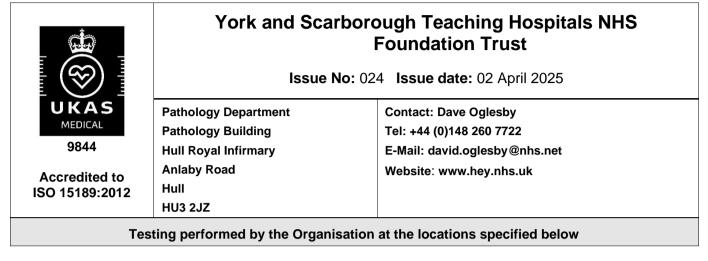
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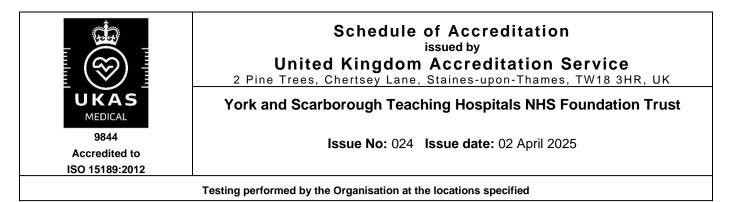
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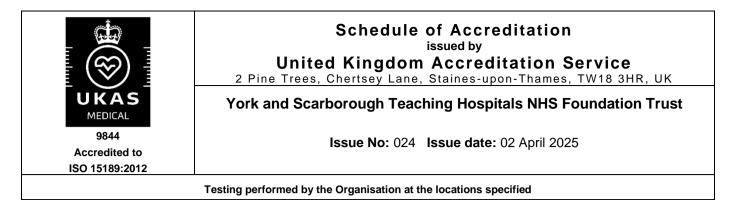
Locations covered by the organisation and their relevant activities

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



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	A
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	A
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	В
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	С
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	D
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	E



DETAIL OF ACCREDITATION			
Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS	Blood Transfusion examination activities for the purpose of clinical diagnosis	Manufacturer's instructions and documented In-house methods using:	
Whole Blood: EDTA samples Red cells and plasma	Blood GroupingA B ORhesus D status	Glass microbead column technology using Ortho Vision analysers SOP BT/GR/001 Glass microbead column technology using manual Ortho BioVue methods SOP BT/GR/004	A
Plasma	Red cell Antibody Screening Antibodies of the following systems: Rhesus Kell Duffy Kidd MNSs P Lutheran Lewis	Glass microbead column technology using Ortho Vision analysers SOPBT/GR/001 & BT/SP/001 Glass microbead column technology using manual Ortho BioVue methods SOP BT/SP/001 & BT/GR/004	
	 Manual testing of patient plasma and donor red blood cells. 	Glass microbead column technology using manual OrthoBioVue. SOP BT/XM/001	



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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)	Blood Transfusion examination activities for the purpose of clinical diagnosis (cont'd)	<u>Manufacturer's instructions and</u> <u>documented In-house methods</u> <u>using:</u>	A
Red cells	Direct anti-globulin test	Glass microbead column technology using Ortho Vision analysers	
		SOP BT/SP/002 & BT/GR/001	
		Glass microbead column technology using manual Ortho BioVue methods	
		SOP BT/SP/002	
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/SP/004	
Red cells	Kleihauer test for estimation of foetal-maternal haemorrhage	Manual modified Kleihauer-Betke method. SOP BT/SP/005 & BT/SP/006	
	Coagulation examination activities for the purpose of clinical diagnosis	Manufacturer's instructions and documented In-house methods using:	
Plasma (tri-sodium citrate)	Blood Coagulation	Sysmex Coagulation Auto Analyser	
	Prothrombin time	Optical clot detection	
	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	SOP HA/G/501 Routine coagulation	
	Reptilase time Mixing tests	SOP HA/G/501 Routine coagulation	



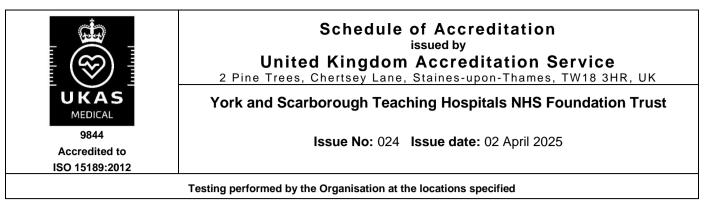
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HUMAN BODY FLUIDS (cont'd)	<u>Coagulation examination</u> activities for the purpose of clinical diagnosis (cont'd)	Manufacturer's instructions and documented In-house methods using:	A
		Sysmex Coagulation CN6000 and CN3500	
Plasma (tri-sodium citrate)	D-Dimer	Immunoassay HA/G/501	
	Anti-Xa levels	Chromogenic detection SOP HA/G/501 Routine coagulation	
	Factor's: VII IX XI XII V X II VIII	Clot based optical assay SOP HA/G/503 Coagulation laboratory specialist	
	Lupus anticoagulant	Clot based optical assay SOP HA/G/503 Coagulation laboratory specialist	
	Von Willebrand factor antigen Von Willebrand factor activity	Latex base turbidometric assay SOP HA/G/503 Coagulation laboratory specialist	
	Inhibitor Screen and Bethesda Assay		
	Chromogenic Factor VIII	Chromogenic Assay SOP HA/G/503 Coagulation laboratory specialist	
	Emicizumab Drug Concentration	Clotting assay SOP HA/C/115 Emicizumab Drug Concentration Assay	



Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd)	Haematology examination activities for the purpose of clinical diagnosis		
		Sysmex XN series (XN-9000 HRI and XN-3100 CHH)	
Whole blood in EDTA	Full Blood count: • Haemoglobin • Red Blood Cells • Platelet count • Haematocrit • Mean cell volume • Mean cell distribution width • White cell count • White Cell Differential • Neutrophils • Lymphocytes • Monocytes • Eosinophils • Basophils Reticulocyte count (including immature reticulocyte fraction and haemoglobin content)	SOP HA/G/500 Routine Haematology HA/H/401 Sysmex XN Series – Operation Procedures.	А, В



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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>Haematology examination</u> activities for the purpose of clinical diagnosis (cont'd)	Manufacturer's instructions and documented In-house methods using:	
Whole blood in EDTA	Detection of Nucleated red cell count		
		Manual slide preparation and manual microscopy – May- grunwald Giemsa stain	A
		SOP HA/G/500 Routine Haematology	
	Identification of normal and abnormal morphologies including WBC differential count	Sysmex SP-50 automated slide preparation and manual microscopy May-grunwald Giemsa stain	A
		Manual slide preparation and manual microscopy – May- grunwald Giemsa stain	A
		SOP HA/G/500 Routine Haematology	
	Malaria screening for: <i>P. falciparum</i>	Thick and thin films	А
	P. vivax P. ovale P. malariae	Giemsa stain and manual microscopy	
	P. knowlesi	Apacor Care US Malaria Rapydtest kit	
		SOP HA/H/413 Routine Haematology	
Bone marrow aspirate slides	Reporting of normal and abnormal morphologies	MGG stain using Mirastainer II	
Whole blood in EDTA	Blood film morphology	DI-60 Digital morphology platform and Cellavision client software	А
Whole blood in EDTA, serum, plasma	Detection of infectious mononucleosis heterophile antibodies	Clearview IM II test chromatographic immunoassay kit	А
		SOP HA/G/500 Routine Haematology	



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HUMAN BODY FLUIDS (cont'd)	<u>Haematology examination</u> activities for the purpose of clinical diagnosis (cont'd)	Manufacturer's instructions and documented In-house methods using:	
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	A
		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.'	
Whole blood in EDTA	Antenatal Haemoglobinopathy screening: Detection of haemoglobin variants: HbA2 HbF HbS.	Automated HPLC using TOSOH G11 HA/SOP/HU-34	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/S/004 SICKLEDEX Sickle Solubility	A
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/S/065 - Gel Electrophoresis for Haemoglobinopathies	A
Whole blood in EDTA	Detection of G6PD	Trinity G6PDH reagent, flurorescent monospot test HA/S/063 G6PD	



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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)	Biochemistry examination activities for the purposes of clinical diagnosis	Documented in house methods and manufacturer's instructions for analysis using Beckman AU5800 (HRI) and Beckman AU 680 (CHH)	
	Quantitative determination of:	Kinetic UV Colorimetric	
Serum/plasma	ALT(IFCC) ALP(IFCC) AST CK NAC Ethanol Glucose hexokinase LDH (L-P) IFCC	BI/AU/001 BI/A12/012	А, В
Serum/plasma/urine	Urea STAT	Immunoturbidimetric	
Serum	Alpha-1-antitrypinsin	BI/AU/001	А
CSF/Urine Serum/plasma	UALB Albumin in CSF and Urine B2 Microglobulin C3/C4		
	Complement C-Reactive Protein Haptoglobin IgA IgG IgM Rheumatoid Factor Transferrin Vancomycin		A, B 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 (cont'd)	Biochemistry examination activates for the purposes of clinical diagnosis (cont'd)	Documented in house methods and manufacturer's instructions for analysis using Beckman AU5800 (HRI) and Beckman AU 680 (CHH)	
Serum/Plasma	Quantitative determination of:	BCP Dye-Binding Colorimetric	
	Albumin BCP	BI/AU/001, BI/A12/012	А, В
		Kinetic Colorimetric	
Serum/plasma/urine/ Serum/plasma	Alpha-amylase Gamma- Glutamyltransferase Total Bile Acids		A
		Direct enzymatic	
Plasma	Ammonia (GLDH)	BI/AU/001, BI/A12/012	
		Enzyme immunoassay	
Urine Serum/plasma Urine Serum/plasma	Amphetamine/Ecstasy Benzodiazepines Carbamazepine Methadone metabolite Gentamicin Methotrexate Morphine/codeine/ heroin Phenobarbital Phenytoin THC Cannabis Theophylline Valproic Acid	BI/AU/001, BI/A12/012	



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Materials/Products tested	Type of test/Properties measured/Range of	Standard specifications/	Location
	measurement	Equipment/Techniques used	Code
HUMAN BODY FLUIDS (cont'd)	Biochemistry examination activates for the purposes of clinical diagnosis (cont'd)	Documented in house methods and manufacturer's instructions for analysis using Beckman AU5800 (HRI) and Beckman AU 680 (CHH)	
		Enzymatic	
Serum/plasma	Angiotensin Converting Enzyme (ACE) Bicarbonate	BI/AU/001, BI/A12/012	A
Serum/plasma Serum/plasma/urine	Cholesterol (CHOD-PAP) Creatinine enzymatic		А, В
Serum/plasma	Fructosamine HDL -Cholesterol Lactate Salicylate Acid		A
Serum/plasma Serum/plasma/urine	Triglyceride Uric Acid		
		Photometric /colorimetric	А, В
Serum/plasma/urine Serum/plasma	Calcium (Arsenazo) Direct Bilirubin Inorganic phosphate Iron (TPTZ) Lithium Magnesium	BI/AU/001, BI/A12/012	A
Serum/plasma Urine/CSF	Total Protein Protein		
		Indirect ISE	A, B
Serum/plasma/urine	Chloride Potassium Sodium	BI/AU/001, BI/A12/012	



