

Schedule of Accreditation
 issued by
United Kingdom Accreditation Service

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

 9844 Accredited to ISO 15189:2022	<p style="text-align: center;">York and Scarborough Teaching Hospitals NHS Foundation Trust</p> <p style="text-align: center;">Issue No: 027 Issue date: 07 January 2026</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%; padding: 5px;"> Pathology Department Pathology Building Hull Royal Infirmary Anlaby Road Hull HU3 2JZ </td><td style="width: 50%; padding: 5px;"> Contact: Dave Oglesby Tel: +44 (0)148 260 7722 E-Mail: david.oglesby@nhs.net Website: www.hey.nhs.uk </td></tr> </table>	Pathology Department Pathology Building Hull Royal Infirmary Anlaby Road Hull HU3 2JZ	Contact: Dave Oglesby Tel: +44 (0)148 260 7722 E-Mail: david.oglesby@nhs.net Website: www.hey.nhs.uk
Pathology Department Pathology Building Hull Royal Infirmary Anlaby Road Hull HU3 2JZ	Contact: Dave Oglesby Tel: +44 (0)148 260 7722 E-Mail: david.oglesby@nhs.net Website: www.hey.nhs.uk		
Testing performed by the Organisation at the locations specified below			

Locations covered by the organisation and their relevant activities

Location details	Activity	Location code	
Address Pathology Laboratory Hull Royal Infirmary Anlaby Road Hull HU3 2JZ	Local contacts Jennifer Williams Jennifer.williams69@nhs.net Jennifer Fulthorpe j.fullthorpe@nhs.net Carl Burkinshaw Carl.burkinshaw1@nhs.net Angela Carling angela.carling@nhs.net Mark Hajjawi mark.hajjawi@nhs.uk Lisa Mead: lisa.mead2@nhs.net	Haematology Blood Transfusion Automated Biochemistry Cellular Pathology Specialist Biochemistry and Immunology Microbiology and Virology	A
Address Pathology Laboratory Castle Hill Laboratory Castle Hill Hospital Castle Road Cottingham HU16 5JQ	Local contact Jennifer Williams Jennifer.williams69@nhs.net Carl Burkinshaw Carl.burkinshaw1@nhs.net	Haematology Biochemistry	B



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Site activities performed away from the locations listed above:

Location details	Activity	Location code
Address Women's and Children's Hospital Hull Royal Infirmary Anlaby Road Hull HU3 2JZ	Local contact Amanda Burns Amanda.burns8@nhs.net Tel: 01482 607791	Blood storage & issue only Management of Women's and Children's theatre fridge
Address Hull Royal Infirmary Anlaby Road Hull HU3 2JZ	Local contact Amanda Burns Amanda.burns8@nhs.net Tel: 01482 607791	Blood storage & issue only Management of Tower Block blood fridge
Address Queen's Centre Castle Hill Hospital Castle Road Cottingham HU16 5JQ	Local contact Amanda Burns Amanda.burns8@nhs.net Tel: 01482 607791	Blood storage & issue only Management of Day unit blood fridge Management of Cardiology Unit blood fridge
Hospital Wards Hull Royal Infirmary Anlaby Road Hull HU3 2JZ	Local contact Alex Clubley alexandra.clubley@nhs.net Tel: 01482 607726	Point of Care Testing Clinical Chemistry
Hospital Wards Castle Hill Hospital Castle Road Cottingham HU16 5JQ	Local contact Alex Clubley alexandra.clubley@nhs.net Tel: 01482 607726	Point of Care Testing Clinical Chemistry
Adult outpatients Clinic East Riding Hospital Swinemoor Lane Beverley HU17 0FA	Local contact Alex Clubley alexandra.clubley@nhs.net Tel: 01482 607726	Point of Care Testing Clinical Chemistry



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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 Whole Blood: EDTA samples Red cells and plasma	<u>Blood Transfusion examination activities for the purpose of clinical diagnosis</u> Blood Grouping <ul style="list-style-type: none">• A B O• Rhesus D status	Manufacturer's instructions and documented In-house methods using: Glass microbead column technology using Ortho Vision analysers SOP BT/SOP/HU-3 ABO / RhD Grouping and Antibody Screening Glass microbead column technology using manual Ortho BioVue methods	A
Plasma	Red cell Antibody Screening Antibodies of the following systems: <ul style="list-style-type: none">• Rhesus• Kell• Duffy• Kidd• MNSs• P• Lutheran• Lewis Compatibility Testing <ul style="list-style-type: none">• Manual testing of patient plasma and donor red blood cells.	Glass microbead column technology using Ortho Vision analysers SOP BT/SOP/HU-3 ABO / RhD Grouping and Antibody Screening SOP BT/SOP/HU-5 Antibody Identification (Panels) Glass microbead column technology using manual Ortho BioVue methods SOP BT/SOP/HU-5 Antibody Identification (Panels) SOP BT/SOP/HU-3 ABO / RhD Grouping and Antibody Screening Glass microbead column technology using manual OrthoBioVue. SOP BT/SOP/HU-20 Serological Crossmatch and Issue Procedure	



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HUMAN BODY FLUIDS (cont'd)	<u>Blood Transfusion examination activities for the purpose of clinical diagnosis</u> (cont'd)	Manufacturer's instructions and documented In-house methods using:	
Red cells	Direct anti-globulin test	Glass microbead column technology using Ortho Vision analysers SOP BT/SOP/HU-6 Direct Antiglobulin Test (DAT) SOP BT/SOP/HU-3 ABO / RhD Grouping and Antibody Screening Glass microbead column technology using manual Ortho BioVue methods SOP BT/SOP/HU-6 Direct Antiglobulin Test (DAT)	A
Red cells	Rhesus phenotype and Kell type to include the specific antigens: D, C, c, E, e, K	Glass microbead column technology using: Ortho Vision analysers SOP BT/SOP/HU-7 Rh Phenotyping	
Red cells	Kleihauer test for estimation of foetal-maternal haemorrhage	Manual modified Kleihauer-Betke method. SOP BT/SOP/HU-9 Preparation and Staining of Kleihauer Slides SOP BT/SOP/HU-10 Kleihauer Reading / Reporting of Slides and Follow Up Testing	



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HUMAN BODY FLUIDS (cont'd)	<u>Coagulation examination activities for the purpose of clinical diagnosis</u>	Manufacturer's instructions and documented In-house methods using:	
Plasma (tri-sodium citrate)	Blood Coagulation Prothrombin time Activated partial Thromboplastin time using Actin FS, Actin FSL and Pathromtin Clauss Fibrinogen Thromboplastin time Fibrinogen Thrombin time INR for warfarin therapy APTT/APTR for Heparin monitoring Reptilase time Mixing tests	Sysmex Coagulation Auto Analyser Optical clot detection SOP HA/SOP/HU-37 Routine Coagulation Tests SOP HA/SOP/HU-37 Routine Coagulation Tests Sysmex Coagulation CN6000 and CN3500	A
Plasma (tri-sodium citrate)	D-Dimer Anti-Xa levels Factor's: VII IX XI XII V X II VIII Lupus anticoagulant	Immunoassay SOP HA/SOP/HU-37 Routine Coagulation Tests Chromogenic detection SOP HA/SOP/HU-39 Biophen Heparin LRT LMWH Anti-Xa Assay Clot based optical assay SOP HA/SOP/HU-40 Factor Assays Clot based optical assay SOP HA/SOP/HU-38 Lupus Anticoagulant Screening on the Sysmex CN Series Coagulometers	



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HUMAN BODY FLUIDS (cont'd) Plasma (tri-sodium citrate) (cont'd)	<u>Coagulation examination activities for the purpose of clinical diagnosis</u> (cont'd) Von Willebrand factor antigen Von Willebrand factor activity Inhibitor Screen and Bethesda Assay Chromogenic Factor VIII <u>Emicizumab Drug Concentration</u>	Manufacturer's instructions and documented In-house methods using: Latex base turbidometric assay SOP HA/SOP/HU-41 Von Willebrand Antigen and Activity Assay Clot based Optical Detection and Chromogenic Assay SOP HA/SOP/HU-27 Screen for an Inhibitor of the Intrinsic Pathway SOP HA/SOP/HU-28 Bethesda Assay for an Inhibitor of the Intrinsic Pathway Chromogenic Assay SOP HA/SOP/HU-42 Chromogenic FVIII Assay (Human) SOP HA/SOP/HU-44 Chromogenic FVIII Assay (Bovine) Clot based Optical Assay SOP HA/SOP/HU-48 Emicizumab Drug Concentration Assay on the CN Series Coagulometer	A



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HUMAN BODY FLUIDS (cont'd) Whole blood in EDTA	<u>Haematology examination activities for the purpose of clinical diagnosis</u> Full Blood count: <ul style="list-style-type: none">• Haemoglobin• Red Blood Cells• Platelet count• Haematocrit• Mean cell volume• Mean cell haemoglobin• Red cell distribution width• White cell count• White Cell Differential• Neutrophils• Lymphocytes• Monocytes• Eosinophils• Basophils Nucleated Red Blood Cells Fluorescent Platelet Count Reticulocyte count (including immature reticulocyte fraction and haemoglobin content)	Sysmex XN series (XN-9000 HRI and XN-3100 CHH) HA/SOP/HU-61 Sysmex XN Series – Operation Procedures.	A, B



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HUMAN BODY FLUIDS (cont'd)	<p><u>Haematology examination activities for the purpose of clinical diagnosis (cont'd)</u></p> <p>Identification of normal and abnormal morphologies including WBC differential count</p> <p>Malaria screening for: <i>P. falciparum</i> <i>P. vivax</i> <i>P. ovale</i> <i>P. malariae</i> <i>P. knowlesi</i></p>	<p>Manufacturer's instructions and documented In-house methods using:</p> <p>Sysmex SP-50 automated slide preparation and manual microscopy May-grunwald Giemsa stain</p> <p>Manual slide preparation and manual microscopy – May-grunwald Giemsa stain</p> <p>SOP HA/SOP/HU-63 Routine Running of the Sysmex SP-50 Slide/Stain Maker</p> <p>SOP HA/SOP/HU-11 Manual Preparation of Blood Films</p> <p>SOP HA/SOP/HU-74 Routine Running and Maintenance of DI-60 Digital Morphology</p> <p>SOP HA/SOP/HU-54 Examination of Blood Films</p> <p>Thick and thin films</p> <p>Giemsa stain and manual microscopy</p> <p>Apacor Care US Malaria Rapydtest kit</p> <p>SOP HA/SOP/HU-73 Rapid Diagnostic Test for Malaria</p> <p>MGG stain using Mirastainer II</p>	A A A
Bone marrow aspirate slides	Reporting of normal and abnormal morphologies		
Whole blood in EDTA	Blood film morphology	DI-60 Digital morphology platform and Cellavision client software	A



