

Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 <p>UKAS MEDICAL 9756</p> <p>Accredited to ISO 15189:2022</p>	<h3>Liverpool University Hospitals NHS Foundation Trust</h3> <p>Issue No: 010 Issue date: 17 November 2025</p>	
	<p>Clinical Sciences Services Building Royal Liverpool Hospital Liverpool University Hospitals Foundation Trust Mount Vernon Street Liverpool L7 8YE</p>	<p>Contact: Ines Santos Tel: +44 (0)151 706 4374 Fax: +44 (0)151 706 5849 E-Mail: Ines.Santos@liverpoolft.nhs.uk Website: www.liverpoolcl.nhs.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 TISSUES AND FLUIDS</p> <p>Cellular and fluid material contained on swabs (Eye, throat, wounds, ear, nose, skin, mouth) Fluids & pus Tissues & biopsies Genital samples Aspirates Samples from sterile sites Sterile fluids including Cerebrospinal fluid Faeces/ rectal swabs Cannulae/tips Respiratory samples (e.g. Sputum, BALs)</p> <p>Blood and fluids from sterile sites.</p>	<p>Microbiology</p> <p><u>Microbiology examination activities for the purpose of clinical diagnosis</u></p> <p>General isolation of micro-organisms of clinical significance</p> <p>Isolation of microorganisms of clinical significance</p>	<p>Procedures documented in manufacturers equipment manuals in conjunction with documented in-house procedures by the following methods:</p> <p>Manual or automated (Kiestra Inoqula) inoculation followed by culture using SOPs: I&I-MM-SOP133 Cystic Fibrosis I&I-MM-SOP96 Wound swabs I&I-MM-SOP61, I&I-MM-SOP51 I&I-MM-SOP83 I&I-MM-SOP97. ENT I&I-MM-SOP17, 18, 19, 20, 21, 44, 45, 74. Tissues and biopsies I&I-MM-SOP83, 135, 174. Urogenital bench I&I-MM-SOP82 GUM bench I&I-MM-SOP56 Respiratory I&I-MM-SOP23 Intraocular fluid I&I-MM-SOP24 Faeces I&I-MM-SOP10 CSF I&I-MM-SOP52 CSF and associated specimens I&I-MM-SOP53 Cannulae/tips I&I-MM-SOP78</p> <p>Liquid media culture using automated continuous monitoring system using: BacTalert and BacTec and: Blood cultures I&I-MM-SOP16</p>



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Microbiology examination activities for the purpose of clinical diagnosis (cont'd)</u>	Procedures documented in manufacturers equipment manuals in conjunction with documented in-house procedures by the following methods:
Cerebrospinal fluid, Joint fluids, ascetic fluids.	Quantification of white and red blood cells and bacteria	Microscopy (inc Gram Staining) : I&I-MM-SOP53, 55, 97, 102
Urine	Quantification of white and red blood cells, bacteria and epithelial cells	Manual or Automated urine analysis using IQ 200 Sprint and SOP Urines I&I-MM-SOP55
Urine	General isolation of micro-organisms of clinical significance	Automated Mast Uri System and Urines I&I-MM-SOP55
Joint fluids	Detection of crystals	I&I-MM-SOP102
Cellular and fluid material contained on swabs	Screening for Methicillin-Resistant <i>Staphylococcus aureus</i> (MRSA)	Manual or automated (Kiestra Inoqula) inoculation followed by culture using SOPs: MRSA Screening I&I-MM-SOP46
	Screening for Methicillin-Sensitive <i>Staphylococcus aureus</i> (MSSA)	LHCH CPS SOP: I&I-MM-SOP50
Cellular and fluid material contained on swabs	Resistance screening for CPE, ESBL,VRE, Ciprofloxacin resistance	Manual inoculation or automated (Kiestra Inoqula) followed by culture using SOPs: LHCH CPS I&I-MM-SOP50 Multi Drug Resistant organism screen I&I-MM-SOP86 NICU Admissions screen I&I-MM-SOP47 NICU Weekly screen I&I-MM-SOP48



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<p>HUMAN TISSUES AND FLUIDS (cont'd)</p> <p>Respiratory samples Urine CSF Sputum Brochoalveolar Lavages Pus Faeces Body Fluids/Aspirates Skin/Tissues PM material Laryngeal Swabs Gastric Lavage</p> <p>Skin Nail Hair Cellular and fluid material contained on swabs</p> <p>Cultures isolated in-house from all samples listed above.</p>	<p><u>Microbiology examination activities for the purpose of clinical diagnosis (cont'd)</u></p> <p>Isolation and presumptive identification of Acid-alcohol fast bacilli (inc. <i>Mycobacterium</i> spp.)</p> <p>General isolation and characterisation of clinically significant fungi</p> <p>Identification of microorganism of clinical significance.</p>	<p>Procedures documented in manufacturers equipment manuals in conjunction with documented in-house procedures by the following methods:</p> <p>Automated culture using BD MGIT and BDFX module:</p> <p>Manual culture on Lowenstein-Jensen medium:</p> <p>Auramine phenol staining and fluorescent microscopy. Ziehl-Neelsen stain and light microscopy:</p> <p>SOP Mycobacteria I&I-MM-SOP22</p> <p>Manual culture and fluorescent microscopy using Calcofluor White stain using SOP: Mycology Bench I&I-MM-SOP64 Fungal microscopy I&I-MM-SOP63</p> <p>Automated Matrix-assisted laser desorption/ionisation (MALDITOF) using: Malditof I&I-MM-SOP72</p> <p>Conventional identification methods including biochemical and latex agglutinations: Organism identification I&I-MM-SOP92 Organism identification test procedures: I&I-MM-SOP100</p>



