


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 <p>UKAS MEDICAL</p> <p>8783</p> <p>Accredited to ISO 15189:2012</p>	<p>NHS Blood & Transplant</p> <p>Issue No: 007 Issue date: 04 April 2024</p>	
	<p>Microbiology Services</p> <p>NHSBT Colindale</p> <p>Colindale Avenue</p> <p>Colindale</p> <p>NW9 5BG</p>	<p>Contact: Dr Holly Ciesielczuk</p> <p>Tel: +44 (0)208 957 2883</p> <p>E-Mail: holly.ciesielczuk@nhsbt.nhs.uk</p> <p>Website: www.nhsbt.co.uk</p>
	<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>Plasma</p>	<p><u>Serological examination activities for the purposes of clinical diagnosis</u></p> <p>Detection of:</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>HBc IgM</p> <p>Anti-HBe</p> <p>HBeAg</p> <p>Detection of:</p> <p>Hepatitis B surface antigen</p> <p>HIV antibody/antigen</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>DiaSorin Liaison XL automated EIA with the following kits: SOP6210</p> <p>LIAISON® HBc IgM assay</p> <p>LIAISON® Anti-HBe assay</p> <p>LIAISON® HBeAg assay</p> <p>DSX Automated EIA and in-house procedure: SOP1607 with the following kits :</p> <p>Murex HbBsAg v3</p> <p>Biorad Monolisa HBsAg Ultra</p> <p>Murex HIV Ag/Ab</p> <p>BioRad Genscreen HIV Ultra Ag/ab</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 within-house procedures:
Plasma	Hepatitis C antibody	Innotest HCV Ab IV Murex HCV Ag/Ab Combination
	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 (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
	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 Fortress HEV IgG kit
	HEV IgM	SOP2740 Fortress HEV IgM kit



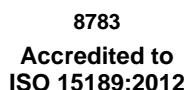
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HUMAN TISSUE AND FLUIDS (cont'd)	<u>Serological examination activities for the purposes of clinical diagnosis (cont'd)</u>	Manufacturer's instructions for equipment in conjunction within-house procedures:
Plasma	Detection of:	Manual Line blots:
	HTLV 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 (HTLV I/II) antibody	
	Trypanosoma cruzi antibody	
	CMV IgG	
	CMV IgM	



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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 within-house procedures:
Serum or Plasma (unless otherwise stated) (cont'd)	Non-specific antibodies to Treponema sp. (syphilis)	Manual methods: Fortress Diagnostics Rapid Plasma Reagin or RPR Card test – manual test SOP2294 RPR
Plasma	<u>Molecular examination activities for the purposes of clinical diagnosis</u> Detection and discrimination of virus type: Hepatitis B DNA Hepatitis C RNA HIV RNA Hepatitis E RNA	Manufacturer's instructions for equipment in conjunction within-house procedures: Grifols Panther extraction and transcription mediated amplification Procleix kits and in-house procedures: SOP3942



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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:
Plasma		
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 and using Rotagene Q amplification real time PCR
Plasma	Hepatitis E RNA	SOP5002 Mikrogen Amplicube
	Cytomegalovirus (CMV) DNA	In house assay SOP4969
Whole Blood	Human T cell Lymphotropic viruses (HTLV/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



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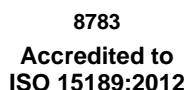
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HUMAN BODY FLUIDS AND TISSUES Blood components implicated in suspected transfusion transmitted infections, visually abnormal components Blood components associated with bacterial screen positive platelet donations Cord blood (pre-inoculated BacT/Alert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



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