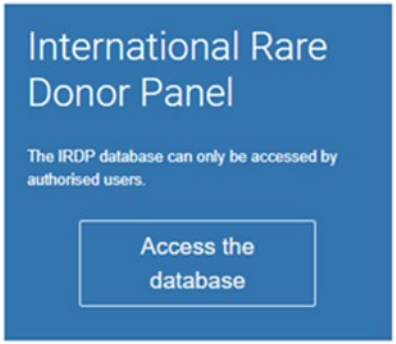


Rare Donor Program

Country: Japan

Country/Region:Japan

Rare Donor Program	
Rare Donor Program	*Yes*
National Regional or Facility based	National
Number of Rare Donors	13,958 ・Group I : 1,806 ・Group II : 12,152
Definition of Rare	This blood group has a low detection frequency (<1%) and is difficult to obtain compatible blood for transfusion. They are managed in the following two groups ・Group I [Note)] : less than 1 in tens of thousands ・Group II: about 1 in 100 to several thousand Note) Those in Group II and Rh-negative, and those with overlapping Group II phenotypes are treated as Group I.
Are the donors listed in the International Rare Donor Panel	No
Frozen Inventory	*Yes*
How are Rare Donors found	Screening test with monoclonal antibody
Number of Rare Donor Units used per year	2,338 units per year
ISBT Rare Donor WP Blood Shipment form used	*no*
Outcome of incompatible transfusion form used	*no*
Most difficult types to find	Rhnull , p
Phenotypes confirmed by molecular testing	Most new rare donors identified have molecular testing performed and serology where antisera is available

Country/Region: Japan

Phenotype	Total Active Donors	Group O	O Positive	O Negative	Other ABO/Rh
GE:-2,-3	8	1	1	0	7
Jk(a-b-)	69	32	32	0	37
Ko	88	29	27	2	59
Kp(b-)	8	1	1	0	7
MkMk	0	0	0	0	0
Rh:-34	0	0	0	0	0
U-	0	0	0	0	0
PP1Pk-	11	2	2	0	9
SC:-1	0	0	0	0	0
En(a-)	2	0	0	0	2
At(a-)	0	0	0	0	0
Di(b-)	4324	1418	1387	31	2906
Jr(a-)	3317	1013	1005	8	2304
Rh null	1	0	0	0	1
Vel(-)	0	0	0	0	0
D--	67	22	22	0	45
Oh	3	3	3	0	0

Country/Region: Japan
How are your rare donors found?

	Yes / No	Method	Comments
Extended phenotyping donors	Yes	All donors typed for Jra, Dib, p, k14, Kpbc and k2 - Beckman Coulter PK7300, PK7400 Selected donors typed for Rh (C, E, c, e) , Fyb, Dia, Jka, Jkb, M, S and Lea - Beckman Coulter PK7300, PK7400	In most cases the rare phenotype is confirmed with molecular testing (genotyping) Where antisera is available phenotype is confirmed by serology.
Extended genotyping donors	No		Where antisera is available phenotype is confirmed by serology.
Family studies	No		
Antibody investigations	Yes	All donors are screened for red cell antibodies using the Bio-Rad Diagnostics IH-1000system	Antibody identification in and donors require the use of many different techniques, including molecular testing to determine the specificity.
Other		NA	NA

