


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 9862 Accredited to ISO 15189:2012	Leeds Teaching Hospitals NHS Trust	
	Issue No: 014 Issue date: 16 May 2025	
	Leeds General Infirmary Old Medical School Great George Street LS1 3EX	Contact: Helen Pritchett Tel: +44 (0)113 39 25697 E-Mail: h.pritchett@nhs.net Website: https://www.leedsth.nhs.uk/a-z-of-services

Testing performed by the Organisation at the locations specified below

Locations covered by the organisation and their relevant activities

Local Contact information:

Contact information		Department
Helen Pritchett	E-Mail: h.pritchett@nhs.net Tel: +44 (0)113 39 25697	Blood Sciences
Wendy Boote	E-Mail: wendy.boote@nhs.net Tel: +44 (0) 113 206 67609	Cellular Pathology
Dr Carys Lippiatt Chloe Chadwick	E-Mail: carys.lippiatt@nhs.net Tel: +44 (0)1132 064852	Specialist Laboratory Medicine
James Steer	E-Mail: leedsth-tr.dna@nhs.net Tel: +44 (0)1132 065205	Genetics



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Laboratory locations:

Location details	Department	Activity	Location code
Address Leeds General Infirmary Old Medical School Great George Street LS1 3EX	Blood Sciences Specialist Laboratory Medicine	Biochemistry and Haematology laboratory service Clinical Immunology	LGI
Chancellor Wing St James's University Hospital Beckett Street LS9 7TF	Blood Sciences Cellular Pathology	Biochemistry and Haematology laboratory service non-gynaecological cytology Reporting of the above Muscle / nerve histopathology, enzyme histochemistry	SJUH
Block 46 St James' University Hospital Beckett Street Leeds LS9 7TF	Specialist Laboratory Medicine	Routine and specialist coagulation, Haemoglobinopathy testing, Antenatal & Newborn Screening, Biochemical Genetics, Metabolics, Toxicology, Trace elements, Immunosuppressant Drug Monitoring, Endocrinology	B46
Bexley Wing St James' University Hospital Beckett Street Leeds LS9 7TF	Cellular Pathology Genetics	Routine diagnostic service for histopathology (including neuropathology and paediatric pathology) Reporting of the above and non gynae cytology Out of hours on call service for urgent frozen sections / diagnosis FISH testing, DNA extraction and quantification, NGS library preparation	BEX
Seacroft Hospital York Road Leeds West Yorkshire LS14 6UH	Cellular Pathology	Andrology (post vasectomy and infertility investigation).	SEA



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Location details	Department	Activity	Location code
Level 9 Gledhow Wing St James's University Hospital Beckett Street Leeds LS9 7TF	Specialist Laboratory Medicine	Cellular Immunology Transplant Immunology	SJUH GW
Clinical Sciences Building St James's University Hospital Becket Street Leeds LS9 7TF	Specialist Laboratory Medicine	NGS library preparation and sequencing, Fragment analysis and sanger sequencing	CSB
Yorkshire and North East Genomic Laboratory Hub Central Lab Ashley Wing St James's University Hospital Leeds LS9 7TF United Kingdom	Genetics	Molecular and Cytogenetics testing	ASH

Additional site activity performed away from the laboratory:

Location details	Activities
On-site Mortuary and Body Store, St James' University Hospital On-site Mortuary and Body Store, Leeds General Infirmary	Storage of bodies Viewing facilities Record keeping (body identification and audit trail)



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DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS	<u>Blood Sciences:</u>	In house documented methods incorporating manufacturers' instructions where relevant	
Serum unless otherwise stated	<u>Clinical Biochemistry examination activities for the purpose of clinical diagnosis</u>	Siemens Chemistry XPT (LGI) and Atellica Analyser (SJUH) using suppliers' methods unless otherwise stated and SOPs BSCH-SOP-1 (XPT) and BSCH-SOP-2 (Atellica). General Biochemistry:	
Serum, Plasma	Adjusted/corrected Calcium	By calculation	LGI SJUH
Serum, CSF	Angiotensin Converting Enzyme	Enzymatic kinetic assay	LGI
Serum, Plasma	Albumin	Colourimetric bromocresol purple (BCP) dye-binding	LGI SJUH
Serum, Plasma	Alanine amino-transferase ALT	Modified IFCC enzymatic assay	LGI SJUH
Serum, Plasma	Alkaline phosphatase ALP	IFCC standardised enzymatic assay	LGI SJUH
Plasma	Ammonia	GLDH Catalysis	LGI SJUH
Serum, Plasma	Amylase	Ethylidene Blocked-pNPG7	LGI SJUH
Serum, Plasma	Aspartate amino-transferase AST	Modified IFCC enzymatic assay	LGI SJUH
Serum, Plasma	Bicarbonate	Enzymatic kinetic assay	LGI SJUH
Serum	Bile Acid	Colourimetric enzymatic assay	LGI
Serum, Plasma	Bilirubin	Vanadate Oxidation	LGI SJUH



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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd)	<u>Clinical Biochemistry examination activities for the purpose of clinical diagnosis</u> (cont'd)	In house documented methods incorporating manufacturers' instructions where relevant	
Serum unless otherwise stated (cont'd)		Siemens Chemistry XPT (LGI) and Atellica Analyser (SJUH) using suppliers' methods unless otherwise stated and SOPs BSCH-SOP-1 (XPT) and BSCH-SOP-2 (Atellica). General Biochemistry: (cont'd)	
Serum, Plasma, Urine	Calcium	Arsenazo III colourimetric	LGI SJUH
Serum, Plasma, Urine	Chloride	Ion selective electrode - diluted	LGI SJUH
Serum, Plasma	Cholesterol (total)	Enzymatic, Trinder endpoint	LGI SJUH
Serum, Plasma	Conjugated Bilirubin	Vanadate oxidation	LGI SJUH
Serum, Plasma	C-reactive Protein	Latex-enhanced immunoturbidimetric	LGI SJUH
Serum, Plasma	Creatine Kinase	NAC Activated, IFCC	LGI SJUH
Serum, Plasma, Urine	Creatinine	enzymatic	LGI SJUH
Serum, Plasma	eGFR	CKD-EPI Equation	LGI SJUH
Plasma	Ethanol	Enzyme Multiplied Immunoassay Technique (EMIT)	LGI SJUH
Serum, Plasma	Gamma GT	Modified IFCC enzymatic assay	LGI SJUH
Plasma	Glucose	Glucose Oxidase Trinder	LGI SJUH
Serum, Plasma	HDL-Cholesterol	Elimination/ catalase	LGI SJUH



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HUMAN BODY FLUIDS (cont'd)	<u>Clinical Biochemistry examination activities for the purpose of clinical diagnosis</u> (cont'd)	In house documented methods incorporating manufacturers' instructions where relevant	
Serum unless otherwise stated (cont'd)		Siemens Chemistry XPT (LGI) and Atellica Analyser (SJUH) using suppliers' methods unless otherwise stated and SOPs BSCH-SOP-1 (XPT) and BSCH-SOP-2 (Atellica). General Biochemistry: (cont'd)	
Serum	Iron	Colourimetric	LGI SJUH
Plasma	Lactate	Lactate Oxidase, colourimetric	LGI SJUH
Serum, Plasma	Lactate Dehydrogenase LDH	Pyruvate/ Reduced NADH	LGI SJUH
Serum, Plasma	LDL	Friedwald Calculation	LGI SJUH
Serum, Plasma, Urine	Magnesium	Colourimetric, Xylidyl Blue	LGI SJUH
Serum, Plasma, Urine	Phosphate	Phosphomolybdate/UV	LGI SJUH
Serum, Plasma, Urine	Potassium	Ion selective electrode - diluted	LGI SJUH
Serum, Plasma	Protein (Total)	Biuret	LGI SJUH
Serum, Plasma	Salicylate	Enzymatic	LGI SJUH
Serum, Plasma, Urine	Sodium	Ion selective electrode - diluted	LGI SJUH
Serum	Total Iron Binding Capacity	Sequential release and uptake of iron, spectrophotometric	LGI SJUH
Serum, Plasma	Triglycerides	GPO-Trinder	LGI SJUH



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HUMAN BODY FLUIDS (cont'd)	<u>Clinical Biochemistry examination activities for the purpose of clinical diagnosis</u> (cont'd)	In house documented methods incorporating manufacturers' instructions where relevant	
Serum unless otherwise stated (cont'd)		Siemens Chemistry XPT (LGI) and Atellica Analyser (SJUH) using suppliers' methods unless otherwise stated and SOPs BSCH-SOP-1 (XPT) and BSCH-SOP-2 (Atellica). General Biochemistry: (cont'd)	
Serum, Plasma, Urine	Urate	Enzymatic uricase/peroxidase	LGI SJUH
Serum, Plasma, Urine	Urea	Enzymatic urease with glutamate dehydrogenase (GLDH)	LGI SJUH
Urine	Microalbumin	Polyethyleneglycol (PEG)-enhanced	LGI SJUH
Urine	Protein	Immunoturbidimetric assay	LGI SJUH
Serum	Alpha 1 Antitrypsin	Polyethylene glycol-enhanced (PEG) immunoturbidimetric	LGI
Serum	C3	Polyethylene glycol-enhanced (PEG) immunoturbidimetric	LGI
Serum	C4	Polyethylene glycol-enhanced (PEG) immunoturbidimetric	LGI
Serum	Rheumatoid Factor	Latex-enhanced immunoturbidimetric	LGI
Serum	IgA	Polyethylene glycol-enhanced (PEG) immunoturbidimetric	LGI
Serum	IgG	Polyethylene glycol-enhanced (PEG) immunoturbidimetric	LGI
Serum	IgM	Polyethylene glycol-enhanced (PEG) immunoturbidimetric	LGI



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HUMAN BODY FLUIDS (cont'd)	<u>Clinical Biochemistry examination activities for the purpose of clinical diagnosis</u> (cont'd)	In house documented methods incorporating manufacturers' instructions where relevant	
Serum unless otherwise stated (cont'd)		Siemens Chemistry XPT (LGI) and Atellica Analyser (SJUH) using suppliers' methods unless otherwise stated and SOPs BSCH-SOP-1 (XPT) and BSCH-SOP-2 (Atellica). Therapeutic Drug Monitoring:	
Serum, Plasma	Carbamazepine	Enzyme Multiplied Immunoassay Technique (EMIT)	LGI
Serum	Digoxin	Latex-enhanced immunoturbidimetric	LGI SJUH
Serum, Plasma	Lithium	Colourimetric, endpoint	LGI SJUH
Serum, Plasma	Methotrexate	Enzyme immunoassay	LGI SJUH
Serum, Plasma	Paracetamol	Enzymatic	LGI SJUH
Serum, Plasma	Phenobarbitone	EMIT	LGI
Serum, Plasma	Phenytoin	EMIT	LGI
Serum	Theophylline	EMIT	LGI SJUH
Serum, Plasma	Valproate	EMIT	LGI
Serum, Plasma	Gentamicin	EMIT	LGI SJUH
Serum, Plasma	Tobramycin	EMIT	LGI SJUH
Serum, Plasma	Vancomycin	EMIT	LGI SJUH



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HUMAN BODY FLUIDS (cont'd)	<u>Clinical Biochemistry examination activities for the purpose of clinical diagnosis</u> (cont'd)	In house documented methods incorporating manufacturers' instructions where relevant	
Serum unless otherwise stated (cont'd)		Siemens Immulite XPi using suppliers' methods unless otherwise stated and SOP: BSHC-SOP-14 Immunoassay	
EDTA Plasma	ACTH	Solid phase two-site sequential chemiluminescent immunometric assay	LGI
Serum	Growth Hormone	Solid phase two-site sequential chemiluminescent immunometric assay	LGI
Serum	IGF-1	Solid phase enzyme labelled chemiluminescent immunometric assay	LGI
		Centaur XPT (LGI) and Atellica Analyser (SJUH) using suppliers' methods unless otherwise stated and SOPs: BSHC-SOP-13 (Centaur XPT), BSHC-SOP-2 (Atellica). Immunoassay:	
Plasma	NT-Pro BNP	Solid phase two-site sequential chemiluminescent immunometric assay	LGI SJUH
Serum	AFP	Chemiluminescent two-site sandwich immunoassay	LGI SJUH
Serum	CA15-3	Chemiluminescent two-step sandwich immunoassay	LGI SJUH
Serum	CA19-9	Chemiluminescent two-step sandwich immunoassay	LGI SJUH



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HUMAN BODY FLUIDS (cont'd)	<u>Clinical Biochemistry examination activities for the purpose of clinical diagnosis</u> (cont'd)	In house documented methods incorporating manufacturers' instructions where relevant	
Serum unless otherwise stated (cont'd)		Siemens Immulite XPI (LGI) and Atellica Analyser (SJUH) using suppliers' methods unless otherwise stated and SOPs: BSHC-SOP-14 (Immulite), BSHC-SOP-2 (Atellica). Immunoassay	
Serum	CA125	Chemiluminescent two-site sandwich immunoassay	LGI SJUH
Serum	CEA	Chemiluminescent two-site sandwich immunoassay	LGI SJUH
		Centaur XPT (LGI) and Atellica Analyser (SJUH) using suppliers' methods unless otherwise stated and SOPs: BSHC-SOP-13 (Centaur XPT); BSHC-SOP-2 (Atellica). Immunoassay:	
Serum	25OH Vitamin D	Chemiluminescent competitive immunoassay	LGI SJUH
Serum	Cortisol	Chemiluminescent competitive immunoassay	LGI SJUH
Serum	ELF Score (enhanced liver fibrosis score)	By calculation	LGI SJUH
Serum	Ferritin	Chemiluminescent two-site sandwich immunoassay	LGI SJUH
Serum	Folate	Chemiluminescent competitive immunoassay	LGI SJUH
Serum	Free T4	Chemiluminescent competitive immunoassay	LGI SJUH
Serum	FSH	Chemiluminescent two-site sandwich immunoassay	LGI SJUH