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Microbiology examination activities for the purpose of clinical diagnosis</u> (cont'd)	Procedures documented in manufacturers equipment manuals in conjunction with documented in-house procedures by the following methods:
Cultures isolated in house from all samples listed above.	Antimicrobial susceptibility testing of clinically significant bacteria	Manual disc diffusion and/or automated methods using EUCAST methodology: Sensitivity Bench I&I-MM-SOP89 ESBL DMS 1890 Gradient MIC determination by E-test and M.I.C.E: I&I-MM-SOP89 DMS 1824
Fungal cultures isolated in house from samples listed above	Antifungal susceptibility testing of yeasts of clinical significance	Sensititre YeastOne ThermoScientific YO10 by colourimetric microdilution I&I-MM-SOP98
Cultures isolated in house from all samples listed above.	Identification of Staphylococcal isolates	Pro-Lab Staph Xtra latex I&I-MM-SOP100
Cultures isolated in house from all samples listed above.	Serological identification of groups A, B, C, D, F and G of the Lancefield groups of Streptococci grown on agar plates	Pro-Lab Prolex Strep grouping kit I&I-MM-SOP100
Cultures isolated in house from the above	Detection of <i>Salmonella</i> polyvalent 'O' (PSO) and <i>Salmonella</i> polyvalent 'H' (PSH); <i>Shigella</i> species; <i>Vibrio</i> species.	Agglutination using ThermoFisher antisera: I&I-MM-SOP10
Cultures isolated in house from the above	Identification of <i>E. coli</i> O157	<i>E.coli</i> O157 Oxoid Latex Test: I&I-MM-SOP10
Cultures isolated in house from the above	Identification of <i>Campylobacter</i> species and <i>Yersinia</i> species	Light microscopy and Gram stain using: I&I-MM-SOP100, 179



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Microbiology examination activities for the purpose of clinical diagnosis (cont'd)</u>	Procedures documented in manufacturers equipment manuals in conjunction with documented in-house procedures by the following methods:
Faeces and urine	Detection of ova, cysts and parasites (OCP)	Concentration and light microscopic examination using MINI-SYSTEM Total Fix: I&I-MM-SOP178
Faeces	Detection of <i>Cryptosporidium</i> oocysts	Auramine Phenol stain for <i>Cryptosporidium</i> and fluorescent microscopy: I&I-MM-SOP10, 178, 179
Faeces	Detection of <i>Cyclospora</i> and <i>Isospora</i> oocysts	Cold ZN stain and light microscopy: I&I-MM-SOP-10, 178, 179
Sellotape slide/perianal swab	Detection of <i>Enterobius vermicularis</i>	Light Microscopy using: I&I-MM-SOP-10, 178, 179
Urine	Detection of <i>Schistosoma spp</i>	Concentration using centrifugation and examination of deposit using light microscopy using I&I-MM-SOP10, 178
Faeces	Detection of <i>C. difficile</i> GDH antigen.	Alere Tech Lab C.Diff Quik Chek Complete kit : I&I-MM-SOP11
Faeces	Detection of <i>C. difficile</i> toxin A&B	Alere Tech Lab C.Diff Quik Chek Complete kit : I&I-MM-SOP11
Blood Serum CSF Blood Culture		



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Microbiology examination activities for the purpose of clinical diagnosis (cont'd)</u>	Procedures documented in manufacturers equipment manuals in conjunction with documented in-house procedures by the following methods:
Urine	Legionella screening	Binax Now Legionella kit using SOP: I&I-MM-SOP87
Urine	Pneumococcal screening	Binax Now Strep pneumo kit using SOP: I&I-MM-SOP87
CSF Serum	Detection of Cryptococcal antigen.	CRAG LFA Cryptococcal antigen lateral flow assay using: I&I-MM-SOP15
Genital samples	WBCs, Clue Cells and Bacterial vaginosis	Microscopy (including Gram staining and wet preparation using: I&I-MM-SOP82 I&I-MM-SOP80
Corneal impression membrane, Corneal scrape Contact lenses solution	Detection of <i>Acanthamoeba spp</i>	Culture and microscopy using I&I-MM-SOP044
Serum Plasma	Detection of Antibodies to <i>Treponema spp</i>	Manual method using ASI TPHA kit SOP: I&I-VI-SOP-175