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HUMAN BODY FLUIDS (cont'd)	<u>Haematology examination activities for the purpose of clinical diagnosis (cont'd)</u>	Manufacturer's instructions and documented In-house methods using:	
Whole blood in EDTA, serum, plasma	Detection of infectious mononucleosis heterophile antibodies	Clearview IM II test chromatographic immunoassay kit HA/SOP/HU-87 Infectious Mononucleosis Screening	A
Plasma from Whole blood in EDTA	Infectious mononucleosis screen – presence of heterophile antibodies	Dialab DIAQUICK Infectious Mononucleosis Screening cassette using lateral flow technology SOP HA/S/064 Documented in-house methods to meet the requirements of the Sickle Cell and Thalassaemia (SCT) screening programme as defined in the 'NHS Sickle Cell and Thalassaemia Screening Programme: laboratory QA evidence requirements.'	A
Whole blood in EDTA	Antenatal Haemoglobinopathy screening: Detection of haemoglobin variants: HbA2 HbF HbS.	Automated HPLC using TOSOH G11 HA/SOP/HU-34 Routine Use of the HPLC Analyser Used for Haemoglobinopathy Testing	A
Whole blood in EDTA	Quantitation of HbA2, HbF levels and determine the presence of variant haemoglobins		
Whole blood in EDTA	Identification of presence of sickling haemoglobin variant	SICKLEDEX reagent and Sickle-Chex controls, tube-based oxygen reduction turbidity test HA/SOP/HU-78 SICKLEDEX Sickle Solubility	A



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HUMAN BODY FLUIDS (cont'd)	<u>Haematology examination activities for the purpose of clinical diagnosis</u> (cont'd)	Manufacturer's instructions and documented In-house methods using:	
Whole blood in EDTA	Determine the presence of variant haemoglobins – HbA, HbF, HbS, HbC	Sebia HYDRASYS 2 using acid and alkaline gel electrophoresis, migration and staining HA/SOP/HU-88 Gel Electrophoresis for Haemoglobinopathies	A
Whole blood in EDTA	Detection of G6PD	Visual qualitative fluorescence using Trinity Biotech G-6-PDH Deficiency kit SOP HA/SOP/HU-83 G6PD Screening Test	
Serum/plasma	<u>Biochemistry examination activities for the purposes of clinical diagnosis</u> Quantitative determination of: ALT(IFCC)	Documented in house methods and manufacturer's instructions for analysis using Beckman AU5800 (HRI) and Beckman AU 680 (CHH) Kinetic UV Colorimetric SOP CB/SOP/HU-1 Daily Operational Procedure for AU5800 11 and AU5800 22	A, B
Serum/plasma/urine	ALP(IFCC) AST CK NAC Ethanol Glucose hexokinase LDH (L-P) IFCC Urea STAT	SOP CB/SOP/HU-69 Beckman Coulter AU 680 Daily Maintenance Guide Immunoturbidimetric	



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HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry examination activities for the purposes of clinical diagnosis</u> (cont'd)	Documented in house methods and manufacturer's instructions for analysis using Beckman AU5800 (HRI) and Beckman AU 680 (CHH)	
Serum	Alpha-1-antitrypsin	SOP CB/SOP/HU-1 Daily Operational Procedure for AU5800 11 and AU5800 22	A
CSF/Urine	UALB		
Serum/plasma	Albumin in CSF and Urine B2 Microglobulin C3/C4 Complement C-Reactive Protein Haptoglobin IgA IgG IgM Rheumatoid Factor Transferrin Vancomycin		A, B
Serum/Plasma	Quantitative determination of: Albumin BCP	BCP Dye-Binding Colorimetric SOP CB/SOP/HU-1 Daily Operational Procedure for AU5800 11 and AU5800 22 SOP CB/SOP/HU-69 Beckman Coulter AU 680 Daily Maintenance Guide Kinetic Colorimetric	A, B
Serum/plasma/urine/ Serum/plasma	Alpha-amylase Gamma- Glutamyltransferase Total Bile Acids		A
Plasma	Ammonia (GLDH)	Direct enzymatic SOP CB/SOP/HU-1 Daily Operational Procedure for AU5800 11 and AU5800 22 SOP CB/SOP/HU-69 Beckman Coulter AU 680 Daily Maintenance Guide Enzyme immunoassay	



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HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry examination activates for the purposes of clinical diagnosis</u> (cont'd)	Documented in house methods and manufacturer's instructions for analysis using Beckman AU5800 (HRI) and Beckman AU 680 (CHH)	
Urine	Amphetamine/Ecstasy	SOP CB/SOP/HU-1 Daily Operational Procedure for AU5800 11 and AU5800 22 SOP CB/SOP/HU-69 Beckman Coulter AU 680 Daily Maintenance Guide	
Serum/plasma Urine	Benzodiazepines Carbamazepine Methadone metabolite Gentamicin Methotrexate Morphine/codeine/ heroin Phenobarbital Phenytoin		
Serum/plasma Urine Serum/plasma	THC Cannabis Theophylline Valproic Acid		
Serum/plasma	Angiotensin Converting Enzyme (ACE)	Enzymatic SOP CB/SOP/HU-1 Daily Operational Procedure for AU5800 11 and AU5800 22 SOP CB/SOP/HU-69 Beckman Coulter AU 680 Daily Maintenance Guide	A
Serum/plasma Serum/plasma/urine Serum/plasma	Bicarbonate Cholesterol (CHOD-PAP) Creatinine enzymatic Fructosamine HDL -Cholesterol Lactate Salicylate Acid Triglyceride Uric Acid		A, B A
Serum/plasma Serum/plasma/urine			



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HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry examination activates for the purposes of clinical diagnosis</u> (cont'd)	Documented in house methods and manufacturer's instructions for analysis using Beckman AU5800 (HRI) and Beckman AU 680 (CHH) Photometric /colorimetric	
Serum/plasma/urine	Calcium (Arsenazo)	SOP CB/SOP/HU-1 Daily Operational Procedure for AU5800 11 and AU5800 22 SOP CB/SOP/HU-69 Beckman Coulter AU 680 Daily Maintenance Guide	A, B
Serum/plasma	Direct Bilirubin Inorganic phosphate Iron (TPTZ) Lithium Magnesium Total Protein Protein		A
Serum/plasma Urine/CSF		Indirect ISE	
Serum/plasma/urine	Chloride	SOP CB/SOP/HU-1 Daily Operational Procedure for AU5800 11 and AU5800 22 SOP CB/SOP/HU-69 Beckman Coulter AU 680 Daily Maintenance Guide	A, B
	Potassium Sodium		
Serum/plasma	Digoxin	Immuno-inhibition SOP CB/SOP/HU-1 Daily Operational Procedure for AU5800 11	A
		Colorimetric	
Serum/plasma	Total Bilirubin	SOP CB/SOP/HU-1 Daily Operational Procedure for AU5800 11 and AU5800 22 SOP CB/SOP/HU-69 Beckman Coulter AU 680 Daily Maintenance Guide	A, B



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HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry examination activates for the purposes of clinical diagnosis</u> (cont'd) Serum Paracetamol Tobramycin TSH FT4 FT3 Anti TPO Cortisol FSH/LH Prolactin Progesterone Oestradiol Testosterone DHEA AFP CA125 CA153 CA199 CEA PSA HCG B12 Folate Ferritin	Documented in house methods and manufacturer's instructions for analysis using Beckman AU5800 (HRI) and Beckman AU 680 (CHH) Enzyme immunoassay SOP CB/SOP/HU-1 Daily Operational Procedure for AU5800 11 and AU5800 22 Beckman UniCel DXi 800 (Magnetic particle based Chemiluminescence) SOP CB/SOP/HU-22 DxI Operation Protocol	A



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HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry examination activates for the purposes of clinical diagnosis</u> (cont'd)	Documented in house methods and manufacturer's instructions for analysis using: Roche Cobas e411(Magnetic particle based Chemiluminescence) SOP CB/SOP/HU-24 e411 Operation Protocol	A
Serum/plasma	ACTH Trop T (high sensitivity) Pro BNP P1NP Human growth hormone (Hgh) IGFBP-3 IGF-1	IDS-isys (Magnetic particle based Chemiluminescence) SOP CB/SOP/HU-81 IDS iSYS Operation Waters HPLC (High Pressure Liquid Chromatography)	
Serum/plasma	Vitamin A Vitamin E	SOP CB/SOP/HU-102 Analysis of Vitamins A and E by Waters HPLC	



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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) Urine	<p><u>Biochemistry examination activates for the purposes of clinical diagnosis</u> (cont'd)</p> <p>Toxicology Confirmation of the following: Morphine 6-Monoacetylmorphine Morphine Glucuronide Codeine Dihydrocodeine Acetyl codeine Amphetamine Methamphetamine Methylenedioxymetamphetamine (MDMA) Methylenedioxymethamphetamine (MDA) Cocaine metabolite (benzoylecgonine) Pholcodine Oxycodone Tramadol Meconin Methadone Methadone metabolite (EDDP)</p> <p>Buprenorphine/ Norbuprenorphine</p> <p>Cortisol</p> <p>Drug Screening (Chromalynx)</p>	<p>Documented in house methods and manufacturer's instructions for analysis using:</p> <p>Waters Acuity Tandem Quadruple TQD (Tandem Mass Spectrophotometry)</p> <p>SOP CB/SOP/HU-84 Analysis of drugs of abuse</p> <p>SOP CB/SOP/HU-88 Urine Buprenorphine analysis using LC-MS/MS</p> <p>SOP CB/SOP/HU-91 SOP - Urine Cortisol by LC/MS/MS</p> <p>SOP CB/SOP/HU-87 Systematic Toxicological Analysis Using LC/MS and ChromaLynx</p>	A



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HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry examination activates for the purposes of clinical diagnosis</u> (cont'd)	Documented in house methods and manufacturer's instructions for analysis using: Waters Acuity Tandem Quadruple Micromass Quattro XE Mass (Tandem Mass Spectrophotometry)	
Serum/plasma	Tacrolimus/FK506 Ciclosporin Testosterone and Androstenedione Vitamin D	SOP CB/SOP/HU-96 LC/MSMS Analysis of Tacrolimus and Ciclosporin SOP CB/SOP/HU-97 LC/MS/MS Analysis of Steroid Hormones BI/M/52 Agilent 220FZ/220Z (Atomic Absorption spectrophotometry)	A
Serum/plasma	Trace Metals: Copper Zinc Selenium	BI/M/AA/007 BI/M/AA/007 BI/M/AA/011	
Whole blood	Lead	Lead BI/M/AA/008 Helena SAS-3	
CSF	Xanthochromia	Northstar BIO-UV (Spectrophotometry) SOP CB/SOP/HU-163 Assessment of CSF Xanthochromia by Spectrophotometric Scanning Advanced Instrument Osmometer 3320 (freezing point osmometry)	
Serum/plasma/urine	Osmolality	BI/M/002	
Sweat	Chloride	Sherwood 926 Chloride meter BI/M/016	
Faeces	FIT - Faecal immunochemical testing - Haemoglobin	HM-KACKarc SOP CB/SOP/HU-73 HM-JACKarc standard operating procedure	



