Rare Donor Program

Country: Australia

Australia

Rare Donor Program	
Rare Donor Program	Yes
National Regional or Facility based	National
Number of Rare Donors	617
Definition of Rare	Someone who is negative for a high prevalence antigen where the frequency of this antigen negative phenotype is less than 1 in 1000. People with a combination of antigen negative phenotypes where that combination has a prevalence of less than 1 in 1000 may also be considered rare.
Are the donors listed in the International Rare Donor Panel	Yes
Frozen Inventory	Yes
How are Rare Donors found	Selected donor phenotyping and genotyping Corresponding antibody detected in a donor or patient Family studies
Number of Rare Donor Units used per year	<10 units per year
ISBT Rare Donor WP Blood Shipment form used	Yes
Outcome of incompatible transfusion form used	Yes
Most difficult types to find	Rh_{null}
Phenotypes confirmed by molecular testing	Most new rare donors identified have molecular testing performed and serology where antisera is available

Australia

Phenotype	Total Active Donors	Group O	O Positive	O Negative	Other ABO/Rh
GE:-2,-3	1	0	0	0	1
Jk(a-b-)	19	9	9	0	10
Ko	0	0	0	0	0
Kp(b-)	6	3	2	1	3
MkMk	0	0	0	0	0
Rh:-34	0	0	0	0	0
U-	1	1	1	0	0
PP1Pk-	1	1	1	0	0
SC:-1	0	0	0	0	0
En(a-)	0	0	0	0	0
At(a-)	0	0	0	0	0
Di(b-)	3	1	1	0	0
Jr(a-)	1	0	0	0	1
Rh null	0	0	NA	NA	0
Vel(-)	7	7	5	2	0
D--	1	1	1	NA	0
Oh Positive	0	NA	NA	NA	NA
Oh Negative	0	NA	NA	NA	NA

Australia
How are your rare donors found?

	Yes / No	Method	Comments
Extended phenotyping donors	Yes	All donors typed for Rh (C, E, c, e) and K - Beckman Coulter PK7300 K+ donors typed for k – Manual tube or CAT Selected donors (6% donations) typed for Fy^a, Fy^b, Jk^a, Jk^b, M, S and s – Immucor Neo	In most cases the rare phenotype is confirmed with molecular testing (genotyping or NGS)
Extended genotyping donors	Yes	Selected donors (1% donations) genotyped using Immucor BeadChip HEA Kit	Where antisera is available phenotype is confirmed by serology.
Family studies	Yes	Recruitment of family of donors and patients	Information to recruit family of donors is provided to the donor for discussion with family members. Family of patients are contacted via the treating clinician with patient consent.
Antibody investigations	Yes	All donors are screened for red cell antibodies using the Immucor NEO.	Antibody identification in patients and donors may require the use of many different techniques, including molecular testing to determine the specificity.
Other	NA	NA	NA

Red Cell Product Specifications

Country: Australia

Australia

Donor Selection – Whole Blood		
Donation	Voluntary	
Age or Weight Restrictions	New donors: 18 to 75 years >50 kg	
Donation Interval	84 days (12 weeks)	
Sexual Activity Precautions	Positive for HIV, Hepatitis B/C, or HTLV	Permanent deferral
	Male to male sex	3 month deferral
	Sex worker or contact with sex worker	3 month deferral
Travel Exclusions *If donor has returned from an area endemic for the listed infectious illnesses*	Dengue	4 week deferral
	Ebola	8 week deferral
	Malaria	Antibody screening: If donor has visited in previous 3 years or lived for 6 or more months continuously
	West Nile Virus	4 week deferral
Lifestyle	Acupuncture, piercing or tattoo	4 month deferral
	Drug use (Non-prescribed injected)	5 year deferral
	Incarceration	Deferral for 12 months from date of release
CJD geographic restrictions	Being removed as a deferral reason in 2022	
COVID restrictions	COVID19 vaccine administration	3 days deferral
	COVID infection	7 day deferral from last symptoms
	Household contact	According to the relevant public health guidelines

Australia

Mandatory Infectious Diseases Screening of Blood Products		
	Screening test	**Risk of blood transfusion transmission**
HIV	HIV-1/2 Ab (also detects HIV p24 Ag) & RNA by NAT	1 in 1 million risk of blood transfusion transmission
HCV	HCV Ab & RNA by NAT	<1 in 1 million risk of blood transfusion transmission
HCB	HBsAg & HBV DNA by NAT	<1 in 1 million risk of blood transfusion transmission
Syphilis	Treponemal Ab	<1 in 1 million risk of blood transfusion transmission
HTLV (1 & 2)	HTLV-1/2 Ab for new donors or leucocyte components	<1 in 1 million risk of blood transfusion transmission
CMV	Not routinely screened If required, donor CMV IgG Ab negative products used Leucodepleted blood products are considered CMV safe	<1 in 1 million risk of blood transfusion transmission
Zika Virus	NA	Given the low number of imported ZIKV infections reported in Australia, the absence of reported local transmission, the limited distribution of mosquito vectors and rarity of reported transfusion-transmission cases worldwide, at present ZIKV represents a low risk to blood safety in Australia.
West Nile Virus	NA	The probability of an Australian donor visiting the affected area, becoming infected and subsequently returning to donate while in the asymptomatic viraemic period is estimated to be very low. When this probability reaches a predefined level, additional safety measures would be considered.
Babesia	NA	Given that only a single case of babesiosis has been reported in Australia, Babesia spp. currently represent a low risk to blood safety in Australia.
Trypanosoma cruzi (T. cruzi) Chagas Disease	NA	Only two cases of human Chagas' disease (both imported) have been reported in Australia. Given the small number of cases reported in Australia and the absence of reported local transmission, T. cruzi represents a low risk to blood component safety in Australia.