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<p>HUMAN TISSUES AND FLUIDS (cont'd)</p> <p>Respiratory samples Urine CSF Sputum Brochoalveolar Lavages Pus Faeces Body Fluids/Aspirates Skin/Tissues PM material Laryngeal Swabs Gastric Lavages</p> <p>In house cultures of Ps.aeruginosa</p>	<p><u>Molecular examination activities for the purpose of clinical diagnosis</u></p> <p>Mycobacterial DNA MultiDrug Resistance Genes Common Mycobacterial species</p> <p>Detection of pseudomonas types (for cross infection and cohorting)</p>	<p>Hain Fluorotype MTB PCR Hain Genotype MTBDRplus Hain Genotype Mycobacterium CM : I&I-MM-SOP34</p> <p>Biosystems GeneAmp PCR system 2700 using: I&I-MM-SOP57</p>



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HUMAN BODY FLUIDS	<u>Virology</u> <u>Serology examinations for the purpose of clinical diagnosis</u>	Documented in house methods incorporating manufacturers' instructions where relevant using: Diasorin Liaison XL (chemiluminescence) I&I-VI-SOP-22
Serum and plasma	Detection of: CMV avidity CMV IgG CMV IgM EBNA EBV IgM EBV IgG HSV IgG Syphilis 2 nd line test Toxoplasma IgG Toxoplasma IgM Parvovirus IgG Parvovirus IgM HTLV I&II VZV IgG HIV Ag/Ab HBc Ab confirmation Measles IgG Helicobacter pylori faecal Ag	I&I-VI-SOP-153 I&I-VI-SOP-154 I&I-VI-SOP-155 I&I-VI-SOP-156 I&I-VI-SOP-158 I&I-VI-SOP-157 I&I-VI-SOP-159 I&I-VI-SOP-160 I&I-VI-SOP-161 I&I-VI-SOP-162 I&I-VI-SOP-163 I&I-VI-SOP-164 I&I-VI-SOP-165 I&I-VI-SOP-166 I&I-VI-SOP-167 I&I-VI-SOP-168 I&I-VI-SOP-169 I&I-VI-SOP-136
Faeces		
Serum and plasma	Detection of: Measles IgG Brucella IgG Brucella IgM Brucella CAPT	DS2 ELISA I&I-VI-SOP-14 I&I-VI-SOP-63 I&I-VI-SOP-67 I&I-VI-SOP-68 I&I-VI-SOP-76
	Antibody detection:	AutoBlot 3000 immunoassay
Serum / EDTA	Confirmation of HCV	SOP I&I-VI-SOP-20
Serum / EDTA	Confirmation of HIV	SOP I&I-VI-SOP-20



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HUMAN BODY FLUIDS (cont'd)	<u>Serology examinations for the purpose of clinical diagnosis</u> (cont'd)	Documented -in-house methods to meet the requirements of the IDPS screening programme(s) as defined in the 'Infectious diseases in pregnancy screening screening: laboratory QA evidence requirements' (relevant tests marked with*)
Serum, plasma, EDTA	Detection of:	Roche COBAS 8000 (e801) random access immunoassay analyser I&I-VI-SOP-59
	HIV Ag*	I&I-VI-SOP-59
	HIV Ab*	I&I-VI-SOP-59
	Hepatitis C Ab	I&I-VI-SOP-59
	Hepatitis B core Ab*	I&I-VI-SOP-59
	Syphilis*	I&I-VI-SOP-59
	Hepatitis B surface Ag*	I&I-VI-SOP-59
	Hepatitis B surface Ab	I&I-VI-SOP-59
	Hepatitis B core IgM	I&I-VI-SOP-59
	HBeAb*	I&I-VI-SOP-59
	Anti HBeAg*	I&I-VI-SOP-59
	Hepatitis A IgG	I&I-VI-SOP-59
	Hepatitis A IgM	I&I-VI-SOP-59
	Rubella	I&I-VI-SOP-59
Serum / EDTA plasma	Detection of antibodies to Antistreptolysin O (ASO)	Biokit Rheumajet ASO latex agglutination kit I&I-VI-SOP-61
Serum / EDTA plasma	Detection of Rheumatoid factor	Biokit Rheumajet RF latex agglutination kit I&I-VI-SOP-66
Serum / EDTA Plasma	Detection of non-specific antibodies to <i>T.pallidum</i>	ASI RPR reditest kit I&I-VI-SOP-131
Serum / plasma	Brucella IgG & IgM	Brucella Microagglutination test I&I-VI-SOP-78



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HUMAN BODY FLUIDS (cont'd)	<u>Molecular examinations for the purposes of clinical diagnosis</u>	Documented in house methods incorporating manufacturers' instructions where relevant using:
Extracted DNA	Detection of Brucella spp DNA	Real time Multiplex PCR Roche Light cycler 480 In House kit I&I-VI-SOP-137
Rectal swabs	Detection of DNA: Carbapenemase producing Enterobacteriaceae (CPE)	Real time PCR Cepheid GeneXpert PCR using SOP: CARBA-R kit I&I-VI-SOP-148
Serum and Plasma		Nucleic acid extraction using: 1: QIAgen QIASymphony I&I-VI-SOP3
CSF Bronchial washings Nasopharyngeal aspirates		2: QIAgen QIAcube I&I-VI-SOP-2 QIAamp Minelute Virus Spin Kit I&I-VI-SOP-6
Sputum/Induced Sputum Swabs in Viral Transport Media (skin, nose/throat, eye, genital) Vesicle Fluid Aqueous/Vitreous fluid Faeces Urine Biopsy (brain, lung, colon)		