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HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry examination activates for the purposes of clinical diagnosis</u> (cont'd)	Documented in house methods and manufacturer's instructions for analysis using: Manual test: Colorimetric	
Urine	Urine oxalate	SOP CB/SOP/HU-122 Urine Oxalate	A
Faeces	Paraquat	SOP CB/SOP/HU-121 Qualitative Test for Paraquat in Urine	
Urine	Calculated Tests (data from primary tests, primary test sample requirements listed under that test) 24hr Urine Calcium	ELISA Schebo Pancreatic Elastase kit SOP CB/SOP/HU-40 Blood Sciences Offline Calculated Tests	
Urine	24hr Urine Creatinine		
Urine	24hr Urine Phosphate		
Urine	24hr Urine Potassium		
Urine	24hr Urine Sodium		
Urine	24hr Urine Uric Acid		
Urine	Albumin: Creatinine Ratio		
Urine	Protein: Creatinine Ratio		
Serum	Calcium, adjusted		
Urine	Calcium: Creatinine Excretion Ratio		
Urine	Calcium: Creatinine Ratio		
Serum and urine	Creatinine Clearance (L/24hr)		
Serum and urine	Creatinine Clearance (mL/min)		
Serum	eGFR (CKD-EPI)		
Serum	Non-HDL Cholesterol		



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HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry examination activates for the purposes of clinical diagnosis</u> (cont'd) Calculated Tests (data from primary tests, primary test sample requirements listed under that test) Serum Urine Serum Serum Serum Serum and urine Urine Whole blood	Documented in house methods and manufacturer's instructions for analysis using: LDL-Cholesterol Protein:Creatinine Ratio Free androgen index AKI Globulins Renal tubular absorption of phosphate (TmP/GFR) 24hr Urine Uric Acid <u>Provision of Point of Care testing</u> Glucose	A
		Roche Accuchek Inform II glucose dehydrogenase method SOP PC/SOP/HU-26 Roche Inform II Glucose Meter Standard Operating Procedure	A - E

(See Appendix 1 for details of accredited examinations at location types)



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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/Equipment/Techniques used	Location Code
HUMAN BODY TISSUE SAMPLES Fixed, fresh and frozen tissue, excisional and incisional biopsies and surgical resection specimens	<u>Histopathology & Neuropathology</u> Routine Histopathology & Neuropathology examination activities: Examination of tissues to identify or exclude morphological and cytological abnormalities for the purposes of clinical diagnosis	Documented in house methods and manufacturer's instructions for analysis using: Macroscopic and Microscopic examination: SOP CP/SOP/HU-123 Specimen Dissection and Processing and as appropriate to specimen type CP/INF/HU-76 Specimen Codes and Points: General specimens Cardiothoracic GIT and Liver Gynaecological Head and Neck Skin Soft Tissue and Bone Urology Breast Central and peripheral nervous system Ophthalmic <u>Specimen dissection & tissue processing</u> Documented in-house procedure SOP CP/SOP/HU-123 Specimen Dissection and Processing in conjunction with manufacturer's instructions for Peloris II & Leica ASP 300 tissue processors <u>Tissue Embedding</u> Documented in-house procedure SOP CP/SOP/HU-112 Tissue Embedding in conjunction with manufacturer's instructions for Leica EG1160, Leica Histocore Arcadia and Medite tissue embedding centres	A



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HUMAN BODY TISSUE SAMPLES (cont'd) Fixed, fresh and frozen tissue, excisional and incisional biopsies and surgical resection specimens DIF: Skin, renal and buccal mucosa biopsy Frozen sections Intra-operatives: Central and peripheral nervous system.	<u>Histopathology & Neuropathology</u> (cont'd) Routine Histopathology & Neuropathology examination activities: Examination of tissues to identify or exclude morphological and cytological abnormalities for the purposes of clinical diagnosis Diagnostic Frozen sections and Intra-operatives – frozen / smears	Documented in house methods and manufacturer's instructions for analysis using: <u>Tissue Sectioning</u> Documented in-house procedure SOP CP/SOP/HU-113 Microtomy .. Sections are produced on microtomes; Leica RM2235, Leica RM2135 and Leica Histocore Biocut. Direct immunofluorescence SOP CP/SOP/HU-17 Direct Immunofluorescence Technique (DIF) SOP CP/SOP/HU-17 DIF Antibody Dilutions SOP CP/SOP/HU-13 Preparation of Intra-Operative Smears SOP CP/SOP/HU-10 Frozen Section Procedure Documented in-house procedure SOP CP/SOP/HU-9 (special techniques) in conjunction with manufacturer's instructions for the Leica cryostat CM1900 and CM1850 SOP CP/SOP/HU-10 Frozen Section Procedure CP/SOP/HU-13 Preparation of Intra-operative Smears <u>Staining</u> Automated Routine Stains	A



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HUMAN BODY TISSUE SAMPLES (cont'd) Fixed, fresh and frozen tissue; excisional and incisional biopsies and surgical resection specimens	<u>Routine Histopathology & Neuropathology examination activities:</u> Examination of tissues to identify or exclude morphological and cytological abnormalities for the purposes of clinical diagnosis Nuclei and other cellular components Acid mucins, elastic fibres & connective tissue Acid and neutral mucins Acid mucopolysaccharides Amyloid Elastic fibres Protozoans Gram +/- organisms Fungi Haemosiderin Basement membrane	Documented in-house procedure SOP CP/SOP/HU-114 Routine Staining in conjunction with manufacturer's instructions for & Leica Autostainer XL and Dako Coverstainer Haematoxylin & Eosin CP/SOP/HU-11 Rapid Haematoxylin and Eosin for Frozen Sections & CP/SOP/HU-92 Haematoxylin and Eosin manual and CP/SOP/HU-114 Routine Staining automated Manual Special Stains: Documented in-house procedure SOP CP/SOP/HU-83 Special Staining. Alcian Blue EVG (Millers) CP/SOP/HU-87 Alcian Blue PAS & Diastase CP/SOP/HU-85 Alcian Blue pH 2.5 CP/SOP/HU-86 Congo Red CP/SOP/HU-69 Elastic van Gieson (Millers) CP/SOP/HU-88 Giemsa CP/SOP/HU-89 Gram CP/SOP/HU-90 Grocott Gomori CP/SOP/HU-91 Iron (Perls Prussian Blue) CP/SOP/HU-93 Jones Methenamine Silver CP/SOP/HU-94	A



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HUMAN BODY TISSUE SAMPLES (cont'd) Fixed, fresh and frozen tissue; excisional and incisional biopsies and surgical resection specimens	<u>Routine Histopathology & Neuropathology examination activities:</u> Examination of tissues to identify or exclude morphological and cytological abnormalities for the purposes of clinical diagnosis (cont'd) Nuclei and other cellular components (cont'd) Melanin Connective tissue Melanin Fibrin Hepatitis B and copper – associated protein PAS +ve substances e.g.: glycogen (and cells of pituitary) and fungi Reticulin fibres Amyloid Metachromatic substances Connective tissue Calcium Spirochetes Tubercle bacilli (TB) Mycobacterium leprae bacilli	Documented in house methods and manufacturer's instructions for analysis using: Haematoxylin & Eosin CP/SOP/HU-11 Rapid Haematoxylin and Eosin for Frozen Sections & CP/SOP/HU-92 Haematoxylin and Eosin manual and CP/SOP/HU-114 Routine Staining automated Masson-Hamperl CP/SOP/HU-95 Masson's Trichrome CP/SOP/HU-96 Melanin Bleach CP/SOP/HU-97 MSB CP/SOP/HU-99 Orcein (Shikata's) CP/SOP/HU-100 Periodic Acid Schiff, CP/SOP/HU-101 Reticulin (Gordon and Sweet) CP/SOP/HU-102 Sirius Red CP/SOP/HU-103 Toluidine blue CP/SOP/HU-104 Van Gieson CP/SOP/HU-105 Von Kossa CP/SOP/HU-106 Warthin Starry CP/SOP/HU-107 Ziehl – Neelsen CP/SOP/HU-109 Wade fite modified ZN CP/SOP/HU-108	A



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HUMAN BODY TISSUE SAMPLES (cont'd) Fixed, fresh and frozen tissue; excisional and incisional biopsies and surgical resection specimens	<u>Routine Histopathology & Neuropathology examination activities:</u> Examination of tissues to identify or exclude morphological and cytological abnormalities for the purposes of clinical diagnosis (cont'd) Human Body Tissue Samples	Documented in house methods and manufacturer's instructions for analysis using: Molecular Diagnostic examination activities: Examination of tissues to identify or exclude mutations within DNA for the purpose of clinical diagnosis, prognosis and treatment options. NRAS/BRAF KRAS EGFR BRAF MSI	A
HUMAN BODY TISSUE SAMPLES & cell blocks	<u>Immunocytochemistry:</u> Immunocytochemistry examination activities: Examination of tissues to identify or exclude morphological and cytological abnormalities for the purposes of clinical diagnosis ACTH secreting cells - pituitary Smooth muscle actin Epithelial cells Foetal liver cells	Documented in-house procedure SOP CP/SOP/HU-32 Molecular Diagnostics over-arching SOP in conjunction with manufacturer's instructions for Biocartis Idylla Molecular platform and test cartridges. Documented in-house procedure SOP CP/SOP/HU-45 Immunocytochemistry Over-arching SOP in conjunction with manufacturer's instructions for & Dako Omnis immunocytochemistry stainers and using antibodies: ACTH ACTIN AE1/3 AFP	



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HUMAN BODY TISSUE SAMPLES & cell blocks (cont'd)	Immunocytochemistry: (cont'd) Immunocytochemistry examination activities: Examination of tissues to identify or exclude morphological and cytological abnormalities for the purposes of clinical diagnosis (cont'd) HGPIN, prostate adenocarcinoma Astrocytoma identification Scattered T cells in germinal centres and mantle zone B cells Epithelial cells of the colon Luminal cells of fallopian tube Parafollicular C cells of the thyroid Smooth muscle of blood vessels and of bowel wall Peripheral nerve ganglion Epithelial cells of the colon All germinal centre cells of tonsil Langerhans Cell in skin Germinal mantle zone B lymphocytes Activated lymphocytes and plasma cells. RS cells in Hodgkin's lymphoma Endothelial cells, activated B & T lymphocytes	Documented in-house procedure SOP CP/SOP/HU-45 Immunocytochemistry Over-arching SOP in conjunction with manufacturer's instructions for & Dako Omnis immunocytochemistry stainers and using antibodies: AMACR ATRX BCL-2 BEP4 CA125 CALCITONIN CALDESMON CALRETININ CAM5.2 CD10 CD1A CD20 CD30 CD31	A



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HUMAN BODY TISSUE SAMPLES & cell blocks (cont'd)	Immunocytochemistry: (cont'd) Immunocytochemistry examination activities: Examination of tissues to identify or exclude morphological and cytological abnormalities for the purposes of clinical diagnosis (cont'd) Endothelial cells T lymphocytes All leucocytes Peripheral nerves Macrophages Mantle zone B cells, germinal centre B cells, plasma cells T cells, cytotoxic suppressor cells Endothelial cells Normal and neoplastic plasma cells, epithelium cells Adenocarcinoma and carcinoid (intestinal epithelium). CEA glycoproteins in adenocarcinoma Islets of Langerhan cells of the pancreas Squamous epithelium epithelial Umbrella cells of ureter	Documented in-house procedure SOP CP/SOP/HU-45 Immunocytochemistry Over-arching SOP in conjunction with manufacturer's instructions for & Dako Omnis immunocytochemistry stainers and using antibodies: CD34 CD3 CD45 CD56 CD68 CD79 CD8 CD99 CD138 CDX-2 CEA CHROMOAGRANIN CK 14 CK19 CK20	A



