

APPENDIX B: BLOOD DONOR PRE-SCREENING SOP**Blood Donor Pre-Screening Standard Operating Procedures**

This Standard Operating Procedure (SOP) accompanies the Whole Blood Transfusion Clinical Practice Guideline published by the Joint Trauma System, the DoD Center of Excellence for Trauma.

1.0 Material and Equipment

Use the following:

- ASBP 572- Emergency Whole Blood (EWB)
- Clip Boards
- Gloves
- Testing Collection Set: premade bags with 2x2 gauze, 2 red top tubes, 4 purple top tubes,
Note: More tubes may be required if using short draw or small volume tubes
Note: Gold/yellow top (serum separator) tubes may be substituted for red top tubes.
Note: Pearl top (plasma preparation) tubes may be substituted for 3 of the purple top tubes.
- Blood Collection Needles
- BD Vacutainer Hubs
- Coban
- Assigned Pre Screen ISBT Labels (500 number series)
- Sharps Containers
- ABO/Rh Testing Card (e.g., Eldon Military Kit or other FDA-approved device)
- Centrifuge
- Disposable Pipettes
- Plastic Aliquot tubes/lids 13X100mm (or 12X75mm)
- Para-Film
- Biohazard Bags
- Trash Bags
- Leak Resistant Chucks
- Disposable Lab Coats
- Cold Packs
- Test Tube Racks

2.0 Records/Forms

- ASBP 572-EWB, Form 147, Form 148
- Theater Medial Data Store (TMDS), Blood Portal

3.0 Quality Control

- If possible, perform quality check on ABO/Rh Testing Card (See package inserts for procedures).
- Medical personnel should be trained by blood donor center/Blood Support Detachment or other qualified personnel.

4.0 Procedure

Pre-screening of a prospective emergency whole blood donor pool is mandatory. Development of a pre-screened donor pool should be considered a commander's priority when preparing for deployment and/or after arrival into theater. It is imperative that a donor pool once established is maintained because of the frequent redeployment of units out of theater and change of assigned personnel. Due diligence in establishing a pre-screened whole blood donor pool will decrease the risk of transmitting infectious disease while simultaneously increasing the efficiency of the whole blood collection process.

Perform the following steps when pre-screening donors:**1. Prepare for donor pre-screening event**

Coordinate with appropriate units/contacts for times and location of event. May need to conduct a site survey to ensure appropriate site (i.e. space, lighting, privacy for interview). Samples need to be sent to the testing lab/donor center/blood support detachment as soon as possible after collection, so prior coordination with transport assets is a must.

2. Conduct the pre-screening event

- **Medical history:** Provide prospective donor an ASBP 572-EWB– ensure demographic info is legible and as complete as possible.
- **Interview:** Trained medical personnel will need to determine if the donor is eligible to donate based on the information collected.

NOTE: ONLY GROUP A questions (1-8) on the ASBP 572-EWB must be completed by the donor for pre-screening.

- If/Then Scenarios
 - a. **If:** Response to question 1 is “Yes” AND Responses for questions 2-8 are “No”
Then: Document acceptability of Group A question responses on ASBP 572-EWB and proceed to step 3
 - b. **If:** There are any “Yes” responses for questions 2-8 AND/OR Response to question 1 is “No”
Then: Document the reason for the “Yes” response (questions 2-8) or “No” response to question 1. Defer the donor and document unacceptability of Group A question responses on ASBP 572-EWB.

3. Phlebotomy

- a. Collect 4 Purple Top and 2 Red Top tubes and label with small Pre-Screen (500 number series will be used in theater) ISBT labels (without barcodes).
- b. Apply the same ISBT label number to the ASBP 572-EWB. If no ISBT labels available, label tubes with donor’s full name and DoP ID.

4. Register donor in TMDS per Manage Donations/Donors

See steps below in section 5.0 Maintain Database (TDMS)

Note: Rapid Infectious Disease Testing is not required for the pre-screen of donors. If performed, see Emergency Whole Blood Collection SOP for instructions.

5. Perform ABO/Rh Testing

- a. Utilizing blood from purple top tube, perform ABO/Rh confirmation using Eldon Card or other FDA-approved method to verify ABO listed on ASBP 572-EWB. (Refer to package inserts and approved facility/unit SOPs for further instructions).
- b. Record Lot # of reagents, EXP Date and Results on Form 147.
- c. Record blood type in TMDS.

