(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:	www.bag.admin.ch
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 Immunogentics (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
Donor policy	
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
IDM Testing	
CMV IgG is tested at donor workup: Cytomegalovirus (CMV) Antibody testing IgG	Yes
CMV IgM is tested at donor workup: Cytomegalovirus (CMV) Antibody testing IgM	Yes
CMV Total is tested at donor workup:	Yes
EBV IgG is tested at donor workup: Epstein-Barr Virus Antibody testing IgG	Yes
EBV IgM is tested at donor workup: Epstein-Barr Virus Antibody testing IgM	Yes
HBV (NAT) is tested at donor workup: Hepatitis B nucleic acid testing	Yes
HBc Ab is tested at donor workup: Hepatitis B core antibody testing	Yes
HBs Ag is tested at donor workup: Hepatitis B Surface antigen testing	Yes
HCV (NAT) is tested at donor workup: Hepatitis C nucleic acid testing	Yes
HCV Ab is tested at donor workup: Hepatitis C antibody testing	Yes
HIV–1 Ab is tested at donor workup: Human Immunodeficiency Virus HIV-1 antibody testing	Yes
HIV–2 Ab is tested at donor workup: Human Immunodeficiency Virus HIV-2 antibody testing	Yes
HIV (NAT) is tested at donor workup: Human Immunodeficiency Virus nucleic acid testing	Yes
HIV p24 Ag is tested at donor workup: Human Immunodeficiency Virus p24 antigen testing	On Request
HTLV-I is tested at donor workup: Human T-Lymphotropic Virus type I testing	Yes
HTLV-II is tested at donor workup: Human T-Lymphotropic Virus type II testing	Yes
STS (Serological) is tested at donor workup: Serological tests for syphilis	Yes
STS FTA-ABS (verification test) is tested at donor workup: Serological test for syphilis	Yes
WNV-NAT is tested at donor workup: West Nile Virus nucleic acid testing	On Request
Other tests performed:	Anti-HBs incl. titer, Anti-Toxoplasmosis

Testing	
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
Retention policy	
Donor records relating to the medical and HPC collection process are retained for:	20-30 years (depending on data), according to national law