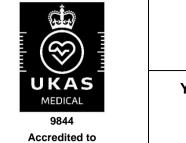
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HUMAN BODY FLUIDS (cont'd)	Biochemistry examination activates for the purposes of clinical diagnosis (cont'd)	Documented in house methods and manufacturer's instructions for analysis using Beckman AU5800 (HRI) and Beckman AU 680 (CHH)	
		Immuno-inhibition	
Serum/plasma	Digoxin	BI/AU/001, BI/A12/012	А
		Colorimetric	
Serum/plasma	Total Bilirubin	BI/AU/001, BI/A12/012	А, В
Serum	Paracetamol	Enzyme immunoassay BI/AU/001	А
	Tobramycin	Beckman UniCel DXi 800 (Magnetic particle based Chemiluminescence)	
	TSH FT4 FT3 Anti TPO Cortisol FSH/LH Prolactin Progesterone Oestradiol Testosterone DHEA AFP CA125 CA153 CA199 CEA PSA HCG B12 Folate Ferritin	BI/S/700	



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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)	Biochemistry examination activates for the purposes of clinical diagnosis (cont'd)	Documented in house methods and manufacturer's instructions for analysis using:	
Serum/plasma	ACTH Trop T (high sensitivity) Pro BNP P1NP	Roche Cobas e411(Magnetic particle based Chemiluminescence) BI/S/414	A
	Human growth hormone (Hgh) IGFBP-3 IGF-1	IDS-isys (Magnetic particle based Chemiluminescence) BI/S202	
Serum/plasma	Vitamin A Vitamin E	Phadia Unicap 250 BI/M19	



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HUMAN BODY FLUIDS (cont'd)	Biochemistry examination activates for the purposes of clinical diagnosis (cont'd)	Documented in house methods and manufacturer's instructions for analysis using:	
		Waters Acquity Tandem Quadruple TQD (Tandem Mass Spectrophotometry)	A
Urine	Toxicology Confirmation of the following: Morphine 6-Monoacetylmorphine Morphine Glucuronide Codeine Dihydrocodeine Acetyl codeine Amphetamine Methamphetamine Methylenedioxymetamfetamin e (MDMA) Methylenedioxyamfetamine (MDA) Cocaine metabolite (benzoylecgonine) Pholcodine Oxycodone Tramadol Meconin Methadone Methadone metabolite (EDDP) Buprenorphine/ Norbuprenorphine Cortisol Drug Screening (Chromalynx)	BI/M/60 BI/M/TOX/131 BI/M/60 BI/G3	



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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)	Biochemistry examination activates for the purposes of clinical diagnosis (cont'd)	Documented in house methods and manufacturer's instructions for analysis using:	
		Waters Acquity Tandem Quadruple Micromass Quattro XE Mass (Tandem Mass Spectrophotometry)	A
Serum/plasma	Tacrolimus/FK506 Ciclosporin	BI/M/043	
	Testosterone and Androstenedione Vitamin D	BI/M/42 BI/M/52	
Serum/plasma	Trace Metals:	Agilent 220FZ/220Z (Atomic Absorption spectrophotometry)	
	Copper Zinc Selenium	BI/M/AA/007 BI/M/AA/007 BI/M/AA/011	
Whole blood	Lead	Lead BI/M/AA/008	
CSF	Xanthochromia	Helena SAS-3 Northstar BIO-UV (Spectrophotometry) BI/M/022 Advanced Instrument Osmometer	
Serum/plasma/urine	Osmolality	3320 (freezing point osmometry) BI/M/002	
Sweat	Chloride	Sherwood 926 Chloride meter BI/M/016	
Faeces	FIT - Faecal immunochemical testing - Haemoglobin	HM-KACKarc BI/S613	



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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)	Biochemistry examination activates for the purposes of clinical diagnosis (cont'd)	Documented in house methods and manufacturer's instructions for analysis using:	
		Manual test: Colorimetric	А
Urine	Urine oxalate	BI/M/006	
	Paraquat	BI/M/TOX/013	
Faeces		ELISA Schebo Pancreatic Elastase kit	
Urine Urine Urine Urine Urine Urine Serum Urine Urine Serum and urine Serum and urine Serum Serum	Calculated Tests (data from primary tests, primary test sample requirements listed under that test) 24hr Urine Calcium 24hr Urine Creatinine 24hr Urine Phosphate 24hr Urine Potassium 24hr Urine Sodium 24hr Urine Uric Acid Albumin: Creatinine Ratio Protein: Creatinine Ratio Calcium, adjusted Calcium: Creatinine Excretion Ratio Calcium: Creatinine Ratio Creatinine Clearance (L/24hr) Creatinine Clearance (mL/min) eGFR (CKD-EPI) Non-HDL Cholesterol	BSI/167	



