

Regulatory Survey ION-2197

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General	
The information has been reviewed in year :	
Organisation name:	China Marrow Donor Program
Organisation ION:	ION-2197
Country:	China
Year the registry started operations:	2001

Products		comment
Do you provide HPC, Marrow?	no	
Do you provide HPC, Apheresis?	yes	
Do you provide HPC, Cord Blood?	no	
Do you provide MNC, Apheresis?	no	
Do you provide NC, Whole Blood?	no	

Product quantity		
Data valid for year	2021	
Number of products	National	International
HPC, Marrow products:	0	0
HPC, Apheresis:	1898	3
HPC, Cord:	0	0

License	
Organisation is licensed/accredited by the Competent Authority:	yes
Comment:	
Name of Competent Authority:	Red Cross Society of China
Date of last inspection:	
Link to website of Competent Authority:	https://www.redcross.org.cn/
Can you provide the Legal documentation from the Competent Authority that your organisation is allowed to operate as a registry ?	yes
Is your registry WMDA Certified, WMDA Qualified or WMDA Accredited?	WMDA Accredited
The registry is accredited by any other organisation:	no
If yes, by which organisation?	

Affiliation	
The registry works with the following number of affiliated donor centres:	
The registry audits its donor centres:	
The registry works with the following number of affiliated collection centres:	

Ther registry audits its collection centres:	
The registry works with the following number of affiliated Cord Blood Banks:	
The registry audits its Cord Blood Banks:	
The registry works with the following number of affiliated transplant centres:	
The registry audits its transplant centres:	
The registry works with the following number of affiliated IDM Testing Laboratories:	
The registry audits its IDM Testing Laboratories:	
The registry works with the following number of affiliated HLA/other DNA markers testing laboratories:	
The registry audits its HLA/other DNA markers testing laboratories:	
The registry would be able to provide a full list of name/addresses of each affiliated and their licence/accreditation status, on request:	yes
The Cord Blood Banks are FACT-NetCord accredited:	
If yes, the following Cord Blood Bank(s) are accredited:	
The registry is able to provide a copy of all the certificates:	yes
Affiliated centres comply with WMDA Standards and applicable national regulations:	
The registry has requirements for affiliated centres in addition to WMDA Standards and applicable national regulations:	
If yes, what are these requirements?	

Donor policy

All donors are unpaid volunteers:	yes
All donors are informed about donation process and associated risks:	yes
Donors sign a valid informed consent to donate in the presence of a medical doctor/health care personnel/registry staff:	yes
The registry has systems in place to protect and control access to donor/patient records:	yes
The registry maintains donor anonymity:	yes
The registry has detailed donor evaluation and exclusion criteria in place:	yes
The registry has donor evaluation and exclusion criteria that do meet or exceed the WMDA guidelines:	yes

IDM

IDM	Tested	Method	Days between test and sampling /workup
ALT/ASTALT/AST ratio, De-Ritis-Quotient	-		
ChagasChagas, T. cruzi	-		
CMV IgGCytomegalovirus (CMV) Antibody testing IgG	Yes		
CMV IgMCytomegalovirus (CMV) Antibody testing IgM	Yes		
CMV TotalCytomegalovirus Total	Yes		
EBV IgGEpstein-Barr Virus Antibody testing IgG	On request		
EBV IgMEpstein-Barr Virus Antibody testing IgM	On request		
HAV (NAT)Anti-hepatitis A virus nucleic acid testing	-		
HBV (NAT)Hepatitis B nucleic acid testing	On request		
HBc AbHepatitis B core antibody testing	Yes		
HBs AgHepatitis B Surface antigen testing	Yes		

HCV (NAT)Hepatitis C nucleic acid testing	On request		
HCV AbHepatitis C antibody testing	Yes		
HEV (NAT)Hepatitis E Virus nucleic acid testing	On request		
HIV (NAT)Human Immunodeficiency Virus nucleic acid testing	On request		
HIV-1 AbHuman Immunodeficiency Virus HIV-1 antibody testing	On request		
HIV-2 AbHuman Immunodeficiency Virus HIV-2 antibody testing	On request		
HIV p24Human Immunodeficiency Virus p24 antigen testing	On request		
HTLV-IGHuman T-Lymphotropic Virus type I testing	No	Donor samples will be provided for HTLV testing on request from the requesting registry.	
HTLV-IIHuman T-Lymphotropic Virus type II testing	No	Donor samples will be provided for HTLV testing on request from the requesting registry.	
MalariaMalaria	-		
HSVHerpes Simplex Virus	-		
STSSerological tests for syphilis	No		
STS FTA-ABSSerological test for syphilis	No		
ToxoplasmosisToxoplasmosis	-		
VZVVaricella Zoster Virus	-		
WNV-NATWest Nile Virus nucleic acid testing	No		
Other tests performed	On request		



Comment

Donors requested for international exchange will be tested for ABO/Rh at the time of verification typing.