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HUMAN BODY FLUIDS (cont'd)	<u>Molecular examinations for the purposes of clinical diagnosis</u> (cont'd)	Documented in house methods incorporating manufacturers' instructions where relevant using:
Extracted nucleic acid using above method as denoted 1,2 above	Quantitative and Qualitative* detection of:	Real time Multiplex PCR: Roche Light cycler 480 I&I-VI-SOP-51
DNA (1,2)	Adenovirus	I&I-VI-SOP75
DNA (1,2)	CMV	I&I-VI-SOP75
DNA (1,2)	EBV	I&I-VI-SOP75
DNA (1,2)	BK virus	I&I-VI-SOP-80
DNA (1,2)	JC virus	I&I-VI-SOP-80
DNA (1,2)	HSV*	I&I-VI-SOP-49
DNA (1,2)	VZV*	I&I-VI-SOP-49
RNA (1,2)	Enterovirus*	I&I-VI-SOP-48
RNA (1,2)	Parechovirus*	I&I-VI-SOP-48
RNA (1)	Norovirus*	I&I-VI-SOP-46
DNA (1,2)	Pneumocystis jirovecii*	I&I-VI-SOP-53
Nucleic acids (1)	Gastroenteritis panel*: (Rotavirus, Adenovirus, Astrovirus, Sapovirus)	I&I-VI-SOP-50
Nucleic acids (1,2)	Respiratory panel*: (Influenza A, and B, Parainfluenza 1-4, Adenovirus, Respiratory Syncytial Virus, Rhinovirus, Metapneumovirus, Coronavirus)	I&I-VI-SOP-45
Nucleic acids (1,2)	Lower Respiratory*: Atypical panel (Legionella pneumophila, Mycoplasma pneumoniae, Chlamydia pneumoniae)	I&I-VI-SOP-47



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<p>HUMAN BODY FLUIDS (cont'd)</p> <p>Combined nose/throat swabs in VTM/UTM Tracheal aspirate</p> <p>Faeces</p>	<p><u>Molecular examinations for the purposes of clinical diagnosis (cont'd)</u></p> <p>Detection of SARS-CoV-2 RNA, specific gene sequences the N2 and E</p> <p>Norovirus</p>	<p>Documented in house methods incorporating manufacturers' instructions where relevant using:</p> <p>RT PCR using Cepheid GeneXpert using the Xpress SARS-CoV-2 assay, SOP I&I-VI-SOP-101 Cepheid Infinity Automated Rapid Viral Molecular tests</p> <p>RT PCR using Cepheid GenXpert Infinity</p>
<p>HUMAN BODY FLUIDS AND TISSUES</p> <p>Peripheral blood, lymph node or spleen</p>	<p><u>Histocompatibility and Immunogenetics</u></p> <p><u>Histocompatibility and Immunogenetics testing for the purpose of clinical diagnosis:</u></p> <p><u>DNA extraction for further downstream processes</u></p>	<p>In house documented methods and manufacturer's instructions using:</p> <p>DNA extraction and quantitation in support of PCR-SSP, PCR-SSOP, QPCR and NGS typing:</p> <ul style="list-style-type: none"> • I&I-H&I-MOL-SOP-16 QIAGEN QIAamp DSP DNA BLOOD MINI KIT • I&I-H&I-MOL-SOP-41 QIAGEN QIAamp DSP DNA BLOOD MIDI KIT • I&I H&I MOL-SOP-25 automated QIASymphony and Qiagen DSP DNA Mini kits



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<p>HUMAN BODY FLUIDS AND TISSUES (cont'd)</p> <p>DNA extracted from peripheral blood, lymph node or spleen</p>	<p><u>Histocompatibility and Immunogenetics testing for the purpose of clinical diagnosis</u> (cont'd)</p> <p><u>HLA Typing:</u></p> <p>HLA class I & class II typing in support of the following:</p> <ul style="list-style-type: none"> • Haematopoietic stem cell transplantation. • Solid organ transplantation • HLA typing for disease association • Drug hypersensitivity (mainly abacavir) <p>HLA Loci for which typing services are available: HLA-A, -B, -C, DRB1, DRB3,4,5, -DQA1, DQB1, DPA1, DPB1</p>	<p>In house documented methods and manufacturer's instructions using:</p> <p>PCR-SSP low resolution HLA typing:</p> <p>PCR thermalcyclers; MJ Research PTC100, G-Storm Agarose gel electrophoresis UV Camera</p> <ul style="list-style-type: none"> • I&I-H&I-MOL-SOP-11 HLA TYPING BY ONE LAMBDA MICRO SSP • I&I-H&I-MOL-SOP-26 HLA B*27 TYPING USING HISTOTYPE PCR-SSP KITS <p>I&I-H&I-INF-77 I&I-H&I-MOL-SOP-34 I&I-H&I-MOL-SOP-38 I&I-H&I-GEN-SOP-14 I&I-H&I-MOL-SOP-20 – B57 I&I-H&I-MOL-SOP-29 I&I-H&I-MOL-SOP-22 I&I-H&I-INF-93 I&I-H&I-INF-62 I&I-H&I-INF-58 I&I-H&I-INF-64</p>