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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)	Biochemistry examination activates for the purposes of clinical diagnosis (cont'd)	Documented in house methods and manufacturer's instructions for analysis using:		
	Calculated Tests (data from primary tests, primary test sample requirements listed under that test)		A	
Serum Urine Serum Serum Serum Serum and urine	LDL-Cholesterol Protein:Creatinine Ratio Free androgen index AKI Globulins Renal tubular absorption of phosphate (TmP/GFR)			
Urine	24hr Urine Uric Acid <u>Provision of Point of Care</u> <u>testing in accordance with ISO</u> <u>22870: 2016 related to the</u> <u>following:</u>			
Whole blood	Glucose	Roche Accuchek Inform II glucose dehydrogenase method UI/P/AI/020	A - E	
(See Annondix 1	for dotails of approxited or	vaminations at location types		
	(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	<u>Histopathology &</u> <u>Neuropathology</u>	Documented in house methods and manufacturer's instructions for analysis using:	
Fixed, fresh and frozen tissue; excisional and incisional biopsies and surgical resection specimens	Routine Histopathology & Neuropathology examination activities: Examination of tissues to identify or exclude morphological and cytological abnormalities for the purposes of clinical diagnosis	Macroscopic and Microscopic examination: SOP HP/PROC/0102 and as appropriate to specimen type: 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</u> <u>processing</u> Documented in-house procedure SOP HP/PROC/0200 in conjunction with manufacturer's instructions for Peloris II & Leica ASP 300 tissue processors <u>Tissue Embedding</u> Documented in-house procedure SOP HP/PROC/0300 in conjunction with manufacturer's instructions for Leica EG1160,Leica Histocore Arcadia and Medite tissue embedding centres	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 TISSUE SAMPLES (cont'd)	Histopathology & Neuropathology (cont'd)	Documented in house methods and manufacturer's instructions for analysis using:	
Fixed, fresh and frozen tissue, excisional and incisional biopsies and surgical resection specimens	Routine Histopathology & Neuropathology examination activities: Examination of tissues to identify or exclude morphological and cytological abnormalities for the purposes of clinical diagnosis	<u>Tissue Sectioning</u> Documented in-house procedure SOP HP/PROC/0400. Sections are produced on microtomes; Leica RM2235, Leica RM2135 and Leica Histocore Biocut.	A
DIF: Skin, renal and buccal mucosa biopsy		Direct immunofluorescence HP/PROC/0802 Direct Immunofluorescence Technique (DIF) HP/PROC/0803 DIF Antibody Dilutions	
Frozen sections Intra-operatives: Central and peripheral nervous system.	Diagnostic Frozen sections and Intra-operatives – frozen / smears	HP/PROC/0819 Preparation of Intra-Operative Smears HP/PROC/0815 Frozen Section Procedure Documented in-house procedure SOP HP/PROC/0800 (special techniques) in conjunction with manufacturer's instructions for the Leica cryostat CM1900 and CM1850 <u>Staining</u> Automated Routine Stains	



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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 (cont'd) Fixed, fresh and frozen tissue; excisional and incisional biopsies and surgical resection specimens	Routine Histopathology & <u>Neuropathology examination</u> <u>activities</u> : Examination of tissues to identify or exclude morphological and cytological abnormalities for the purposes of clinical diagnosis	Documented in-house procedure SOP HP/PROC/0500 in conjunction with manufacturer's instructions for & Leica Autostainer XL and Dako Coverstainer	
	Nuclei and other cellular components	Haematoxylin & Eosin HP/PROC/0804 & HP/PROC/0612 manual and HP/PROC/0500 automated	A
		Manual Special Stains:	
		Documented in-house procedure SOP HP/PROC/0600.	
	Acid mucins, elastic fibres & connective tissue	Alcian Blue EVG (Millers) (HP/PROC/0637)	
	Acid and neutral mucins	Alcian Blue PAS & Diastase (HP/PROC/0603)	
	Acid mucopolysaccharides	Alcian Blue pH 2.5 (HP/PROC/0604)	
	Amyloid	Congo Red (HP/PROC/0606)	
	Elastic fibres	Elastic van Gieson (Millers) (HP/PROC/0608)	
	Protozoans	Giemsa (HP/PROC/0609)	
	Gram +/- organisms	Gram (HP/PROC/0610)	
	Fungi	Grocott Gomori (HP/PROC/0611)	
	Haemosiderin	Iron (Perls Prussian Blue) (HP/PROC/0613)	
	Basement membrane	Jones Methenamine Silver (HP/PROC/0614)	



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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 (cont'd) Fixed, fresh and frozen tissue; excisional and incisional biopsies and surgical resection specimens	Routine Histopathology & Neuropathology examination activities: Examination of tissues to identify or exclude morphological and cytological abnormalities for the purposes of clinical diagnosis (cont'd)	Documented in house methods and manufacturer's instructions for analysis using:	A
	Nuclei and other cellular components (cont'd)	Haematoxylin & Eosin HP/PROC/0804 & HP/PROC/0612 manual and HP/PROC/0500 automated	
	Melanin	Masson-Hamperl (HP/PROC/0617)	
	Connective tissue	Masson's Trichrome (HP/PROC/0618)	
	Melanin	Melanin Bleach (HP/PROC/0619)	
	Fibrin	MSB (HP/PROC/0621)	
	Hepatitis B and copper – associated protein	Orcein (Shikata's) (HP/PROC/0623)	
	PAS +ve substances e.g.: glycogen (and cells of pituitary) and fungi	Periodic Acid Schiff, (HP/PROC/0624)	
	Reticulin fibres	Reticulin (Gordon and Sweet) (HP/PROC/0626)	
	Amyloid	Sirius Red (HP/PROC/0627)	
	Metachromatic substances	Toluidine blue (HP/PROC/0630)	
	Connective tissue	Van Gieson (HP/PROC/0632)	
	Calcium	Von Kossa (HP/PROC/0633)	
	Spirochetes	Warthin Starry (HP/PROC/0634)	
	Tubercle bacilli (TB)	Ziehl – Neelsen (HP/PROC/0635)	
	Mycobacterium leprae bacilli	Wade fite modified ZN (HP/PROC/0639)	



