


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

 <p>UKAS MEDICAL 8783</p> <p>Accredited to ISO 15189:2012</p>	<h3>NHS Blood and Transplant</h3> <p>Issue No: 004 Issue date: 01 September 2021</p>	
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<p>Testing performed at the above address only</p>		

DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
<p>HUMAN TISSUE AND FLUIDS</p> <p>Serum or Plasma unless otherwise stated</p>	<p><u>Serological examination activities for the purposes of clinical diagnosis</u></p> <p>Detection of:</p> <p>Anti-Hepatitis B surface antibody</p> <p>Epstein Barr virus (EBV) IgG</p> <p>Epstein Barr virus (EBV) IgM</p> <p>Toxoplasma IgM and competition</p> <p>Cytomegalovirus (CMV) IgG</p> <p>Cytomegalovirus (CMV) IgM</p> <p>Detection of:</p> <p>Hepatitis B surface antigen</p> <p>HIV antibody/antigen</p> <p>Hepatitis C antibody</p>	<p>Manufacturer's instructions for equipment in conjunction within-house procedures:</p> <p>Biomerieux Vidas Blue Enzyme Linked Fluorometric Assay (ELFA) and in-house procedure: SOP1398</p> <p>DSX Automated EIA and in-house procedure: SOP1607 with the following kits :</p> <p>Murex HbsAg v3 Biorad Monolisa HBsAg Ultra</p> <p>Murex HIV Ag/Ab BioRad Genscreen HIV Ultra Ag/ab</p> <p>Innotest HCV Ab IV Murex HCV Ag/Ab Combination</p>



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HUMAN TISSUE AND FLUIDS (cont'd)	<u>Serological examination activities for the purposes of clinical diagnosis (cont'd)</u>	Manufacturer's instructions for equipment in conjunction with in-house procedures:
Serum or Plasma (unless otherwise stated) (cont'd)	Detection of: (cont'd)	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 (HTLV I/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
	Neutralisation of HBsAg	SOP1229 Diasorin Murex kit
	Neutralisation of HBsAg	SOP1229 Biorad kit
	Anti HBc IgM	SOP2740 Monolisa anti HB IgM kit
	HEV IgG	SOP2740 Fortress HEV IgG kit
	HEV IgM	SOP2740 Fortress HEV IgM kit



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HUMAN TISSUE AND FLUIDS (cont'd)	<u>Serological examination activities for the purposes of clinical diagnosis (cont'd)</u>	Manufacturer's instructions for equipment in conjunction with in-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	



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HUMAN TISSUE AND FLUIDS (cont'd)	<u>Molecular examination activities for the purposes of clinical diagnosis (cont'd)</u>	Manufacturer's instructions for equipment in conjunction within-house procedures:
Serum or Plasma (unless otherwise stated) (cont'd)	Detection of:	Extraction using Qiagen EZ1 Advanced XL and PCR using Rotagene Q amplification real time PCR and in- house procedures:
Whole Blood	Human T cell Lymphotropic viruses (HTLVI/II) pvDNA	In house assay SOP4658
Plasma	Zika virus RNA	Real Star Altona Zika SOP5245
	Detection of :	Extraction using Qiagen EZ1 Advanced XL and PCR using Aria MX real time PCR
Plasma	Hepatitis E RNA	SOP5002 Mikrogen Amplicube
	Cytomegalovirus (CMV) DNA	In house assay SOP4969
	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



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



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<p>HUMAN BODY FLUIDS AND TISSUES (cont'd)</p> <p>Broths and culture plates pre-inoculated containing human tissues and fluids</p> <p>Amnion</p> <p>Skin</p> <p>Bone donations (deceased donors)</p> <p>Tendon donations for irradiation</p> <p>Decontaminated tendon donations</p> <p>Cardiovascular grafts (heart, femoral, pericardium)</p> <p>Menisci, Osteochondral donations</p> <p>Clinically significant bacterial and fungal isolates from sample types listed above</p> <p>Tissue samples</p>	<p><u>Microbiology examination activities for the purposes of clinical diagnosis (cont'd)</u></p> <p>Detection and isolation of clinically relevant bacteria and fungi</p> <p>Identification of clinically relevant bacterial and fungal isolates</p>	<p>Manufacturer's instructions for Don Whitley WASP automated and manual subculture methods in conjunction with in house documented methods</p> <p>SOP1386 Receipt and Reconciliation of Tissue and Associated Samples</p> <p>Manufacturer's instructions for Biomerieux MALDI ToF mass spectroscopy or in conjunction with in house documented methods:</p> <p>SOP5054</p> <p>Manufacturer's instructions for Becton Dickinson BBL Crystal colorimetric assays in conjunction with in house documented method</p> <p>SOP1014</p> <p>SOP 1037 Reporting of tissues.</p>
END		