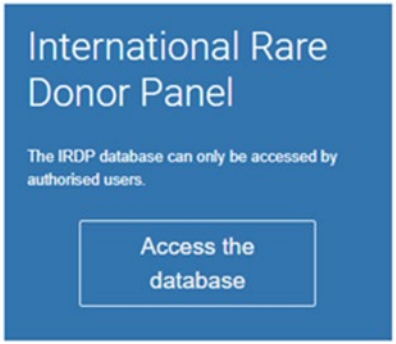


Rare Donor Program

Country: United States

Country: USA

Rare Donor Program	
Rare Donor Program	Yes
National Regional or Facility based	National (44 Red Cross and 42 AABB-accredited US-based IRLs)
Number of Rare Donors	~88,500 active US-based donors
Definition of Rare	1) Lacking high prevalence antigen (<1/1000 donors) 2) Characterized RH variant alleles with hrB-, hrS-, hrB+vw/- phenotypes 3) Multiple common antigen negatives 3a. R1, R2, R0, or rr AND K- AND Fy(a-) or Fy(b-) AND Jk(a-) or Jk(b-) AND S- or s- 3b. R1, R2 or rr AND K- AND Fy(a-b-) 4) IgA deficient (levels <0.05mg/dL 5) Rare Rh phenotype
Are the donors listed in the International Rare Donor Panel	Yes
Frozen Inventory	Held locally, no data available
How are Rare Donors found	Most by RBC genotyping panels, some by serologic screening
Number of Rare Donor Units used per year	~1000 cases, 2159 units
ISBT Rare Donor WP Blood Shipment form used	Yes (for international cases only)
Outcome of incompatible transfusion form used	Yes
Most difficult types to find	E- hr^{S}- (multiple alleles), Sec- (*RHCE*CeRN* homozygous) O neg U-, O neg Jk(a-b-)
Phenotypes confirmed by molecular testing	U-, Hy-, Jo(a-), V-, VS-

Country: USA

Phenotype	Total Active Donors	Group O	O Positive	O Negative	Other ABO/Rh
GE:-2,-3	18	14	14	0	3 A pos 1 B pos
Jk(a-b-)	37	25	25	0	6 Bpos,1 A neg,5 Apos
Ko	3	2	1	1	1 A pos
Kp(b-)	109	74	53	21	4 B pos 9 A neg 21 A pos 1 AB
MkMk	0	2	2	0	0
Rh:-34	0				
U-	1130	777	720	57	196 A pos 123 B pos 17 B neg 16 A neg 1 AB pos
PP1Pk-	34	11	11	0	14 A pos 6 A neg 3 B pos
SC:-1	1	0			1 A neg
En(a-)	0				
At(a-)	3	3	3	0	
Di(b-)	40	29	29	0	
Jr(a-)	10	5	4	1	
Rh null	3			0	3 A neg
Vel(-)	111	86	72	14	15 A pos 7 A neg 1 B neg 1 B pos 1 AB pos
D--	14	6	6		1 B pos
Oh	15			1 Oh D-	

Country: USA
How are your rare donors found?

	Yes / No	Method	Comments
Extended phenotyping donors	Yes, by some and in some instances	Manual tube and automated typing depending on the antigen and center	
Extended genotyping donors	Yes	Red Cross uses Agena HemoID DQS, OneBlood Uses Grifols IDCoreXT, Versiti uses locally-developed Lab-developed test, LifeShare uses HaploGenX HemoSelect	Unable to specify all methods used
Family studies	Sometimes		
Antibody investigations	Sometimes		
Other			