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HUMAN BODY TISSUE SAMPLES & cell blocks (cont'd)	Immunocytochemistry: (cont'd) Immunocytochemistry examination activities: Examination of tissues to identify or exclude morphological and cytological abnormalities for the purposes of clinical diagnosis (cont'd) Squamous epithelium Squamous epithelium Transitional epithelium of ureter Mast cells, GIST Epithelial cells Cytomegalovirus infected cells Smooth & striated muscle cells Gastrointestinal stromal tumours Epstein Barr virus infected cells Epithelial cell membranes Epithelial cells of the kidney FSH secreting cells of the pituitary G - cells of stomach Bladder cancers, breast cancer Epithelial cells of sweat glands Astrocytes	Documented in-house procedure SOP CP/SOP/HU-45 Immunocytochemistry Over-arching SOP in conjunction with manufacturer's instructions for & Dako Omnis immunocytochemistry stainers and using antibodies: CK34BE12 CK5/6 CK7 CKIT CKPAN CMV DESM DOG1 EBV E-CAD EMA FSH GASTRIN GATA3 GCDF GFAP	A



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HUMAN BODY TISSUE SAMPLES & cell blocks (cont'd)	Immunocytochemistry: (cont'd) Immunocytochemistry examination activities: Examination of tissues to identify or exclude morphological and cytological abnormalities for the purposes of clinical diagnosis (cont'd) GH secreting cells of pituitary hepatocytes Trophoblasts of placenta, secreting HCG Melanoma cells H-pylori bacterium Oligo dentrogloma Leydig and Steroli cells in testis Insulin secreting cells in pancreas Proliferating cells in germinal centre B cells LH secreting cells in pituitary Dendrites and perikarya of neurons Melanocytes Mesothelial cells, some epithelial cells of tonsil Mismatch repair protein MLH1 Mismatch repair protein MSH2 Mismatch repair protein MSH6	Documented in-house procedure SOP CP/SOP/HU-45 Immunocytochemistry Over-arching SOP in conjunction with manufacturer's instructions for Dako Omnis immunocytochemistry stainers and using antibodies: GH HSA HCG HMB45 HPYL IDH-1 INHIBIN INSULIN Ki67 LH Map-2 MELAN A MESOTHELIN MLH1 MSH2 MSH6	A



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HUMAN BODY TISSUE SAMPLES & cell blocks (cont'd)	Immunocytochemistry: (cont'd) Immunocytochemistry examination activities: Examination of tissues to identify or exclude morphological and cytological abnormalities for the purposes of clinical diagnosis (cont'd) Small muscle myosin Alveolar macrophages, pneumocytes, lung adenocarcinoma Neurons Neuroendocrine & neuronal cells Embryonic cells and germ cell tumours Cervical intraepithelial neoplasia Squamous cell carcinoma Colon adenoca Squamous epithelium Tumour types including thyroid, renal cell and ovarian serous carcinomas PD-L1 protein expression Pituitary marker somatotroph cell adenoma Trophoblasts of placenta Mismatch repair protein PMS2 Polyoma virus	Documented in-house procedure SOP CP/SOP/HU-45 Immunocytochemistry Over-arching SOP in conjunction with manufacturer's instructions for Dako Omnis immunocytochemistry stainers and using antibodies: MYOSIN Napsin-A NFP NSE OCT3/4 P16 P40 P53 P63 PAX-8 PDL1 PIT-1 PLAP PMS2 POLV	A



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HUMAN BODY TISSUE SAMPLES & cell blocks (cont'd)	Immunocytochemistry: (cont'd) Immunocytochemistry examination activities: Examination of tissues to identify or exclude morphological and cytological abnormalities for the purposes of clinical diagnosis (cont'd) PRL secreting cells of pituitary Epithelial cells of proximal tubules of kidney Schwann cell, adipocytes, cartilage Pituitary marker gonadotroph cell adenoma Islets of Langerhans cells of pancreas Follicular epithelial cells of thyroid TSH secreting cells of the pituitary Pituitary marker corticotroph cell adenoma Follicular epithelial cells of thyroid, Type II pneumocytes i.e.; smooth muscle, endothelium, lymphocytes Cells of mesenchymal origin Mesenchymal cells Prostatic epithelium used for Prostatic adenocarcinoma	Documented in-house procedure SOP CP/SOP/HU-45 Immunocytochemistry Over-arching SOP in conjunction with manufacturer's instructions for Dako Omnis immunocytochemistry stainers and using antibodies: Prl RCC S100 SF-1 SYNAPTOPHYSIN TYHROGLOBULIN TSH T-PIT TTF1 Vimentin WT1 NKX3.1	A



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HUMAN BODY TISSUE SAMPLES & cell blocks (cont'd)	<p>Immunocytochemistry: (cont'd) Immunocytochemistry examination activities: Examination of tissues to identify or exclude morphological and cytological abnormalities for the purposes of clinical diagnosis (cont'd)</p> <p>Diagnosis and classification of benign prostate lesions, prostate adenocarcinomas and high-grade intraepithelial neoplasia</p> <p>Used in the diagnosis of HCC, Hepatoblastoma, melanoma, testicular germ cell tumours and Wilms' tumour</p> <p>Nuclear staining significant in fibroblasts, nuclear staining is significant in epithelial cells, used in various carcinoma</p> <p>Melanoma marker including spindle cell and desmoplastic subtypes</p> <p>Present in Lymphatic endothelium and other cells used to aid the identification of lymphovascular space invasion</p>	<p>Documented in-house procedure SOP CP/SOP/HU-45 Immunocytochemistry Over-arching SOP in conjunction with manufacturer's instructions for Dako Omnis immunocytochemistry stainers and using antibodies:</p> <p>Dual Staining (AMACR/P63)</p> <p>Glypican-3</p> <p>Bata Catenin</p> <p>SOX-10</p> <p>D240</p>	A



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HUMAN BODY TISSUE SAMPLES & cell blocks (cont'd)	Immunocytochemistry: (cont'd) Immunocytochemistry examination activities: Examination of tissues to identify or exclude morphological and cytological abnormalities for the purposes of clinical diagnosis (cont'd) Breast carcinoma Breast cancer and normal gland Breast cancer ALK positive non-small cell lung carcinomas	Documented in-house procedure SOP CP/SOP/HU-45 Immunocytochemistry Over-arching SOP in conjunction with manufacturer's instructions for Ventana Ultra immunocytochemistry stainers and using antibodies: HER 2 OEST PROG ALK	A



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HUMAN BODY TISSUE SAMPLES, fine needle aspirates & brushings Including Urine, nipple discharge, cyst fluid, skin scrapings, synovial fluid, CSF, sputum, bronchial washings / brushings, pleural fluid, peritoneal ascites, pericardial fluid, FNA solid organ, Endoscopic USScan guided FNA and USScan guided transbronchial FNA	<p><u>Non-gynaecological cytology examination activities:</u></p> <p>Examination of tissues to identify or exclude morphological and cytological abnormalities for the purposes of clinical diagnosis</p> <p>Basic cellular components on fixed preparations and air-dried preparations (HG)</p>	<p><u>Sample preparation, processing & routine staining</u></p> <p>Documented in-house procedure SOP CP/SOP/HU-70 Preparation of diagnostic cytology specimens in conjunction with manufacturer's instructions for Hologic T2000 using:</p> <p>Papanicolaou stain CP/SOP/HU-81 Cytology Staining Procedures</p> <p>Hema- Gurr (HG) rapid stain CP/SOP/HU-81 Cytology Staining Procedures</p> <p>Dako Coverstainer - automated H&E CP/SOP/HU-114 <u>Routine Staining</u></p> <p><u>Interpretive Microscopy</u></p> <p>Leica Microscope Nikon Microscope Olympus Microscope</p> <p>CP/INF/HU-76 Specimen Codes and Points and as appropriate to specimen type</p>	A



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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	<u>Immunological examinations for the purpose of clinical diagnosis</u> <u>Autoimmune Disease Testing</u>		A
Serum	Liver, kidney, stomach & nuclear/cytoplasmic specific antibodies (IgG). Anti-Neutrophil cytoplasmic antibodies (IgG) Endomysial antibodies (IgA & IgG) Skin (IgG) Antibodies	Manual slide preparation or Automated slide preparation in conjunction with manufacturer's instructions using: Indirect immunofluorescence microscopy using the following SOP's: IM/SOP/SHY-14 LKS Screen Indirect Immunofluorescence Manual Set Up and Reading IM/SOP/SHY-11 ANCA by Indirect Immunofluorescence Manual Set Up and Reading IM/SOP/SHY-13 Endomysial Antibodies by Indirect Immunofluorescence Manual Set Up and Reading IM/SOP/SHY-15 Skin Autoantibodies by Indirect Immunofluorescence Manual Method IM/SOP/SHY-18 Maintenance and use of Werfen Quantalyser 3000	
Serum	Crithidia (IgG) Antibodies	Manual slide preparation followed by indirect immunofluorescence microscopy using the following SOP: IM/SOP/SHY-47 Crithidia Indirect Immunofluorescence Manual Set Up	
Serum	Cyclic Citrullinated Peptide antibodies CCP (IgG)	Werfen Bioflash using a chemiluminescent immunoassay SOP IM/SOP/SHY-17 Operation and Maintenance of Werfen BioFlash	



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HUMAN BODY FLUIDS (cont'd)	<u>Immunological examinations for the purpose of clinical diagnosis</u> (cont'd) <u>Autoimmune Disease Testing</u> (cont'd)		A
Serum	Coeliac Screen: Tissue transglutaminase Ab tTG (IgA) IgG Tissue transglutaminase tTG (IgG) Deamidated gliadin peptide Ab DGP (IgA) Deamidated gliadin peptide Ab DGP (IgG)	Werfen Aptiva using particle-based multi-analyte technology (PMAT) SOP IM/A/036 Operation and Maintenance of the Aptiva	
Serum	Vasculitis Screen (IgG): Glomerular basement protein Ab (GBM) Proteinase 3 Ab (PR3) Myeloperoxidase Ab (MPO)	Werfen Bioflash using a chemiluminescent immunoassay SOP IM/SOP/SHY-17 Operation and Maintenance of Werfen BioFlash	
Serum	Antiphospholipid screen (IgG): Cardiolipin Ab Beta-2-glycoprotein I Ab (B2GP)	Werfen Bioflash using a chemiluminescent immunoassay SOP IM/SOP/SHY-17 Operation and Maintenance of Werfen BioFlash	
Serum	Antinuclear antibodies (IgG): Double stranded DNA Ro52 Ro60 La SmRNP Sm RNP-68 RNP-A Chromatin Ribosomal P Scl-70 Centromere B Jo-1	Werfen Aptiva using particle-based multi-analyte technology (PMAT) SOP IM/SOP/SHY-19 Operation and Maintenance of the Aptiva	