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HUMAN BODY TISSUE SAMPLES (cont'd) Fixed, fresh and frozen tissue; excisional and incisional biopsies and surgical resection specimens	Routine Histopathology & <u>Neuropathology examination</u> <u>activities:</u> Examination of tissues to identify or exclude morphological and cytological abnormalities for the purposes of clinical diagnosis (cont'd)	Documented in house methods and manufacturer's instructions for analysis using:	A
FFPE slides (formalin fixed paraffin embedded) and frozen sections		Interpretive/diagnostic microscopy (HP/CONS/001)	
Human Body Tissue Samples	Molecular Diagnostic examination activities: Examination of tissues to identify or exclude mutations within DNA for the purpose of clinical diagnosis, prognosis and treatment options.	Documented in-house procedure SOP MD/PROC/0100 in conjunction with manufacturer's instructions for Biocartis Idylla Molecular platform and test cartridges.	
	NRAS/BRAF KRAS EGFR BRAF MSI		
HUMAN BODY TISSUE SAMPLES & cell blocks	Immunocytochemistry: Immunocytochemistry examination activities: Examination of tissues to identify or exclude morphological and cytological abnormalities for the purposes of clinical diagnosis	Documented in-house procedure SOP HP/PROC/0700 in conjunction with manufacturer's instructions for & Dako Omnis immunocytochemistry stainers and using antibodies:	
	Germinal centre macrophages - tonsil	A-1-AT	
	ACTH secreting cells - pituitary	АСТН	
	Smooth muscle actin	ACTIN	
	Epithelial cells	AE1/3	
	Foetal liver cells	AFP	



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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 & 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)	Documented in-house procedure SOP HP/PROC/0700 in conjunction with manufacturer's instructions for & Dako Omnis immunocytochemistry stainers and using antibodies:	A
	HGPIN, prostate adenocarcinoma	AMACR	
	Astrocytoma identification	ATRX	
	Scattered T cells in germinal centres and mantle zone B cells	BCL-2	
	Epithelial cells of the colon	BEP4	
	Luminal cells of fallopian tube	CA125	
	Parafollicular C cells of the thyroid	CALCITONIN	
	Smooth muscle of blood vessels and of bowel wall	CALDESMON	
	Peripheral nerve ganglion	CALRETININ	
	Epithelial cells of the colon	CAM5.2	
	All germinal centre cells of tonsil	CD10	
	Langerhans Cell in skin	CD1A	
	Germinal mantle zone B lymphocytes	CD20	



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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 & 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)	Documented in-house procedure SOP HP/PROC/0700 in conjunction with manufacturer's instructions for & Dako Omnis immunocytochemistry stainers and using antibodies:	A
	Activated lymphocytes and plasma cells. RS cells in Hodgkins lymphoma	CD30	
	Endothelial cells, activated B & T lymphocytes	CD31	
	Endothelial cells	CD34	
	T lymphocytes	CD3	
	All leucocytes	CD45	
	Peripheral nerves	CD56	
	Macrophages	CD68	
	Mantle zone B cells, germinal centre B cells, plasma cells	CD79	
	T cells, cytotoxic suppressor cells	CD8	
	Endothelial cells	CD99	
	Normal and neoplastic plasma cells, epithelium cells	CD138	
	Adenocarcinoma and carcinoid (intestinal epithelium).	CDX-2	
	CEA glycoproteins in adenocarcinoma	CEA	
	Islets of Langerhan cells of the pancreas	CHROMOAGRANIN	



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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 & 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)	Documented in-house procedure SOP HP/PROC/0700 in conjunction with manufacturer's instructions for & Dako Omnis immunocytochemistry stainers and using antibodies:	A
	Squamous epithelium	CK 14	
	epithelial	CK19	
	Umbrella cells of ureter	CK20	
	Squamous epithelium	CK34BE12	
	Squamous epithelium	CK5/6	
	Transitional epithelium of ureter	СК7	
	Mast cells, GIST	СКІТ	
	Epithelial cells	CKPAN	
	Cytomegalovirus infected cells	CMV	
	Smooth & striated muscle cells	DESM	
	Gastrointestinal stromal tumours	DOG1	
	Epstein Barr virus infected cells	EBV	
	Epithelial cell membranes	E-CAD	
	Epithelial cells of the kidney	ЕМА	
	FSH secreting cells of the pituitary	FSH	



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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 & 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)	Documented in-house procedure SOP HP/PROC/0700 in conjunction with manufacturer's instructions for Dako Omnis immunocytochemistry stainers and using antibodies:	A
	G - cells of stomach	GASTRIN	
	Bladder cancers, breast cancer	GATA3	
	Epithelial cells of sweat glands	GCDF	
	Astrocytes	GFAP	
	GH secreting cells of pituitary	GH	
	hepatocytes	HSA	
	Trophoblasts of placenta, secreting HCG	HCG	
	Melanoma cells	HMB45	
	H-pylori bacterium	HPYL	
	Oligo dentroglioma	IDH-1	
	Leydig and Steroli cells in testis	INHIBIN	
	Insulin secreting cells in pancreas	INSULIN	
	Proliferating cells in germinal centre B cells	Ki67	