Red Cell Product Specifications

Country: United States

Country: USA

Donor Selection

Donation	Voluntary	
Age or Weight Restrictions	17 years of age and older (16 years of age permitted in some states with parental/guardian consent) Must weigh at least 110 lbs, For donors <18 years of age: females under 5'5" and males under 5' must meet additional height and weight requirements	
Donation Interval	56 days (8 weeks) for whole blood collection	
Sexual Activity Precautions	Sex with person positive for HIV, Hepatitis B/C, or HTLV	3 month deferral for HIV, 12 month deferral for HBV or symptomatic HCV, no deferral for asymptomatic HCV; no specific guidance for HTLV contact (addressed on case-by-case basis)
	Male to male sex (MSM) or female to MSM sex	3 month deferral but will change in a few months
	Sex worker or received payment for sex	3 month deferral
	Use of non-prescribed needles	3 month deferral
Travel Exclusions **If donor has returned from an area endemic for the listed infectious illnesses**	Dengue	No deferral defined but malaria deferral results covers travel to most endemic areas
	Ebola	No widespread transmission reported by FDA or CDC: no deferral/self-deferral If widespread transmission reported: indefinite deferral if ever infected with Ebola or 8 week deferral for travel to endemic country or contact with person/material infected with Ebola
	Malaria	Travel to endemic country: 3 month deferral, Lived >5 years in an endemic country: 3 year deferral, Malaria treatment completion: 3 year deferral
	West Nile Virus	120 day deferral after diagnosis, all donors screened using NAT testing
	Zika Virus	120 day deferral from symptom resolution
Lifestyle	Acupuncture Piercing Tattoo	No deferral No deferral if single use equipment used; if reusable equipment used or unknown: 3 month deferral No deferral if performed at state-regulated facility, if not state-regulated: 3 month deferral
	Drug use (Non-prescribed injected)	3 month deferral
	Incarceration	If consecutive 72 hours or greater: 12 month deferral from release, if not consecutive or <72 hours: no deferral
CJD restrictions	American Red Cross donor health questionnaire (ARC DHQ) inquires whether donor has a history of dura mater graft. Donors who have received an animal-derived, cadaveric, or allogeneic human-derived dura mater graft or had head or brain surgery without knowledge of whether a dura mater graft was received are deferred indefinitely. Geographic risk regions for bovine spongiform encephalopathy are no longer part of deferral criteria. The following are not addressed in the ARC DHQ but may be information volunteered by donor: Donors who volunteer the following information with transmissible spongiform encephalopathies (TSEs) or a family member diagnosed with a genetic TSE are indefinitely deferred. Donors who received cadaveric pituitary-derived human growth hormone are deferred indefinitely.	
COVID restrictions	COVID-19 vaccination: The ARC DHQ inquires about COVID19 vaccine administration. Donors who receive a non-replicating, inactivated OR RNA-based COVID-19 vaccine manufactured by AstraZeneca, Janssen/J&J, Moderna, Novavax, or Pfizer and have no symptoms have no deferral period. Patients with possible vaccine-associated symptom(s) are temporarily deferred until symptoms resolve. Donors who receive an unknown type of an attenuated COVID-19 vaccine will be deferred for 14 days from date of vaccination.	
	COVID infection: Donors are no longer asked about COVID-19 infection or symptoms preceding day of donation on ARC DHQ. Donors who volunteer the information are deferred for 10 days from: last day of symptoms consistent with COVID-19 infection (with or without COVID-19 testing), or COVID-19 diagnosis from positive diagnostic test without symptoms.	
	Household contact: Donors are no longer asked about COVID-19 contacts on ARC DHQ. There is no deferral if donor is asymptomatic, Donor is deferred for 10 days after symptom resolution if donor is symptomatic.	

