAPAN
NEPAL
BHUTAN
BANGLADESH
INDIA
BURMA
LAOS
TAIWAN
HONG KONG SAR
MACAU SAR
HAINAN
VIETNAM
THAILAND
CAMBODIA
PHILIPPINES
NORTHERN MARIANA ISLANDS
GUAM
MARSHALL ISLANDS
FEDERATED STATES OF MICRONESIA
PALAU
SRI LANKA
BRUNEI
MALAYSIA
MALDIVES
SINGAPORE
INDONESIA
PAPUA NEW GUINEA
SOLOMON ISLANDS
TIMOR-LESTE
NEW CALEDONIA
AUSTRALIA
NEW ZEALAND
FRENCH SOUTHERN & ANTARCTIC LANDS
Boundary representation is not necessarily authoritative.

INFORMED CONSENT FOR PLASMAPHERESIS AND HIV TESTING

1. I understand that plasmapheresis is a process in which the liquid portion of the blood – plasma – is separated from the red cells. I understand an automated apheresis machine will be used, this process involves:
    a) A sterile, one-time use kit will be used for this procedure.
    b) During plasmapheresis donors rest on a donation bed. A needle is placed into a vein in the crux of whichever arm has the most robust vein.
    c) Removal of up to 15% of my total blood volume at one time. Whole blood is mixed with anticoagulant and separated from the red cells. The red cells are then returned to me. This process continues for several cycles.
    d) I may receive up to 250ml of anticoagulant (blood thinner).

2. I understand I can donate plasma one time in seven days,
3. I understand that more frequent donations could cause me complications. I will not participate in more than one plasmapheresis program at a time, and that the donation of Whole Blood or Red Blood Cells while participating in the plasmapheresis program may serve as a basis for an 8-week deferral or a 16-week deferral for a Red Blood Cell donation.

4. The pre-qualification process can take up to 1 hour. The process includes New Donor registration, donor education, health history questions and hands-on physical exam and blood tests. I will be notified within 2-3 days, if I qualify for the plasmapheresis program.

5. Routine donation sessions usually take less than 60 minutes' total. You are encouraged to stay in the center after your donation and enjoy a healthy snack and juice.

6. I understand that prior to donation, I must provide written informed consent for the plasmapheresis procedure.

7. I understand my informed consent will be maintained electronically in my Spectrum Plasma donor record file. Further, I understand that blood establishment records, including donor records, are subject to inspection by FDA and, if applicable, other regulatory agencies.

8. I acknowledge that before I signed the first copy of this informed consent, a qualified licensed nurse or physician explained the hazards of the procedure. Prior to signing consecutive consent forms I read about the potential hazards.

The hazards of the procedure include the following:

a) Light-headedness
b) Fainting
c) Vomiting
d) Hyperventilation
e) Hematoma formation at the site of venipuncture
f) Syncopal reactions due to hypovolemia
g) Post-Donation iron deficiency

Reactions that are unique to plasmapheresis collection procedures include:

a) Allergic reactions such as flushing, itching, hives, abdominal cramps, difficulty breathing, chest pain, or bronchospasm, which may vary in severity from mild to life-threatening.
b) Chills (induced by infusion of room temperature saline or donor blood)
c) Moderate hypocalcemia due to chelation of calcium by metabolized citrate (caused by infusion of anticoagulants containing citrate). This reaction is usually manifested by:
    - Unusual taste or smell

- Tingling around the mouth or fingers
- Muscle discomfort, muscle twitching, or spasms.

d) Symptoms of severe hypocalcemia although rare include:

- Tetany
- Convulsions
- Cardiac arrhythmias

e) Occasionally mild, temporary facial redness or flushing of donors has been reported, most often during return blood cycles.

f) Hemolysis, air embolism and blood clotting

g) Blood loss from the inability to return red blood cells during automated plasmapheresis, which may result in:

- The procedure being terminated, and
- Deferral from donation for 8 weeks.

h) Complications such as a hematoma or localized infection at the venipuncture site.

i) Nausea, vomiting, light-headedness, fainting, or seizures;

j) Bleeding, infection, pain, and the potential need for additional procedures in the event of complications.