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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 & 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)	Documented in-house procedure SOP HP/PROC/0700 in conjunction with manufacturer's instructions for Dako Omnis immunocytochemistry stainers and using antibodies:	A
	LH secreting cells in pituitary	LH	
	Dendrites and perikaya of neurons	Map-2	
	Melanocytes	MELAN A	
	Mesothelial cells, some epithelial cells of tonsil	MESOTHELIN	
	Mismatch repair protein MLH1	MLH1	
	Mismatch repair protein MSH2	MSH2	
	Mismatch repair proteinMSH6	MSH6	
	Small muscle myosin	MYOSIN	
	Alveolar macrophages, pneumocytes, lung adenocarcinoma	Napsin-A	
	Neurons	NFP	
	Neuroendocrine & neuronal cells	NSE	
	Embryonic cells and germ cell tumours	OCT3/4	
	Cervical intraepithelial neoplasia	P16	
	Squamous cell carcinoma	P40	



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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)	Documented in-house procedure SOP HP/PROC/0700 in conjunction with manufacturer's instructions for Dako Omnis immunocytochemistry stainers and using antibodies:	A
	Colon adenoca	P53	
	Squamous epithelium	P63	
	Tumour types including thyroid, renal cell and ovarian serous carcinomas	PAX-8	
	PD-L1 protein expression	PDL1	
	Pituitary marker somatotroph cell adenoma	PIT-1	
	Tropoblasts of placenta	PLAP	
	Mismatch repair protein PMS2	PMS2	
	Polyoma virus	POLV	
	PRL secreting cells of pituitary	Prl	
	Epithelial cells of proximal tubules of kidney	RCC	
	Schwann cell, adipocytes, cartilage	S100	
	Pituitary marker gonadotroph cell adenoma	SF-1	
	Islets of Langerhans cells of pancreas	SYNAPTOPHYSIN	



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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)	Documented in-house procedure SOP HP/PROC/0700 in conjunction with manufacturer's instructions for Dako Omnis immunocytochemistry stainers and using antibodies:	A
	Follicular epithelial cells of thyroid	TYHROGLOBULIN	
	TSH secreting cells of the pituitary	TSH	
	Pituitary marker corticotroph cell adenoma	T-PIT	
	Follicular epithelial cells of thyroid, Type II pneumocytes i.e.; smooth muscle, endothelium, lymphocytes	TTF1	
	Cells of mesenchymal origin	Vimentin	
	Mesenchymal cells	WT1	
	Prostatic epithelium used for Prostatic adenocarcinoma	NKX3.1	
	Diagnosis and classification of benign prostate lesions, prostate adenocarcinomas and high grade intraepithelial neoplasia	Dual Staining (AMACR/P63)	
	Used in the diagnosis of HCC, Hepatoblastoma, melanoma, testicular germ cell tumours and Wilms' tumour	Glypican-3	
	Nuclear staining significant in fibroblasts, nuclear staining is significant in epithelial cells, used in various carcinoma	Bata Catenin	



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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 & 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)	Documented in-house procedure SOP HP/PROC/0700 in conjunction with manufacturer's instructions for Dako Omnis immunocytochemistry stainers and using antibodies:	A
	Melanoma marker including spindle cell and desmoplastic subtypes	SOX-10	
	Present in Lymphatic endothelium and other cells used to aid the identification of lymphovascular space invasion	D240	
		Documented in-house procedure SOP HP/PROC/0700 in conjunction with manufacturer's instructions for Ventana Ultra immunocytochemistry stainers and using antibodies:	
	Breast carcinoma	HER 2	
	Breast cancer and normal gland	OEST	
	Breast cancer	PROG	
	ALK positive non-small cell lung carcinomas	ALK	



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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, 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	-	Sample preparation, processing & routine staining Documented in-house procedure SOP CY-PROC/100 in conjunction with manufacturer's instructions for Shandon Varistain 24-4 and Hologic T2000 using: Papanicolaou stain CY/PROC/111 Hema- Gurr (HG) rapid stain	A
		CY/PROC/111 Dako Coverstainer - automated H&E (HP/PROC/0500) <u>Interpretive Microscopy</u> <u>Leica Microscope</u> <u>Olympus Microscope</u> <u>Olympus Microscope</u> SOP HP/PROC/0102 and as appropriate to specimen type	