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HUMAN BODY FLUIDS (cont'd)	<u>Immunological examinations for the purpose of clinical diagnosis</u> (cont'd) <u>Autoimmune Disease Testing</u> (cont'd)		A
Serum	Intrinsic factor antibodies	Competitive inhibition immunoenzymatic assay in conjunction with manufacturer's instructions using Beckman DXi and using in-house procedures: CB/IFU/HU-65 IFU - Reagent - Intrinsic Factor Antibody IFAb CB/SOP/HU-22 Dxi Operation Protocol	
Serum	Thyroid peroxidase antibodies	Immunoenzymatic sandwich assay in conjunction with manufacturer's instruction using DXi and in-house procedures CB/SOP/HU-22 Dxi Operation Protocol CB/IFU/HU-60 IFU - Reagent - TPO Antibody	
Serum	Extractable Nuclear Antigens (IgG): Ro La Sm SmRNP Jo-1 Scl-70	Eurolimmun EuroblotOne Immunoblot SOP- IM/SOP/SHY-49 Use & Maintenance Of Euroblotone for ENA, Liver & Myositis Profiles	
Serum	Liver antibodies (IgG): Anti-M2 M2-3E LKM 1 SLA/LP LC-1	Eurolimmun EuroblotOne Immunoblot SOP- IM/SOP/SHY-49 Use & Maintenance Of Euroblotone for ENA, Liver & Myositis Profiles	



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HUMAN BODY FLUIDS (cont'd)	<u>Immunological examinations for the purpose of clinical diagnosis</u> (cont'd) <u>Autoimmune Disease Testing</u> (cont'd)		A
Serum	Myositis associated antibodies (IgG): 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 Ro-52	Eurolmmun EuroblotOne Immunoblot SOP- IM/SOP/SHY-49 Use & Maintenance of Euroblotone for ENA, Liver & Myositis Profiles	
Serum	Specific vaccine related antibodies: Pneumococcal Haemophilus influenzae B Tetanus toxoid <u>Immunochemistry</u>	ELISA using Triturus automated processor in conjunction with manufacturer's instructions and in house procedures: IM/A/022	
Serum	Detection and immunotyping of monoclonal paraproteins	Sebia Capillarys Octa 3 using capillary zonal electrophoresis and immunosubtraction SOP IM/SOP/SHY-28 Operation of the Sebia Capillarys 3	
Serum/Urine	Detection and immunotyping of monoclonal paraproteins	Sebia Hydrasys using gel electrophoresis and immunofixation SOP IM/SOP/SHY-27 Operation of Sebia Hydrasys 2	



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HUMAN BODY FLUIDS (cont'd)	<u>Immunological examinations for the purpose of clinical diagnosis</u> (cont'd) <u>Immunochemistry</u> (cont'd)		A
Serum	Cryoglobulins	Visual inspection, Sebia Capillarys Octa 3 using capillary zonal electrophoresis and Sebia Hydrasys gel immunofixation SOP IM/SOP/SHY-22 Cryoglobulin, detection and characterisation	
Serum	Specific proteins: Immunoglobulin G Immunoglobulin M Immunoglobulin A Complement C3 Complement C4 Rheumatoid factor Beta-2-Microglobulin Haptoglobin	Turbidimetry using in-house procedures CB/SOP/HU-1 and in conjunction with manufacturer's instructions using: AU 5800	
Serum	Serum free light chains: Free lambda Free kappa C1 Inhibitor antigenic assay Sensitive IgA Caeruloplasmin	Turbidimetry using in-house procedures and in conjunction with manufacturer's instructions using: Optilite SOP IM/SOP/SHY-25 Use and Maintenance of the Optilite	
EDTA Plasma	C1 inhibitor functional assay	ELISA using Quidel Functional C1e Inhibitor assay kit and in-house procedure IM/M/033 in conjunction with manufacturer's instructions using Triturus plate reader	



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HUMAN BODY FLUIDS (cont'd)	<u>Immunological examinations for the purpose of clinical diagnosis</u> (cont'd) <u>Immunodeficiency</u> Lymphocyte subsets: <ul style="list-style-type: none">• CD45/CD3• CD45/CD3/CD4• CD45/CD3/CD8• CD45/CD19• CD45/CD56/16• CD45/CD3/CD56/16• CD45/CD3/TCRalpha-beta• CD45/CD3/TCRgamm a-delta• CD45/CD3/HLA-DR• T cell subsets for HIV monitoring• CD45/CD3• CD45/CD3/CD4• CD45/CD3/CD8• B Cell subsets• CD45/CD19/CD27- /IgD+• CD45/CD19/CD27+/IgD+• CD45/CD19/CD27+/IgD-• CD21_{lo} B-cells• HLA B27• CD34		A
Whole blood EDTA		Flow cytometry using in-house procedures IM/C/004, IM/C/006, IM/C/007 in conjunction with manufacturer's instructions using: FC500 flow cytometer	
Heparinised whole blood	T-SPOT for TB	Flow cytometry and ELISPOT count using in-house procedures IM/C/031 in conjunction with manufacturer's instructions using: Beckman Coulter FC500 flow cytometer, Microgalaxy CO ₂ Incubator and Zoom XTL-101 stereo microscope.	



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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>Immunological examinations for the purpose of clinical diagnosis</u> (cont'd) <u>Immunodeficiency</u> (cont'd)		A
Heparinised whole blood	Neutrophil function tests: Neutrophil burst test Neutrophil MPO test Reporting proportion of neutrophils positive for DHR activity and MPO staining	Flow cytometry using in-house procedures IM/C/016, IM/C/017 in conjunction with manufacturer's instructions: measured on Beckman Coulter FC500 flow cytometer	
Serum	Total Immunoglobulin E (IgE): Sp. IgE Tryptase PR3/MPO/GBM antibodies (IgG)	Chemiluminescence using in house procedures in conjunction with manufacturer's instruction using Thermo Fisher Unicap 250 SOP CB/SOP/HU-78 Total and Specific IgE SOP CB/SOP/HU-77 Tryptase CB/SOP/HU-74 Vasculitis Testing on the Phadia 250	
Serum	Detection and quantification of specific IgE to the following allergens: Timothy grass Bermuda grass Ragweed Mugwort Wall pellitory Plantain Saltwort Birch Cypress Olive Saltwort Birch <i>Alternaria alternata</i> <i>Aspergillus fumigatus</i> <i>Aspergillus oryzae</i> Dog Cow Cat Horse		



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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>Immunological examinations for the purpose of clinical diagnosis</u> (cont'd) Detection and quantification of specific IgE to the following allergens: (cont'd)	Chemiluminescence using in house procedures in conjunction with manufacturer's instruction using Thermo Fisher Unicap 250 SOP CB/SOP/HU-78 Total and Specific IgE SOP CB/SOP/HU-77 Tryptase	A
Serum (cont'd)	House dust mite Honeybee venom Common wasp venom Paper wasp venom Latex Pineapple Papaya Egg Maxatase Savinase Pig pepsin Kiwi Cashew nut Celery Peanut Brazil nut Milk Hazel nut Carp Cod Soy Glycinin Walnut Apple Shrimp Peach Wheat Bovin thyroglobulin Bahia grass Barley Brome grass Canary grass Cocksfoot Common reed Cultivated oat		



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HUMAN BODY FLUIDS (cont'd)	<u>Immunological examinations for the purpose of clinical diagnosis</u> (cont'd) Detection and quantification of specific IgE to the following allergens: (cont'd)	Chemiluminescence using in house procedures in conjunction with manufacturer's instruction using Thermo Fisher Unicap 250 SOP CB/SOP/HU-78 Total and Specific IgE SOP CB/SOP/HU-77 Tryptase	A
Serum (cont'd)	Cultivated rye Cultivated wheat False oat grass Johnson grass Maize corn Meadow fescue Meadow grass Rye grass Salt grass Velvet grass Sweet vernal grass Wild rye grass Alfalfa Camomile Careless weed Cocklebur Common ragweed Dandelion Dog fennel False ragweed Firebush Giant ragweed Goldenrod Goosefoot Japanese hop Lupin Marguerite Mugwort Nettle Plantain Rape Rough marshelder Saltwort Scale Sheep sorrel		



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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>Immunological examinations for the purpose of clinical diagnosis</u> (cont'd) Detection and quantification of specific IgE to the following allergens: (cont'd)	Chemiluminescence using in house procedures in conjunction with manufacturer's instruction using Thermo Fisher Unicap 250 SOP CB/SOP/HU-78 Total and Specific IgE SOP CB/SOP/HU-77 Tryptase	A
Serum (cont'd)	Sugar beet Sunflower wall pellitory Western ragweed Wormwood Yellow dock Acacia American beech Austaralin pine Blad cypress Bayberry Box elder Cedar Cedar elm Chestnut Common silver birch Cotton wood Cypress Date Douglas fir Elder Elm Eucalyptus European ash Grey alder Hackberry Hazel Horn beam Horse chestnut Italian/Mediterranean/Funeral cypress Japanese cedar Linden Maple leaf sycamore, Melaleuca		



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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>Immunological examinations for the purpose of clinical diagnosis</u> (cont'd) Detection and quantification of specific IgE to the following allergens: (cont'd)	Chemiluminescence using in house procedures in conjunction with manufacturer's instruction using Thermo Fisher Unicap 250 SOP CB/SOP/HU-78 Total and Specific IgE SOP CB/SOP/HU-77 Tryptase	A
Serum (cont'd)	Mesquite Mountain juniper Mulberry Oak Oil Palm Paloverde Pecan, Peppertree Pine Privet Queen palm Red cedar Red mulberry Russian olive Scotch broom Spruce Sweet gum Walnut White ash White hickory White pine Willow Virginia live oak Acremonium kiliense Alternaria alternata Aspergillus flavus Aspergillus fumigatus Aspergillus niger Aspergillus terreus Aureobasidium pullulans Botrytis cinerea Candida albicans Chaetomium globosum Cladosporium herbarum Curvularia lunata		



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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>Immunological examinations for the purpose of clinical diagnosis</u> (cont'd) Detection and quantification of specific IgE to the following allergens: (cont'd)	Chemiluminescence using in house procedures in conjunction with manufacturer's instruction using Thermo Fisher Unicap 250 SOP CB/SOP/HU-78 Total and Specific IgE SOP CB/SOP/HU-77 Tryptase	A
Serum (cont'd)	Epicoccum purpurascens Fusarium proliferatum Setomelanomma rostrata Malassezia spp. Mucor racemosus Penicillium chrysogenum Penicillium glabrum Phoma betae Pityrosporum orbiculare Rhizopus nigricans Staphylococcal enterotoxin A Staphylococcal enterotoxin B Staphylococcal enterotoxin C Staphylococcal enterotoxin TSST Stemphylium herbarum Tilletia tritici Trichoderma viride Trichophyton mentagrophytes var. goetzii Trichophyton mentagrophytes var. interdigitale Trichophyton rubrum Trichosporon pullulans Ulocladium chartarum Budgerigar droppings Budgerigar feathers Canary bird droppings Canary bird feathers Cat dander Chicken droppings Chicken feathers Chicken, serum proteins Chinchilla epithelium Cow dander		