Country: USA

Mandatory Infectious Diseases Screening of Blood ProductsID			
	Screening test	**Confirmatory test**	**Risk of blood transfusion transmission**
HIV	HIV-1 and HIV-2 RNA NAT, HIV-1 (groups M and O)/HIV-2 EIA Multiplex MP-NAT HIV RNA/HCV RNA/HBV DNA NAT with reflex to Multiplex ID-NAT (TMA)	Discriminatory HIV RNA NAT assay (TMA) HIV western blot, an HIV-2 enzyme-linked immunoassay, and an HIV-1 and HIV-2 rapid test	1 per 2.3 million donations
HCV	anti-HCV ELISA Multiplex MP-NAT HIV RNA/HCV RNA/HBV DNA NAT with reflex to Multiplex ID-NAT (TMA)	Discriminatory HCV RNA NAT assay (TMA) If HCV-antibody reactive, but NAT nonreactive: HCV RNA by NAT, if nonreactive: HCV-antibody screening test	1 per 2.6 million donations
HBV	anti-HBsAg EIA, anti-HBc ELISA Multiplex MP-NAT HIV RNA/HCV RNA/HBV DNA NAT (TMA) with reflex to Multiplex ID-NAT (TMA)	Discriminatory HBV DNA NAT assay (TMA) Specific antigen neutralization for HBsAg, if neutralization positive and anti-HBc reactive: HBV NAT	1 per 1.5 million donations
Syphilis	Automated agglutination assay	Serologic test for total antibodies, an enzyme-linked immunoassay, RPR	No cases of transfusion-transmitted syphilis reported since 1960's
HTLV (1 & 2)	Anti-HTLV-1/2 ELISA	Western blot	<1 per 2 million donations
CMV	Selected donors screened with Anti-CMV assay		
Zika Virus	N/A: In May 2021, FDA approved the discontinuation of ZIKV NAT		No suspect transfusion-transmission reported during the period when ZIKV NAT was performed.
West Nile Virus	WNV RNA MAT assay (TMA) First by MP-NAT that triggers targeted ID-NAT in specific geographic areas with positive MP-NAT	Retest WNV NAT assay on alternate sample, if nonreactive: WNV IgG/IgM	
Babesia	RNA NAT assay that detects four species of babesia (TMA) MP-NAT performed in 14 endemic states	Retest NAT on alternate sample	
Trypanosoma cruzi (T. cruzi) Chagas Disease	T. cruzi ELISA Donors tested only once	Enzyme strip immunoassay (ESA)	All reports of transfusion transmission have been from unscreened platelets, except one red cell case, or from whole blood from unscreened donors in Latin America.
	Tests must be FDA approved. Complete list of FDA approved donor screening assays: https://www.fda.gov/vaccines-blood-biologics/complete-list-donor-screening-assays-infectious-agents-and-hiv-diagnostic-assays#Anti-CMV%20Assays%20(detect%20antibodies%20to%20Cytomegalovirus)		

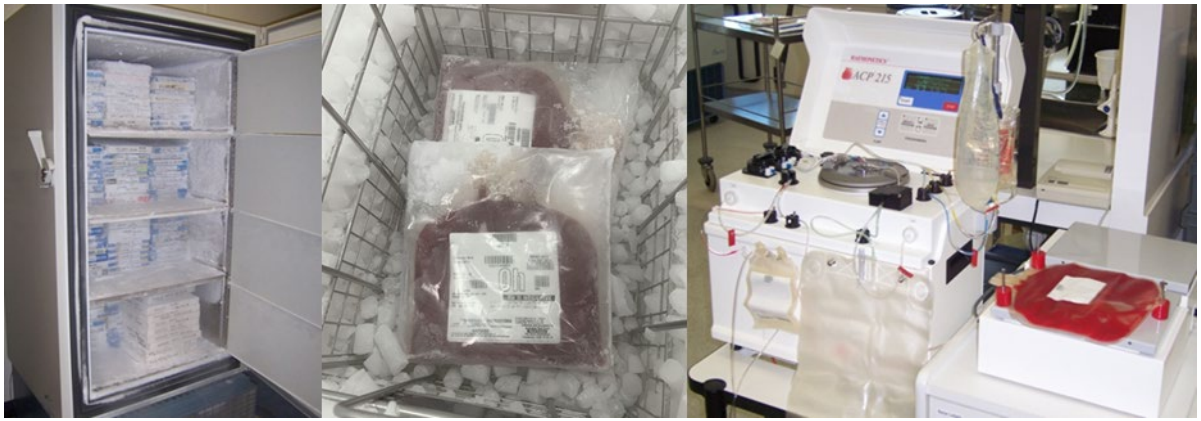
Provides details of antibody and nucleic acid testing
Mark tests as NA when not required
Include details of any additional testing required