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Materials/Products tested measured/Range of				
for the purpose of clinical diagnosisAutoimmune Disease TestingSerumLiver, kidney, stomach & nuclear/cytoplasmic specific antibodies (IgG). Anti-Neutrophil cytoplasmic antibodies (IgG) Endomysial antibodies (IgA & IgG) Skin (IgG) AntibodiesManual slide preparation or Automated slide preparation in conjunction with manufacturer's instructions using: Indirect immunofluorescence microscopy using the following SOP's: IM/A/034SerumCrithidia (IgG) AntibodiesManual slide preparation followed by indirect immunofluorescence microscopy using the following SOP's: IM/A/034SerumCyclic Citrullinated Peptide antibodies CCP (IgG)Werfen Bioflash using a chemiluminescent immunoassay SOP IM/A/037SerumCoeliac Screen: Tissue transglutaminase tTG (IgA) IgG Tissue transglutaminase tTG (IgA) Deamidated gliadin peptide Ab DGP (IgA)Werfen Aptiva using particle-based multi-analyte technology (PMAT) SOP IM/A/036	Materials/Products tested	measured/Range of		Location Code
SerumLiver, kidney, stomach & nuclear/cytoplasmic specific antibodies (IgG). Anti-Neutrophil cytoplasmic 	HUMAN BODY FLUIDS	for the purpose of clinical		A
nuclear/cytoplasmic specific antibodies (IgG). Anti-Neutrophil cytoplasmic antibodies (IgG) Endomysial antibodies (IgA & IgG) Skin (IgG) AntibodiesAutomated slide preparation in conjunction with manufacturer's instructions using: Indirect immunofluorescence microscopy using the following SOP's: IM/A/034SerumCrithidia (IgG) AntibodiesManual slide preparation followed by indirect immunofluorescence microscopy using the following SOP's: IM/A/034SerumCyclic Citrullinated Peptide antibodies CCP (IgG)Warfen Bioflash using a chemiluminescent immunoassay SOP IM/A/037SerumCoeliac Screen: Tissue transglutaminase Ab tTG (IgA) IgG Tissue transglutaminase tTG (IgG) Deamidated gliadin peptide Ab DGP (IgA)Werfen Aptiva using particle-based multi-analyte technology (PMAT) SOP IM/A/036		Autoimmune Disease Testing		
SerumCyclic Citrullinated Peptide antibodies CCP (IgG)by indirect immunofluorescence microscopy using the following SOP: IM/A/009SerumCyclic Citrullinated Peptide antibodies CCP (IgG)Werfen Bioflash using a chemiluminescent immunoassay SOP IM/A/037SerumCoeliac Screen: Tissue transglutaminase Ab tTG (IgA) IgG Tissue transglutaminase tr TG (IgG) Deamidated gliadin peptide Ab DGP (IgA) Deamidated gliadin peptide AbWerfen Aptiva using particle-based multi-analyte technology (PMAT) SOP IM/A/036	Serum	nuclear/cytoplasmic specific antibodies (IgG). Anti-Neutrophil cytoplasmic antibodies (IgG) Endomysial antibodies (IgA & IgG)	Automated slide preparation in conjunction with manufacturer's instructions using: Indirect immunofluorescence microscopy using the following	
antibodies CCP (IgG)chemiluminescent immunoassay SOP IM/A/037SerumCoeliac Screen: Tissue transglutaminase Ab tTG (IgA) IgG Tissue transglutaminase tTG (IgG) Deamidated gliadin peptide Ab DGP (IgA) Deamidated gliadin peptide AbWerfen Aptiva using particle-based multi-analyte technology (PMAT) SOP IM/A/036	Serum	Crithidia (IgG) Antibodies	by indirect immunofluorescence microscopy using the following	
Tissue transglutaminase Ab tTG (IgA) IgG Tissue transglutaminase tTG (IgG) Deamidated gliadin peptide Ab DGP (IgA) Deamidated gliadin peptide Ab	Serum		chemiluminescent immunoassay	
	Serum	Tissue transglutaminase Ab tTG (IgA) IgG Tissue transglutaminase tTG (IgG) Deamidated gliadin peptide Ab DGP (IgA) Deamidated gliadin peptide Ab	multi-analyte technology (PMAT)	



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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)	Immunological examinations for the purpose of clinical diagnosis (cont'd)		A
	<u>Autoimmune Disease Testing</u> (cont'd)		
Serum	Vasculitis Screen (IgG): Glomerular basement protein Ab (GBM) Proteinase 3 Ab (PR3) Myeloperoxidase Ab (MPO)	Werfen Bioflash using a chemiluminescent immunoassay SOP IM/A/037	
Serum	Antiphospholipid screen (IgG): Cardiolipin Ab Beta-2-glycoprotein I Ab (B2GP)	Werfen Bioflash using a chemiluminescent immunoassay SOP IM/A/037	
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/A/036	
Serum	Intrinsic factor antibodies	Competitive inhibition immunoenzymatic assay in conjunction with manufacturer's instructions using Beckman DXi and using in-house procedures: BI/S/7001 BI/S/700	



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HUMAN BODY FLUIDS (cont'd)	Immunological examinations for the purpose of clinical diagnosis (cont'd)		A
	<u>Autoimmune Disease Testing</u> (cont'd)		
Serum	Thyroid peroxidase antibodies	Immunoenzymatic sandwich assay BI/S/700 in conjunction with manufacturer's instruction using DXi and in-house procedures	
Serum	Extractable Nuclear Antigens (IgG): Ro La Sm SmRNP Jo-1 Scl-70	EuroImmun EuroblotOne Immunoblot SOP- IM/A/032	
Serum	Liver antibodies (IgG): Anti-M2 M2-3E LKM 1 SLA/LP LC-1	EuroImmun EuroblotOne Immunoblot SOP- IM/A/032	
Serum	Myositis associated antibodies (IgG): Mi-2 α Mi-2 β TIF1 γ MDA5 NXP2 SAE1 Ku PM-ScI100 PM-ScI75 Jo-1 SRP PL-7 PL-12 EJ OJ Ro-52	Eurolmmun EuroblotOne Immunoblot SOP- IM/A/032	