6. Process Samples for Shipment & Testing

- a. Centrifuge 2 Red Top and 3 Purple Top Tubes for 5 minutes at 4000 RPM.
- b. Label three aliquot (pour off) tubes with corresponding ISBT Labels with small barcodes. Position the ISBT label vertically toward top of tube as shown at left. Write "Serum" on one tube and "Plasma" on the other two tubes. If ISBT labels are not available utilize the Donor's DoD ID or other unique identifier as appropriate to label the pour off tubes.
- c. Place plasma from 3 Purple Top tubes into the 2 aliquot tubes labeled "Plasma".
*3ml sample requirement per aliquot.
- d. Place serum from 2 Red Top tubes into the 1 aliquot tube marked as "Serum". Do not fill over $\frac{3}{4}$ full to allow for expansion from freezing
- e. The seal of capped aliquot tubes should be reinforced with para-film wrap and placed into a biohazard shipping bag or rack. If a rack is not used, rubber-band tubes from the same donor together. Repeat for each series.
- f. Record sample and donor demographic data on Form 148 (Shipping Manifest). Include a printed copy of manifest with shipment and e-mail to donor center, BSD or designated facility, if possible.
- g. Maintain the (pre-screening) ASBP 572-EWB at your site until the potential donor redeploys. As soon as possible ship samples and Form 148 in a blood box (Collins Blood Box) with ice bag(s) to your respective blood detachment or designated receiving facility. E-mail a copy of manifest to BSD or designated facility, if possible, and call to alert about incoming shipment.



NOTE: Samples may be frozen until they can be shipped to a designated laboratory to perform FDA-approved testing. Contact COCOM Joint Blood Program Office (JBPO) for guidance on specimen acceptability requirements.

NOTE: Depending on pre-screening unit location and prior coordination, it may be possible to ship specimens directly to a testing or processing facility without performing the tube centrifugation and sample pour offs. Prior coordination MUST be made with COCOM JBPO or testing facility to ensure samples will remain viable if centrifugation step above will be skipped. All donor tubes MUST be centrifuged and serum/plasma removed from RBCs within 72 hours of collection.

- h. The BSD or designated unit/facility will send all samples to designated laboratory for FDA-approved testing. BSD or designated facility will enter results in TMDS and forward to submitting Role 2 or Role 3 upon completion. In some cases, the submitting Role 2 or Role 3 may have to enter results into TMDS if not supported by a BSD.

NOTE: The prospective donor is NOT considered pre-screened and fully qualified for FWB donation until negative or non-reactive testing results are received from a testing facility. Once confirmatory testing is received back from the testing facility and results entered into TMDS, the donors are prescreened and eligible for donation and can be verified utilizing TMDS.

NOTE: Testing for type O donors may include anti-A and anti-B titer testing. The titer testing must be coordinated with the testing facility prior to sample shipment. Donor should not be used as a universal type O whole blood donor until titer results verify low titer status.

- i. Any positive testing that is received by BSD or unit will be forwarded to Preventive Medicine Consultant or available Provider (MD, DO, PA, NP) to ensure proper donor care and follow-up is initiated. At no time will laboratory staff notify donors directly regarding positive testing results.

5.0 Maintain Database (TMDS)

1. Transfer demographic information from the modified ASBP 572-EWB and Form 147 to Donor Management Database in TMDS. This will act as a deferral list or an eligible donor list when a whole blood drive is necessary. It is recommended that a hard copy of Donor Database and deferral list be printed monthly (or at some regular interval) for use during Emergency Whole Blood Collection when computer assets are unavailable. Information in database must be kept confidential.

NOTE: Ensure TMDS user is logged into TMDS under the correct blood facility account. For TMDS account guidance, contact the COCOM JBPO.

2. To enter demographic data into TMDS, go to the Manage Donation tab and select Donate Product. Enter the Donor SSN, first name, last name in appropriate fields and click NEXT.
3. In Demographic information area, enter donor's ABO/Rh, nationality and branch. Military unit and contact instructions may also be entered in the demographic information fields. Enter donor's redeployment date if known along with further contact information. In the Donation information area, enter the pre-screen date, document status of ASBP 572-EWB completion, donor's ABO/Rh and Donor Identification Number (DIN). Click ADD PRODUCT(S).

Note: If any of the TMDS auto-populated information fields in demographic information area is incorrect, contact the JBPO or TMDS Help Desk for guidance. TMDS contact information can be found on the TMDS log-in screen.

Note: The Donation Location field information will be auto-populated within TMDS.

