

# (archived) Regulatory Survey ION-9341

This data is publicly available. Parent page : ION-9341

| General information  |  |
|--|--|
| organisation name  | Swiss Transfusion SRC Ltd. Swiss Blood Stem Cells      |
| ION of the organisation  | ION-9341   |
| Products   |  |
| This organisation provides HPC, Marrow   | Yes  |
| This organisation provides HPC, Apheresis  | Yes  |
| This organisation provides HPC, Cord Blood   | Yes  |
| This organisation provides MNC, Apheresis  | Yes  |
| This organisation provides NC, Whole Blood   | Yes  |
| This organisation provides Other products  | Yes  |
| Other products provided:   | NK cells, platelets                                    |
| Number of adult donor products shipped in the last 3 years:  | 163  |
| Domestic shipments:  | 21   |
| International shipments:   | 142  |
| Licences and accreditations  |  |
| organisation is licensed/accredited by a national regulatory body/accrediting agency:  | Yes  |
| Name of Competent Authority/national regulatory body:  | Federal Office of Public Health                        |
| Date of last inspection:   | 25. February 2016                                      |
| Link to website of competent authority/national regulatory body:   | <a href="http://www.bag.admin.ch">www.bag.admin.ch</a> |
| Legal documentation from the national government that your organisation is allowed to operate as a registry can be provided:   | Yes  |
| Serious adverse events and reactions are reported and investigated:  | Yes- Mandatory reporting required                      |
| Affiliated centres   |  |
| This organisation has affiliated Donor Centres   | Yes  |
| This organisation has affiliated Collection Centres  | Yes  |
| This organisation has affiliated Cord Blood Banks  | Yes  |
| This organisation has affiliated Transplant Centres  | Yes  |
| This organisation has affiliated IDM Testing Laboratories  | Yes  |
| This organisation has affiliated HLA/other DNA markers Testing Laboratories  | Yes  |
| There is a full list of affiliated centres with their license / accreditation status available:  | Not available  |
| The full list of affiliated centres list can be obtained:  |  |
| Affiliated centres are required to be licensed by a national regulatory body and/or have an internationally recognised accreditation (e.g. European Federation of Immunogenetics (EFI), NetCord-FACT, JACIE) | Yes  |
| Affiliated centres comply with WMDA standards and applicable national regulations:   | Yes  |
| We have requirements for affiliated centres in addition to WMDA Standards and applicable national regulations:   | Yes  |
| We audit affiliated centres for compliance with applicable standards, national regulations and your organisation's requirements:   | Yes  |

|   |   |
|---|---|
| If Yes, the frequency of audits is :  | Audit schedule for affiliated partners is available |
| <b>Donor policy</b>   |   |
| Volunteer donors are unpaid:  | Yes   |
| Donors are informed about donation process and associated risks:                            | Yes   |
| Donors sign a valid informed consent to donate:   | Yes   |
| We have systems in place to protect and control access to donor/patient records:            | Yes   |
| Our organisation maintains donor anonymity:   | Yes   |
| Detailed donor evaluation and exclusion criteria in place?                                  | Yes   |
| Detailed donor evaluation and exclusion criteria meet the WMDA guidelines?                  | Yes   |
| <b>IDM Testing</b>  |   |
| CMV IgG is tested at donor workup:<br>Cytomegalovirus (CMV) Antibody testing IgG            | Yes   |
| CMV IgM is tested at donor workup:<br>Cytomegalovirus (CMV) Antibody testing IgM            | Yes   |
| CMV Total is tested at donor workup:  | Yes   |
| EBV IgG is tested at donor workup:<br>Epstein-Barr Virus Antibody testing IgG               | Yes   |
| EBV IgM is tested at donor workup:<br>Epstein-Barr Virus Antibody testing IgM               | Yes   |
| HBV (NAT) is tested at donor workup:<br>Hepatitis B nucleic acid testing                    | Yes   |
| HBc Ab is tested at donor workup:<br>Hepatitis B core antibody testing                      | Yes   |
| HBs Ag is tested at donor workup:<br>Hepatitis B Surface antigen testing                    | Yes   |
| HCV (NAT) is tested at donor workup:<br>Hepatitis C nucleic acid testing                    | Yes   |
| HCV Ab is tested at donor workup:<br>Hepatitis C antibody testing                           | Yes   |
| HIV–1 Ab is tested at donor workup:<br>Human Immunodeficiency Virus HIV-1 antibody testing  | Yes   |
| HIV–2 Ab is tested at donor workup:<br>Human Immunodeficiency Virus HIV-2 antibody testing  | Yes   |
| HIV (NAT) is tested at donor workup:<br>Human Immunodeficiency Virus nucleic acid testing   | Yes   |
| HIV p24 Ag is tested at donor workup:<br>Human Immunodeficiency Virus p24 antigen testing   | On Request  |
| HTLV-I is tested at donor workup:<br>Human T-Lymphotropic Virus type I testing              | Yes   |
| HTLV-II is tested at donor workup:<br>Human T-Lymphotropic Virus type II testing            | Yes   |
| STS (Serological) is tested at donor workup:<br>Serological tests for syphilis              | Yes   |
| STS FTA-ABS (verification test) is tested at donor workup:<br>Serological test for syphilis | Yes   |
| WNV-NAT is tested at donor workup:<br>West Nile Virus nucleic acid testing                  | On Request  |
| Other tests performed:  | Anti-HBs incl. titer, Anti-Toxoplasmosis            |

|  |  |
|--|--|
| <b>Testing</b>   |  |
| Full donor screening for infectious disease risk is performed at the following stage:  | Verification Typing  |
| Physical exam and relevant donor testing is performed at the following stage:  | Workup   |
| Infectious disease testing is performed at the following stage:  | Verification Typing  |
| A sample for additional donor testing can be provided upon request:  | Yes  |
| All donor testing (at work up) for infectious disease is performed in a laboratory certified/licensed by a national regulatory agency:         | Yes  |
| The kits used for donor testing (at work up) for infectious disease are licensed/approved for use on donors by the national regulatory agency? | Yes  |
| HLA typing for patient specific request is performed in an appropriately accredited laboratory:  | Yes  |
| Sterility testing is performed on the adult donor product:   | Yes  |
| <b>Retention policy</b>  |  |
| Donor records relating to the medical and HPC collection process are retained for:   | 20-30 years (depending on data), according to national law |