Red Cell Product Specifications

Country:Japan

Country/Region:Japan

Donor Selection-Whole Blood

Donation	Voluntary		
Age or Weight Restrictions	Volume Collected Age Body Weight	200mL 16-69 years Males: 45 kg or more , Females: 40 kg or more	400mL Males: 17-69 years , Females: 18-69 years Males and females: 50 kg or more
	*Considering donors health, donors from 65 to 69 years of age can donate their blood provided that they have donated at least once between the ages of 60-64.		
Donation Interval	200mL: Both males and females can donate blood from the same day of the week 4 weeks after the donation. 400mL: Males can donate blood from the same day of the week 12 weeks after the donation. Females can donate blood from the same day of the week 16 weeks after the donation.		
Sexual Activity Precautions	Positive for HIV, Hepatitis B/C, or HTLV	Permanent deferral	
	Male to male sex	6 month deferral	
	Sex worker or contact with sex worker	6 month deferral	
Travel Exclusions If donor has returned from an area endemic for the listed infectious illnesses	Dengue	Postponed for one month after healing	
	Ebola	NA	
	Malaria	①Do not draw blood from individuals with a history of malaria. ②Travelers to malaria-endemic areas(long-term residents) . ・Stay in a malaria-endemic area for more than one month is postponed for one year after returning (entering) the country. ・If you have malaria-like symptoms after returning (entering) from a malaria-endemic area, your stay will be postponed until infection is ruled out. ・A stay in a malaria-endemic area for more than one year is postponed for three years after returning (entering) the country.	
	West Nile Virus	Postponed for 6 month after healing	
Lifestyle	Acupuncture, piercing or tattoo	6 month deferral	
	Drug use (Non-prescribed injected)	Indefinite extension	
	Incarceration	NA	
CJD restrictions	Stay in the UK for a total of 31 days or more between January 1980 and December 1996		
Covid restrictions	COVID19 vaccine administration	24 hours deferral for recombinant vaccine 48 hours deferral for mRNA vaccine 6 weeks deferral for viral vector vaccine	
	COVID infection	4 weeks deferral after symptoms are disappeared	
	Household contact	2 weeks deferral	

Country/Region: Japan

Mandatory Infectious Diseases Screening of Blood Products

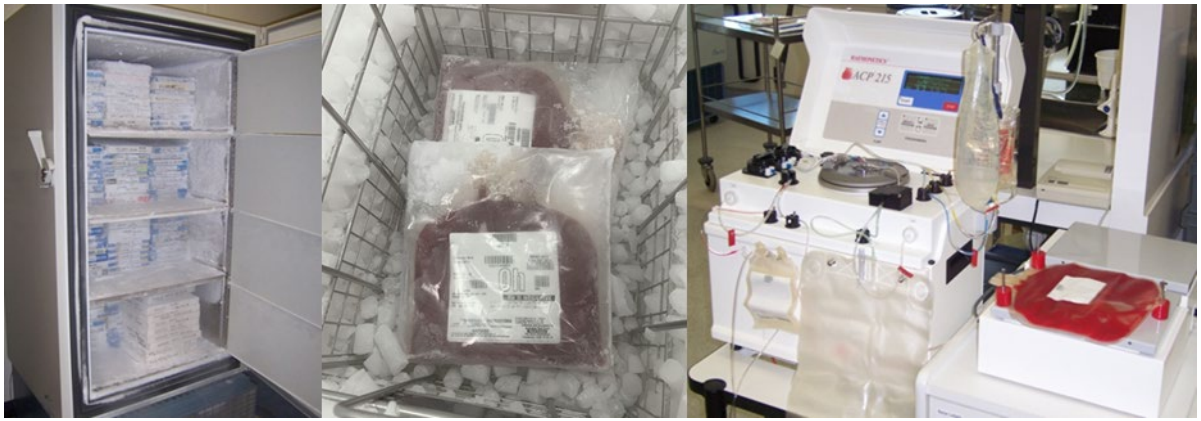
	Screening test	Risk of blood transfusion transmission
HIV	Anti-HIV-1 and Anti-HIV2 test & HIV1/2RNA by NAT	<1 in 10 million risk of blood transfusion transmission
HCV	Anti-HCV test & RNA by HCV NAT	<1 in 10 million risk of blood transfusion transmission
HBV	Hepatitis B Virus test (HBsAg, Anti-Hbc and Anti-HBs) & HBV DNA by NAT	<1 in 1 hundred thousand risk of blood transfusion transmission
Syphilis	Examination for the presence of an antibody that is formed in people infected with a microorganism called Treponema pallidum is conducted.	<1 in 10 million risk of blood transfusion transmission
HTLV (1 & 2)	Anti-HTLV-1 test	<1 in 10 million risk of blood transfusion transmission
CMV	Not routinely screened If required, donor CMV IgG Ab negative products used	<1 in 10 million risk of blood transfusion transmission
Zika Virus	NA	
West Nile Virus	NA	
Babesia	NA	
Trypanosoma cruzi (T. cruzi) Chagas Disease	Antibody testing for Chagas disease on all eligible blood samples	In order to prevent transfusion transmission of Chagas disease, an infectious disease that occurs mainly in Central and South America, safety measures have been implemented since October 15, 2012 (Heisei 24), whereby blood donated by donors who meet certain conditions, such as having lived or stayed in the target countries or regions in Central and South America, is not used for transfusion but as raw blood for plasma fractionated products.
Human parvovirus	B19 Antigen test	