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<p>HUMAN BODY FLUIDS AND TISSUES (cont'd)</p> <p>DNA extracted from peripheral blood, lymph node or spleen</p>	<p><u>Histocompatibility and Immunogenetics testing for the purpose of clinical diagnosis</u> (cont'd)</p> <p><u>HLA Typing:</u></p> <p>HLA class I & class II typing in support of the following:</p> <ul style="list-style-type: none"> • Haematopoietic stem cell transplantation. • Solid organ transplantation • HLA typing for disease association • Drug hypersensitivity (mainly abacavir) <p>HLA Loci for which typing services are available: HLA-A, -B, -C, DRB1, DRB3,4,5, -DQA1, DQB1, DPA1, DPB1</p>	<p>In house documented methods and manufacturer's instructions using:</p> <p><u>Related documented in-house procedures and supporting SOPs:</u></p> <p>PCR-SSO intermediate resolution typing:</p> <p>PCR thermocyclers; MJ Research PTC100, G-Storm Agarose gel electrophoresis UV Camera, Luminex Liquichip 200 LABXpress automated station</p> <p>Labtype HLA-A, -B, -C, DRB1, DRB3,4,5, DQA1, DQB1, DPA1, DPB1</p> <ul style="list-style-type: none"> • I&I-H&I-MOL-SOP-6 Routine HLA Typing using Labtype Luminex kits- DNA sample preparation and amplification set up for half volume • I&I-H&I-INF-87 LABXPRESS-ROUTINE HLA TYPING USING LABTYPE LUMINEX KITS • I&I-H&I-MOL-SOP-8 LABTYPE HLA ANALYSIS USING FUSION 4.1 SOFTWARE <p>I&I-H&I-INF-77 I&I-H&I-INF-88 I&I-H&I-INF-62</p>



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<p>HUMAN BODY FLUIDS AND TISSUES (cont'd)</p> <p>DNA extracted from peripheral blood, lymph node or spleen</p>	<p><u>Histocompatibility and Immunogenetics testing for the purpose of clinical diagnosis</u> (cont'd)</p> <p><u>HLA Typing:</u></p> <p>HLA class I & class II typing in support of the following:</p> <ul style="list-style-type: none"> • Haematopoietic stem cell transplantation. • Solid organ transplantation • HLA typing for disease association • Drug hypersensitivity (mainly abacavir) <p>HLA Loci for which typing services are available: HLA-A, -B, -C, DRB1, DRB3,4,5, -DQA1, DQB1, DPA1, DPB1</p>	<p>In house documented methods and manufacturer's instructions using:</p> <p><u>Related documented in-house procedures and supporting SOPs:</u></p> <p>Next Generation Sequencing (NGS) based allele resolution HLA typing:</p> <p>PCR thermocyclers; MJ Research PTC100, G-Storm Agarose gel electrophoresis UV Camera, Qubit, Illumina Miseq</p> <ul style="list-style-type: none"> • I&I-H&I-MOL-SOP-14 NGS: FINAL LIBRARY PREPARATION AND MISEQ LOADING • I&I-H&I-MOL-SOP-44: Analysis of NGSgo®-MX11-3 HLA Typing Results Using NGSengine® Software • I&I-H&I-MOL-SOP-46 Reporting NGS HLA Typing results <p>I&I-H&I-MOL-SOP-42 I&I-H&I-MOL-SOP-43 Qubit I&I-H&I-INF-62 I&I-H&I-INF-64 I&I-H&I-INF-52 I&I-H&I-INF-58</p>



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<p>HUMAN BODY FLUIDS AND TISSUES (cont'd)</p> <p>Serum Peripheral blood</p>	<p><u>Histocompatibility and Immunogenetics testing for the purpose of clinical diagnosis</u> (cont'd)</p> <p><u>HLA-specific antibody screening and characterisation:</u></p> <p>Antibody screening and characterisation in support of the following:</p> <ul style="list-style-type: none"> • Pre-transplant HLA-specific alloantibody screening • Post-transplant HLA-specific alloantibody detection and donor specific antibody monitoring <p>HLA-specific antibodies directed against products of the following loci can be detected: HLA-A, -B, -C, DRB1, DRB3,4,5, -DQA1, DQB1, DPA1, DPB1</p>	<p>In house documented methods and manufacturer's instructions using:</p> <p><u>Related documented in-house procedures and supporting SOPs:</u></p> <p>HLA-Specific Antibody Screening and Characterisation:</p> <p>Antibody screening and characterisation assays are performed using OneLambda Labscreen reagents and analysed using a Luminex 200 Luminex analyser supported by the LABXpress automated platform.</p> <p>Results are analysed using HLA Fusion version 4.1</p> <ul style="list-style-type: none"> • I&I-H&I-INF-86 LABXPRESS – HLA ANTIBODY SCREENING AND IDENTIFICATION USING LABSCREEN MIXED BEADS AND LABSCREEN SINGLE ANTIGEN BEADS • I&I-H&I-SER-SOP-76 Reporting of HLA antibody screening results on Telepath and the laboratory H&I Database <p>I&I-H&I-INF-83 I&I-H&I-SER-SOP-29 I&I-H&I-SER-SOP-21 I&I-H&I-GEN-SOP-35</p>