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HUMAN BODY FLUIDS (cont'd)	<u>Clinical Biochemistry examination activities for the purpose of clinical diagnosis</u> (cont'd)	In house documented methods incorporating manufacturers' instructions where relevant	
Serum unless otherwise stated (cont'd)		Siemens Immulite XPI (LGI) and Atellica Analyser (SJUH) using suppliers' methods unless otherwise stated and SOPs: BSHC-SOP13 (Immulite), BSHC-SOP-2 (Atellica). Immunoassay	
Serum	HCG (total) for the purposes of pregnancy marker only	Chemiluminescent two-site sandwich immunoassay	LGI SJUH
Serum	Hyaluronic Acid (HA)	Chemiluminescent two-site sandwich immunoassay	LGI SJUH
Serum	LH	Chemiluminescent two-site sandwich immunoassay	LGI SJUH
Serum	Oestradiol	Chemiluminescent competitive immunoassay	LGI SJUH
		Centaur XPT (LGI) and Atellica Analyser (SJUH) using suppliers' methods unless otherwise stated and SOPs BSHC-SOP-13 (Centaur XPT); BSHC-SOP-2 (Atellica). Immunoassay:	
Serum	Parathyroid Hormone	Chemiluminescent two-site sandwich immunoassay	LGI SJUH
Serum	Procalcitonin	Chemiluminescent two-site sandwich immunoassay	LGI SJUH
Serum	Pro collagen type III	Chemiluminescent two-site sandwich immunoassay	LGI SJUH
Serum	Progesterone	Chemiluminescent competitive immunoassay	LGI SJUH
Serum	Prolactin	Chemiluminescent two-site sandwich immunoassay	LGI SJUH



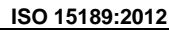
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HUMAN BODY FLUIDS (cont'd)	<u>Clinical Biochemistry examination activities for the purpose of clinical diagnosis</u> (cont'd)	In house documented methods incorporating manufacturers' instructions where relevant	
Serum unless otherwise stated (cont'd)		Centaur XPT (LGI) and Atellica Analyser (SJUH) using suppliers' methods unless otherwise stated and SOPs: BSHC-SOP-13 (Centaur XPT); BSHC-SOP-2 (Atellica). Immunoassay:	
Serum	Prostate Specific Antigen (PSA)	Chemiluminescent two-site sandwich immunoassay	LGI SJUH
Serum	SHBG	Chemiluminescent two-site sandwich immunoassay	LGI
Serum	Testosterone	Chemiluminescent competitive immunoassay	LGI SJUH
Serum	Tissue inhibitor of matrix metalloproteinase (TIMP-1)	Chemiluminescent two-site sandwich immunoassay	LGI SJUH
Serum	Thyroid Peroxidase Ab (TPO)	Chemiluminescent competitive immunoassay	LGI SJUH
Serum	Total T3	Chemiluminescent competitive immunoassay	LGI SJUH
Serum	Troponin I	High-sensitivity Chemiluminescent three-site sandwich immunoassay	LGI SJUH
Serum	TSH	Chemiluminescent two-site sandwich immunoassay	LGI SJUH
Serum	Vitamin B12	Chemiluminescent competitive immunoassay	LGI SJUH
Serum, Plasma, Urine	Osmolality	Advanced Instruments Osmometer 2020, freezing point depression using suppliers' methods unless otherwise stated and SOP BSHC-SOP-15	LGI SJUH



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HUMAN BODY FLUIDS (cont'd)	<u>Clinical Biochemistry examination activities for the purpose of clinical diagnosis</u> (cont'd)	In house documented methods incorporating manufacturers' instructions where relevant	
Serum unless otherwise stated (cont'd)		Centaur XPT (LGI) and Atellica Analyser (SJUH) using suppliers' methods unless otherwise stated and SOPs: BSHC-SOP-13 (Centaur XPT); BSHC-SOP-2 (Atellica). Immunoassay:	
EDTA Whole Blood	Haemoglobin HbA1c	TOSOH G11 HPLC using suppliers' methods unless otherwise stated and SOP BSHC-SOP-102	LGI



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HUMAN BODY FLUIDS (cont'd)	<u>Haematology examination activities for the purpose of clinical diagnosis</u>	In house documented methods incorporating manufacturers' instructions where relevant	
EDTA Whole Blood	Full Blood Count (Red Blood Cells, White Blood Cells, Haemoglobin, MCV, MPV, Neutrophils, Lymphocytes, Monocytes, Eosinophils, Basophils, Monocytes, Platelets, Reticulocytes)	Siemens Advia 2120i Cytochemical flow cell technology using suppliers' methods unless otherwise stated and SOP BSHC-SOP-4	LGI SJUH
EDTA Whole Blood	Detection of normal and abnormal morphologies with WBC differential count where indicated	Blood film assessment (peripheral) with microscopic analysis Advia Autoslide Siemens Hematek ProLab Poly Staining Unit for: <ul style="list-style-type: none"> Preparation and staining of adult samples Staining only of paediatric/low volume adult samples that have been prepared manually Manual film preparation and staining - requesting, prep and staining [SOP BSHC-SOP-8] How to Report a Blood Film [SOP BSHC-SOP-10] Blood Film Selection criteria and referral guidance [SOP BSHC-SOP-6]	LGI LGI & SJUH
EDTA Whole Blood	Infectious Mononucleosis screen (detection of infectious mononucleosis heterophile antibodies)	Accusay Mono IM kit [SOP BSHC-SOP-5]	LGI SJUH



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HUMAN BODY FLUIDS (cont'd)	<u>Haematology examination activities for the purpose of clinical diagnosis (cont'd)</u>	In house documented methods incorporating manufacturers' instructions where relevant	
EDTA Whole Blood	Detection of malarial parasites: Parasite detected/not detected. Speciated from morphology: P. falciparum, P. vivax, P. ovale, P. malariae, P. knowlesi	Manual thick (field stain A and B) and thin (Giemsa stain) blood film examination using light I microscopy [SOP BSHC-SOP-9]	LGI SJUH
EDTA Whole Blood	Detection of Plasmodium spp. DNA	Alethia Malaria molecular assay using the Alethia Incubator/reader. Amplification and detection of a specific region of the plasmodium genome via loop-mediated amplification (LAMP) technology, BSHC-SOP-11]	LGI SJUH
EDTA Whole Blood	Sickle cell solubility	Sickle Check Kit (detection of haemoglobin S) BSHC-SOP-54 Werfen TOP (750 -LGI) (550 – SJUH) BSHC-SOP-3 Turbidimetric endpoint detection	LGI SJUH
Citrated Plasma	APTT		LGI SJUH
Citrated Plasma	Clauss Fibrinogen		LGI SJUH
Citrated Plasma	DDimer level		LGI SJUH
Citrated Plasma	Derived Fibrinogen		LGI SJUH
Citrated Plasma	INR		LGI SJUH
Citrated Plasma	LMW Heparin (Anti Xa)		LGI SJUH



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HUMAN BODY FLUIDS (cont'd)	<u>Haematology examination activities for the purpose of clinical diagnosis (cont'd)</u>	In house documented methods incorporating manufacturers' instructions where relevant	
Citrated Plasma	Prothrombin Time		LGI SJUH
Citrated Plasma	Thrombin Time		LGI SJUH
Citrated Plasma	Reptilase		LGI
EDTA Plasma	Plasma Viscosity	Benson Viscometer (distance travelled using constant pressure / time) using suppliers' methods unless otherwise stated and BSHC-SOP-57	LGI SJUH
EDTA Plasma	Erythrocyte Sedimentation Rate	Starrsed auto compact infrared absorption readings of red cell sedimentation using suppliers' methods unless otherwise stated and SOP BSHC-SOP-7	LGI
Blood (Red Cell Lysate)	Glucose-6-Phosphate Dehydrogenase (G6PD)	Siemens Atellica Analyser Using Photometric Detection – Kinetic SOP: BSHC-SOP-12	SJUH



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HUMAN BODY TISSUE AND FLUIDS	<u>Examination activities in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis</u>	Macroscopic and Microscopic examination: Documented in house methods incorporating manufacturers' instructions where relevant:	
Body fluids / Fine needle aspirations, urines and bronchial/ sputum samples	<u>Diagnostic Non Gynae Cytopathology</u>	Sample preparation (Rotina 380 centrifuge, , Shandon cytospin 4): CPATH-SOP-CYTO-2 Preparation of Non Gynae Samples CPATH-SOP—HP-107 Preparation of Cell blocks	SJUH SJUH
	Visualisation of nuclear detail in cells present	CPATH-SOP-CYTO-15 H&E (automated using Jung Autostainer) CPATH-COSHH-10 Papanicolaou (automated using Jung Autostainer) CPATH-COSHH-12 Rapid Romanowsky Stain	SJUH
Slides prepared in house as above	Morphological assessment and interpretation/diagnosis	CPATH-SOP-CYTO-8 Medical reporting of Non-Gynae cytology	BEX



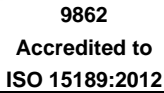
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<p>HUMAN BODY TISSUE AND FLUIDS (cont'd)</p> <p>Tissue / organs</p>	<p><u>Examination activities in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd)</u></p> <p><u>Histopathology</u></p>	<p>Macroscopic and Microscopic examination:</p> <p>Documented in house methods incorporating manufacturers' instructions where relevant:</p> <p>Tissue dissection:</p> <p>CPATH-SOP-HP-156 Cut Up of Specimens by Biomedical Scientists</p> <p>HPSOP 0305 Cut Up of Specimens by Medical Staff CPATH-SOP-HP-125</p> <p>CPATH-REC-527 Guidelines For Inflating A Lung</p> <p>CPAYH-SOP-HP-65 Handling of CJD Specimens</p> <p>CPATH-SOP-HP-125 Further Blocks</p> <p>CPATH-REC-526 Guidelines for Opening a Fresh Uterus</p> <p>CPATH-REC-527 Guidelines on Opening a Kidney</p> <p>CPATH-SOP-HP-66 Renal Biopsy Procedure</p> <p>CPATH-SOP-MED-1 Dissection of gall bladder resection specimens</p> <p>CPATH-SOP-MED-2 Dissection of appendiceal resection specimens</p> <p>CPATH-SOP-MED-30 Cut up of gynae specimens</p>	<p>BEX</p>



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HUMAN BODY TISSUE AND FLUIDS (cont'd)	<u>Examination activities in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd)</u>	Macroscopic and Microscopic examination: Documented in house methods incorporating manufacturers' instructions where relevant:	BEX
Tissue / organs (cont'd)	<u>Histopathology (cont'd)</u>	Tissue processing: CPATH-SOP-HP-160 Processing tissue using the Sakura X-Press (small urgent biopsies and neuropath specimens) Embedding: CPATH-SOP-HP-109 Embedding paraffin wax impregnated tissues Microtomy: CPATH-SOP-HP-114 Sectioning using rotary microtome CPATH-SOP-HP-28 Sectioning using automated microtome CPATH-SOP-HP-28 Sectioning of Problem Blocks CPATH-SOP-HP-27 Sections/levels required for particular tissue types Frozen Sections: CPATH-SOP-HP-22 Leica 1950 cryostat CPATH-SOP-HP-23 Specimens Requiring Frozen Sections CPATH-SOP-HP-18 Preparation of Split Skin Biopsies for Immunofluorescence	



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HUMAN BODY TISSUE AND FLUIDS (cont'd)	<u>Examination activities in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd)</u>	Macroscopic and Microscopic examination: Documented in house methods incorporating manufacturers' instructions where relevant:	BEX
Tissue / organs (cont'd)	<u>Histopathology (cont'd)</u>	Frozen Sections: CPATH-SOP-HP-23 Processing and Embedding of Alopecia Cases and other Paraffins CPATH-SOP-MED-43 Protocol for Transplant Donor Lesion Biopsies – Frozen Sections	
Tissue	Identification of basophilic and eosinophilic structures	Routine Haematoxylin and Eosin Staining Automated: CPATH-SOP-HP-63 Use and maintenance of Spectra Autostainer/coverslipper Manual: CPATH-SOP-HP-4 Mayers haematoxylin and eosin for rapid method for frozen sections	
Tissue	<u>Histopathology - Identification of:</u> Acid and neutral mucins Diastase resistance acidic and neutral mucins Mucins, glycogen Diastase resistance mucin Basement membranes, fungi	Automated: CPATH-SOP-HP-54HPSOP 657 Use of theAgilent Artisan Link Pro for Special stain techniques ABPAS ABPAS+D PAS DPAS ExPAS	BEX



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HUMAN BODY TISSUE AND FLUIDS (cont'd)	<u>Examination activities in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd)</u>	Macroscopic and Microscopic examination: Documented in house methods incorporating manufacturers' instructions where relevant:	BEX
Tissue (cont'd)	<u>Histopathology - Identification of: (cont'd)</u>	Automated: CPATH-SOP-HP-54 Use of the Artisan Link Pro for Special stain techniques	
	Basement membranes, fungi	ExDPAS	
	Fungi	Grocott	
	Iron (ferric)	Perls	
	Reticulin fibers	Retic	
	Spirochetes, H.Pylori	Warthin & Starry	
	Amyloid	Congo Red	
	Copper/Hepatitis B	Orcein	
	Sulphated acid mucins	CPATH-SOP-HP-29 Alcian blue pH1.0	
	Acid mucins	CPATH-SOP-HP-30 Alcian blue pH2.5	
	Acid mucins/connective tissue	CPATH-SOP-HP-31 Alcian blue van gieson	
	Acid mucins/connective tissue/elastic	CPATH-SOP-HP-53 Alcian blue elastic van gieson	
	AL amyloid	CPATH-SOP-HP-32 Congo red potassium permanganate	
	Nissl granules and neurones	CPATH-SOP-HP-33 Cresyl violet	
	Elastic/connective tissue	CPATH-SOP-HP-34 Elastic van gieson	