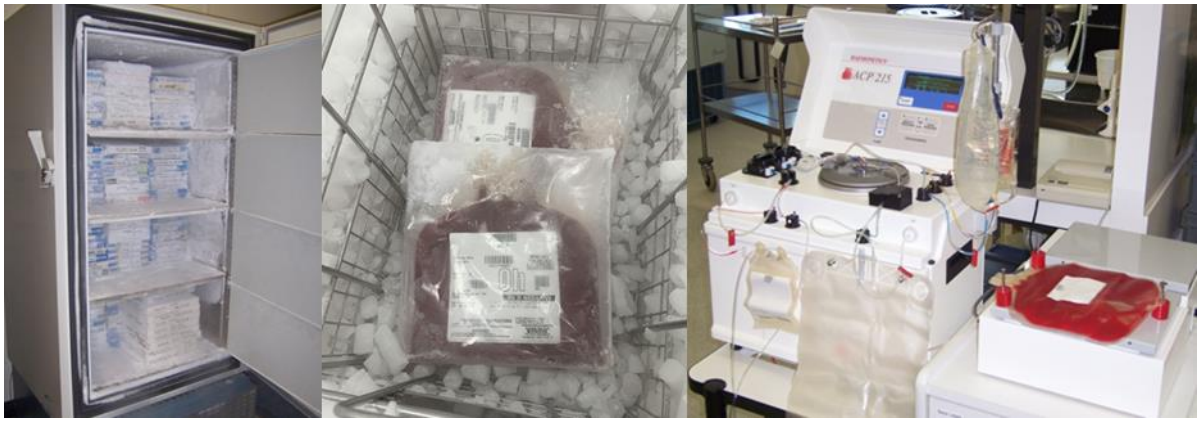
Provides details of antibody and nucleic acid testing
Mark tests as NA when not required
Include details of any additional testing required

Australia

Red Cells	Leucocyte Depleted	Paediatric Leucocyte Depleted	Washed Leucocyte Depleted
Description	A red cell component obtained by removing most of the plasma after centrifuging whole blood collected into anticoagulant. The red cells may be resuspended in other additives to prolong storage and are filtered to remove most leucocytes.	A leucocyte depleted red cell component divided into four packs of equal volume for the purpose of reducing donor exposure for small paediatric transfusions and to minimise product wastage.	Red cells leucocyte depleted are washed with sterile SAG-M solution using a manual process to remove the majority of unwanted plasma proteins, antibodies and electrolytes. The washed red cells are resuspended in SAG-M2 additive solution.
Anticoagulant	Citrate phospahte dextrose (CPD) 66.5 mL +/- 10% per pack of whole blood	Citrate phospahte dextrose (CPD)	Citrate phospahte dextrose (CPD) 66.5 mL +/- 10% per pack of whole blood
Additive Solution	Saline adenine glucose mannitol (SAG-M) 105 +/- 10% mL	Saline adenine glucose mannitol (SAG-M)	Saline adenine glucose mannitol (SAG-M2) 100 +/- 10% mL
Average volume	260 +/- 15 mL	60 +/- 4 mL	258 +/- 18 mL
Storage Duration	42 days	35 days	28 days
Leukofiltration	leucocyte reduced to <1x10^6/unit		
Storage Temperature	2°C to 6°C		
Transport Temperature	2°C to 10°C		
Modifications	Phenotyped, CMV seronegative, irradiated		
Irradiation Policy	Gamma irradiation: 25-50Gy or X-ray irradiation		