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

Country/Region: Japan

Red Cell Blood Product

Description	①Red Blood Cells, Leukocytes ReducedA mixture of approximately 46 mL and 92 mL of red blood cell preservation additive solution (MAP solution) with a small amount of CPD solution in a red blood cell layer from which most of the white blood cells and plasma have been removed from 200 mL or 400 mL of human blood mixed with 28 mL or 56 mL of blood preservation solution (CPD solution), respectively. ②Washed Red Cells, Leukocytes Reduced, NISSEKI Approximately 45 mL and 90 mL of saline solution are added to the erythrocyte layer after removing most of the leukocytes and plasma from 200 mL or 400 mL of human blood, respectively, and then washed with saline solution. ③Frozen Thawed Red Cells, Leukocytes Reduced, NISSEKI A mixture of 200 mL or 400 mL of human blood, from which the majority of leukocytes and plasma have been removed, with the erythrocyte layer frozen and preserved with the addition of freeze protection solution, which is then thawed, washed off, and mixed with approximately 46 mL and 92 mL of additive solution for erythrocyte preservation (MAP solution), respectively, containing a small amount of final washing solution. ④Blood for Exchange Transfusion, Leukocytes Reduced, NISSEKI Approximately 60 mL or 120 mL of AB human plasma with most of the leukocytes removed from 200 mL or 400 mL of human blood is added to a layer of washed O red blood cells with most of the leukocytes and plasma removed. The human plasma contains a blood preservation solution (CPD solution) derived from raw blood.
Anticoagulant	①～④:CPD solution （Citrate phospahte dextrose）
Additive Solution	① and ③ : MAP solution （Mannitol-adenine phosphate） ②:saline solution
Leukofiltration	leucocyte reduced to <1x10^6/unit
Average volume	200mL origin ①:108～158mL ②:108～158mL ③:Calculated by actual capacity ④:123～173mL 400mL origin ①:220～320mL ②:220～320mL ③:Calculated by actual capacity ④:250～350mL
Storage Temperature	①～④:2 to 6° C
Transport Temperature	①～④:2 to 6° C
Storage Duration	①:21 days after blood collection ②:48 hours after manufacture ③:4 days after manufacture ④:48 hours after manufacture
Irradiation Policy	X-ray irradiation: 15 Gy but not more than 50 Gy
Other	