9. I understand that frequent plasmapheresis donors might experience changes in blood protein levels, hemoglobin, IgG levels which may necessitate deferment or removal from the program. I understand that Spectrum Plasma will collect samples to test **mean corpuscular volume (MCV), which is a measure of the average size of the red blood cells and** is performed to diagnose anemia. Additionally, a total serum protein (SPE), including immunoglobulin levels, these samples will be collected and tested at least every 4 months, and if the results are not within required limits, I will be removed from the program until the values return to normal. Further, donor screening will be completed prior to each donation to check my total protein levels, blood pressure, temperature, pulse, weight, height and hematocrit. If any of these levels are outside the required range, I understand I will be temporarily deferred from donating until they return to normal.
10. **Donor Responsibilities:**
    a) To reduce the risk of infection, I should leave my bandage in place for 2 hours after each donation.
    b) I understand I must actively participate in the accurate identification of myself. I will be asked for my social security number and my photograph will be taken to aid in my identification. I understand I will be asked for my full name and date of birth during each step of the process. I have provided Spectrum Plasma a valid form of identification and my Social Security number, to ensure I am registered accurately.
    c) I understand I should have a nutritious meal before donating. I will drink plenty of non-caffeinated, non-alcoholic beverages before and after donation.
    d) If at any time in the donation process, I am not feeling well, I will notify a member of the staff to assist me.
    e) If I experience a reaction after leaving Spectrum Plasma I agree to call the center or seek medical evaluation or treatment. If I refuse or decline to seek medical treatment or transportation to the emergency room or medical facility, I am assuming the risk that my condition may become worse or cause additional medical complications to develop, up to, and including death.

11. I consent to have my blood tested for the presence of transmissible disease agents and other antibodies. If the results of tests for communicable disease agents are reactive, positive, or outside of normal limits the consequences could include:
    a. Detection of infectious agents such as Human Immunodeficiency Virus (HIV), or hepatitis, West Nile Virus. If I test positive for a transmissible disease I agree to be contacted by mail.
    b. I understand I may be temporarily or permanently deferred from donation, as required by FDA and State regulations.
    c. I understand my results will be reported to public health officials per state law, and a subsequent public health investigation may occur.
    d. I understand that I should not donate in order to receive infectious disease testing.
12. I understand there is a "window period" for infection (the time interval early in infection during which tests for diseases such as HIV or hepatitis may be negative although infection may still be transmitted). I

promise I am not participating in donation as a means of being tested, and that I am not at risk for transmitting HIV infection to others through this donation.

13. **Female donors:** I understand I cannot donate if I am pregnant. I will report any pregnancies I have ever had in the past to Spectrum Plasma medical staff, and if I become pregnant I will stop donating until 6 weeks' post-partum. Further, I consent to testing for Human Leukocyte Antigen (HLA), an antigen that can sometimes be developed during pregnancy, and is known to cause a rare lung disease in patients that receive a transfusion.

14. I have read and understand The Spectrum Plasma Blood Bank pre-donation information as it applies to the plasmapheresis donation I am about to make. To my knowledge, I have answered all questions truthfully and accurately. I understand the information about the spread of the AIDS virus by blood and blood products. I agree not to donate blood/blood components for transfusion to another person if I think I am at risk for spreading the AIDS virus.

15. I voluntarily donate my blood/blood components to The Spectrum Plasma Blood Bank to use in any way it deems advisable. For that purpose, I consent to related tests, examinations, and procedures determined appropriate by The Spectrum Plasma Blood Bank.

16. I understand that trained personnel will insert a needle into my arm to collect my plasma. The donation of plasma is not completely risk free. I have read and understand these risks as presented in the pre-donation information. I have been given opportunity to ask questions and all the questions I have asked have been answered to my satisfaction.

17. I understand that I am free to withdraw my consent and to discontinue participation in the plasmapheresis program at any time.

THANK YOU FOR DONATING TODAY