

(archived) Regulatory Survey ION-9968

This data is publicly available. Parent page : ION-9968

General information	
organisation name	DKMS UK
ION of the organisation	ION-9968
Products	
This organisation provides HPC, Marrow	Yes
This organisation provides HPC, Apheresis	Yes
This organisation provides HPC, Cord Blood	No
This organisation provides MNC, Apheresis	No
This organisation provides NC, Whole Blood	Yes
This organisation provides Other products	No
Other products provided:	
Number of adult donor products shipped in the last 3 years:	211
Domestic shipments:	69
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:	Anthony Nolan
Date of last inspection:	June 2016
Link to website of competent authority/national regulatory body:	
Legal documentation from the national government that your organisation is allowed to operate as a registry can be provided:	Not applicable
Serious adverse events and reactions are reported and investigated:	Yes- Optionalreporting required
Affiliated centres	
This organisation has affiliated Donor Centres	Not applicable
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:	Not applicable

If Yes, the frequency of audits is :	
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	
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	Yes
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	Yes
Other tests performed:	
Testing	

Full donor screening for infectious disease risk is performed at the following stage:	Workup
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:	30 years