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HUMAN BODY TISSUE AND FLUIDS (cont'd)	<u>Examination activities in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd)</u>	Macroscopic and Microscopic examination: Documented in house methods incorporating manufacturers' instructions where relevant:	BEX
Tissue (cont'd)	<u>Histopathology - Identification of (cont'd):</u>	Manual special staining:	
	H Pylori	CPATH-SOP-HP-35 Giemsa-modified	
	Bone marrow	CPATH-SOP-HP-37 Giemsa-overnight	
	Gram positive bacteria	CPATH-SOP-HP-37 Grams technique	
	Gram positive and negative bacteria	CPATH-SOP-HP-38 Gram twort	
	General tissue morphology	CPATH-SOP-HP-4 Mayers Haematoxylin and Eosin	
	Collagen/muscle	CPATH-SOP-HP-39 Haematoxylin van gieson	
	Acid mucin	CPATH-SOP-HP-52 Hales colloidal iron	
	Myelin	CPATH-SOP-HP-40 Luxol fast blue Haematoxylin and Eosin	
	Melanin	CPATH-SOP-HP-41 Masson Fontana	
	Muscle/collagen	CPATH-SOP-HP-42 Masson Trichrome	
	Paired sections identifies melanin pigment	CPATH-SOP-HP-43 Melanin bleach	



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HUMAN BODY TISSUE AND FLUIDS (cont'd)	<u>Examination activities in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd)</u>	Macroscopic and Microscopic examination: Documented in house methods incorporating manufacturers' instructions where relevant:	BEX
Tissue (cont'd)	<u>Histopathology - Identification of (cont'd):</u>	Manual special staining:	
	Fibrin/connective tissue	CPATH-SOP-HP-44 MSB	
	Copper	CPATH-SOP-HP-45 Rhodanine technique	
	Fat	CPATH-SOP-HP-46 Sudan IV	
	Mast cells	CPATH-SOP-HP-48 Toluidine blue	
	Calcium	CPATH-SOP-HP-49 Von Kossa	
	<i>Mycobacterium leprae</i>	CPATH-SOP-HP-50 Wade fite	
	Tubercle bacilli	CPATH-SOP-HP-50 Ziehl Neelsen	
	Lipids	CPATH-SOP-HP-46 Sudan IV staining (frozen sections only)	



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HUMAN BODY TISSUE AND FLUIDS (cont'd)	<u>Examination activities in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd)</u>	Macroscopic and Microscopic examination: Documented in house methods incorporating manufacturers' instructions where relevant:	BEX
Tissue and cell blocks	<u>Histopathology – identification of:</u>	Automated Immunohistochemical staining, PTLINK/Autostainer CPATH-SOP-HP-55 Preparation of Primary antibodies and associated reagents CPATH-SOP-HP-56 DAKO Autostainer Link 48 CPATH-SOP-HP-57 DAKO PTLINKs for antigen retrieval Using the following monoclonal, polyclonal and cocktail antibodies:	
	Amyloid deposits	AMYLOID-A	
	Lung cancer	PDL-1	
	Marker of normal throid/lung tumours	TTF-1	
		Automated Immunohistochemical staining, Leica Bond III Immunostainer using the following monoclonal, polyclonal and cocktail antibodies: CPATH-SOP-HP-61 Use of Leica Bond III Immunostainer	
	A1-AT deiciency	A1-AT	
	Pituitary hormone	ACTH	
	Epithelial marker	AE1/3	
	Primary liver tumours/yolk sac tumours	AFP	
	Prostate cancer	AMACR	
	Prostate/breast marker	ANDROGEN R	



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HUMAN BODY TISSUE AND FLUIDS (cont'd)	<u>Examination activities in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd)</u>	Macroscopic and Microscopic examination: Documented in house methods incorporating manufacturers' instructions where relevant:	BEX
Tissue and cell blocks (cont'd)	<u>Histopathology – identification of (cont'd):</u>	Automated Immunohistochemical staining, Leica Bond III Immunostainer using the following monoclonal, polyclonal and cocktail antibodies (cont'd):	
	Lewy bodies /Parkinsons disease	A-SYN	
	Melanocytic lesions	BAP1	
	Neuronal damage	BAPP	
	Marker for apoptosis	BCL-2	
	Epithelial marker	BER-EP4	
	Senile plaques in Alzheimers disease	B-AMYLOID	
	Fibromatous lesions	B-CATENIN	
	Germ cell tumours	B-HCG	
	Marker of breast tumours	BRST-2 (GCDFP15)	
	Marker of ovarian tumours	CA125	
	Tumours of GI tract and pancreas	CA19.9	
	Marker of thyroid tumours	CALCITONIN	
	Marker of smooth muscle	CALDES	
	Marker for mesothelioma	CALRET	
	Marker of rejection in renal/liver transplants	C4D	



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HUMAN BODY TISSUE AND FLUIDS (cont'd)	<u>Examination activities in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd)</u>	Macroscopic and Microscopic examination: Documented in house methods incorporating manufacturers' instructions where relevant:	BEX
Tissue and cell blocks (cont'd)	<u>Histopathology – identification of (cont'd):</u>	Automated Immunohistochemical staining, Leica Bond III Immunostainer using the following monoclonal, polyclonal and cocktail antibodies (cont'd):	
	Langerhan cells	CD1A	
	T lymphocytes	CD3	
	T helper lymphocytes	CD4	
	T supressor lymphocytes	CD8	
	Lymphoid/endometrial malignancies	CD10	
	Hogkins lymphoma	CD15	
	B lymphocytes	CD20	
	Lymphoma marker	CD21	
	Hogkins lymphoma	CD30	
	Endothelial marker	CD31	
	Endothelial marker	CD34	
	Lymphocyte marker	CD45	
	Marker of nerve/neuroendocrine tumours	CD56	
	Histiocytes/macrophages	CD68	
	B lymphocytes	CD79a	
	Ewings sarcoma	CD99	



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HUMAN BODY TISSUE AND FLUIDS (cont'd)	<u>Examination activities in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd)</u>	Macroscopic and Microscopic examination: Documented in house methods incorporating manufacturers' instructions where relevant:	BEX
Tissue and cell blocks (cont'd)	<u>Histopathology – identification of (cont'd):</u>	Automated Immunohistochemical staining, Leica Bond III Immunostainer using the following monoclonal, polyclonal and cocktail antibodies (cont'd):	
	Mesothelioma marker	CD141	
	Histiocytes/macrophages	CD163	
	GI tract tumours	CDX2	
	Epithelial marker	CEA-M	
	Epithelial marker/liver tumour marker	CEA-P	
	Neuroendocrine cells	CHROMO	
	Epithelial marker	CK5	
	Epithelial marker	CK5/6	
	Epithelial marker	CK7	
	Epithelial marker/mallory bodies	CK8/18	
	Epithelial marker	CK14	
	Epithelial marker	CK19	
	Epithelial marker	CK20	
	Gastrointestinal stromal tumour marker	C-KIT (CD117)	
	Cytomegalovirus infection	CMV	



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HUMAN BODY TISSUE AND FLUIDS (cont'd)	<u>Examination activities in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd)</u>	Macroscopic and Microscopic examination: Documented in house methods incorporating manufacturers' instructions where relevant:	BEX
Tissue and cell blocks (cont'd)	<u>Histopathology – identification of (cont'd):</u>	Automated Immunohistochemical staining, Leica Bond III Immunostainer using the following monoclonal, polyclonal and cocktail antibodies (cont'd):	
	Marker of basement membrane	COLL IV	
	Marker of lymphatic channels	D2-40	
	Pan muscle marker	DES	
	Gastrointestinal stromal tumour marker	DOG-1	
	Cell adhesion molecule	E-CAD	
	Epidermal growth factor receptor	EGFR	
	Epithelial marker	EMA	
	Estrogen receptor/ prognostic breast marker	ER	
	Vascular tumours	ERG	
	Pituitary hormone	FSH	
	Marker of gastrin producing tumours	GASTRIN	
	Glial cells benign and malignant	GFAP	
	Pituitary hormone	GH	
	Pancreatic tumour typing	Glucagon	



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HUMAN BODY TISSUE AND FLUIDS (cont'd)	<u>Examination activities in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd)</u>	Macroscopic and Microscopic examination: Documented in house methods incorporating manufacturers' instructions where relevant:	BEX
Tissue and cell blocks (cont'd)	<u>Histopathology – identification of (cont'd):</u>	Automated Immunohistochemical staining, Leica Bond III Immunostainer using the following monoclonal, polyclonal and cocktail antibodies (cont'd):	
	Pancreatic tumour typing	Glucagon	
	Adenoma v HCC	Glutamine Synthetase	
	Liver adenoma/HCC	Glypican-3	
	Hepatitis B infected cells	HEP B c	
	Hepatitis B infected cells	HEP B s	
	Marker of normal/malignant hepatocytes	HEPAR 1	
	Marker of Her2 amplification in breast tumours.	HER 2	
	Melanoma marker	HMB45	
	Epithelial marker	HMC	
	Marker for H pylori	HP	
	Marker for teratoma	HPL	
	Herpes simplex 1 infection	HSV 1	
	Brain tumours	IDH1	
	Lymphoma markers	IgA IgG IgM	
	IgG4 disease marker	IgG4	



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HUMAN BODY TISSUE AND FLUIDS (cont'd)	<u>Examination activities in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd)</u>	Macroscopic and Microscopic examination: Documented in house methods incorporating manufacturers' instructions where relevant:	BEX
Tissue and cell blocks (cont'd)	<u>Histopathology – identification of (cont'd):</u>	Automated Immunohistochemical staining, Leica Bond III Immunostainer using the following monoclonal, polyclonal and cocktail antibodies (cont'd):	
	Granulosa cell tumours Mucinous epithelial ovarian tumours	Inhibin	
	Paediatric tumours	INI-1	
	Pancreatic tumours	Insulin	
	Lymphoma marker	KAPPA	
	Proliferation marker	KI67	
	Lymphoma marker	Lambda	
	Pituitary hormone	LH	
	Head and Neck tumour	Mammaglobin	
	Melanoma marker	MEL-A	
	Mismatch repair protein	MLH 1 MSH 2 MSH6	
	Epithelial marker	MNF	
	MUC4 in tumours	MUC4	
	Marker for rhabdomyosarcoma	MYOD 1	
	Marker for rhabdomyosarcoma	MYOGENIN	
	Neuronal marker	N52	



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Tissue and cell blocks (cont'd)	<u>Histopathology – identification of (cont'd):</u>	Automated Immunohistochemical staining, Leica Bond III Immunostainer using the following monoclonal, polyclonal and cocktail antibodies (cont'd):	
	Neuronal marker	NEU N	
	Neuronal marker	NFP	
	Neuroectodermal marker	NSE	
	Epithelial gynae tumours	PAX-8	
	Marker of CIN	P16	
	Marker of wild type P53 in malignancy	P53	
	Marker of molar pregnancy	p57	
	Marker in breast/prostate tumours	p63	
	Infection with parvo virus	PARVO	
	Marker of neuroblastoma	Phox 2B	
	Marker of germ cell tumours	PLAP	
	Mismatch repair protein	PMS2	
	Polyoma virus infection I renal transplant patients	POLYOMA SV40	
	Pituitary hormone	PROLACTIN	
	Progesterone receptor/prognostic breast marker	PR	



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Tissue and cell blocks (cont'd)	<u>Histopathology – identification of (cont'd):</u>	Automated Immunohistochemical staining, Leica Bond III Immunostainer using the following monoclonal, polyclonal and cocktail antibodies (cont'd):	
	Marker of normal/malignant prostate	PSA	
	Marker of normal/malignant prostate	PSAP	
	Marker of parathyroid tumours	PTH	
	Marker of ovarian malignancy	R1(inhibin)	
	Marker of primary renal carcinoma	RCC	
	Nerve sheath, neural marker	S100	
	Marker of serotonin producing tumours	SEROT	
	Pancreatic tumours	SOMAT	
	Smooth muscle marker	SMA	
	Smooth muscle marker	SMM	
	Marker of neural cells/neuroendocrine tumors	SYNAPT	
	Stat6 Expression	STAT6	
	Tangles in Alzheimers disease	TAU	
	Marker of normal/malignant thyroid	THYROG	



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HUMAN BODY TISSUE AND FLUIDS (cont'd)	<u>Examination activities in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd)</u>	Macroscopic and Microscopic examination: Documented in house methods incorporating manufacturers' instructions where relevant:	
Tissue and cell blocks (cont'd)	<u>Histopathology – identification of (cont'd):</u> Pituitary hormone Tangles, plaques and inclusions in dementia Marker of Mallory bodies. Mesenchymal tumours Wilms tumour/mesothelioma Desmoplastic cell tumour	Automated Immunohistochemical staining, Leica Bond III Immunostainer using the following monoclonal, polyclonal and cocktail antibodies (cont'd): TSH UBIQ brain UBIQ liver Vimentin WT-1 WT-1 C19	BEX
Tissue (Breast primary)	HER2 <u>Histopathology – Enzyme histochemistry</u> <u>Immuno fluorescence (IF) for identification/demonstration of:</u>	Automated Immunohistochemical staining, CPATH-SOP-HP-58: Use of Ventana Benchmark Ultra for HER2 Antibody: anti-HER-2/neu(4B5)	BEX
Tissue (Rectal)	Presence/absence of ganglion cells and acetylcholinesterase when Hirschsprung's disease is suspected	CPATH-SOP-HP-19 Acetylcholinesterase	BEX



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Tissue (Renal)	<u>Histopathology – Enzyme histochemistry</u> <u>Immuno fluorescence (IF) for identification/demonstration of:</u> (cont'd)		
	Immunoglobulins and complement	CPATH-SOP-HP-20 Immunofluorescence staining of renal biopsies Using antibodies IgA IgG IgM C3C C1q Kappa Lambda	BEX
Tissue (Skin)	Immunoglobulins and complement	CPATH-SOP-HP-21 Sectioning & Immunofluorescence Staining of Skin/ Oral/Neuro frozen sections Using antibodies in IgA IgG IgM C3C Fibrinogen	BEX
	<u>Histopathology –</u> Morphological assessment and interpretation/diagnosis:	Using light microscopy and SOPs:	BEX
Slides prepared in house as above (Breast)		CPATH-SOP-MED-5 Dissection and Reporting of Breast Specimens	
Slides prepared in house as above (Gastrointestinal)		CPATH-SOP-MED-6 Reporting of colonic resection specimens with vascular pathology CPATH-SOP-MED-7 Reporting of ileo-colic resection specimens CPATH-SOP-MED-8 Reporting of small intestinal resection specimens CPATH-SOP-MED-9 Reporting of Colorectal Cancer Specimens	