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HUMAN BODY FLUIDS (cont'd)	<u>Immunological examinations for the purpose of clinical diagnosis</u> (cont'd) Detection and quantification of specific IgE to the following allergens: (cont'd)	Chemiluminescence using in house procedures in conjunction with manufacturer's instruction using Thermo Fisher Unicap 250 SOP CB/SOP/HU-78 Total and Specific IgE SOP CB/SOP/HU-77 Tryptase	A
Serum (cont'd)	Deer epithelium Dog dander Duck feathers Ferret epithelium Ferret epithelium Finch feathers Fox epithelium Gerbil epithelium Goat epithelium Goose feathers Guinea pig epithelium Hamster epithelium Horse dander Horse, serum proteins Mink epithelium Mouse epithelium Mouse epithelium, serum proteins and urine proteins Mouse serum proteins Mouse urine proteins Parakeet droppings Parakeet feathers Parakeet serum Parrot feathers Pigeon droppings Pigeon feathers Rabbit epithelium Rabbit, serum proteins Rabbit, urine proteins Rat epithelium Rat epithelium, serum proteins and urine proteins Rat serum proteins Rat urine proteins Reindeer epithelium		



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HUMAN BODY FLUIDS (cont'd)	<u>Immunological examinations for the purpose of clinical diagnosis</u> (cont'd) Detection and quantification of specific IgE to the following allergens: (cont'd)	Chemiluminescence using in house procedures in conjunction with manufacturer's instruction using Thermo Fisher Unicap 250 SOP CB/SOP/HU-78 Total and Specific IgE SOP CB/SOP/HU-77 Tryptase	A
Serum (cont'd)	Rat epithelium, serum proteins and urine proteins Rat serum proteins Sheep epithelium Swine epithelium Turkey feathers Storage mite House dust mite Berlin beetle Blood worm Cockroach Fire ant Grain weevil Green nimitti Horse fly Mediterranean flour moth Moth Bumble bee venom European paper wasp White faced hornet Amoxicilloyl Ampicilloyl Cefaclor Chlorhexidine Chymopapain Gelatin bovine Insulin bovine Insulin human Insulin porcine Penicilloyl G Penicilloyl V Pholcodine Morphine Suxamethonium (succinylcholine)		



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HUMAN BODY FLUIDS (cont'd)	<u>Immunological examinations for the purpose of clinical diagnosis</u> (cont'd) Detection and quantification of specific IgE to the following allergens: (cont'd)	Chemiluminescence using in house procedures in conjunction with manufacturer's instruction using Thermo Fisher Unicap 250 SOP CB/SOP/HU-78 Total and Specific IgE SOP CB/SOP/HU-77 Tryptase	A
Serum (cont'd)	Abachi wood dust Bougainvillea Castor bean Chloramin T Cotton seed Ethylene oxide Ficus Formaldehyde/Formalin Green coffee bean Hexahydrophthalic anhydrid Isocyanate HDI Isocyanate MDI Isocyanate TDI Ispaghula Methyltetrahydrophthalic anhydrid Phthalic anhydride Silk Silk waste Sunflower seed Trimellitic anhydride fish feed Cotton Daphni Seminal fluid Streptavidin Tobacco leaf Anisakis Ascaris Apple Apricot Asparagus Aubergine Avocado <i>Persea americana</i> Bamboo shoot		



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HUMAN BODY FLUIDS (cont'd)	<u>Immunological examinations for the purpose of clinical diagnosis</u> (cont'd) Detection and quantification of specific IgE to the following allergens: (cont'd)	Chemiluminescence using in house procedures in conjunction with manufacturer's instruction using Thermo Fisher Unicap 250 SOP CB/SOP/HU-78 Total and Specific IgE SOP CB/SOP/HU-77 Tryptase	A
Serum (cont'd)	Banana Beetroot Blackberry Blueberry Broccoli Brussel sprouts Cabbage Carambola Carrott Cauliflower Cherry Cucumber Fennel Fig Garlic Grape Grapefruit Guava Jack fruit Jujube Kiwi Lemon Lettuce Lime Litchi Mandarin (tangerine, clementine, satsumas) Mango Melon Olive (black, fresh) Onion Orange Papaya Passion fruit Pear		



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HUMAN BODY FLUIDS (cont'd)	<u>Immunological examinations for the purpose of clinical diagnosis</u> (cont'd) Detection and quantification of specific IgE to the following allergens: (cont'd)	Chemiluminescence using in house procedures in conjunction with manufacturer's instruction using Thermo Fisher Unicap 250 SOP CB/SOP/HU-78 Total and Specific IgE SOP CB/SOP/HU-77 Tryptase	A
Serum (cont'd)	Persimon Pineapple Plum Potato Pumpkin Raspberry Red currant Rose hip Spinach Strawberry Sweet potato Tomato Watermelon Almond Barley Blue vetch Cashew nut Chickpea Coconut Common millet Fenugreek Foxtail millet Gluten Green bean Japanese millet Lentil Lima bean Linseed Lupin seed Macadamia Pea Peanut Pecan nut Pine nut Pistachio		



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HUMAN BODY FLUIDS (cont'd)	<u>Immunological examinations for the purpose of clinical diagnosis</u> (cont'd) Detection and quantification of specific IgE to the following allergens: (cont'd)	Chemiluminescence using in house procedures in conjunction with manufacturer's instruction using Thermo Fisher Unicap 250 SOP CB/SOP/HU-78 Total and Specific IgE SOP CB/SOP/HU-77 Tryptase	A
Serum (cont'd)	Poppy seed Pumpkin seed Quinoa Rape seed Red kidney bean Rice Rye Sesame seed Soybean Spelt wheat Sugar-beet seed Sweet chestnut White bean Allspice Anise Basil Bay leaf Black pepper Caraway Cardamon Chilipepper Clove Coriander Curry Dill Fennel seed Ginger Green pepper Lovage Mace Marjoram Mint Mustard Oregano Paprika		



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HUMAN BODY FLUIDS (cont'd)	<u>Immunological examinations for the purpose of clinical diagnosis</u> (cont'd) Detection and quantification of specific IgE to the following allergens: (cont'd)	Chemiluminescence using in house procedures in conjunction with manufacturer's instruction using Thermo Fisher Unicap 250 SOP CB/SOP/HU-78 Total and Specific IgE SOP CB/SOP/HU-77 Tryptase	A
Serum (cont'd)	Parsley Saffron Sage Tarragon Thyme Vanilla Abalone Anchovy Blue mussel Catfish Chub mackerel Clam Crab Crayfish Eel Grouper Gulf flounder Haddock Hake Halibut Herring Jack mackerel Langust Lobster Mackerel Megrim Octopus Orange roughy Oyster Pacific squid Plaice Pollock Red snapper Salmon Sardine		



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HUMAN BODY FLUIDS (cont'd)	<u>Immunological examinations for the purpose of clinical diagnosis</u> (cont'd) Detection and quantification of specific IgE to the following allergens: (cont'd)	Chemiluminescence using in house procedures in conjunction with manufacturer's instruction using Thermo Fisher Unicap 250 SOP CB/SOP/HU-78 Total and Specific IgE SOP CB/SOP/HU-77 Tryptase	A
Serum (cont'd)	Japanese Pilchard Sardinops melanosticta Scallop Shrimp Snail Sole Squid Swordfish Tilapia Trout Tuna Walleye pike Whitefish Chicken Gallus spp. Egg white Egg yolk Turkey meat Chicken Cheese, cheddar type Cheese, mold type Cow's whey Goat milk Mare's milk Milk Milk, boiled Sheep milk Sheep whey Carob (E410) Guar, guar gum (E412) Gum arabic (E414) Tragacanth (E413) Cochineal extract (Carmine red) (E120) Cacao Coffee		



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HUMAN BODY FLUIDS (cont'd) Serum (cont'd)	<p><u>Immunological examinations for the purpose of clinical diagnosis</u> (cont'd)</p> <p>Detection and quantification of specific IgE to the following allergens: (cont'd)</p> <p>Honey Hop Malt Mushroom Tea Yeast</p> <p><u>Food mixes of:</u></p> <p>Peanut, Hazel nut, Brazil nut, Almond, Coconut</p> <p>Fish, Shrimp, Blue mussel, Tuna, Salmon</p> <p>Wheat, Oat, Maize, Sesame seed, Buckwheat</p> <p>Egg white, Milk, Fish, Wheat, Peanut, Soybean</p> <p>Tomato, Yeast, Garlic, Onion, Celery</p> <p>Hazel nut, Brazil nut, Orange, Apple, Cacao</p> <p>Almond, Kiwi, Melon, Banana, Grape</p> <p>Pork, Beef, Egg yolk, Chicken, Turkey</p> <p>Maize, Pea, White bean, Carrot, Broccoli</p>	<p>Chemiluminescence using in house procedures in conjunction with manufacturer's instruction using Thermo Fisher Unicap 250</p> <p>SOP CB/SOP/HU-78 Total and Specific IgE SOP CB/SOP/HU-77 Tryptase</p>	A



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Serum (cont'd)	<p><u>Immunological examinations for the purpose of clinical diagnosis</u> (cont'd)</p> <p>Detection and quantification of specific IgE to the following allergens: (cont'd)</p> <p><u>Food mixes of:</u> (cont'd)</p> <p>Rye, Rice, Potato, Mushroom, Pumpkin</p> <p>Pea, White bean, Carrot, Potato</p> <p>Tomato, Spinach, Cabbage, Paprika</p> <p>Orange, Apple, Banana, Peach</p> <p>Strawberry, Pear, Lemon, Pineapple</p> <p>Apple, Banana, Pear, Peach</p> <p>Pea, Peanut, Soybean</p> <p>Carrot, Potato, Spinach, Cucumber</p> <p>Wheat, Rye, Barley, Rice</p> <p>Kiwi, Melon, Banana, Peach, Pineapple</p> <p>Pecan nut, Cashew nut, Pistachio, Walnut</p>	<p>Chemiluminescence using in house procedures in conjunction with manufacturer's instruction using Thermo Fisher Unicap 250</p> <p>SOP CB/SOP/HU-78 Total and Specific IgE</p> <p>SOP CB/SOP/HU-77 Tryptase</p>	A



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HUMAN BODY FLUIDS (cont'd)	<u>Immunological examinations for the purpose of clinical diagnosis</u> (cont'd) Detection and quantification of specific IgE to the following allergens: (cont'd) <u>Food mixes of:</u> (cont'd) Serum (cont'd)	Chemiluminescence using in house procedures in conjunction with manufacturer's instruction using Thermo Fisher Unicap 250 SOP CB/SOP/HU-78 Total and Specific IgE SOP CB/SOP/HU-77 Tryptase	A
	Pork, Beef, Chicken meat, Turkey meat Hazel nut, Shrimp, Kiwi, Banana Sesame seed, Yeast, Garlic, Celery		