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<p>HUMAN BODY FLUIDS AND TISSUES (cont'd)</p> <p>Cells extracted from peripheral blood, lymph node and spleen tissue</p>	<p><u>Histocompatibility and Immunogenetics testing for the purpose of clinical diagnosis</u> (cont'd)</p> <p>Detection of IgG HLA antibodies to donor T and B lymphocytes</p>	<p>In house documented methods and manufacturer's instructions using:</p> <p>Flow cytometry crossmatching using BD FACSLytic Flow cytometer</p> <ul style="list-style-type: none"> • I&I-H&I-SER-SOP-32: FACSLytic-Flow cytometry crossmatch <p>I&I-H&I-SER-SOP-33 I&I-H&I-SER-SOP-30 I&I-H&I-INF-73 I&I-H&I-INF-74 I&I-H&I-INF-65 I&I-H&I-INF-SOP-65 I&I-H&I-INF-81</p>



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HUMAN BODY FLUIDS	Clinical Immunology <u>Immunological examinations for the purpose of clinical diagnosis</u> <u>Autoimmune Disease Testing</u>	Procedures documented in relevant equipment manuals and in house documented procedures by the following methods
Serum, plasma	Anti-Nuclear antibodies	Manual slide preparation or Automated slide preparation in conjunction with manufacturer's instructions using: Indirect immunofluorescence microscopy
Serum, plasma	MPO/R3 Anti-Neutrophil Cytoplasmic Antibody (ANCA) screen	Automated indirect immunofluorescence on Quantalyser 240 slide processor using human epithelia type 2 (Hep 2) antibodies, Werfen HEP2 kit I&I-CI-AI-SOP19
Serum, plasma	Endomysial antibodies (IgA)	First line ANCA screen performed by Phadia ELIA (MPO and PR3), Manual indirect immunofluorescence on ethanol and formalin fixed ANCA slides (Inova) I&I-CI-AI-SOP3
Serum	Endomysial antibodies (IgG)	Manual indirect immunofluorescence, Inova monkey Manual Enzyme linked Immunosorbent assay (ELISA)
Serum, plasma	Haemophilus Influenzae type B antibodies	Binding Site manual ELISA and Dynex DS2 analyser. Reported in mg/L. I&I-CI-AI-SOP-13
	Tetanus Antibody	Binding Site manual ELISA and Dynex DS2 analyser. I&I-CI-AI-SOP-12



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HUMAN BODY FLUIDS (cont'd)	<u>Immunological examinations for the purpose of clinical diagnosis</u> (cont'd)	Procedures documented in relevant equipment manuals and in house documented procedures by the following methods
Serum, plasma	Intrinsic factor antibody	Orgentec manual ELISA and Dynex DS2 analyser. I&I-CI-AI-SOP-14.
Blood plasma	Detection of Interferon-gamma	Automated Interferon-gamma release assay QuantiFERON-TB Gold plus ELISA on Dynex DS2 I&I-CI-AI-SOP-8 Euroimmune immunoblot kit and Euroimmune EuroBlotOne, and result interpretation using EUROLinScan. Qualitative reporting. I&I-CI-AI-SOP-5,
Serum, plasma	Extractable Nuclear Antigens: Ro La Sm RMP Scl-70 Jo-1 Ro-52	
Serum/plasma	Antibodies to the following antigens: AMA-M2 M2-3E Sp100 PML gp210, LKM-1 LC-1 SLA/LP Ro52	Liver Immunoblot qualitative assay I&I-CI-AI-SOP-5



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HUMAN BODY FLUIDS (cont'd)	<u>Immunological examinations for the purpose of clinical diagnosis</u> (cont'd)	Procedures documented in relevant equipment manuals and in house documented procedures by the following methods
Serum, plasma	Myositis antibodies: Mi2-alpha and beta, TIF1gamma MDA5 NXP2 SAE1 Ku PM-Scl100 Pm-Scl75 Jo-1, SRP PL-7 PL-12 EJ OJ	Euroimmune immunoblot kit and Euroimmune EuroBlotOne, and result interpretation using EUROLIne Scan Myositis immunoblot qualitative assay I&I-CI-AI-SOP-5 AIS047
Serum	Kappa and Lambda free light chains C1 Esterase Inhibitor IgG4	Turbidimetry using Optilite analyser I&I-CI-IC-SOP-6