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<p>HUMAN BODY TISSUE AND FLUIDS (cont'd)</p> <p>Slides prepared in house as above (Thoracic, skin)</p>	<p><u>Examination activities in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd)</u></p> <p><u>Histopathology –</u> Morphological assessment and interpretation/diagnosis: (cont'd)</p>	<p>Macroscopic and Microscopic examination:</p> <p>Documented in house methods incorporating manufacturers' instructions where relevant:</p> <p>Using light microscopy and SOPs:</p> <p>CPATH-SOP-MED-10 Reporting of resections for pancreatic, ampullary and bile duct carcinoma</p> <p>CPATH-SOP-MED-11 Reporting of stomach resection specimens</p> <p>CPATH-SOP-MED-12 Reporting of oesophageal resection specimens</p> <p>CPATH-SOP-MED-47 Reporting of endomucosal resection specimens (EMR)</p> <p>CPATH-SOP-MED-39 Reporting of liver resections not transplant</p> <p>CPATH-SOP-MED-13 Reporting of skin specimens, biopsies and resections</p> <p>CPATH-SOP-MED-14 Reporting of lung resection specimens</p> <p>CPATH-SOP-MED-15 Reporting of Thoracic lung biopsies and segmental excisions</p> <p>CPATH-SOP-MED-48 Reporting of Soft Tissue tumours specimens, core biopsies, excisions, amputations</p>	BEX



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

Leeds Teaching Hospitals NHS Trust
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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
<p>HUMAN BODY TISSUE AND FLUIDS (cont'd)</p> <p>Slides prepared in house as above (Head & neck)</p> <p>Slides prepared in house as above (Neuropathology)</p>	<p><u>Examination activities in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd)</u></p> <p><u>Histopathology</u> – Morphological assessment and interpretation/diagnosis (cont'd):</p>	<p>Macroscopic and Microscopic examination:</p> <p>Documented in house methods incorporating manufacturers' instructions where relevant:</p> <p>Using light microscopy and SOPs:</p> <p>CPATH-SOP-MED-16 Reporting of oral mucosal specimens for tumours</p> <p>CPATH-SOP-MED-17 Reporting of thyroid specimens</p> <p>CPATH-SOP-MED-18 Reporting of small mucosal specimens</p> <p>CPATH-SOP-MED-19 Reporting of small bone specimens</p> <p>CPATH-SOP-MED-20 Reporting of salivary gland specimens for tumours</p> <p>CPATH-SOP-MED-21 Reporting of radical neck dissection specimens</p> <p>CPATH-SOP-MED-22 Reporting of maxillectomy specimens for tumours</p> <p>CPATH-SOP-MED-23 Reporting of laryngectomy specimens for tumours</p> <p>CPATH-SOP-MED-24 Reporting of Globes</p> <p>CPATH-SOP-MED-25 Reporting the examination of orbital exenterations</p>	BEX



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<p>HUMAN BODY TISSUE AND FLUIDS (cont'd)</p> <p>Slides prepared in house as above (Urology)</p> <p>Slides prepared in house as above (Urology)</p> <p>Slides prepared in house as above (Skin)</p>	<p><u>Examination activities in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd)</u></p> <p><u>Histopathology</u> – Morphological assessment and interpretation/diagnosis (cont'd):</p>	<p>Macroscopic and Microscopic examination:</p> <p>Documented in house methods incorporating manufacturers' instructions where relevant:</p> <p>Using light microscopy and SOPs:</p> <p>CPATH-SOP-MED-26 Reporting of wedge excisions - eyelid lesions</p> <p>CPATH-SOP-MED-27 Reporting of Temporal Artery Specimens</p> <p>CPATH-SOP-MED-28 Reporting of Trabeculectomy Specimens</p> <p>CPATH-SOP-MED-29 Reporting a penetrating keratoplasty (Cornea)</p> <p>CPATH-SOP-MED-34 Prostatic biopsies, transurethral or open prostatic resections and radical prostatectomies</p> <p>CPATH-SOP-MED-35 Adult renal parenchymal tumours</p> <p>CPATH-SOP-MED-36 Penile biopsies and resections</p> <p>CPATH-SOP-MED-37 Testicular biopsies and resections, retroperitoneal lymph node dissections</p> <p>CPATH-SOP-MED-38 Urinary bladder, ureteric, renal pelvic and urethral specimen</p> <p>CPATH-SOP-HP-21 Screening of skin biopsies by Immunofluorescence</p>	



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<p>HUMAN BODY TISSUE AND FLUIDS (cont'd)</p> <p>Digital images from slides prepared in house as above</p>	<p><u>Examination activities in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis</u> (cont'd)</p> <p><u>Histopathology</u> – Morphological assessment and interpretation/diagnosis (cont'd):</p>	<p>Macroscopic and Microscopic examination:</p> <p>Documented in house methods incorporating manufacturers' instructions where relevant:</p> <p>Using digital pathology (slide scanners and viewing software):</p> <p>Slide Scanning CPATH-SOP-HP-166 Scanning Digital Cases Using Leica GT450 Scanners</p> <p>Slide Reporting CPATH-SOP-HP-64 Reporting digital slides using Sectra IDs&</p>	



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HUMAN BODY TISSUE AND FLUIDS (cont'd)	<u>Examination activities in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd)</u>	Macroscopic and Microscopic examination: Documented in house methods incorporating manufacturers' instructions where relevant:	
Tissue	<u>Muscle / Nerve Histopathology</u>	Frozen section preparation (Microm Cryostat): CPATH-SOP-23 Cryostat Section Preparation for Histochemistry Sample preparation techniques: CPATH-COSHH-32 Tissue Quenching for Histochemistry CPATH-SOP-SPH-12 CPATH-SOP-SPH-13 Specimen Handling for Muscle, Nerve, Rectal, Skin and Conjunctival Biopsies	SJUH
	Identification of basophilic and eosinophilic structures	CPATH-SOP-HP-4 Haematoxylin and Eosin Staining Method (cryostat sections)	SJUH
	<u>Muscle / Nerve Histopathology</u> - Identification of:	Manual special staining techniques:	SJUH
	Glycogen	CPATH-SOP-HP-8 Periodic Acid Schiff (PAS) and Diastase-PAS Staining Method for Cryostat Sections	
	Mitochondria and their distribution	CPATH-SOP-HP-3 Gomori Trichrome CPATH-SOP-HP-16 Succinate Dehydrogenase Demonstration	



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HUMAN BODY TISSUE AND FLUIDS (cont'd)	<u>Examination activities in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd)</u>	Macroscopic and Microscopic examination: Documented in house methods incorporating manufacturers' instructions where relevant:	
Tissue (Muscle)	<u>Muscle / Nerve Histopathology</u> - Identification of normal /abnormal muscle fibre elements	CPATH-SOP-HP-15 Immunocytochemical Sarcolemmal Staining Method (Real) Using the following monoclonal, polyclonal and antibodies: Dystrophin 1 Dystrophin 2 Dystrophin 3 Alpha Sarcoglycan BetaSarcoglycan Gamma Sarcoglycan Delta Sarcoglycan Emerin Dysferlin Merosin Spectrin	SJUH
Tissue (Surgical and MH muscle)	Identification of nucleated cells <u>Muscle / Nerve Histopathology - identification /demonstration of:</u> Acid Phosphatase Fibres with abnormal COX activity Myoadenylate Deaminase Adenosine triphosphatase	MHC-1 (HLA-ABC) Enzyme histochemical staining CPATH-SOP-SPH-12 Specialist Histopathology Staining Panels CPATH-SOP-HP-1 Acid Phosphatase – Naphthol AS-BI Phosphate CPATH-SOP-HP-16 Combined Demonstration of Cytochrome Oxidase & Succinate Dehydrogenase CPATH-SOP-HP-2 Cytochrome Oxidase Demonstration CPATH-SOP-HP-5 Myoadenylate Deaminase Demonstration CPATH-SOP-HP-6 Myosin ATPase Staining Method	SJUH



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HUMAN BODY TISSUE AND FLUIDS (cont'd)	<u>Examination activities in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd)</u>	Macroscopic and Microscopic examination: Documented in house methods incorporating manufacturers' instructions where relevant:	
Tissue (Muscle)	<u>Muscle / Nerve Histopathology - identification /demonstration of:</u>	Manual tinctorial Stain techniques for:	SJUH
Tissue (Surgical and MH muscle) (cont'd)	NADH	CPATH-SOP-HP-7 NADH - Tetrazolium Reductase Demonstration	
	PFK and Aldolase activity	CPATH-SOP-HP-9 Phosphofructokinase and Aldolase Demonstration	
	Myophosphorylase in muscle	CPATH-SOP-HP-13 Phosphorylase Demonstration	
	Presence and distribution of lipid in muscle	CPATH-SOP-HP-10 P-Phenylene diamine Staining Method CPATH-SOP-HP-14 Sudan Black B Staining Method	
	Myelin in nerves	CPATH-SOP-SPH-12 Palade Fixation/Staining Method	
	Internode length, fibre diameter and myelin degeneration	CPATH-SOP-HP-11 Teased Nerve Procedure	
Slides prepared in house as above	<u>Muscle / Nerve Histopathology - Morphological assessment and interpretation/diagnosis</u>	CPATH-SOP-MED-3 Reporting of muscle biopsy specimen examination and handling	BEX
		CPATH-SOP-MED-4 Reporting of peripheral nerve biopsy specimen examination	BEX
FFPE sections prepared in house as above	<u>Molecular Pathology</u> Detection of BRAF mutation at codon 600	RT-PCR CPATH-SOP-HP-60 Idylla™ System	BEX



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HUMAN BODY FLUIDS	<u>Andrological examination activities for the purposes of clinical diagnosis</u>		
Semen	<u>Post vasectomy:</u> Detection of sperm	Based on 2016 Laboratory guidelines for post vasectomy semen analysis: Association of Biomedical Andrologists, the British Andrology Society and the British Association of Urological Surgeons) Manual method using large volume chambers/ manual microscopy OR wet prep and centrifugation and documented in-house procedure CPATH-SOP-AND-5 Post vasectomy testing	SEA
Semen	<u>Fertility testing:</u> Volume pH Sperm morphology excluding TZI scoring Sperm concentration Sperm motility	Based on WHO laboratory manual for the examination and processing of human semen (Sixth edition 2021) and manual method / documented in-house procedures: CPATH-SOP-AND-1 Infertility testing CPATH-SOP-AND-2 Sperm density CPATH-SOP-AND-3 Motility testing CPATH-SOP-AND-4 Sperm morphology Volume/weight Colorimetric strips Stained slides (H&E) microscopy (Bright field) Improved Neubauer counting chambers and Microscopy (Phase contrast) Microscopy (Phase contrast)	SEA



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HUMAN BODY FLUIDS (cont'd)	<u>Andrological examination activities for the purposes of clinical diagnosis</u>		
	<u>Coagulation/Haematology</u>		SEA
Blood	Routine coagulation: PT & INR, APTT, APTT Ratio Thrombin Time, Reptilase time, D-dimer. Derived Fibrinogen, Clauss Fibrinogen. Automated 50:50 Mix Reptilase time	ACL TOP 750 CTS - turbidimetric, chromogenic and latex enhanced immunoassay. ACL TOP 750 CTS routine operation SLM-SC-SOP-1 Investigation of prolonged thrombin time using reptilase SLM-SC-SOP-2 All tests using Hemosil Reagents except Reptilase time - PEFakit (Pentapharma)	B46
	<u>Examination activities for the purpose of clinical diagnosis (cont'd)</u>	In-house documented procedures incorporating manufacturers' instructions where relevant. Using Suppliers methods except where stated as In-House	



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HUMAN BODY FLUIDS (cont'd)	<u>Coagulation/Haematology (cont'd)</u>		
Blood	Thrombophilia and Lupus anticoagulant: Protein C, Antithrombin, Free Protein S, Dilute Russel Viper Venom Test (DRVVT) Screen and Confirm, APTT-SP/ Actin FS	Thrombophilia and Antiphospholipid Antibody screening SLM-SC-SOP-3 All tests use Hemosil Reagents except Actin FS - Siemens Dade Reagent	B46
Blood	Factor Assays Extrinsic: FII, FV, FVII, FX Intrinsic: FVIII, FVIII ReFacto, FIX, FXI, FXII, Chromogenic factor VIII	Factor Assays on the ACL TOP 750 CTS Specialist Coagulation SLM-SC-SOP-3 All deficient / calibration plasma are Hemosil Reagents except Pfizer Refacto AF Lab Standard used for calibration of Refacto factor VIII. Chromogenic factor VIII - Chromogenix	B46
Blood	Von Willibrand Screen: Von Willibrand factor antigen, Von Willibrand ristocetin co factor (Automated),	Factor Assays on the ACL TOP 750 CTS Specialist Coagulation SLM-SC-SOP-4 Hemosil Reagents	B46
Blood	Anti Xa assays: Low molecular weight heparin (anti XA) Fondaparinux Rivaxaban Danapariod Unfractionated Heparin Apixaban anti-Xa Edoxaban anti-Xa	Anti Xa assay to monitor Low Molecular Weight Heparin SLF Monitoring of Anti-Xa and Anti-Thrombin agents SLM-SC-SOP-6 All test using Hemosil reagents except Fondaparinux and Edoxaban anti-Xa – Stago reagents, and Danapariod - Hyphen Biomed reagents. Fondaparinux, Danapariod, Edoxaban – In-House methods	B46