4. In product description field, enter E9999V00 – PRE-SCREEN. In the expiration date field, enter date 90 days from today and click Add Product.
5. Verify donation ID, product description, product type, ABO/Rh and expiration date are correct, then click NEXT.
6. Carefully Re-verify all demographic data that populates on the screen, then click Confirm Donation. Prospective donor is now entered in TMDS.
7. From Manage Donation tab, select Update Donation. Enter donation ID number and click NEXT.
8. Enter ABO/Rh test result and date tested from Form 147 under Rapid Testing Results. In "Samples sent to" field, select BSD or unit from pull down menu and enter date samples were sent out from your facility. Now click Update Tests.

9. To register another donor, select Donate Product under Manage Donation tab and repeat process above.
10. Once pre-screen donations have been created utilizing the process above, a re-deployment date must be entered to ensure the active donor list will auto-update upon donor's exodus from theater. To accomplish this, select Manage Donor from beneath Manage Donor tab. Enter donor SSN and click Next. Select re-deployment date from the calendar tool in the "Update Re-deployment Date" field and click Update Donor. Once the displayed entry is confirmed to be correct, click Confirm Update. TMDS will now remove donor from active donor list on the re-deployment date that was entered.
11. BSD or designated unit will populate donor testing results and forward to submitting facility. Donor alerts will also be activated by BSD or unit, as necessary. This data, once populated, will be the basis by which potential donors will be deemed fully qualified for Fresh Whole Blood (FWB) donations, should the need for a Walking Blood Bank (WBB) arise at your facility.

NOTE: In some cases, the submitting Role 2 or Role 3 may have to enter results into TMDS if not supported by a BSD.

NOTE: Investing time and care into building a donor pool will make performing whole blood drives easier and safer when the time comes. Your donor pool does not need to be enormous. 50 people covering most of the blood types (O, A, B) is ideal for most locations.

Remember whole blood must be transfused group specific or from a group O/low titer donor.

6.0 Sources

- AABB Technical Manual, current edition.
- AABB Standards for Blood Banks and Transfusion Services, current edition.
- JTS Clinical Practice Guideline: Fresh Whole Blood (FWB) Transfusion
- Theater Medical Data Store (TMDS) System User's Manual, current edition.

7.0 Forms

- ASBP 572-EWB (Emergency Whole Blood)
- Form 147–Eldon Card ABO/Rh Typing Record
- Form 148–Pre-Screen/Whole Blood Sample Shipping Manifest

~ END ~

BLOOD DONOR PRE-SCREENING SOP ENCLOSURES (1)

ASBP 572: Emergency Whole Blood (front)

