

# Regulatory Survey ION-2197

The data provided on this page is updated by the organisations.

The WMDA makes no representations or express or implied warranties regarding any information on this page.

Use of any information provided on this site does not and is not intended to create a contractual or other relationship.

| 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:                                                                                           | <a href="https://www.redcross.org.cn/">https://www.redcross.org.cn/</a> |
| 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-IHuman 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.