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HUMAN BODY FLUIDS (cont'd)	<u>Examination activities for the purpose of clinical diagnosis</u> (cont'd)	In-house documented procedures incorporating manufacturers' instructions where relevant. Using Suppliers methods except where stated as In-House	
Blood	<u>Coagulation/Haematology</u> (cont'd) Direct Thrombin Inhibitors Agatroban, Dabigatran	Monitoring of Anti-Xa and Anti-Thrombin agents SLM-SC-SOP-6. Direct Thrombin Inhibitors and Dabigatran - Hemosil reagents. Agatroban - Hyphen Biomed, Agatroban - In House	B46
Blood	Alpha 2 antiplasmin, Plasminogen	Factor Assays on the ACL TOP 750 CTS Specialist Coagulation SLM-CP-SOP-4. ACL TOP 750 CTS Routine Operation Hemosil Reagents:	B46
Blood	Quantification of inhibitors to coagulation factors V, VII, VIII, IX	Bethesda Assay-using 37° C incubator/water bath and detection by ACL TOPs by Turbidimetric clot detection method. Reported in BU/ml SLM-SC-SOP-5	B46
Citrated Plasma	Emicizumab assay Quantification of inhibitors to porcine factor VIII Quantification of inhibitors to factor VIII in patients taking Emicizumab	Bethesda Porcine (Obizur) FVIII Inhibitor assay Bethesda Chromogenic FVIII (bovine) (emicizumab) Inhibitor assay Manual / ACL TOP 750. Coagulometric. SOP SLM-SC-SOP-5	B46



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HUMAN BODY FLUIDS (cont'd)	<u>Examination activities for the purpose of clinical diagnosis</u> (cont'd)	In-house documented procedures incorporating manufacturers' instructions where relevant. Using Suppliers methods except where stated as In-House	
Blood	<u>Coagulation/Haematology</u> (cont'd) Factor XIII, H.I.T screen	Spectrophotometer- Bio Tek UVICON XL Factor XIII Assay examination procedure SLM-SC-SOP-7 HIT-Ab PF4-H-SLM-SC-SOP-8 - ACL TOP 750 CTS Factor XIII- Siemens Berichrom H.I.T screen- Hemosil PCR: Cepheid Genexpert Dx, dual channel analyser:	B46
Blood/DNA extract	Factor 5 Leiden, Factor 2 gene mutation	GeneXpert Hemosil FII & FV cartridges performing real time PCR. Use of the GenExpert SLM-SC-SOP-9	B46
Blood	Platelet investigations: Ristocetin Cofactor Assay	Helena AggRAM Ristocetin Cofactor Assay SLM-SC-SOP-10 Helena Biosciences reagents	B46



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HUMAN BODY FLUIDS (cont'd)	<u>Examination activities for the purpose of clinical diagnosis (cont'd)</u>	In-house documented procedures incorporating manufacturers' instructions where relevant. Using Suppliers methods except where stated as In-House	
Blood (Adult and Antenatal samples)	Haemoglobinopathy screening:	Documented -in-house methods to meet the requirements of the Sickle cell and Thalassaemia (SCT) screening programme screening programme(s) laboratory QA evidence requirements'	
Dried blood spots (Newborn)	Identification and quantification of Hb variants HbF, HbA, HbS, HbC, HbDPunjab, HbE, HbOArab plus HPFH, Delta/Beta Thalassaemia and compound heterozygotes of the above.	Menarini Hb9210 Resolution - High performance liquid chromatography (HPLC) - Haemoglobin peak analysis and quantitation. Operation of the Menarini Hb9210 Resolution HPLC System SLM-HBO-SOP-15	B46
Dried blood spots (newborn) and adult confirmation	Identification and quantification of Hb variants - HbF, HbA, HbS, HbC, HbDPunjab, HbE, HbOArab plus HPFH, Delta/Beta Thalassaemia and compound heterozygotes of the above.	TMS identification of Hb variants (S, C, D punjab, E and O arab) by electron spray mass spectrometry - using the SpotOn HbS TMS kit Spot-On Haemaglobinopathy screening kit for MSMS SLM-HBO-SOP-1 ABSciex API 4000 TMS SLM-HBO-SOP-14	B46
Blood and dried blood spots	Abnormal Haemoglobin variants	Iso Electric Focussing Multiphor electrophoresis tanks IEF resolve systemHb kit SLM-HBO-SOP-6	B46



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HUMAN BODY FLUIDS (cont'd)	<u>Examination activities for the purpose of clinical diagnosis (cont'd)</u>	In-house documented procedures incorporating manufacturers' instructions where relevant. Using Suppliers methods except where stated as In-House	
	<u>Antenatal & Newborn Screening</u>	Documented -in-house methods to meet the requirements of the Fetal Anomaly Screening Programme laboratory QA evidence requirements'	
Blood	Antenatal screening for Downs, Edwards and Patau: Alpha Feto Protein (AFP), free β -Human Chorionic Gonadotrophin (β -HCG), plasma free Oestriol (UE3) and pregnancy associated plasma protein A (PAPP-A), Inhibin A and Total HCG (Second Trimester Downs Screening)	Autodelfia 1235 AutoDELFIA UE3 - solid phase competitive fluoroimmuno assay, AutoDELFIA PAPP-A, AFP, free beta HCG & Inhibin A - solid phase, two site fluoroimmunometric assays direct sandwich technique Downs screening SLF2BGN009 AutoDELFIA, Use of SLM-SBG-SOP-72	B46
Bloodspot	Newborn screening for Cystic Fibrosis: Immunoreactive trypsinogen (IRT)	Autodelfia 1235 Delfia neonatal IRT (Immuno Reactive Trypsin) kit fluoroimmunometric assay. AutoDELFIA, Use of SLM-SBG-SOP-72 Screening for Cystic Fibrosis SLM-SBG-SOP-2	B46
Bloodspot	Newborn Screening for Hypothyroidism and Hypothyroidism in Downs patients: Thyroid stimulating hormone (hTSH)	Autodelfia 1235 AutoDELFIA neonatal hTSH (human Thyroid Stimulating Hormone) kit fluoroimmunometric assay. AutoDELFIA, Use of SLM-SBG-SOP-72 Screening for Hypothyroidism Neonatal TSH SLM-SBG-SOP-3	B46



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	<u>Antenatal & Newborn Screening (cont'd)</u>	Documented -in-house methods to meet the requirements of the Newborn Blood Spot Screening Programme: laboratory QA evidence requirements'	
Bloodspot	Newborn screening for Glutaric Aciduria Type 1 (GA1), Homocystinuria (pyridoxine non-responsive) (HCU), Isovaleric Acidaemia (IVA), Maple Syrup Urine Disease (MSUD), Medium Chain Acyl-CoA Dehydrogenase Deficiency (MCADD), Phenylketonuria (PKU) & Tyrosinaemia Type 1. Analytes tested: Phenylalanine and Tyrosine - (PKU/Tyrosinaemia Type I) Methionine - HCU Glutaryl carnitine (C5-DC) - GA1 Isovalerylcarnitine (C5) - IVA Octanoylcarnitine (C8) – and Decanoylcarnitine (C10) - MCADD Leucine - MSUD	Tandem mass spectrometry. Underivatised samples, electrospray ionisation (ESI), MRM analysis using: - API 6500 SLM-SBG-SOP-4 SLM-SBG-SOP-5 - Tandem tests	B46
Sweat	Sweat test for Cystic Fibrosis: Chloride concentration	Wescor sweat inducer model 3710 - pilocarpine iontophoresis stimulation. Macroduct sweat collector. Sherwood chloride analyser 926. Sweat testing, collection and analysis procedure SLM-SBG-SOP-6	B46



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Plasma/serum, urine, CSF	<u>Biochemical Genetics</u> Amino acid analysis: Quantitative amino acid analysis	Biochrom 30+ analysers -ion exchange chromatography to separate amino acids with visualisation at 570 nm and 440nm. Use of Biochrom amino acid analysers, SLM-SBG-SOP-27	B46
Urine	Qualitative amino acid analysis	2-directional thin layer chromatography (TLC) with visual assessment of stained plates Urine Amino Acid Analysis by 2D TLC SLM-SBG-SOP-19	B46
Urine	Organic acid analysis - qualitative	Agilent 8890 gas chromatograph with 5977B mass selective detector and/or Use of Agilent 8890 & 5975B Gas Chromatographs with Mass Selective Detectors (GCMS) SLM-SBG-SOP-7	B46
Urine	Quantitation of HMMA and HVA	Urine organic acids by GCMS SLM-SBG-SOP-26 HVA and HMMA by GCMS SLM-SBG-SOP-8 MDS Sciex/Applied Biosystems MS/MS API 6500 API 6500, Use of SLM-SBG-SOP-4	B46
Bloodspot	Dietary monitoring: Phenylalanine Tyrosine	LC-MS/MS (MRM analysis - in-house method) Diet monitoring SLM-SBG-SOP-9	B46



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	<u>Biochemical Genetics</u> (cont'd)		
Plasma, Urine	Creatine metabolites: Creatine	LC-MS/MS (MRM analysis - in-house method)	B46
Urine only	Guanidinoacetic acid (GAA) Creatinine	Creatine and GAA by LCMSMS SLM-SBG-SOP-10	
Blood	White cell cystine, (TMS)	LC-MS/MS (MRM analysis - in-house method) White cell cystine, stage 2, Cystine analysis by TMS. SLM-SBG-SOP-31	B46
Blood	White cell cystine (protein assay)	Cobas Mira Plus : Modified Lowry protein assay measuring absorbance at 600nm. White cell cystine protein assay SLM-SBG-SOP-36	B46
Plasma	Total homocysteine	Cobas Mira Plus Axis Shield 2-step enzyme assay, measurement of NADH conversion to NAD+ at 340nm. Total plasma homocysteine SLM-SBG-SOP-23	B46
Urine	Mono- and disaccharide sugars	Thin layer chromatography with visual assessment of stained plates: Sugar Thin Layer Chromatography - in-house method SLM-SBG-SOP-17	B46
Urine	Oligosaccharides	Oligosaccharides by Thin Layer Chromatography (in-house method) SLM-SBG-SOP-18	B46
Urine	Sialic acids	Sialic Acids by Thin Layer Chromatography (in-house method) SLM-SBG-SOP-35	B46



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Urine	<u>Biochemical Genetics</u> (cont'd) Mucopolysaccharides	Precipitation, extraction and 1D-electrophoresis with visual assessment of plates (in-house method) Mucopolysaccharides SLM-SBG-SOP-20	B46
Urine	Glucose, ketones, pH, protein, blood, nitrites and leucocytes	Bayer Multisix8 SG. Siemens Clinitek Status Urine Dipstick Reader. Multistix tests in urine SLM-SBG-SOP-28	B46
Serum	Biotinidase	Manual enzyme assay. Biochrom Photometer, Lightwave II spectrophotometric absorbance at 546nm. (In-house method) Biotinidase SLM-SBG-SOP-14	B46
Blood	Galactosaemia screen: Galactose-1-Phosphate Uridyl Transferase (Gal-1-PUT)	Manual spot test with visual assessment of fluorescence under long wavelength ultra violet light. Galactosaemia screening test (in-house method) SLM-SBG-SOP-15	B46



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HUMAN BODY FLUIDS	<u>Examination activities for the purpose of clinical diagnosis</u> (cont'd)	In-house documented procedures incorporating manufacturers' instructions where relevant. Using Suppliers methods except where stated as In-House	
Urine	<u>Biochemical Genetics</u> (cont'd) Purines and Pyrimidines - Uric acid - Xanthine - Hypoxanthine - Deoxyadenosine - Deoxyinosine - Inosine - Uracil - Thymine - Thymidine - Orotic acid - AICAR - 2,8-dihydroxyadenine - Dihydrouracil - Dihydrothymine - N-C-B-Alanine - N-C-B-AIBA - Orotidine - Dihydroorotate - Succinyladenosine	LC-MS/MS API 5000 Mass spectrometry SOP: SLM-SBG-SOP-45	B46
Urine	<u>Metabolics</u> Total Metanephtrines	MDS Sciex/Applied Biosystems MS/MS API 5000 Shimadzu Prominence HPLC System Acidic hydrolysis and HPLC separation prior to ionisation and quantitation on TMS. Analysis of Total Urine Metanephtrines by LC MS MS (in-house method) SLM-MTTI-SOP-1	B46



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HUMAN BODY FLUIDS (cont'd)	<u>Examination activities for the purpose of clinical diagnosis</u> (cont'd)	In-house documented procedures incorporating manufacturers' instructions where relevant. Using Suppliers methods except where stated as In-House	
Plasma, Urine	<u>Metabolics</u> (cont'd) 5-hydroxyindole acetic acid (5-HIAA)	Shimadzu Prominence HPLC system. Separation by HPLC with detection by native fluorescence (in-house method) 5-HIAA in plasma by HPLC SLM-MTTI-SOP-2 Determination of 5-HIAA in urine (in-house method) SLM-MTTI-SOP-3	B46
Urine	Dopamine	MDS Sciex/Applied Biosystems MS/MS API 6500 Shimadzu Prominence HPLC System. Extracted using ion-exchange chromatography. Measurement by LC-MS/MS (in-house method). Analysis of Urine Dopamine (in-house method) SLM-MTTI-SOP-18	B46



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HUMAN BODY FLUIDS (cont'd)	<u>Examination activities for the purpose of clinical diagnosis</u> (cont'd)	In-house documented procedures incorporating manufacturers' instructions where relevant. Using Suppliers methods except where stated as In-House	
Urine	<u>Metabolics</u> (cont'd) Urine Drugs of Abuse 6-monoacetylmorphine, morphine, codeine, dihydrocodeine, amphetamine, 11-nor-9-carboxy-delta-9-tetrahydrocannabinol, nordiazepam, oxazepam, benzoylecgonine, methadone, EDDP, buprenorphine, norbuprenorphine, amphetamine, MDMA, MDA. Ketamine, norketamine, tramadol, Pholcodine and Oxycodone	Applied Biosystems / Sciex API 5000 mass spectrometer Shimadzu Prominence HPLC system Glucuronidase hydrolysis and solvent extraction. LC-MS/MS analysis. 13 drugs with quantitative and 8 drugs with qualitative reporting. Quantitative measurements by comparison to 5 calibrators. Qualitative measurements by comparing retention times and MRM ion ratios with spiked urine Urine Drugs of Abuse using the API 5000 (in-house method) SLM-MTTI-SOP-5	B46