PRE-SCREEN / EMERGENCY WHOLE BLOOD DONATION RECORD						DONATION IDENTIFICATION NUMBER (DIN)	
Form is only to be used for pre-screening or collecting donors in support of contingency / deployed operations.						Use Donor SSN if ISBT # Not Available)	
TODAY'S DATE	NAME (Last, First, Middle Initial)	RANK/RATE	USA USMC	USAF CIV	USN	SSN:	
UNIT	UNIT LOCATION (Base and State)	AOR BASE & TENT# (if deployed)	DOB (DDMMYYYY)		SEX: M F		ABO/Rh (Blood Type)
CURRENT MAILING ADDRESS			EMAIL ADDRESS			BEST CONTACT PHONE NUMBER	
Group A Questions (ALL DONORS Must Complete)							
1	Have you read and do you understand the educational materials provided to you?	Y	N	5	Have you ever received money, drugs, or other payment for sex?	Y	N
2	Have you ever used needles to take drugs, steroids, or anything not prescribed by your doctor?	Y	N	6	Have you ever had cancer, heart problems, bleeding conditions, or lung disease?	Y	N
3	Have you taken any of the medications listed on the back of this form within the timeframes shown? If Yes, write medications here: _____	Y	N	7	Have you ever had hepatitis, or have you ever taken medication for treatment or exposure to hepatitis?	Y	N
4	Have you ever had a positive test for the HIV/AIDS virus?	Y	N	8	Have you ever had Malaria, Chagas or Babesiosis?	Y	N
Interviewer: Document review and eligibility below for walking blood bank (WEB) and/or low titer group O whole blood (LTOWB) donor program.							
DONORS: If you are being prescreened for a WEB or LTOWB program, STOP!! Answer no more questions and sign at the bottom. If you are here to donate a unit of blood, proceed to Group B Supplemental Questions and then sign at the bottom.							
Group A responses acceptable (all no except Q1)?		All disease tests negative?		Eligible for WEB?	Titer Result (If group O):	Eligible for LTOWB?	Approving Official
Y N		Y N		Y N	(accept if < 256)	Y N	Y N NA
***Interviewer (initials):							
Comments:							
Group B Supplemental Questions (Complete if Donating a Unit of Blood Today)							
9	Are you feeling healthy and well today?	Y	N	18	In the past 12 months, have you lived with or had sex with a person who has hepatitis?	Y	N
10	<u>Female donors:</u> Have you ever been pregnant or are you pregnant now?	Y	N	19	In the past 12 months, have you had a transplant (such as organ, tissue, or bone marrow) or graft (such as bone or skin)?	Y	N
11	<u>Female donors:</u> Have you had sexual contact with a male who had sexual contact with another male in the past 12 months?	Y	N	20	In the past 12 months, have you had sexual contact with anyone who has HIV/AIDS or has had a positive test for the HIV/AIDS virus?	Y	N
12	<u>Male donors:</u> In the past 12 months, have you had sexual contact with another male?	Y	N	21	In the past 12 months, have you come into contact with someone else's blood?	Y	N
13	Are you currently taking malaria prophylaxis?	Y	N	22	In the past 12 months, have you had an accidental needle-stick?	Y	N
14	Are you currently taking any medications for an infection?	Y	N	23	In the past 12 months, have you had a blood transfusion?	Y	N
15	Have you had physical contact with someone who was vaccinated for smallpox in the past 8 weeks?	Y	N	24	In the past 12 months, have you had sexual contact with anyone who takes money or drugs or other payment for sex?	Y	N
16	In the past 48 hours, have you taken aspirin or anything that has aspirin in it?	Y	N	25	In the past 12 months, have you had or been treated for syphilis or gonorrhea?	Y	N
17	In the past 8 weeks, have you donated blood, platelets, or plasma?	Y	N	26	In the past 12 months, have you had sexual contact with anyone who has ever used needles to take drugs or steroids, or anything not prescribed by their doctor?	Y	N
Comments:							
Today's Date:	Temperature: °F/°C (≤ 99.5°F/37.5°C)	Blood Pressure: /		Pulse: (50-100 bpm)	Hemoglobin: Male: ≥ 13.0 g/dL Female: ≥ 12.5 g/dL	Weight: (≥ 110 pounds/50kg)	Vital Signs Tech:
Does Donor Qualify? Y N	Phlebotomist	Start Time	Stop Time (-15 mins)	Bag Manufacturer	Lot #	Expiration Date:	Segment #
***Reviewer (initials):							
I verify that I have answered the questions honestly, I had an opportunity to ask questions, I consent to donating blood today, and I feel my blood is safe to be transfused. If I am donating a unit of whole blood today, my blood <u>will NOT be tested</u> for viral diseases prior to transfusion due to the emergency situation. If for any reason I feel that my blood may not be safe, I will not donate today.							
_____ Donor's Signature						_____ Date	

ASBP 572-EWB (Emergency Whole Blood), 5 Apr 2018

ASBP 572: Emergency Whole Blood (back)

DONOR EDUCATIONAL MATERIAL

Blood donation is a voluntary process requiring the collection of approximately 450-500 mL of blood. The usual collection time ranges from 5 to 10 minutes. Complications at the venipuncture site may include, but are not limited to: discomfort, bruising, swelling, or infection. Other complications could occur during or after your donation such as: fatigue, light-headedness, dizziness, nausea, vomiting, and/or fainting. On very rare occasions, a more severe reaction may occur.

MEDICATION LIST: Donors **SHOULD NOT** discontinue medications prescribed by their physician in order to donate blood. Certain medications in your system can cause harm to some patients if your blood is transfused. If your last dose of the following medications was taken within the timeframe listed, you should not donate today nor should you participate in a walking blood bank program because the medication has not cleared from your system.