Country: USA

Red Cell Products	Leukocyte Depleted	Pediatric Leukocyte Depleted	Washed Leukocyte Depleted
Description	Unit of whole blood collected into anticoagulant with in-line pre-storage leukofiltration is subsequently centrifuged with majority of plasma removed, +/- additive solution added. Alternatively, red cell unit(s) may be collected with anticoagulant by apheresis +/- additive solution added.	Leukocyte depleted red cell unit, <10 days storage at time of release, may have 4-6 additional bags attached by sterile welding to allow hospital to aliquot into smaller uniform units for distribution	Whole blood or apheresis red cell unit is washed in sodium chloride and resuspended in variable amount of 0.9% saline +/- low concentration (e.g. 0.2%) dextrose solution using an automated cell processor, with intention to remove majority of plasma proteins including antibodies and supernatant electrolytes.
Anticoagulant	Acid citrate dextrose solution A (ACD-A), citrate phosphate dextrose (CPD), citrate phosphate dextrose adenine (CPDA-1), citrate phosphate double dextrose(CP2D) Approx ratio 1:14 anticoagulant:whole blood	Acid citrate dextrose solution A (ACD-A), citrate phosphate dextrose (CPD), citrate phosphate dextrose adenine (CPDA-1), citrate phosphate double dextrose(CP2D) Approx ratio 1:14 anticoagulant:whole blood	Acid citrate dextrose solution A (ACD-A), citrate phosphate dextrose (CPD), citrate phosphate dextrose adenine (CPDA-1), citrate phosphate double dextrose(CP2D) Approx ratio 1:14 anticoagulant:whole blood
Additive Solution	AS-1 (Adsol), AS-3 (Nutricel), AS-5 (Optisol), AS-7 (SOLX) 100 mL in 450 mL total whole blood collection, 110 mL in 500 mL total whole blood collection	AS-1 (Adsol), AS-3 (Nutricel), AS-5 (Optisol), AS-7 (SOLX) 100 mL in 450 mL total whole blood collection, 110 mL in 500 mL total whole blood collection	No AS added back post-washing at ARC.
Average volume	Volume varies based on addition of AS	Same as standard red cell units	(180 mL+ /unit based on saline resuspension volume and goal hematocrit)
Storage Duration	21 days for CPD, 35 days for CPDA-1; 42 days for AS solutions	21 days for CPD, 35 days for CPDA-1; 42 days for AS solutions	24 hours after initiation of washing procedure in an open system.
Leukofiltration	Leukocyte reduced to $\leq$ 5 x 10^6 WBCs in $\geq$ 95% of units tested		
Storage Temperature	1°C to 6°C		
Transport Temperature	1°C to 10°C		
Modifications	CMV seronegative, irradiated, Hgb S negative, phenotyped/antigen(s) negative		
Irradiation Policy	X-ray irradiation or gamma ray (25-50 Gy) irradiation*		

Country: USA

	Frozen Leukocyte Depleted
Description	Used primarily to preserve red cell units from donors of rare phenotypes, either autologous or for use for patients with similar phenotype/genotype requirements.
Anticoagulant	Acid citrate dextrose solution A (ACD-A), citrate phosphate dextrose (CPD), citrate phosphate dextrose adenine (CPDA-1), citrate phosphate double dextrose(CP2D)
Additive Solution	Glycerol is added to red cells as a cryoprotectant prior to freezing process
Leukofiltration	Leukocyte reduced to <5x10^6/unit
Average volume	≥ 180 mL / unit (ARC specifies ≥ 180 g weight)
Storage Temperature	≤ -65°C, frozen within 6 days of collection* 1°C to 6°C once thawed
Transport Temperature	≤ -65°C while frozen 1°C to 10°C once thawed
Storage Duration	10 years frozen** Once thawed, expiration is 24 hours from initiation of thawing process with an open system (used at ARC), ≤ 14d if closed system used
Irradiation Policy	Gamma irradiation: 25-50Gy or X-ray irradiation***
Other	After thawing, glycerol is removed from the component prior to transfusion by washing the cells with sodium chloride. After washing, the red cells are resuspended in 0.9% sodium chloride +/- low concentration (e.g. 0.2%) dextrose.