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HUMAN BODY FLUIDS AND TISSUES Aspirates Cellular and fluid material contained on swabs and cannulae	<u>Microbiology examination for the purposes of clinical diagnosis</u> General isolation of microorganisms of clinical significance.	In house documented methods based on related UK Standards for Microbiology investigations (UKHSA SMIs): Manual inoculation followed by culture using: Ears examination MB/SOP/HU-51 Ear Examination Procedure Eye examination MB/SOP/HU-27 Eye Examination Procedure General bench SOP MB/SOP/HU-31 Clinical General & Hot Bench Procedure	A
Faeces		Enteric processing MB/SOP/HU-49 Enteric Processing Procedure Campylobacter MB/SOP/HU-21 Campylobacter Procedure E.coli O157 MB/SOP/HU-50 Ecoli 0157 Procedure Yersinia MB/SOP/HU-52 Yersinia Procedure Vibrio/Plesiomonas/Aeromonas MB/SOP/HU-53 Vibrio/Aeromonas/Plesiomonas Procedure Salmonella MB/SOP/HU-54 Salmonella Procedure Shigella MB/SOP/HU-57 Shigella Species Procedure	
Fluids (incl. contact lenses fluid)		Investigation of Continuous Ambulatory Peritoneal Dialysis (CAPD) Fluid MB/SOP/HU-36CSF MB/SOP/HU-29 CSF Procedure Ascitic fluids MB/SOP/HU-31 Clinical General & Hot Bench Procedure	



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Microbiology examination for the purposes of clinical diagnosis</u> (cont'd)	In house documented methods based on related UK Standards for Microbiology investigations (UKHSA SMIs):	A
Genital samples		Genital bench specimen processing MB/SOP/HU-56 Genital Bench - Specimen Processing/Medical Laboratory Assistant Duties	
Samples from sterile sites		Prosthetic joint associated tissue samples MB/SOP/HU-46 Prosthetic Joint Associated Tissue Samples	
Tissues		Clinical and hot bench specimen processing MB/SOP/HU-31 Clinical General & Hot Bench Procedure	
Urine	Detection, identification and quantification of:	General urine methods MB/SOP/HU-12 Urine Procedure Urine sample processing MB/SOP/HU-48 Urine Sample Processing Staining (inc Gram) and microscopic examination using: MB/SOP/HU-7 Gram stain Procedure MB/SOP/HU-16 Mycology Methods Standard Operating Procedure MB/SOP/HU-29 CSF Procedure MB/SOP/HU-31 Clinical General & Hot Bench Procedure (Ascitic fluid – cell count)	
Aspirates Cellular and fluid material contained on swabs and cannulae Fluids Tissues Cultures isolated in house from the above	White blood cells Red blood cells Bacterial cells Yeast cell and fungal hyphae		



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Microbiology examination for the purposes of clinical diagnosis</u> (cont'd)	In house documented methods based on related UK Standards for Microbiology investigations (UKHSA SMIs):	A
Whole blood	General isolation of microorganisms of clinical significance.	Automated culture using BD BACTEC FX continuous monitoring system MB/SOP/HU-28 Blood Culture Procedure	
Urine	Quantification of white and red blood cells, bacteria and epithelial cells	Automated urine analysis using Sedimax image urine analyser. Sedimax automated image urine analyser MB/SOP/HU-44 SediMAX Analyser Procedures	
Cerebral fluid samples	Quantification of white and red blood cells and bacteria	Microscopy (inc. Gram Stain) using MB/SOP/HU-29 CSF Procedure MB/SOP/HU-31 Clinical General & Hot Bench Procedure Gram stain	
Female genital tract swabs	Microscopic diagnosis of bacterial vaginosis	Microscopy examination (Hay's criteria) using: MB/SOP/HU-30 Genital Samples Procedure MB/SOP/HU-56 Genital Bench - Specimen Processing/Medical Laboratory Assistant Duties Genital bench specimen processing	
Swabs	Screening for Methicillin resistant <i>Staphylococcus aureus</i> (MRSA)	Manual inoculation and culture using MB/SOP/HU-55 Resistance screening - Specimen Processing MB/SOP/HU-58 MRSA/MSSA Screening SOP MRSA/MSSA screening	
Sputum	General isolation of microorganisms of clinical significance	Manual inoculation and culture using: Culture media, growth SOP MB/SOP/HU-4 Sputum Sample Processing-MLA	



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Microbiology examination for the purposes of clinical diagnosis</u> (cont'd)	In house documented methods based on related UK Standards for Microbiology investigations (UKHSA SMIs):	A
Bronchial lavage	General isolation of microorganisms of clinical significance (cont'd)	Manual inoculation and culture using: Respiratory investigations MI/1026 Respiratory Fluid Sample Processing MB/SOP/HU-81 Legionella Investigation MB/SOP/HU-100 Bordetella Reading/Identification	
Rectal swabs	Screening for Vancomycin resistant enterococci (VRE)	Manual inoculation and culture using MB/SOP/HU-55 Resistance screening - Specimen Processing resistance screening and: MB/SOP/HU-60 Vancomycin Resistant Enterococci (VRE) Screening	
Faeces	Screening for Extended spectrum betalactamases (ESBL)	MB/SOP/HU-64 Extended Spectrum Beta-Lactamases (ESBL) Screening SOP	
Rectal swabs	Screening for Extended spectrum betalactamases (ESBL)	MI/706 MB/SOP/HU-64 Extended Spectrum Beta-Lactamases (ESBL) Screening SOP	
Faeces and rectal swabs	Screening for Carbapenamase producing Enterobacteriaceae (CPE)	MB/SOP/HU-147 CPE Screening	
Faeces and rectal swabs	Trans-rectal screening for Carbapenamase producing Enterobacteriaceae (CPE) and Ciprofloxacin and Gentamicin resistance	MB/SOP/HU-63 TRUS Biopsy Screening	



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Microbiology examination for the purposes of clinical diagnosis</u> (cont'd)	In house documented methods based on related UK Standards for Microbiology investigations (UKHSA SMIs):	A
Respiratory samples Urine Tissue Swabs (including endoscopy) Body fluids	Presumptive identification of Acid-alcohol fast bacilli (inc. <i>Mycobacterium spp</i>)	Fluorescent microscopy using Auramine stain. Mycobacterial investigations MB/SOP/HU-33 Mycobacterial Investigations (TB)	
Respiratory samples Urine Tissue Swabs (including endoscopy) Body fluids	Isolation and presumptive identification of Acid-alcohol fast bacilli (inc <i>Mycobacterium spp</i>)	Automated culture using BD MGIT continuous monitoring system. MB/SOP/HU-28 Blood Culture Procedure Fluorescent microscopy as above.	
Whole Blood	Isolation and presumptive identification of Acid-alcohol fast bacilli (inc <i>Mycobacterium spp</i>)	Automated culture using BD BacTec 40 continuous monitoring system. MB/SOP/HU-28 Blood Culture Procedure Fluorescent microscopy as above.	
Hair, skin, nail	General isolation and characterisation of clinically significant fungi.	Manual culture and Calcofluor white fluorescent microscopy using MB/SOP/HU-16 Mycology Methods Standard Operating Procedure	
Cultures isolated in house from the above	Identification of clinically significant bacteria.	Biochemical profile determination using automated Matrix-assisted laser desorption/ionisation (MALDITOF) MB/SOP/HU-11 Maldi Biotyper MB/SOP/HU-6 VITEK MB/SOP/HU-40 API	
Whole blood – positive blood culture specimens	Direct identification of clinically significant bacteria.	Matrix-assisted laser desorption/ionisation (MALDITOF) MB/SOP/HU-11 MaldiBiotyper	



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Microbiology examination for the purposes of clinical diagnosis</u> (cont'd)	In house documented methods based on related UK Standards for Microbiology investigations (UKHSA SMIs):	A
Cultures isolated in house from the above	Antimicrobial susceptibility testing of clinically significant bacteria.	Manual disc diffusion and/or automated methods using EUCAST methodology using MB/SOP/HU-59 EUCAST method of disc diffusion Gradient MIC determination by E-test using MB/SOP/HU-94 Minimum inhibitory concentration (MIC) method	
Fungal cultures isolated in house from the above	Antifungal Susceptibility Testing of Yeasts of clinical significance.	Sensititre YeastOne (Trek Diagnostic Systems) by colourimetric microdilution MB/SOP/HU-70 Yeast Sensitivity Testing	
Culture isolated in house from the above	Identification of Staphylococcal isolates	Prolab Staphylococcal Latex Agglutination kit MB/SOP/HU-146 Staph Latex MB/SOP/HU-104 Tube Coagulase Test	
Culture isolated in house from the above	Serological identification of groups A, B, C, D, F and G of the Lancefield groups of Streptococci grown in agar plates.	Prolex Streptococcal Grouping latex Kit MB/SOP/HU-62 Streptococcal Grouping Test	
Urine	Detection of Legionella antigen	Binax NOW Legionella Urinary Antigen Test kit by Alere MB/SOP/HU-61 Legionella Antigen SOP	
Culture isolated in house from the above	Detection of <i>Salmonella</i> polyvalent 'O' (PSO) and 'H' (PSH); <i>Shigella spp.</i> <i>Vibrio spp.</i>	Salmonella MB/SOP/HU-54 Salmonella Procedure Shigella MB/SOP/HU-57 Shigella Species Procedure Vibrio/Plesiomonas/Aeromonas MB/SOP/HU-53 Vibrio/Aeromonas/Plesiomonas Procedure	



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Microbiology examination for the purposes of clinical diagnosis</u> (cont'd)	In house documented methods based on related UK Standards for Microbiology investigations (UKHSA SMIs):	A
Female genital swabs	Detection of <i>Trichomonas vaginalis</i>	Broth culture and light microscopy MB/SOP/HU-56 Genital Bench - Specimen Processing/Medical Laboratory Assistant Duties	
Faeces	Detection of <i>Helicobacter pylori</i> antigen	Pro-flow Lateral flow kit MB/SOP/HU-39 Examination of Human Stool for Helicobacter Pylori Antigen	
Faeces	Identification of <i>E.coli</i> O157	Prolex latex kit using E coli O157 MB/SOP/HU-50 Ecoli 0157 SOP	
Faeces	Detection of ova, cysts and parasites (OCP)	Concentration and light microscopic examination using MB/SOP/HU-23 Parasite Procedure	
Faeces	Detection of <i>Cryptosporidium</i> oocysts	Fluorescent microscopy (Auramine stain) using MB/SOP/HU-13 Auramine Phenol Stain (Cryptosporidia)	
Faeces	Identification of Cyclospora by microscopy		
Faeces	Detection of <i>C.difficile</i> GDH antigen	MB/SOP/HU-82 Clostridium Difficile Testing Procedure	
Faeces	Detection of <i>C.difficile</i> toxin A &B	DS2 automated EIA platform using MB/SOP/HU-41Techlab Cdif MB/SOP/HU-37 DS2 OperationCheck and manual lateral flow Techlab Cdif chek complete Lateral flow Techlab Cdif Chek complete using MB/SOP/HU-42 TECHLAB® C.DIFF QUIK CHEK COMPLETE®	