Prescreen or Donating Blood Today:

Erivedge, Odomzo	Soriatane	Bovine Insulin, Human Growth Hormone, Tegison
2 years	3 years	EVER in your life

Donating Blood Today (must screen donor for drugs below AND list above if donating whole blood):

Eliquis, Feldene, Fragmin, LovenoX, Pradaxa, Savaysa, Xarelto	Arixtra, Brilinta, Coumadin, Effient, LMW Heparin, Jantoven, Warfilone		
2 days	7 days		
Plavix, Ticlid, Zontivity	Absorica, Accutane, Amnesteem, Claravis, Myorisan, Propecia, Proscar, Sotret, Zenatane	Avodart, Jalyn	Experimental Meds/Vaccines
14 days	1 month	6 months	1 year

Your signature on the other side of this form acknowledges that you understand the questions and this educational material and that you agree to not donate any blood products if you are at risk of transmitting Human Immunodeficiency Virus (HIV) or any other virus. We know that you would not donate unless you think your blood is safe. However, in order for us to assess all risks that may affect you or a patient receiving a transfusion, it is essential that you answer each question completely and accurately on the other side of this form. If you do not understand a question, ask a staff member. All information you provide is confidential. It is critical that you alert your unit provider or medic if any of your responses change or if you have any concerns about the safety of your blood. This will facilitate notification and follow up testing for the recipient if needed.

Your blood will be tested for several types of viral markers including Hepatitis B, Hepatitis C, HIV, syphilis and other infections. You will be notified about any positive test result which may disqualify you from donating in the future, and your name will be entered onto a list of permanently deferred donors. If testing does not occur (due to specimen acceptability) or if testing results are not clearly negative or positive, your name may be placed on a deferral list without you being informed until the results are further clarified. For active duty personnel and reservists, positive screening and confirmatory results will be forwarded to appropriate medical personnel for further evaluation and "fitness for duty" determination (if required).

HIGH RISK BEHAVIORS:

Certain diseases such as HIV/AIDS and hepatitis can be spread through sexual contact OR by sharing drug needles/syringes. These viruses can enter your blood stream and can be transmitted to another person who is transfused with your blood, plasma, or platelets. Sexual contact includes: Vaginal contact (contact between penis and vagina), oral sex (mouth or tongue on someone's vagina, penis, or anus), and/or anal sex (contact between penis and anus). **YOUR BLOOD CAN TRANSMIT DISEASES**, including HIV/AIDS, even if you feel well and all your tests are normal. This is because even the best tests cannot detect the virus for a period of time after you are infected.

DO NOT DONATE IF YOU:

- Have AIDS or have ever had a positive HIV test
- Have ever used needles to take any drugs not prescribed by your doctor
- Are a male who has had sexual contact with another male in the past 12 months
- Have ever taken money, drugs or other payment for sex
- Have had sexual contact in the past 12 months with anyone described above
- Have had syphilis or gonorrhea in the past 12 months
- Have been in juvenile detention, lockup, jail or prison for more than 72 consecutive hours in the past 12 months

DO NOT DONATE TO GET A TEST! If you think you may be at risk

for HIV/AIDS or any other infection, do not donate simply to get a test. See your medical provider to obtain an HIV/AIDS test. The following symptoms can be present before an HIV test turns positive: fever, enlarged lymph glands, sore throat, and/or rash.

NOTIFY YOUR UNIT MEDIC OR UNIT PROVIDER IF:

- Anything changes that would cause a different response to a question
- If you think your blood may not be safe for another person to receive
- If you become sick within 14 days after donating a unit of blood

THANK YOU FOR DONATING BLOOD!

ASBP 572-EWB (Emergency Whole Blood), 5 Apr 2018

BLOOD DONOR PRE-SCREENING SOP ENCLOSURES (2)

Form 147 Eldon Card ABO/Rh Typing Record



Rapid ABO/Rh Testing

Assigned Unit # / Patient ID	Eldon Card ABO/Rh Typing					Tech Initials	
	Lot #						
	Exp:						
	Anti-A	Anti-B	Anti-D	Control	Interpretation		
	+ =	+ =	+ =	+ =			
	+ =	+ =	+ =	+ =			
	+ =	+ =	+ =	+ =			
	+ =	+ =	+ =	+ =			
	+ =	+ =	+ =	+ =			
	+ =	+ =	+ =	+ =			
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Form 147
V: 20 Dec 2015

Supervisor Review: _____ Date: _____

QA/QC Review: _____ Date: _____

BLOOD DONOR PRE-SCREENING SOP ENCLOSURES (3)

Form 148–Pre-Screen/Whole Blood Sample Shipping Manifest

Prescreen/Whole Blood Sample Shipping Manifest

Blood Unit Number			Donation Date	Donor Name		Branch of Service	Nationality	SSN or ID #	DOB	FOB/Base	Unit	Donation Type (PS or FWB)
Facility ID (W0138)	YR	Unit Id #		ABO RH	Last							

Form 148
V. May 2012