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HUMAN BODY FLUIDS (cont'd)	<u>Immunological examinations for the purpose of clinical diagnosis</u> (cont'd)	Procedures documented in relevant equipment manuals and in house documented procedures by the following methods
Serum	<u>Immunochemistry</u> Cyclic citrullinated peptide (CCP) antibody Ds DNA screen. Extractable nuclear antigen (ENA) screen (Symphony) IgA Tissue transglutaminase Glomerular basement membrane (GBM) antibodies Myeloperoxidase (MPO sensitive) antibody quantitation Proteinase 3 (PR3 sensitive) antibody quantitation Avian precipitins IgG Aspergillus Tryptase	Phadia 250 EliA fluorescent enzyme sandwich immunoassay. I&I-CI-IC-SOP-3,
Serum	Lymphocyte markers (% and absolute): CD3 CD4 CD8 CD19 CD56	Flow cytometry using BD FACSLyric and Duet I&I-C-IC-SOP-13



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HUMAN BODY FLUIDS (cont'd)	<u>Immunological examinations for the purpose of clinical diagnosis</u> (cont'd)	Procedures documented in relevant equipment manuals and in house documented procedures by the following methods
Serum	Paraprotein quantitation	Sebia Capillarys capillary zone electrophoresis, CAPILLARYS 3 OCTA using Albumin result from UKAS accredited Laboratory 9785. I&I-CI-IC-SOP-8
Urine	Free light chains quantitation	Sebia Hydrasys on gel electrophoresis using total protein result from UKAS accredited Laboratory 9785. I&I-CI-IC-SOP-7
Serum	Monoclonal protein typing	Immunofixation using Sebia Hydrasys 2 Scan and Hydrigel 9IF I&I-CI-IC-SOP-8
Urine	Bence Jones Protein	Electrophoresis and Immunofixation using Sebia Hydrasys 2 scan. I&I-CI-IC-SOP-7
Results of the tests below from ISO 15189:2022 accredited laboratory (UKAS reference 9785)	Interpretation and reporting of:	I&I-CI-IC-SOP-8, I&I-CI-IC-SOP-9, I&I-CI-GEN-SOP-8, I&I-CI-GEN-SOP-2
Serum Beta-2-microglobulin	Serum Beta-2 microglobulin	
Complement C3 and C4 from serum	Complement C3 and C4 from serum	
IgG, IgA and IgM quantitation from serum	IgG, IgA and IgM quantitation from serum	
Serum	IgE total	Phadia 250 –Immunocap. ICS-CI-IC-SOP-3



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HUMAN BODY FLUIDS (cont'd)	<p><u>Immunological examinations for the purpose of clinical diagnosis</u> (cont'd)</p> <p><u>Allergy related testing</u></p> <p>Detection and quantification of specific IgE to the following allergens:</p> <ul style="list-style-type: none"> Almond nut Alternia alternata Alpha-amylase Apple Aspergillus Fumig. Avian antibodies Bee Venom Beef Banana Brazil Nut Budgie Droppings Morphine Pholcodine Ampicilloyl Amoxicilloyl Gelatin Chlorhexidine Candida Albicans Dog Dander Cat Epithelium E1 Cheddar cheese Coconut Chicken Cashew nut Cod Cladosporium Herb. Cotton fibre Crab Cotton seed D.farinae Acarus siro L. Destructor Dog Dander IgE Canary bird dropping 	<p>Procedures documented in relevant equipment manuals and in house documented procedures by the following methods</p> <p>Phadia 250 –Immunocap ICS-CI-IC-SOP-3</p>



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<p>HUMAN BODY FLUIDS (cont'd)</p>	<p><u>Immunological examinations for the purpose of clinical diagnosis</u> (cont'd)</p> <p>Detection and quantification of specific IgE to the following allergens (cont'd): Parrot feathers Pigeon feathers Chicken Droppings Chicken, S.proteins Guinea pig epith. Goose feathers Budgerigar droppings Budgie serum protein Goat epithilium Sheep epithelium Chicken feathers Duck feathers Egg White Buckwheat Pea Lima bean Pecan nut Pistachio Trout Clam Lemon Grapefruit Pineapple Blackberry Spinach Lettuce Cabbage Paprika Tea Pumpkin nGal d 2 Ovalbumin nGal d 1 Ovomuroid Lentil Apricot Cherry Cucumber Egg</p>	<p>Procedures documented in relevant equipment manuals and in house documented procedures by the following methods</p> <p>Phadia 250 –Immunocap ICS-CI-IC-SOP-3</p>



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HUMAN BODY FLUIDS (cont'd)	<p><u>Immunological examinations for the purpose of clinical diagnosis</u> (cont'd)</p> <p>Detection and quantification of specific IgE to the following allergens (cont'd):</p> <ul style="list-style-type: none"> Pine Nut Plaice Plum Grape Broccoli Green Pepper Caraway Cardamon Basil Fennel Black pepper Oregano Turkey meat Red Kidney Bean Blueberry Date Oyster Cauliflower Papaya Carob (E410) Sweet chestnut Mandarin Langust Fenugreek Sardine (Pilchard) Carrot Anchovy Rape seed Coriander Garlic Crayfish Red Currant Watermelon Orange Mint Lupin Seed Cochineal extract 	<p>Procedures documented in relevant equipment manuals and in house documented procedures by the following methods</p> <p>Phadia 250 –Immunocap ICS-CI-IC-SOP-3</p>