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HUMAN BODY FLUIDS (cont'd)	<u>Examination activities for the purpose of clinical diagnosis (cont'd)</u>	In-house documented procedures incorporating manufacturers' instructions where relevant. Using Suppliers methods except where stated as In-House	
Urine	<u>Toxicology and trace elements</u> Pregabalin and gabapentin	MDS Sciex/Applied Biosystems MS/MS API 5000 Shimadzu Prominence HPLC System Extraction by commercial ion-exchange column. Analysis by LC-MS/MS. Quantitative measurements by comparison to 5 calibrators. Reported qualitatively with respect to cutoff. Gabapentin and pregabalin and urine by LCMSMS (in-house method) SLM-MTTI-SOP-6	B46
Blood	Copper, zinc and selenium	Agilent 7700 ICPMS (collision cell) with ASX-500 autosampler: Following dilution in a basic solution Copper zinc and selenium in plasma (in-house method) SLM-MTTI-SOP-7	B46
	Lead	Following dilution in an ammonia solution via measurement of Isotopes 206,207 & 208 atomic mass units Analysis of Blood Lead by ICPMS (in-house method) SLM-MTTI-SOP-8	B46



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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd)	<u>Examination activities for the purpose of clinical diagnosis</u> (cont'd)	In-house documented procedures incorporating manufacturers' instructions where relevant. Using Suppliers methods except where stated as In-House	
	<u>Toxicology and trace elements</u> (cont'd)		
Blood	Mercury (Hg)	Following dilution in an ammonia solution via measurement of isotopes 200 & 202 atomic mass units Analysis of Blood Mercury Hg by ICPMS (in-house method) SLM-MTTI-SOP-9	B46
	Chromium, Cobalt and Manganese	Following dilution in an ammonia solution Analysis of Blood and Plasma Chromium, Cobalt and Manganese by ICPMS (in-house method) SLM-MTTI-SOP-10 Agilent 7700 ICPMS with ASX-500 autosampler:	B46
Urine	Cadmium (Cd)	Via measurement of Isotopes 111, 114 & 112 atomic mass units Analysis of Urine Cadmium (Cd) by ICPMS (in-house method) SLM-MTTI-SOP-11	B46
Plasma	Aluminium (Al)	Plasma aluminium by ICPMS (in-house method) SLM-MTTI-SOP-12	B46
Liver needle biopsy or tissue block	Tissue Copper (Cu) and Iron (Fe)	Nitric acid digestion. Analysis of Tissue Copper Cu and Iron Fe by ICPMS (in-house method) SLM-MTTI-SOP-13	B46



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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd)	<u>Examination activities for the purpose of clinical diagnosis</u> (cont'd)	In-house documented procedures incorporating manufacturers' instructions where relevant. Using Suppliers methods except where stated as In-House	
	<u>Toxicology and trace elements</u> (cont'd)		
Urine	Copper (Cu), Lead (Pb) and Mercury (Hg)	Cu measured by collision cell. Pb & Hg measured in non-collision mode (in-house methods) SLM-MTTI-SOP-14 Analysis of Urine Copper (Cu), Lead (Pb) and Mercury (Hg) by ICP	B46
Blood	Arsenic	Following dilution in an ammonia solution SLM-MTTI-SOP-15 Arsenic in blood	B46
Urine	Arsenic	Following dilution in nitric acid Arsenic in urine (in-house method) SLM-MTTI-SOP-16	B46
Blood	Cadmium (Cd)	Following dilution in an ammonia solution via measurement of Isotopes 111, 112 & 114 atomic mass units Analysis of Blood Cadmium Cd by ICPMS (in-house method) SLM-MTTI-SOP-17	B46



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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd)	<u>Examination activities for the purpose of clinical diagnosis (cont'd)</u>	In-house documented procedures incorporating manufacturers' instructions where relevant. Using Suppliers methods except where stated as In-House	
Blood	<u>Endocrinology</u> Dihydroepiandrosterone Sulphate (DHAS)	Siemens Immunulite Xpi chemilumescence SOP BSHC-SOP-14 and SLM-END-SOP-22	LGI
Heparinized plasma/Serum	Androstenedione	LC-MS/MS API5000 LC-MS/MS tandem mass spectrometer: Extraction into tert-butyl-methyl ether (MTBE). Deuteriated internal standard. Electrospray ionisation with multiple reaction monitoring (MRM) mode; detection of 2 precursor (parent) to fragment (daughter) ion transitions Determination of Androstenedione in plasma by Tandem Mass Spectrometry (in-house method) SLM-END-SOP-2 API5000 setting up to run routine endocrinology methods SLM-END-SOP-1	B46
Heparinized plasma/Serum	Testosterone	Precipitation of protein using zinc sulphate/methanol. Electrospray ionisation with multiple reaction monitoring (MRM) mode; Deuteriated internal standard Detection of 2 precursor (parent) to fragment (daughter) ion transitions Testosterone by TMS (in-house method) SLM-END-SOP-3	B46



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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd)	<u>Examination activities for the purpose of clinical diagnosis</u> (cont'd)	In-house documented procedures incorporating manufacturers' instructions where relevant. Using Suppliers methods except where stated as In-House	
	<u>Endocrinology</u> (cont'd)	LC-MS/MS API5000 LC-MS/MS tandem mass spectrometer:	
Heparinized plasma/Serum	Dihydrotestosterone (DHT)	Dihydrotestosterone by LC-MS/MS tandem mass spectrometer API5000 Sciex SLM-END-SOP-21	B46
Urine	Urinary free cortisol	Extraction into dichloromethane. Deuteriated internal standard. Electrospray ionisation with multiple reaction monitoring (MRM) mode Detection of 2 precursor (parent) to fragment (daughter) ion transitions	B46
		Urinary free cortisol by Tandem Mass Spectroscopy (in-house method) SLM-END-SOP-4	
		LC-MS/MS API5000 LC-MS/MS tandem mass spectrometer:	
Plasma	Plasma renin activity (PRA)	Generation of Angiotensin I from angiotensinogen which is proportional to plasma renin activity. Angiotensin I is extracted using SPE. Deuteriated internal standard. Electrospray ionisation with multiple reaction monitoring (MRM) mode and detection of 2 precursor (parent) to fragment (daughter) ion transitions.	B46
		Plasma renin activity by Tandem Mass Spectroscopy (in-house method) SLM-END-SOP-5	



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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd)	<u>Examination activities for the purpose of clinical diagnosis</u> (cont'd)	In-house documented procedures incorporating manufacturers' instructions where relevant. Using Suppliers methods except where stated as In-House	
	<u>Endocrinology</u> (cont'd)	LC-MS/MS API5000 LC-MS/MS tandem mass spectrometer:	
Heparinized plasma/Serum	17 alpha OH progesterone	Extraction into tert-butyl-methyl ether (MTBE)/ Precipitation of protein using zinc sulphate/methanol. Deuteriated internal standard. Electrospray ionisation with multiple reaction monitoring (MRM) mode; detection of 2 precursor (parent) to fragment (daughter) ion transitions,	B46
	Aldosterone	17 alpha OH progesterone by Tandem Mass Spectroscopy (in-house method) SLM-END-SOP-6 Extraction into tert-butyl-methyl ether (MTBE). Deuteriated internal standard. Atmospheric pressure chemical ionisation (APCI). Multiple reaction monitoring (MRM) mode detecting 2 precursor (parent) to fragment (daughter) ion transitions. Aldosterone by Tandem Mass Spectroscopy (in-house method) SLM-END-SOP-7	B46



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HUMAN BODY FLUIDS (cont'd)	<u>Examination activities for the purpose of clinical diagnosis (cont'd)</u>	In-house documented procedures incorporating manufacturers' instructions where relevant. Using Suppliers methods except where stated as In-House	
Serum	<u>Clinical Immunology</u> Autoantibody identification: Antinuclear Antibodies (includes antibodies to dsDNA, Ro, Ro52, Ro60, La, Sm, RNP, RNP 68, RNP A, SmRNP, Jo-1, Scl-70, Centromere, Chromatin, and Ribo) Anti-CCP Ab Anti-tTG Ab Anti-Phospholipid Ab (anti-Cardiolipin IgG and anti-Beta-2 Glycoprotein I) Anti-GBM Ab Anti-PR3 Ab Anti-MPO Ab	Bio-Rad Bioplex 2200 – multiplex magnetic bead technology (Luminex) SLM-CI-SOP-1	LGI
Faeces	Faecal haemoglobin	Faecal haemoglobin detection (for screening purposes) by Faecal immunochemical test (FIT); turbidometry using the HM-JACKArc analyser alpha laboratories SLM-CI-SOP-2	LGI
Blood	Infliximab	Detection of Infliximab drug level anti-Infliximab antibodies by ELISA using Dynex DS2 SLM-CI-SOP-4	LGI
Serum	Anti-GAD Ab	Alere/Dynex DS2 analyser ELISA plate reader for manual assays and processing of automated ELISAs SLM-CI-SOP-6	LGI



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HUMAN BODY FLUIDS (cont'd)	<u>Examination activities for the purpose of clinical diagnosis (cont'd)</u>	In-house documented procedures incorporating manufacturers' instructions where relevant. Using Suppliers methods except where stated as In-House	
Serum	<u>Clinical Immunology (cont'd)</u> ANA (Hep2) Antineutrophil Cytoplasmic Ab Autoimmune Liver Disease Ab (Includes gastric parietal cell Ab, mitochondrial Ab, smooth muscle Ab and liver kidney microsomal Ab) Pancreatic Islet Cell Ab Bullous Abs Steroidal Cell Ab (Includes Ovarian Ab, adrenal Ab and Testis Ab) Cerebellar Ab Striated Muscle Ab Crithidia Ab IgG and IgA Endomysial Ab	Werfen Quantalyser slide processor & Leica DMRB Fluorescence microscope – Indirect Immunofluorescence SLM-CI-SOP-5	LGI
Serum	Myositis associated Ab Mi-2 α , Mi-2 β , TIF1 γ , MDA5, NXP2, SAE1, Ku, PM-Scl100, PM-Scl75, Jo-1, SRP, PL-7, PL-12, EJ, OJ and Ro-52) Scleroderma Ab (Scl-70, CENP A, CENP B, RP11 and RP155 (RNA Polymerase III subunits), Fibrillarin, NOR90, Th/To, PM-Scl100, PM-Scl75, Ku, PDGFR (platelet derived growth factor receptor) and Ro-52) Autoimmune Liver Disease Ab (AMA-M2, M2-3E, Sp100, PML, LKM-1, LC, SLA/LP and Ro-52) Neuronal Ab ANA Ab	EUROBlotOne for Immunoblotting assays (commercial kit- Euroimmun) Strips coated with highly purified antigens are incubated with samples. Bound antibodies detected with enzyme-labelled anti-human IgG conjugate and evaluated digitally. SLM-CI-SOP-30	LGI



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HUMAN BODY FLUIDS (cont'd)	<u>Examination activities for the purpose of clinical diagnosis (cont'd)</u>	In-house documented procedures incorporating manufactures' instructions where relevant. Using Suppliers methods except where stated as In-House	
Serum	<u>Clinical Immunology (cont'd)</u> Functional antibodies (specific microbial protein antibodies) (to Anti-Haemophilus influenzae type B antibodies (HiB), Anti-tetanus toxoid antibodies (TET) and Anti-Pneumococcal antibodies (PCP)	Alere/Dynex DS2 automated ELISA analyser Binding site kits SLM-CI-SOP-1	LGI
Serum	<u>Proteins:</u> Quantitation of paraproteins Identification of paraproteins by immunosubtraction	Sebia Capillarys2 – CZE Sebia Hydrasys – Gel electrophoresis Helena IEF	LGI
Fluid	β 2- transferrin	Sebia Capillarys2 Serum protein electrophoresis using Sebia CAPILLARYS system Qualitative analysis of serum proteins to identify presence of abnormal protein and protein group increase/decrease SLM-CI-SOP-8 Sebia Hydrasys Detection of Beta-2 transferrin SLM-CI-SOP-9	LGI



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HUMAN BODY FLUIDS (cont'd)	<u>Examination activities for the purpose of clinical diagnosis (cont'd)</u>	In-house documented procedures incorporating manufactures' instructions where relevant. Using Suppliers methods except where stated as In-House	
Serum	<u>Proteins:</u> (cont'd) Cryoglobulins	Sample cooling/heating from/up to 37C with visual inspection of the aliquot for cryoprecipitate. Typing of positives on Sebia Hydrasys SLM-CI-SOP-10 Investigation of cryoglobulins	LGI
Urine	Qualitative analysis of Urine proteins to identify presence of abnormal protein and protein group increase/decrease.	Sebia Hydrasys High resolution urine electrophoresis using the Sebia Hydrasys system SLM-CI-SOP-11	LGI
CSF	Oligoclonal bands	Helena Titan Gel IEF chamber 4065 Isoelectric focussing of CSF IgG SLM-CI-SOP-12	LGI
Serum and Urine	Paraprotein identification: IgG/IgA/IgM/Kappa/Lambda/IgD/IgE/ free Kappa light chains/free Lambda light chains	Sebia Hydrasys Serum and urine immunofixation (Hydrasys) SLM-CI-SOP-13	LGI
Serum	Alpha-1 anti-trypsin phenotype	Sebia Hydrasys (Hydrasys) SLM-CI-SOP-14	LGI



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HUMAN BODY FLUIDS (cont'd)	<u>Examination activities for the purpose of clinical diagnosis</u> (cont'd)	In-house documented procedures incorporating manufacturers' instructions where relevant. Using Suppliers methods except where stated as In-House	
Serum	<u>Proteins:</u> (cont'd) Specific Proteins: α1-antitrypsin α1-acid glycoprotein anti-Streptolysin O β2-microglobulin Caeruloplasmin C1 esterase inhibitor Complement (C3, C4) Haptoglobin Immunoglobulins (GAM) IgG subclasses (IgG1 - IgG4) Serum free light chains (kappa and lambda) Transferrin CSF IgG CSF Alb	Siemens BN*II System Nephelometers Operation of the nephelometer - Siemens BNII system SLM-CI-SOP-15	LGI
CSF CSF			
Serum	Total Haemolytic Complement (CH100 - classical pathway)	Total Haemolytic complement functional assay - classical pathway (radial immunodiffusion) SLM-CI-SOP-16	LGI
Serum	C1 esterase inhibitor (functional)	Manual chromogenic assay C1-Esterase Inhibitor functional assay SLM-CI-SOP-17	LGI
Serum	Allergy: Total IgE Tryptase Specific IgE Specific IgG antibodies to Aspergillus fumigatus, Saccharopolyspora rectivirgula (previously known as Micropolyspora faenii), Thermactinomyces vulgaris, pigeon and budgie serum See APPENDIX 1	Phadia ImmunoCap 250. Fluorescent enzyme immuno assay (FEIA). SOP SLM-CI-SOP-18	LGI



