

Regulatory Survey ION-8941

This data is publicly available. Parent page : ION-8941

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| General information | |
| organisation name | Ossium Health |
| ION of the organisation | ION-8941 |
| Products | |
| This organisation provides HPC, Marrow | |
| This organisation provides HPC, Apheresis | |
| This organisation provides HPC, Cord Blood | |
| This organisation provides MNC, Apheresis | |
| This organisation provides NC, Whole Blood | |
| This organisation provides Other products | |
| Other products provided: | |
| Number of adult donor products shipped in the last 3 years: | |
| Domestic shipments: | |
| International shipments: | |
| Licences and accreditations | |
| organisation is licensed/accredited by a national regulatory body/accrediting agency: | |
| Name of Competent Authority/national regulatory body: | |
| Date of last inspection: | |
| 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: | |
| Serious adverse events and reactions are reported and investigated: | |
| Affiliated centres | |
| This organisation has affiliated Donor Centres | |
| This organisation has affiliated Collection Centres | |
| This organisation has affiliated Cord Blood Banks | |
| This organisation has affiliated Transplant Centres | |
| This organisation has affiliated IDM Testing Laboratories | |
| This organisation has affiliated HLA/other DNA markers Testing Laboratories | |
| There is a full list of affiliated centres with their license / accreditation status 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) | |
| Affiliated centres comply with WMDA standards and applicable national regulations: | |
| We have requirements for affiliated centres in addition to WMDA Standards and applicable national regulations: | |
| We audit affiliated centres for compliance with applicable standards, national regulations and your organisation's requirements: | |

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

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