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HUMAN BODY FLUIDS (cont'd)	<p><u>Immunological examinations for the purpose of clinical diagnosis</u> (cont'd)</p> <p>Detection and quantification of specific IgE to the following allergens (cont'd): Cranberry Raspberry Sage Macadamia Nut rPen a 1 Tropomyosin rAra h8 (Peanut) rGly m4 (Soy) Blue mussel Tuna Salmon Omega-5 gliadin rPru p1 (rPeach) Haddock rPru p3 (rPeach) rAra h1 (Peanut) rAra h2 (rPeanut) rAra h 3 Peanut rCor a8 (Hazel nut) rAra h9 (Peanut) rCor a1 (Hazel)</p> <p>Grey Alder T2 Fig F328 Anise F271 rAct d 8 PR-10, Kiwi nGly m 5, Soy nGly m 6 Glycinin rCor a14 (Hazel nut) Strawberry nCor a9 (Hazel nut) rJug r 1 Walnut rJug r 3 LTP, Walnut rAna o 3 Cashew nut Onion Rye Sweet Potato Pacific squid</p>	<p>Procedures documented in relevant equipment manuals and in house documented procedures by the following methods</p> <p>Phadia 250 –Immunocap ICS-CI-IC-SOP-3</p>



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HUMAN BODY FLUIDS (cont'd)	<p><u>Immunological examinations for the purpose of clinical diagnosis</u> (cont'd)</p> <p>Detection and quantification of specific IgE to the following allergens (cont'd):</p> <ul style="list-style-type: none"> Octopus Barley Oat Egg yolk nBos d4(Lactalbumin) nBos d 5 (Milk) Casein Gluten Maize(corn) Lobster Kiwi Parsley Melon Mustard Rice Mango Chocolate (cacao) Pear Peach Avocado Gliadin Feathers (Fowl) Feathers (Tropical) Mixed nuts Mixed fish Mixed cereal foods IgG Anti-Aspergillus Budgerigar droppings Budgerigar feathers Budgerigar mixture Pigeon mixture Pigeon feathers Cow's milk Timothy Grass Pollen Pigeon serum Grass pollens (GX1) Grass pollens (GX3) 	<p>Procedures documented in relevant equipment manuals and in house documented procedures by the following methods</p> <p>Phadia 250 –Immunocap ICS-CI-IC-SOP-3</p>



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<p>HUMAN BODY FLUIDS (cont'd)</p>	<p><u>Immunological examinations for the purpose of clinical diagnosis</u> (cont'd)</p> <p>Detection and quantification of specific IgE to the following allergens (cont'd): Hazel tree pollen House Dust Mite D1 Hamster epithelium Hazel Nut Horse Dander White faced hornet Horse fly Bumblebee rApi m1 (Honey bee) rVes v5(Common Wasp) rVes v1(Common Wasp) Yellow hornet Cockroach Mosquito European hornet European Paper Wasp Isocyanate Maxatase Savinase Castor bean Isocyanate TDI Isocyanate MDI Isocyanate HDI Formaldehyde Cotton seed Sunflower Latex Cheese, mould type Green Bean Mutton Mixed Moulds MUXF3 CCD, Bromelain Alpha-Galactose Seminal fluid Pigeon droppings Penicilloyl G Penicilloyl V</p>	<p>Procedures documented in relevant equipment manuals and in house documented procedures by the following methods</p> <p>Phadia 250 –Immunocap ICS-CI-IC-SOP-3</p>



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HUMAN BODY FLUIDS (cont'd)	<p><u>Immunological examinations for the purpose of clinical diagnosis</u> (cont'd)</p> <p>Detection and quantification of specific IgE to the following allergens (cont'd):</p> <ul style="list-style-type: none"> Peanut Potato Pork Rat epithelium Rabbit epithelium Cefaclor Gerbil epithelium Mackerel Mushroom Cinnamon Coffee Poppy seed Pumpkin seed Vanilla Honey Squid Clove Ginger Anise Chilipepper Curry (Santa Maria) Nutmeg Passion fruit Goat milk Halibut Lime Hake Chickpea Swordfish Sole Scallop Allspice Olive Elder Pine Sacc. Cerevisiae Silver Birch Pollen 	<p>Procedures documented in relevant equipment manuals and in house documented procedures by the following methods</p> <p>Phadia 250 –Immunocap ICS-CI-IC-SOP-3</p>



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HUMAN BODY FLUIDS (cont'd)	<p><u>Immunological examinations for the purpose of clinical diagnosis</u> (cont'd)</p> <p>Detection and quantification of specific IgE to the following allergens (cont'd): Sesame seed Shrimp Acarus siro Lepidoglyphus destr. Tyrophagus putresc. Glycyphagus domest. Soya Bean Suxamethonium Acacia rBet v1 (Birch) European ash American Beech Olive Tree Pollen Tomato Mixed tree pollens Tree mix Common ragweed Sunflower Mugwort Wasp Venom White bean Wheat Walnut Mixed weed pollens Walnut</p>	<p>Procedures documented in relevant equipment manuals and in house documented procedures by the following methods</p> <p>Phadia 250 –Immunocap ICS-CI-IC-SOP-3</p>
END		