Frozen Inventory

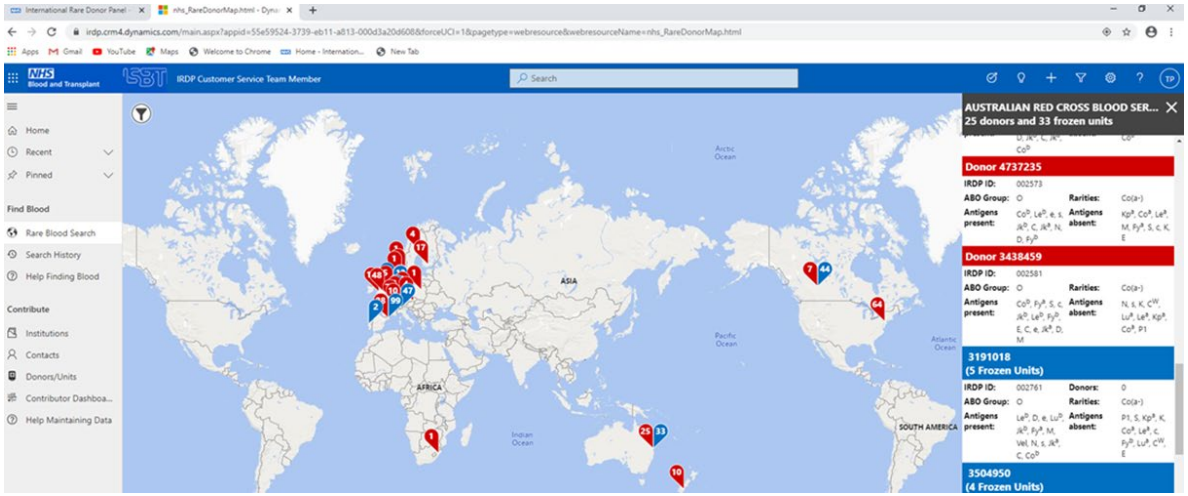
Country:USA

Country: USA

General Information	
Freezing Method	Glycerolization with mechanical refrigeration
Frozen Expiry (years)	10 years
Storage Temperature	-65°C
Can inventory be issued and sent frozen	Yes
Thawing Method	Heat block followed by sequential wash with 12%, 1.6%, and 0.9% NaCl
Thawed Expiry (days)	Varies If open system, 24 hours If closed system, >24hr <14d
Additive Solution	0.9% NaCl +/- low concentration (e.g 0.2%) Dextrose
Irradiation Policy	Not required but can be performed upon request
IUT and Neonate use	Varies Red Cross does not adjust the Hct of deglycerolized units, but provide a washed reconstituted product that can have Hct adjusted
Supply out of date Policy	Frozen expiry- potential to extend rare units to 30 years using Medical Review Board process

Country: USA

Product Specifications	
Volume	≥ 180 mL / unit (ARC specifies ≥ 180 g weight)
Supernatant Haemoglobin	Visual inspection, guidance to identify < 0.8% hemolysis
Haematocrit	35% - 80% Washed product with specific request for high HCT must be minimum HCT of 80% (Typically requested for intrauterine transfusion product)
Haemoglobin	> 42.5 g mean component total Hgb / unit in at least 95% of all tested packed red cell units
Osmolarity	N/A
Residual leucocyte content	Leukocyte reduced to <5x10^6/unit
Sterility	N/A
Other	Quality control parameter for washed, deglycerolized red cells: ≥ 80% and ≤ 100% red blood cell recovery in 100% products QC tested



Ordering and Shipping

Country:USA

Country: USA

Exporting	
Request form available	ARDP Form 9: International Request Form
Government Requirements	Center for Disease Control (CDC) International Trade Administration (ITA)
Regulatory Requirements	Waybill
Rare Donor Program Requirements	ARDP Form 10: Customer Invoice ARDP Form 11: International Exports Tracking Form ARDP Form 12: Unit Information for International Shipment to shipping facility Photograph of labeled unit including phenotype Temperature Logger approval letter, if applicable
Other	

Country: USA

Importing	
Government Requirements	Investigational New Drug (IND) or emergency (eIND) from the US Food and Drug Administration (FDA)
Regulatory Requirements	IND or eIND requires patient consent, physician authorization with care plan
Rare Donor Program Requirements	• That no/insufficient units found within the US • That compatible family members have been ruled out as donors, when applicable and when possible • That antibody has been found to be clinically significant using Monocyte Monolayer Assay (MMA), when possible
Other	