Frozen Inventory

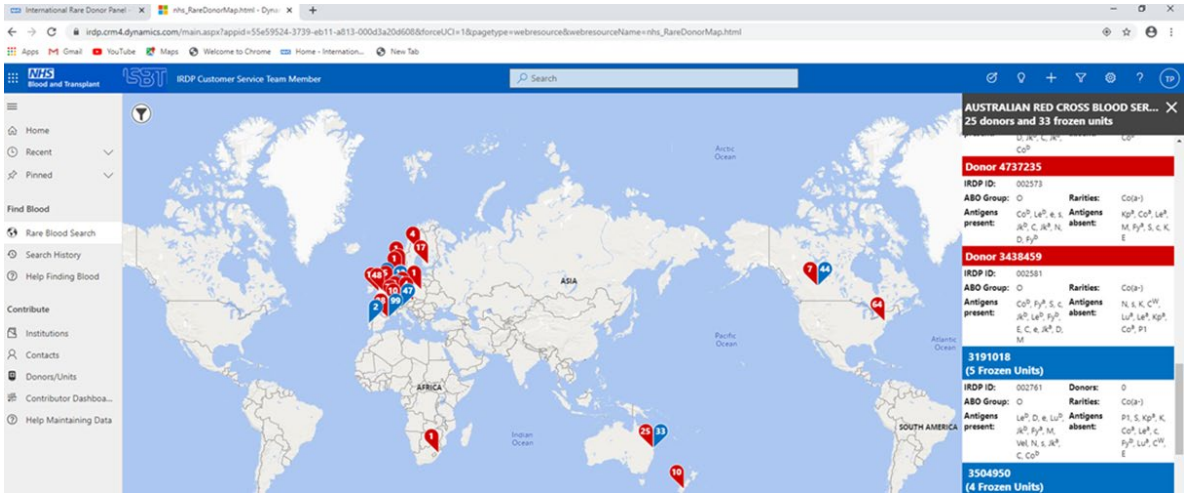
Country:Japan

Country/Region: Japan

General Information	
Freezing Method	Freeze damage protection liquid SF-60 using Haemonetics ACP-.215 cell washer SF-60 Composition: Concentrated glycerol 60.0g , 70% sodium lactate 2.57g, Potassium chloride 0.02g, Dihydrogen phosphate Sodium 0. 26g
Frozen Expiry (years)	10 years
Storage Temperature	≤ -65ºC
Can inventory be issued and sent frozen	Yes
Thawing Method	Three-component washing method using Haemonetics ACP-.215 cell washer Chemical solution 1：8% sodium chloride solution Chemical solution 2：1.6% sodium chloride solution Chemical solution 3：0.8% sodium chloride solution and 0.2% glucose solution
Thawed Expiry (days)	4 days after manufacture
Additive Solution	MAP solution （Mannitol-adenine phosphate）
Irradiation Policy	X-ray irradiation: 15 Gy but not more than 50 Gy
IUT and Neonate use	Not a registered process, but may be issued as a patient tailored product
Supply out of date Policy	Exceptionally rare units may be retained past their expiration date but will not be supplied.

Country/Region: Japan

Product Specifications	
Volume	Calculated by actual capacity
Supernatant Haemoglobin	Total hemoglobin volume Must be at least 12 g per 200 mL whole blood collection origin.
Haematocrit	Control strategy value after addition of MAP solution 50-60%.
Haemoglobin	NA
Osmolarity	NA
Residual leucocyte content	< 1.0×10^6/unit
Sterility	No growth
Other	NA



Ordering and Shipping

Country:Japan

Country/Region: Japan

Exporting	
Request form available	The products are not in violation of paragraphs 1 through 15 of Appendix 1 and Appendix 2 of the Export Trade Control Order. The products are not intended for any military use.
Government Requirements	・Certificate of Non-Applicability stating that the product does not violate the Export Trade Control Order of the Ministry of Economy, Trade and Industry ・Customs invoice
Regulatory Requirements	Approval of the Minister of Economy, Trade and Industry under the Foreign Exchange and Foreign Trade Law
Rare Donor Program Requirements	・Preferred courier ： World Couriers ・A request form showing the contents of the request. Rare blood needed, ABOblood type, RhDblood type, number of units needed, whether or not frozen blood thawing technology is available, desired delivery date, and delivery address (contact person, address, phone number, and email address).
Other	NA

Country/Region: Japan

Importing	
Government Requirements	Confirmation by the Minister of Health, Labor and Welfare in accordance with the law and Application procedures for import confirmation as stipulated
Regulatory Requirements	The purpose of the importation is limited to "to be used by the importing health care professional to diagnose or treat his/her own patients (or animals in the case of veterinarians) under his/her own responsibility in cases where there is a medical emergency and no alternative products are available in Japan.
Rare Donor Program Requirements	A copy of all test results for the donation e.g. blood group, phenotype and infectious disease screening Temperature monitored transport (Preferred courier：World Couriers)
Other	NA