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HUMAN BODY FLUIDS (cont'd)	<u>Examination activities for the purpose of clinical diagnosis (cont'd)</u>	In-house documented procedures incorporating manufacturers' instructions where relevant. Using Suppliers methods except where stated as In-House	HUMAN BODY FLUIDS
	<u>Cellular Immunology</u>		
Blood	Primary Immune Deficiency: Lymphocyte function /anti CD3 assay. Functional activation of lymphocytes in response to stimulation with anti-CD3 Ab (counts per minute)	Wallac LKB Beta counter Cell harvester: Skatron AS semi-automated cell harvester Lymphocyte function test SLM-CEI-SOP-1	SJUH GW
Blood	Functional Neutrophil assay: Respiratory burst of neutrophils in response to <i>E coli</i> or PMA	FACSCanto II (Becton Dickinson) Flow Cytometer Neutrophil function test SLM-CEI-SOP-2	SJUH GW
Blood	Lymphocyte subsets: Extended phenotyping (HLA-DR on B cells and monocytes, T cell receptor expression, naïve T cells and HLA-DR +ve T cells) B cell panel: Measurement of memory B cells	FACSCanto II Flow cytometer Lymphocyte subsets on flow cytometer SLM-CEI-SOP-5 Extended immune cell phenotyping SLM-CEI-SOP-3 B Cell Phenotyping SLM-CEI-SOP-6	SJUH GW
Blood	CD34	Becton Dickinson Anti-human CD34 Flow cytometry using BD FACS Canto II	SJUH GW



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HUMAN BODY FLUIDS (cont'd)	<u>Examination activities for the purpose of clinical diagnosis (cont'd)</u>	In-house documented procedures incorporating manufacturers' instructions where relevant. Using Suppliers methods except where stated as In-House	
Blood/lymph node/spleen	<u>Transplant Immunology</u> DNA Extraction	DNA extraction: Automated: Maxwell RSC System Manual – Qiagen spin column Manual - Rapid salting out in-house DNA Quantitation: Thermo Fisher Nanodrop Spectrophotometer Amplification: Applied Biosystems Proflex 2 and Geneamp 9700	SJUH GW
DNA extracted from sample types listed above	HLA Typing including disease association: HLA-A HLA-B HLA-C HLA-DRB1 HLA-DRB3 HLA-DRB4 HLA-DRB5 HLA-DQB HLA-DQA HLA-DPB1 HLA B*57:01 HLA B*27	PCR-SSO using ThermoFisher LabXpress and Labscan 3D and OneLambda LabType kits with analysis by HLA Fusion RT-PCR using Quantstudio DX and Quantstudio 6PRO real-time PCR instrument and OneLambda LinkSeq typing kit PCR SSP using Readygene kit and Agarose gel electrophoresis of HLA PCR products. Imaging using Syngene Ingenius imager HLA-B*57:01 Testing by PCR-SSP ReadyGene kit HLA-B*27 Testing by PCR-SSO OneLambda Labtype kit	SJUH GW



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HUMAN BODY FLUIDS (cont'd)	<u>Examination activities for the purpose of clinical diagnosis (cont'd)</u>	In-house documented procedures incorporating manufacturers' instructions where relevant. Using Suppliers methods except where stated as In-House	
	<u>Transplant Immunology (cont'd)</u>		
Blood/lymph node/spleen (cont'd)	HLA Typing: (cont'd) HLA-A HLA-B HLA-C HLA-DRB1 HLA-DRB3 HLA-DRB4 HLA-DRB5 HLA-DQB HLA-DQA HLA-DPA1 HLA-DPB1	Next Generation Sequencing Fluorostar Omega fluorimeter Qubit Holotype HLA 24/11 kit Illumina MiSeq (SLM-TI-SOP-67)	SJUH GW
Blood	HLA Antibody screening/specificity analysis: HLA A, B, C (Class I) HLA-DR, DQ, DP (Class II) (IgG)	Automated and/or manual set up and automated read: ThermoFisher LABXpress, Labscan 3D and Luminex 200 and OneLambda Labscreen kit Analysis by HLA Fusion	SJUH GW
Blood/lymph node/spleen	Detection of IgG HLA specific antibodies to donor T and B lymphocytes	Flow Cytometry BD FACSCanto II Flow cytometer	SJUH GW
Previous donor/patient typing and antibody results using the methods above	Virtual Crossmatch	Review of data according to SLM-TI-SOP-25 Virtual Crossmatch Transplant and SLM-TI-SOP-11 Compiling the Virtual Crossmatch list	SJUH GW



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<p>HUMAN TISSUE AND FLUIDS</p> <p>Human DNA / RNA Blood, saliva, tissue, paraffin embedded tissue amniotic fluid, chorionic villus sampling (CVS) Extracted DNA from external sources</p>	<p><u>Genetics</u></p> <p><u>Molecular genetic examinations for the purpose of clinical diagnosis (including predictive and prenatal) for a range of disorders:</u></p> <p><u>DNA/RNA Extraction, quantification and quality check for subsequent in-house analysis (see below), referral to specialist centres and long-term storage</u></p>	<p>In house documented methods incorporating manufacturers' instructions where relevant</p> <p>Using a combination of the methods listed below, supported by:</p> <ol style="list-style-type: none"> 1. DNA Extraction by: Automated EZ1 robot: (LG-SR-SOP-1) 2. Automated Chemagic and Chemagic 360i: ((LG-SR-SOP-2)) 3. Manual extraction of cfDNA from plasma with Qiagen QIAamp kit: (LG-SR-SOP-3)) 4. Automated extraction using Maxwell RSC 48 extraction robot SOP LG-SR-SOP-4 5. DNA Quantification by Nanodrop spectrophotometer and Tecan plate reader F200 (PicoGreen) or Qubit: LG-SR-SOP-5 6. Amplification by Polymerase Chain Reaction/PCR (Thermocyclers: LG-PCR-SOP-12, Tecan Robot: LG-NGS-SOP-1) 7. Sanger DNA sequencing (Applied Biosystems (AB) Analysers 3730, 3500XL: LG-PCR-SOP-1) 8. Multiplex Ligation-dependent Probe Amplification, (AB, Thermocyclers: LG-PCR-SOP-12) 9. Gel Electrophoresis (LG-PCR-SOP-3) 10. Fragment analysis (AB) : LG-PCR-SOP-4) (Applied Biosystems (AB) Analysers 3730, 3500XL: LG-PCR-SOP-1) 	<p>BEX</p> <p>ASH CSB</p>



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HUMAN TISSUE AND FLUIDS (cont'd)	<u>Molecular genetic examinations for the purpose of clinical diagnosis (including predictive and prenatal) for a range of disorders</u> (cont'd)	<p>In house documented methods incorporating manufacturers' instructions where relevant</p> <p>11.NGS Library preparation: (Sureselect – custom targeting and clinical exomeillumina , Sureselect Library Prep: LG-NGS-SOP-2</p> <p>Agilent Bravo: LG-NGS-SOP-2 Sciclone SureSelect Library Preparation: LG-NGS-SOP-11 Tecan Liquid Handling SOP: LG-NGS-SOP-1</p> <p>Agilent Bioanalyser: LG-NGS-SOP-14</p> <p>Covaris LE220: LG-NGS-SOP-12 Quantitative DNA analysis (PicoGreen): LG-NGS-SOP-20</p> <p>Next Generation Sequencing: sequencing and dosage analysis:</p> <p>12. NovaSeq 6000</p> <p>13. CFEU2 (Cystic Fibrosis Base - Yourgene) (Thermocyclers, AB : LG-PCR-SOP-5) 14. MFI-Y Plus (Male Factor Fertility Base- Yourgene) (Thermocyclers, AB: LG-PCR-SOP-6)</p>	<p>CSB BEX</p> <p>CSB</p> <p>ASH</p>



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<p>HUMAN TISSUE AND FLUIDS (cont'd)</p> <p>Human DNA obtained from:</p> <p style="margin-left: 20px;">A. blood, saliva, tissue, paraffin embedded tissue</p> <p style="margin-left: 20px;">B. amniotic fluid, chorionic villus sampling (CVS)</p>	<p><u>Molecular genetic examinations for the purpose of clinical diagnosis (including predictive and prenatal)</u> (cont'd)</p>	<p>In house documented methods incorporating manufacturers' instructions where relevant</p>	<p>ASH or ASH & CSB, or ASH, CSB & BEX (see techniques 1,2,4-8, 10, 11,12, above)</p>
<p>A, B</p>	<p>Li-Fraumeni syndrome</p>	<p>LG-IC-SOP-6</p>	
<p>A</p>	<p>Selected Gene Panel (Agilent Custom Design) including: Ataxia/Neuropathy panel BOB (Breast, ovarian, bowel) panel Cancer panel Connective tissue disorders panel Core (FH and CF) panel Dystonia/Paroxysmal (DYT) panel Gastrohepatology panel Haematology panel HSP/Degenerative disorders panel LGMD and MH panel Respiratory diseases panel Somatic BRCA panel YNExome panel (includes mitochondrial disorder targets)</p>	<p>LG-IC-SOP-4LG-NGS-SOP-6LG-NGS-SOP-6aLG-NGS-SOP-2</p>	<p>ASH or ASH & CSB, or ASH, CSB & BEX (see techniques 1.2.4-8,10, .11.12 above)</p>
<p>A, B</p>	<p>Variant Confirmation</p>	<p>LG-RD-SOP-33</p>	



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HUMAN TISSUE AND FLUIDS (cont'd)	<u>Molecular genetic examinations for the purpose of clinical diagnosis (including predicative and prenatal)</u> (cont'd)	In house documented methods incorporating manufacturers' instructions where relevant	
A,B	Cystic Fibrosis	LG-PCR-SOP-5	ASH or ASH & CSB, or ASH, CSB & BEX (see techniques 1,2,4-8, 10-13 above)
A (Blood only)	Y Chromosome Microdeletions	LG-PCR-SOP-6	ASH, CSB & BEX (See techniques 2, 5, 6, 10, 14 above)
A,B	DNA Profiling	LG-PCR-SOP-7	
Blood (EDTA anticoagulant), amniotic fluid, chorionic villus or solid tissue	Detection of aneuploidy of chromosomes 13, 18, 21	QF-PCR analysis involving DNA extraction followed by molecular analysis of DNA dosage for rapid aneuploidy using ABI 3500 or ABI 3730 gene scanner (LG-CF-SOP-24, LG-CF-SOP-30; LG-PP-SOP-1, LG-PP-SOP-15, LG-PP-SOP-17)	ASH & BEX (See techniques 1, 2, 4, 5, 6, 10)
Paraffin embedded Tissue	Human identity testing for detection of specimen mix up	Microsatellite PCR test to identify DNA variation at multiple genomic loci known to be unique to individuals using Thermal cycler, ABI 3500XL or ABI 3730 genetic analyser, LG-SO-SOP-3	ASH & BEX (See techniques 4, 5, 6, 10 above)



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HUMAN TISSUE AND FLUIDS (cont'd)	<u>Molecular genetic examinations for the purpose of clinical diagnosis (including predicative and prenatal)</u> (cont'd)	In house documented methods incorporating manufacturers' instructions where relevant	
Peripheral Blood	Detection of variants of DPYP gene indicating vulnerability to 5FU toxicity. Eleucie DPYD detection from the following alleles: c.1679T>G c.1905+1G>A c.2846A>T c.483+18G>A c.1129-5923C>G c.1236G>A.	Genotyping: Yourgene DPYD kit and analysis on using ABI 3500XL or ABI 3730 genetic analyser LG-IC-SOP-15	ASH & BEX (See techniques 4, 5, 6, 7, 9 above)
FFPE Tumour	Detection of methylation of the MLH1 gene (by DNA sequencing test)	Pyrosequencing involving DNA extraction followed by MLH1 methylation using Pyromark Q48 LG-PCR-SOP-11, LG-PCR-SOP-10, LG-NGS-SOP-5	ASH



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HUMAN TISSUE AND FLUIDS (cont'd)	<u>Molecular genetic examinations for the purpose of clinical diagnosis (including predicative and prenatal)</u> (cont'd)	In house documented methods incorporating manufacturers' instructions where relevant	
Blood plasma	Mutation testing of circulating tumour DNA - targeted mutation testing of the EGFR gene	Separation of blood plasma from whole blood, DNA extraction from blood plasma. Targeted EGFR mutation detection by real-time PCR using the Qiagen Rotagene Q and Therascreen Plasma RGQ PCR kit (LG-SO-SOP-24)	ASH & BEX (See techniques 3, 5 above)
Bone marrow, Blood	DNA extraction for the purposes of external Whole Genome Sequencing	Automated extraction using Chemagic and Chemagic 360i: (LG-SR-SOP-2)	BEX
HUMAN BODY FLUIDS/TISSUE	<u>Cytogenetics examination activities for the purpose of clinical diagnosis</u>	In house documented methods incorporating manufacturers' instructions where relevant	
Amniotic fluid, chorionic villus, solid tissue, blood (lithium heparin), bone marrow	Karyotype	Culture and karyotype analysis using G-banding LG-CF-SOP-3 and light microscope using SOPs: LG-CF-SOP-4, LG-CF-SOP-6, LG-PP-SOP-11, LG-PPSOP-4 (amniotic fluid) LG-CF-SOP-5, LG-CF-SOP-6, LG-PP-SOP-11,, LG-PPSOP-4 (chorionic villus) Culture and karyotype analysis using G-banding LG-CF-SOP-3 and image analysis via automatic slide scanner /Cytovision using SOPs: LG-CF-SOP-7, LG-CF-SOP-6, LG-PP-SOP-5, LG-PP-SOP-12, LG-PP-SOP-4 (solid tissue)	ASH



