Schedule of Accreditation

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NHS Blood & Transplant

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Testing performed at the above address only

DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN TISSUE AND FLUIDS	Serological examination activities for the purposes of clinical diagnosis	Manufacturer's instructions for equipment in conjunction within-house procedures:
Serum or Plasma unless otherwise stated	Detection of:	Biomerieux Vidas Blue Enzyme Linked Fluorometric Assay (ELFA) and in-house procedure: SOP1398
	Epstein Barr virus (EBV) IgG	
	Epstein Barr virus (EBV) IgM	
	Toxoplasma IgM and competition	
Plasma	Qualitative Detection of:	DiaSorin Liaison XL automated EIA with the following kits: SOP6210
	HBc IgM	LIAISON® HBc IgM assay
	Anti-HBe	LIAISON® Anti-HBe assay
	HBeAg	LIAISON® HBeAg assay
	Cytomegalovirus (CMV) IgG	SOP 6210 Diasorin Liaison CMV IgG II CLIA assay and XL platform
	Cytomegalovirus (CMV) IgM	SOP 6210 Diasorin Liaison CMV IgM II CLIA assay and XL platform
	Detection of:	DSX Automated EIA and in-house procedure: SOP1607 with the following kits:
	Hepatitis B surface antigen	Murex HbBsAg v3 Biorad Monolisa HBsAg Ultra
	HIV antibody/antigen	Murex HIV Ag/Ab BioRad Genscreen HIV Ultra Ag/ab

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN TISSUE AND FLUIDS (cont'd)	Serological examination activities for the purposes of clinical diagnosis (cont'd)	Manufacturer's instructions for equipment in conjunction within-house procedures:
Plasma (cont'd)	Qualitative Detection of: (cont'd)	DiaSorin Liaison XL automated EIA with the following kits: SOP6210
	Hepatitis C antibody	Innotest HCV Ab IV Murex HCV Ag/Ab Combination
Plasma	Detection of:	DSX Automated EIA and in-house procedure: SOP1607 with the following kits:
	Syphilis IgG/IgM and total antibody	Murex ICE Syphilis Captia Syphilis TA 480
	Human T Lymphotropic virus (HTLVI/II) antibody	Murex HTLV I/II GE81 Diapro HTLV Ultra
	anti-Hepatitis B core antibody	Murex Anti HBc
	Pan malarial sp. antibody	Cellabs pan Malaria Diapro Malaria Ab
Plasma	Detection of:	Manual EIA and in-house procedure:
	Syphilis IgM	SOP 2740 Captia kit
	Malaria Ab	SOP2740 Captia Malaria EIA
	Weiner Chagas Ab assay (T.cruzi)	SOP2740 Manual EIA
	Neutralisation of HBsAg	SOP1229 Diasorin Murex kit
	Neutralisation of HBsAg	SOP1229 Biorad kit
	HEV IgG	SOP2740 Fortess HEV IgG kit
	HEV IgM	SOP2740 Fortess HEV IgM kit

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN TISSUE AND FLUIDS (cont'd)	Serological examination activities for the purposes of clinical diagnosis (cont'd)	Manufacturer's instructions for equipment in conjunction within-house procedures:
Plasma	Detection of:	Manual Line blots:
	HTLV I/II antibody	SOP2737 MP Diagnostics HTLV Blot 2.4
	Syphilis antibody	SOP2737 Inno-LIA Syphilis score
	HCV antibody	SOP2737 Inno-LIA HCV score
	Detection of:	Abbott Architect i1000SR immunoassay and in-house procedure: SOP3472 SOP2332 Serological screening
	Hepatitis B surface antigen	
	anti-Hepatitis B core antibody	
	Hepatitis B surface antibody	
	HIV antibody/ antigen	
	Hepatitis C antibody	
	Syphilis total antibody	
	Human T Lymphotropic virus (HTLVI/II) antibody	
	Trypanosoma cruzi antibody	
	CMV IgG	
	CMV IgM	
		Manual methods:
Plasma	Specific antibodies to *Treponema pallidum* (Syphilis)	Fortress TPHA assay SOP1211 – Performance of Syphilis Haemagglutination Assay

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN TISSUE AND FLUIDS (cont'd)	Molecular examination activities for the purposes of clinical diagnosis	Manufacturer's instructions for equipment in conjunction within-house procedures:
Plasma	Detection and discrimination of virus type:	Grifols Panther extraction and transcription mediated amplification Procleix kits and in-house procedures: SOP3942
	Hepatitis B DNA	
	Hepatitis C RNA	
	HIV RNA	
	Hepatitis E RNA	
Serum or Plasma (unless otherwise stated) (cont'd)	Detection of:	Extraction using Qiagen EZ1 & EZ2 Advanced XL and PCR using Aria MX real time PCR
Plasma	Hepatitis E RNA	SOP5002 Mikrogen Amplicube
Whole Blood	Human T cell Lymphotropic viruses (HTLVI/II) pvDNA	In house assay SOP4658
	Hepatitis B DNA quantitation	In house assay SOP4727
Whole Blood	Plasmodium falciparum DNA	In house assay SOP5009
Whole Blood	Non-falciparum (P. ovale, vivax, malariae and knowlesi) DNA	In house assay SOP5009
Plasma	West Nile Virus (WNV) RNA	SOP4736 WNV Altona RealStar WNV RT-PCR Kit 2.0 EZ1 or EZ2 Advanced XL Extraction & RT PCR using Aria Mx

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS AND TISSUES	Microbiology examination activities for the purposes of clinical diagnosis	Manufacturer's instructions for Biomerieux BactAlert (reflectance measurement from colorimetric change) in conjunction with in-house documented methods:
Blood components implicated in suspected transfusion transmitted infections, visually abnormal components	Detection and isolation of clinically relevant bacteria and fungi	SOP914 – Microbiological Investigation of Transfusion Reactions and Visually Abnormal Blood Components
Blood components associated with bacterial screen positive platelet donations		SOP3371 – Confirmatory Testing of Screened Platelets and Associated packs
Cord blood (pre-inoculated BacT/Alert bottles)		SOP1042
Autologous and Allogeneic Serum Eye Drops (pre-inoculated BacT/Alert bottles)		SOP1043
Stem cell Samples (pre-inoculated BacT/Alert bottles)		SOP3336
Broths and culture plates pre-inoculated containing human tissues and fluids	Detection and isolation of clinically relevant bacteria and fungi	Manual subculture methods in conjunction with in-house documented methods
Frozen Femoral Heads	Detection and isolation of clinically relevant bacteria and fungi	SOP1041

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS AND TISSUES (cont'd)	Microbiology examination activities for the purposes of clinical diagnosis (cont'd)	Manual subculture methods in conjunction with in-house documented methods
Broths and culture plates pre-inoculated containing human tissues and fluids Amnion Skin Bone donations (deceased donors) Tendon donations for irradiation Decontaminated tendon donations Cardiovascular grafts (heart, femoral, pericardium) Menisci, Osteochondral donations	Detection and isolation of clinically relevant bacteria and fungi	SOP1386 Receipt and Reconciliation of Tissue and Associated Samples
Clinically significant bacterial and fungal isolates from sample types listed above Tissue samples	Identification of clinically relevant bacterial and fungal isolates	Manufacturer's instructions for Biomerieux MALDI ToF mass spectroscopy or in conjunction with in-house documented methods: SOP5054 SOP 1037 Reporting of tissues.
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