Australia

	For Intrauterine Transfusion	Frozen Leucocyte Depleted
Description	A hyper-concentrated red cell component less than five days old with a haematocrit of 0.70–0.85 obtained by removing most of the plasma/additive solution. The red cells may be resuspended in additive solution to achieve the desired haematocrit.	Used for patients with rare red cell phenotypes, or multiple red cell antibodies and for autologous collections when liquid-preserved blood cannot fulfil demands. **Can be supplied internationally as a frozen product and thawed locally**
Anticoagulant	Citrate phospahte dextrose (CPD)	Citrate phospahte dextrose (CPD)
Additive Solution	Saline adenine glucose mannitol (SAG-M2)	Glycerol is added to red cells as a cryoprotectant
Leukofiltration	leucocyte reduced to <1x10^6/unit	leucocyte reduced to <1x10^6/unit
Average volume	>220 mL	>185 mL
Storage Temperature	2°C to 6°C	-65°C to -80°C Frozen within 7 days of collection 2°C to 6°C once thawed
Transport Temperature	2°C to 10°C	Below -65°C 2°C to 10°C once thawed
Storage Duration	24 hours post irradiation 48 hours post hyperconcentration	10 years
Irradiation Policy	Gamma irradiation: 25-50Gy or X-ray irradiation Red cells for IUT must be irradiated. Once irradiated the component must be used within 24 hours.	Gamma irradiation: 25-50Gy or X-ray irradiation
Other	ABO, RhD compatible with both mother and fetus, K negative. Should be antigen-negative for maternal alloantibodies, IAT crossmatch compatible with the maternal plasma and CMV seronegative. If the fetal blood group is unknown use group O, RhD negative red cells.	Prior to transfusion, glycerol must be removed from the thawed component by washing the cells with sodium chloride. After washing, the red cells are resuspended in additive solution or and must be used within 24 hours. There will be some loss of red cells during the freezing and thawing process. When requesting frozen red cells it should be noted that thawing and processing time is several hours.



Frozen Inventory

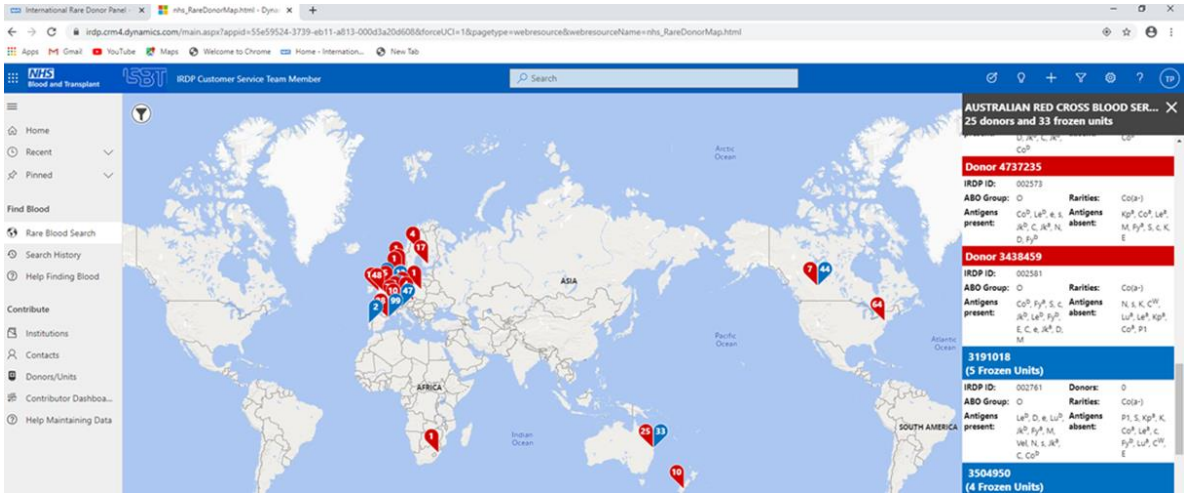
Country: Australia

Australia

General Information	
Freezing Method	Glycerolyte 57 using Haemonetics ACP-.215 cell washer
Frozen Expiry (years)	30 years Exceptionally rare units may be retained beyond expiry . If required for issue they are released as a non-confirming product
Storage Temperature	≤ -65^{o}C
Can inventory be issued and sent frozen	Yes
Thawing Method	Deglycerolisation with 12% and 0.9% saline using Haemonetics ACP-.215 cell washer
Thawed Expiry (days)	24 hours
Additive Solution	SAGM
Irradiation Policy	Not a registered process, but may be issued as a patient tailored product
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 beyond expiry . If required for issue they are released as a non-confirming product

Australia

Product Specifications	
Volume	> 185mL
Supernatant Haemoglobin	<0.2 g/unit
Haematocrit	0.35 – 0.70 (L/L)
Haemoglobin	≥36 (6/unit)
Osmolarity	≤367 (mOSm/KgH2O)
Residual leucocyte content	< 1.0 x 10^6/unit)
Sterility	No growth
Other	NA



Ordering and Shipping

Country: Australia

Australia

Exporting	
Request form available	Yes
Government Requirements	National Blood Authority Approval to Supply Blood Products to Organisations for Use Overseas facilitated by Lifeblood Customs invoice supplied by Lifeblood
Regulatory Requirements	TGA Export Permit supplied by Lifeblood
Rare Donor Program Requirements	Preferred courier – World Couriers Completed request form
Other	NA

Australia

Importing	
Government Requirements	NA
Regulatory Requirements	Notification of requirement to import via the TGA Special Access Scheme - Category A
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

Acknowledgment

Australian governments fund the Australian Red Cross Lifeblood to provide blood, blood products and services to the Australian community.