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HUMAN BODY FLUIDS/TISSUE (cont'd)	<u>Cytogenetics examination activities for the purpose of clinical diagnosis (cont'd)</u>	In house documented methods incorporating manufacturers' instructions where relevant	
Amniotic fluid, chorionic villus, solid tissue, blood (lithium heparin), bone marrow (cont'd)	Karyotype (cont'd)	LG-CF-SOP-1, LG-CF-SOP-14, LG-PP-SOP-9, LG-PP-SOP-3, LG-PP-SOP-5, LG-PP-SOP-12,, LG-PP-SOP-2 (blood) LG-CF-SOP-2, LG-PP-SOP-5, LG-PP-SOP-12,, LG-SO-SOP-6 (bone marrow)	ASH
Blood (lithium heparin anticoagulant)	Karyotype	Culture and karyotype analysis using G-banding and image analysis via automatic slide scanner /Cytovision LG-CF-SOP-1, LG-CF-SOP-3, LG-PP-SOP-3, LG-PP-SOP-5, LG-PP-SOP-12,, LG-PP-SOP-2	ASH
Bone marrow	Karyotype	Culture and karyotype analysis using G-banding and image analysis via automatic slide scanner /Cytovision LG-CF-SOP-2, LG-CF-SOP-3, LG-PP-SOP-5, LG-PP-SOP-12,, LG-SO-SOP-6	ASH
Illumina Bead Array GTC Files received from ISO 15189 accredited laboratory 9028	Interpretation of data to detect microscopic chromosomal imbalance (gains and losses) expressed as changes to copy number in: Postnatal disorders, prenatal diagnosis, neoplastic genetics	SNP array analysis using Illumina BlueFuse Multi software and SOP LG-RD-SOP-18	ASH
Fixed cells/Formalin Fixed Paraffin Embedded tissue (FFPE) from: Peripheral Blood Bone Marrow Amniotic fluid CVS- Chronic villus samples Solid tissues Solid tumours Buccal smears	Detection of chromosomal aberrations loci changes including confirmation of array CGH findings and rearrangements in the diagnosis of haematological malignancy, bone marrow failure syndromes, constitutional disorders, solid tumours	Pre analytical preparation of tissues for Fluorescent in situ hybridisation procedures (FISH) using Hybrite, Water bath, hot-plate and SOPs: LG-CF-SOP-9 (FFPE slides) (fixed suspension samples) followed by:	BEX



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<p>HUMAN BODY FLUIDS/TISSUE (cont'd)</p> <p>Fixed cells/Formalin Fixed Paraffin Embedded tissue (FFPE) from: Peripheral Blood Bone Marrow Amniotic fluid CVS- Chronic villus samples Solid tissues Solid tumours Buccal smears (cont'd)</p>	<p><u>Cytogenetics examination activities for the purpose of clinical diagnosis (cont'd)</u></p> <p>Break-apart probes Fusion product probes Single copy probes to detect gain or loss of a specific locus</p>	<p>In house documented methods incorporating manufacturers' instructions where relevant</p> <p>Fluorescent in situ hybridization (FISH) analysis of metaphase and interphase cells using commercial (and including probe validation/verification) using Cyto-vision analysis system and Fluorescent microscopy as defined in SOP LG-SO-MISC-4 v1.16 in conjunction with SOPs LG-CF-SOP-10, LG-CF-SOP-9, LG-SO-SOP-14, LG-CF-SOP-12, LG-CF-SOP-11</p>	BEX
END			



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APPENDIX 1

Phadia Specific IgE	
Code	Item Description
ImmunoCAPS	
Foods	
f1	Egg white
f2	Milk
f3	Cod
f4	Wheat
f5	Rye
f6	Barley
f7	Oat
f8	Maize
f9	Rice
f10	Sesame
f11	Buckwheat
f12	Pea
f13	Peanut
f14	Soya
f15	White Bean
f17	Hazel Nut
f18	Brazil Nut
f20	Almond
f23	Crab
f24	Shrimp
f25	Tomato
f26	Pork
f27	Beef
f31	Carrot
f33	Orange
f35	Potato
f36	Coconut
f37	Blue Mussel
f40	Tuna
f41	Salmon
f42	Haddock
f44	Strawberry
f45	Yeast



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Phadia Specific IgE

Code	Item Description
ImmunoCAPS	
f47	Garlic
f48	Onion
f49	Apple
f50	Chub Mackerel
f51	Bamboo Shoot
f54	Sweet potato
f55	Common millet
f56	Foxtail millet
f57	Japanese millet
f58	Pacific squid
f59	Octopus
f60	Jack mackerel, Scad
f61	Sardine, Japanese Pilchard
f75	Egg Yolk
f76	nBos d4 alpha-lactalbumin, Milk
f77	nBos d5 beta-lactoglobulin, Milk
f79	Gluten
f80	Lobster
f81	Cheese (cheddar type)
f82	Cheese (mould type)
f83	Chicken
f84	Kiwi fruit
f85	Celery
f86	Parsley
f87	Melon
f88	Mutton
f89	Mustard
f90	Malt
f91	Mango
f92	Banana
f93	Cacao
f94	Pear
f95	Peach
f96	Avocado
f98	Gliadin



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Phadia Specific IgE

Code	Item Description
ImmunoCAPS	
f124	Spelt Wheat
f147	Gulf flounder
f182	Lima bean
f201	Pecan nut
f202	Cashew nut
f203	Pistachio nut
f204	Trout
f205	Herring
f206	Mackerel
f207	Clam
f208	Lemon
f209	Grapefruit
f210	Pineapple
f211	Blackberry
f212	Mushroom
f213	Rabbit
f214	Spinack
f215	Lettuce
f216	Cabbage
f217	Brussel Sprout
f218	Paprika
f219	Fennel
f221	Coffee
f222	Tea
f224	Poppy seed
f225	Pumpkin
f226	Pumpkin seed
f227	Sugar-beet seed
f231	Boiled milk
f232	nGal d2 Ovalbumin, Egg
f233	nGal d1 Ovomucoid, Egg
f234	Vanilla
f235	Lentil
f236	Cow's whey
f237	Apricot



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Phadia Specific IgE

Code	Item Description
ImmunoCAPS	
f242	Cherry
f244	Cucumber
f245	Egg
f246	Guar, guar gum (E412)
f247	Honey
f253	Pine nut, pignoles
f254	Plaice
f255	Plum
f256	Walnut
f258	Squid
f259	Grape
f260	Broccoli
f261	Asparagus
f262	Aubergine
f263	Green pepper
f264	Eel
f265	Caraway
f266	Mace
f267	Cardamom
f268	Clove
f269	Basil
f270	Ginger
f271	Anise
f272	Tarragon
f273	Thyme
f274	Marjoram
f275	Lovage
f276	Fennel, Fresh
f277	Dill
f278	Bay Leaf
f279	Chilli pepper
f280	Black pepper
f281	Curry
f283	Oregano
f284	Turkey meat



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Phadia Specific IgE

Code	Item Description
ImmunoCAPS	
f285	Elk/moose meat
f286	Mare's milk
f287	Red kidney bean
f288	Blueberry
f289	Date
f290	Oyster
f291	Cauliflower
f292	Guava
f293	Papaya
f294	Passion fruit
f295	Carambola
f296	Carob (E410)
f297	Gum arabic (E414)
f298	Tragacanth (E413)
f299	Sweet chestnut
f300	Goat milk
f301	Persimon
f302	Mandarin
f303	Halibut
f304	Langust (spiny lobster)
f305	Fenugreek
f306	Lime
f307	Hake
f308	Sardine
f309	Chickpea
f310	Blue vetch
f311	Megrim
f312	Sword fish
f313	Anchovy
f314	Snail
f315	Green bean
f316	Rape seed
f317	Corriander
f318	Jack fruit
f319	Beetroot



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Phadia Specific IgE

Code	Item Description
ImmunoCAPS	
f320	Crayfish
f321	Horse meat
f322	Red Currant
f323	nGal d3 Conalbumin
f324	Hop
f325	Sheep milk
f326	Sheep whey
f328	fig
f329	Watermelon
f330	Rose Hip
f331	Saffron
f332	Mint
f333	Linseed
f334	nBos d Lactoferrin, Milk
f335	Lupin seed
f336	Jujube
f337	Sole
f338	Scallop
f339	Allspice
f340	Cochineal extract
f342	Olive
f343	Raspberry
f344	Sage
f345	Macadamia nut
f346	Abalone
f347	Quinoa
f348	Litchi
f351	rPen a1 Tropomyosin, Shrimp
f352	rAra h8 peanut comp
f353	rGly m4 PR-10, Soy
f354	rBer e1 Brazil nut
f355	rCyp c1 Carp
f369	Cat Fish
f381	Red snapper
f384	Whitefish (Inconnu)



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Phadia Specific IgE

Code	Item Description
ImmunoCAPS	
f410	Grouper
f412	Orange roughly
f413	Pollock
f414	Tilapia
f415	Walleye pike
f416	Omega-5 Gliadin
f422	rAra h1 peanut comp
f423	rAra h2 peanut comp
f424	rAra h3 peanut comp
f425	rCor a8 (H nut comp)
f427	rAra h9 peanut comp
f428	rCor a1 (H nut comp)
f439	rCor a14 (H nut comp)
f440	nCor a9 (H nut comp)
f441	rJug r1 Walnut
f442	rJug r3 LTP, Walnut
fx1	(f13, f17, f18, f20, f36) Nut Mix
fx2	(f3, f24, f37, f40, f41) Seafood mix
fx3	(f4, f7, f8, f10, f11) cereal mix
fx5	(f1, f2, f3, f4, f13, f14) common food mix
fx9	(f20, f84, f87, f92, f259) Mixed fruit 1
fx15	(f33, f49, f92, f95) Mixed fruit 2
fx16	(f44, f94, f208, f210) Mixed fruit 3
fx22	(f201, f202, f203, f256) mixed nuts
fx71	(f265, f266, f267, f268) Spice Mix
fx74	(f3, f205, f206, f254) Mixed Fish
Mites	
d1	Dermatophagoides pteronyssinus - HDM
d2	Dermatophagoides farinae - HDM
Insect and Venoms	
i1	Honey bee
i3	Common wasp (yellow jacket)
i70	Fire ant
i71	Mosquito
i75	European hornet



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Phadia Specific IgE

Code	Item Description
ImmunoCAPS	
i204	Horse fly
Occupational	
k70	Green coffee bean
k72	Ispaghula
k75	Isocyanate TDI (Toluene diisocyanate)
k76	Isocyanate MDI (Diphenylmethane diisocyanate)
k77	Isocyanate HDI (Hexamethylene diisocyanate)
k78	Ethylene oxide
k79	Phthalic anhydride
k80	Formaldehyde/Formalin
k82	Latex
k84	Sunflower seed
k86	Trimellitic anhydride, TMA
k87	nAsp 021 alpha-amylase
Drugs	
c1	Penicilloyl G
c2	Penicilloyl V
c5	Ampicilloyl
c6	Amoxicilloyl
c7	Cefaclor
c8	Chlorhexidine
c71	Insulin bovine
c73	Insulin human
c74	Gelatin bovine
c202	Suxamethonium
c260	Morphine
Epidermals and Animal Proteins	
e1	Cat dander
e3	Horse dander
e4	Cow dander
e5	Dog dander
e6	Guinea pig epithelium
e7	Pigeon droppings
e70	Goose feathers
e71	Mouse epithelium



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Phadia Specific IgE

Code	Item Description
ImmunoCAPS	
e72	Mouse urine proteins
e73	Rat epithelium
e74	Rat urine proteins
e77	Budgerigar droppings
e78	Budgerigar feathers
e80	Goat epithelium
e81	Sheep epithelium
e82	Rabbit epithelium
e83	Swine epithelium
e84	Hamster epithelium
e85	Chicken feathers
e86	Duck feathers
e87	Rat epithelium serum and urine proteins
e88	Mouse epithelium serum and urine proteins
e89	Turkey feathers
e196	Parakeet feathers
e197	Parakeet droppings
e200	Canary bird droppings
e201	Canary bird feathers
e208	Chinchilla epithelium
e211	Rabbit urine proteins
e213	Parrot feathers
e215	Pigeon feathers
ex71	(e70, e85, e86, e89) Feather mix
ex72	(e78, e201, e196, e213, e214) Cage bird mix
Microorganisms	
m2	Cladosporium herbarum
m3	Aspergillus fumigatus
m5	Candida albicans
m6	Alternaria alternata
m80	Staphylococcal enterotoxin A
m81	Staphylococcal enterotoxin B
m202	Acremonium kiliense
m227	Malassezia
mx1	(m1, m2, m3, m6) Mould Mix



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Phadia Specific IgE

Code	Item Description
ImmunoCAPS	
Weed Pollens	
w6	Mugwort
w203	Rape
wx3	(w6, w9, w10, w12, w20) Weed Mix
Tree Pollens	
t2	Grey alder
t3	Common silver birch
t4	Hazel
t7	Oak
t8	Elm
t11	Maple leaf sycamore, London plane
t16	White pine
t17	Japanese cedar
t25	European ash
t201	Spruce
tx8	(t1, t3, t4, t7, t11) tree mix
tx9	(t2, t3, t4, t7, t12) Tree Mix 2
Grass Pollens	
g1	Sweet vernal grass
g5	Rye-grass
g6	Timothy grass
g12	Cultivated rye
gx3	(g1, g5, g6, g12, g13) Grass mix
Miscellaneous	
o1	Cotton, crude fibers
o70	Seminal fluid
o215	nGal-alpha-1,3-Gal (alpha-Gal) Thyroglobulin, bovine
pax4	(f4, f14, k87, i202) Millers mix
Phadiatop	Inhaled allergen mix