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Microbiology examination for the purposes of clinical diagnosis</u> (cont'd)	In house documented methods based on related UK Standards for Microbiology investigations (UKHSA SMIs):	A
Faeces	Detection of Rotavirus antigen	DS2 automated EIA platform, EIA Rota Premier meridian, antigen kit using MB/SOP/HU-38 and MB/SOP/HU-37 DS2 Operation	
Blood	Detection of Gamma interferon antigen <u>Molecular examination activities for the purpose of clinical diagnosis</u>	DS2 automated EIA MI/064 and MI/062 4 Documented in house methods incorporating manufacturer's instructions where relevant using Cepheid GeneXpert real time PCR SOP VI/SOP/SHY-43	A
Cultures isolated in house from the above	Detection of MRSA	MB/SOP/HU-156 Cepheid MRSA Staph	
Faeces	Detection of Norovirus	MB/SOP/HU-32	
Faeces	Detection of <i>C. difficile</i> toxin	VI/SOP/SHY-43	
Nasopharyngeal swabs, nose and throat swabs	Quad test - detection of RSV and Influenza A & B, RSV and SARS-CoV-2	VI/SOP/SHY-43	
EDTA Plasma	HIV virus RNA	VI/SOP/SHY-44 CEPHEID GeneXpert HIV-1 XC Viral Load	
EDTA Plasma	Hepatitis C virus RNA	VI/SOP/SHY-45 CEPHEID GeneXpert HCV Viral Load	
EDTA Plasma	Hepatitis B virus DNA	VI/SOP/SHY-46 CEPHEID GeneXpert HBV Viral Load	
Sputum, bronchial lavage	Detection of <i>Mycobacterium tuberculosis</i> nucleic acid and rifampicin resistance.	Cepheid GeneXpert real time PCR using SOP MB/SOP/HU-47 Cepheid MTB RIF SOP	



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Molecular examination activities for the purpose of clinical diagnosis (cont'd)</u>	Documented in house methods incorporating manufacturer's instructions where relevant using Cepheid GeneXpert real time PCR SOP VI/SOP/SHY-43	A
Pernasal aspirate/swab	RSV RNA	MB/SOP/HU-159 Xpert® Xpress SARS-CoV-2/Flu/RSV plus	
	Influenza RNA	MB/SOP/HU-159 Xpert® Xpress SARS-CoV-2/Flu/RSV plus	
Nasal swab	MRSA DNA	MB/SOP/HU-156 Cepheid MRSA Staph	
		Elitech InGenius nucleic acid extraction and PCR system VI/SOP/SHY-13 Elitech InGenius Platform procedures (Equipment Management)	
CSF, skin, eye, throat, vesicle & genital swabs	HSV I & II	VI/SOP/SHY-14 Qualitative Examination of Patient Samples for Routine Viral Pathogens Using ELITe InGenius PCR System	
CSF	Adenovirus Varicella Zoster virus	VI/SOP/SHY-14 Qualitative Examination of Patient Samples for Routine Viral Pathogens Using ELITe InGenius PCR System	
Urine	Enterovirus Parechovirus virus CMV (qualitative)	VI/SOP/SHY-14 Qualitative Examination of Patient Samples for Routine Viral Pathogens Using ELITe InGenius PCR System	
	Quantification of:		
EDTA/plasma	EBV viral load CMV viral load BKV viral load	VI/SOP/SHY-16 CMV, EBV, BK Virus Examination	
Urine	<i>Mycoplasma genitalium</i> and associated macrolide resistance genes <i>Mycoplasma genitalium</i> DNA	VI/SOP/SHY-17 <i>Mycoplasma genitalium</i> Detection and Macrolide Resistance Screening Using the ELITe InGenius PCR System	



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Molecular examination activities for the purpose of clinical diagnosis (cont'd)</u>	Documented in house methods incorporating manufacturers' instructions where relevant using: Elitech InGenius nucleic acid extraction and PCR system VI/SOP/SHY-13 Elitech InGenius Platform procedures (Equipment Management)	A
Genital swabs, urine	<i>C. trachomatis</i> DNA	VI/SOP/SHY-24 Cepheid GeneXpert CT/NG Assay	
Genital swabs, urine	<i>N. gonorrhoeae</i> DNA	VI/SOP/SHY-24 Cepheid GeneXpert CT/NG Assay	
Genital swabs, urine	<i>T. vaginalis</i> DNA	VI/007 BioFire FilmArray Torch multiplex PCR technology	
Nasopharyngeal secretion	<u>Respiratory Pathogens (RP2) plus Panel:</u> Adenovirus Coronavirus 229E, Coronavirus HKU1 Coronavirus NL63 Coronavirus OC43 Human Rhinovirus/Enterovirus Human metapneumovirus Influenza B Influenza A including subtypes H1, H1-2009 and H3 Parainfluenza virus 1 Parainfluenza virus 2 SARS-CoV-2	MB/SOP/HU-45 FilmArray® RP2.1 plus Panel	



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HUMAN BODY FLUIDS AND TISSUES (cont'd) Nasopharyngeal secretion (cont'd)	<u>Molecular examination activities for the purpose of clinical diagnosis (cont'd)</u> <u>Respiratory Pathogens (RP2) plus Panel:</u> Parainfluenza virus 3 Parainfluenza virus 4 Respiratory syncytial virus Middle East Respiratory Syndrome Coronavirus (MERS-CoV) Chlamydia pneumoniae B. pertussis (ptxP) Bordetella parapertussis (IS1001) Mycoplasma pneumoniae <u>Pneumonia panel plus</u> Parainfluenza virus 3 Parainfluenza virus 4 Respiratory syncytial virus Middle East Respiratory Syndrome Coronavirus (MERS-CoV) Chlamydia pneumoniae B. pertussis (ptxP) Bordetella parapertussis (IS1001) Mycoplasma pneumoniae	Documented in house methods incorporating manufacturers' instructions where relevant using: MB/SOP/HU-45 FilmArray® RP2.1 plus Panel BioFire FilmArray Torch multiplex PCR technology MB/SOP/HU-45 FilmArray® RP2.1 plus Panel	A



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HUMAN BODY FLUIDS AND TISSUES (cont'd) Bronchoalveolar lavage, Sputum	<u>Molecular examination activities for the purpose of clinical diagnosis (cont'd)</u> <u>Pneumonia panel plus (cont'd)</u> Acinetobacter calcoaceticus-baumannii complex Klebsiella oxytoca Serratia marcescens Enterobacter cloacae complex Klebsiella pneumoniae group Staphylococcus aureus Escherichia coli Moraxella catarrhalis Streptococcus agalactiae Haemophilus influenzae Proteus spp. Streptococcus pneumoniae Klebsiella aerogenes Pseudomonas aeruginosa Streptococcus pyogenes Chlamydia pneumoniae Legionella pneumophila Mycoplasma pneumoniae Chlamydia pneumoniae Legionella pneumophila Mycoplasma pneumoniae Adenovirus Human Rhinovirus/Enterovirus Middle East Respiratory Syndrome (MERS-CoV) Coronavirus Influenza A Parainfluenza Virus Human Metapneumovirus Influenza B Respiratory Syncytial Virus CTX-M NDM mecA/C and MREJ IMP OXA-48-like VIM KPC	Documented in house methods incorporating manufacturers' instructions where relevant using: BioFire FilmArray Torch multiplex PCR technology using MB/SOP/HU-45 FilmArray® RP2.1 plus Panel	A



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HUMAN BODY FLUIDS AND TISSUES (cont'd) CSF	<u>Molecular examination activities for the purpose of clinical diagnosis (cont'd)</u> <u>Meningitis/Encephalitis Panel</u> Escherichia coli K1, Haemophilus influenzae, Listeria monocytogenes, Neisseria meningitidis, Streptococcus agalactiae, Streptococcus pneumoniae, Cryptococcus gattii/neoformans, Cytomegalovirus, Herpes simplex virus 1, Herpes simplex virus 2, Human herpesvirus 6, Enterovirus, Human parechovirus, Varicella zoster virus.	Documented in house methods incorporating manufacturers' instructions where relevant using: MB/SOP/HU-74 FilmArray Meningitis/Encephalitis Panel SOP	A



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Serological activities for the purpose of clinical diagnosis</u>	Documented in house methods incorporating manufacturers' instructions where relevant using: Documented in-house methods to meet the requirements of the Infectious Diseases in Pregnancy screening programme (relevant tests marked with *) as defined in the Quality Assurance evidence requirements:	A
Serum	Microbial serology for: Hepatitis A Total Ab Hepatitis A IgM Hepatitis B surface antibody Hepatitis B core total Ab Hepatitis C antibody CMV IgG Rubella IgM Rubella IgG HIV antigen/antibody* Hepatitis B Sag*	Beckman Coulter -UniCel Dxi 800 Procedures: VI/SOP/SHY-12 Virology Unicel Dxi Analyser (Equipment Management) Hepatitis results protocol: VI/SOP/SHY-41 HIV results protocol: VI/SOP/SHY-21	
Serum	HIV antigen/antibody* Hepatitis A IgM Hepatitis C Ab Hepatitis B eAg/Ab Hepatitis B core IgM Hepatitis B surface antigen* Toxoplasma Ab Hepatitis E IgM Hepatitis E IgG Hepatitis B core Ab* Mumps IgG	VIDAS 30 Enzyme Immunoassay with fluorescence (ELFA), VI/SOP/SHY-19 Biomerieux VIDAS 30 Procedures	



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HUMAN BODY FLUIDS AND TISSUES (cont'd) Serum	<u>Serological activities for the purpose of clinical diagnosis</u> (cont'd) Microbial Serology for: CMV IgG/IgM CMV IgG avidity Parvovirus IgG/M HTLV Ab Syphilis Ab* EBV VCA IgG/M EBV EBNA IgG VZ IgG Measles IgG/M Mumps IgM	Documented in house methods incorporating manufacturers' instructions where relevant using: Documented in-house methods to meet the requirements of the Infectious Diseases in Pregnancy screening programme (relevant tests marked with *) as defined in the Quality Assurance evidence requirements: DiaSorin Liaison XL VI/SOP/SHY-2 Diasorin Liaison XL (Equipment Management) (chemiluminescence)	A

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Appendix 1

C Hull Royal Infirmary - Wards	Glucose	C Hull Royal Infirmary - Clinics/outpatient	Glucose
HRI Gastro	x	HRI Acute care, ambulatory	x
HRI Diabetes	x	HRI Respiratory	x
HRI Neurology	x	HRI General surgery	x
HRI Stroke	x	HRI Diabetes	x
HRI Orthopaedic	x	HRI Renal	x
HRI Medical	x	HRI Medical day unit	x
HRI General medicine (COVID-19)	x	HRI Medical OPD	x
HRI Ophthalmology	x	HRI Orthopaedic OPD	x
HRI Respiratory (COVID-19)	x	HRI Xray	x
HRI General medicine (COVID-19)	x	HRI Surgical	x
HRI Neurology	x	HRI Acute care - ED	x
HRI Respiratory	x	HRI Endoscopy	x
HRI Winter ward	x	HRI Ophthalmology OP	x
HRI General surgery	x	HRI Ophthalmology Clinic	x
HRI Rheumatology	x	HRI Fracture Clinic	x
HRI Vascular	x	HRI discharge lounge	x
HRI Medical Elderly	x	HRI Antenatal clinic	x
HRI Acute Medical Unit	x	HRI occupational therapy	x
HRI Frailty Assessment Beds	x	HIR Surgical OPD	
HRI Surgery	x		
HRI Gynae	x		
HRI Gynae surgery	x		
HRI Labour ward (antenatal)	x		
HRI Labour ward (neonatal)	x		
HRI Antenatal	x		
HRI Postnatal	x		
HRI Surgery - theatre	x		
HRI ICU - theatre	x		
HRI Acute care	x		
HRI Surgical	x		
HRI Medical	x		
HRI NICU	x		
HRI OPD	x		
HRI SCBU	x		
HRI Paed assessment unit	x		



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