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HUMAN BODY FLUIDS (cont'd)	Immunological examinations for the purpose of clinical diagnosis (cont'd)		A
	<u>Autoimmune Disease Testing</u> (cont'd)		
Serum	Specific Mitochondrial Antibodies (IgG/IgM): Anti-M2/M4/M9	Manual line blots in conjunction with manufacturer's instructions and in-house procedures: IA/A/030	
Serum	Specific vaccine related antibodies: Pneumococcal Haemophilus influenzae B Tetanus toxoid	ELISA using Triturus automated processor in conjunction with manufacturer's instructions and in house procedures: IM/A/022	
	Immunochemistry		
Serum	Detection and immunotyping of monoclonal paraproteins	Sebia Capillarys Octa 3 using capillary zonal electrophoresis and immunosubtraction SOP IM/M/042	
Serum/Urine	Detection and immunotyping of monoclonal paraproteins	Sebia Hydrasys using gel electrophoresis and immunofixation SOP IM/M/043	
Serum	Cryoglobulins	Visual inspection, Sebia Capillarys Octa 3 using capillary zonal electrophoresis and Sebia Hydrasys gel immunofixation SOP IM/M/009	
Serum	Specific proteins: Immunoglobulin G Immunoglobulin M Immunoglobulin A Complement C3 Complement C4 Rheumatoid factor Beta-2-Microglobulin Haptoglobin	Turbidimetry using in-house procedures BI/AU/001 and in conjunction with manufacturer's instructions using: AU 5800	



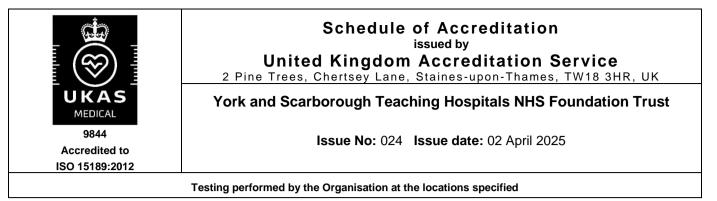
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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd)	Immunological examinations for the purpose of clinical diagnosis (cont'd)		A
	Immunochemistry (cont'd)		
Serum	Serum free light chains: Free lambda Free kappa C1 Inhibitor antigenic assay Sensitive IgA	Turbidimetry using in-house procedures IM/M/031, IM/M/037 and in conjunction with manufacturer's instructions using: Optilite SOP IM/M/040	
	Caeruloplasmin		
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	



Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd)	Immunological examinations for the purpose of clinical diagnosis (cont'd) Immunodeficiency		A
Whole blood EDTA	Lymphocyte subsets: • CD45/CD3 • CD45/CD3/CD4 • CD45/CD3/CD8 • CD45/CD3/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- /lgD+ • CD45/CD19/CD27+/l gD+ • CD45/CD19/CD27+/l gD- • CD21 $_{10}$ B-cells • HLA B27 • CD34	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.	



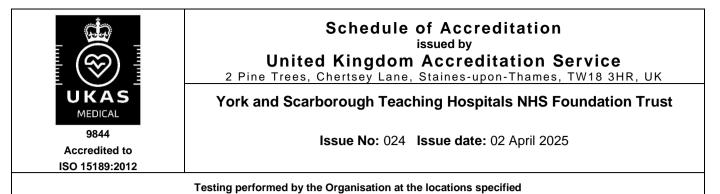
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HUMAN BODY FLUIDS (cont'd)	Immunological examinations for the purpose of clinical diagnosis (cont'd)		A
	Immunodeficiency (cont'd)		
Heparinised whole blood	Neutrophil function tests: Neutrophil burst test Neutrophil MPO test Reporting proportion of 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 ImmunoglobulinE (IgE): Sp. IgE Tryptase PR3/MPO/GBM antibodies (IgG)	Chemiluminescence using in house procedures BI/S/508.BI/S/509, BI/S/611 in conjunction with manufacturer's instruction using Thermo Fisher Unicap 250	
	Detection and quantification of specific IgE to the following allergens:		
Serum	Timothy grass Bermuda grass Ragweed Mugwort Wall pellitory Plantain Saltwort Birch Cypress Olive Saltwort Birch <i>Alternaria alternata</i> <i>Aspergillus fumigatus</i> Aspergillus oryzae Dog Cow Cat Horse House dust mite Honeybee venom Common wasp venom Paper wasp venom		



Materials/Products tested	Type of test/Properties	Standard specifications/	Location
	measured/Range of measurement	Equipment/Techniques used	Code
HUMAN BODY FLUIDS (cont'd)	Immunological examinations for the purpose of clinical diagnosis (cont'd)		A
	Detection and quantification of specific IgE to the following allergens: (cont'd)	Chemiluminescence using in house procedures BI/S/508.BI/S/509, BI/S/611 in conjunction with manufacturer's instruction using Thermo Fisher Unicap 250	
Serum (cont'd)	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 Cocksfoot Common reed Cultivated oat Cultivated rye Cultivated wheat False oat grass Johnson grass Maize corn Meadow fescue	Thermo Fisher Unicap 250	



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HUMAN BODY FLUIDS (cont'd)	Immunological examinations for the purpose of clinical diagnosis (cont'd)		A
	Detection and quantification of specific IgE to the following allergens: (cont'd)	Chemiluminescence using in house procedures BI/S/508.BI/S/509, BI/S/611 in conjunction with manufacturer's instruction using Thermo Eicher Unicap 250	
Serum (cont'd)	Meadow grass Rye grass Salt grass Velvet grass Sweet vernal grass Wild rye grass Alfafa 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 Sugar beet Sunflower wall pellitory Western ragweed Wormwood Yellow dock Acacia American beech	Thermo Fisher Unicap 250	



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HUMAN BODY FLUIDS (cont'd)	Immunological examinations for the purpose of clinical diagnosis (cont'd)		A
	Detection and quantification of specific IgE to the following allergens: (cont'd)	Chemiluminescence using in house procedures BI/S/508.BI/S/509, BI/S/611 in conjunction with manufacturer's instruction using	
Serum (cont'd)	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 Mesquite Mountain juniper Mulberry Oak Oil Palm Paloverde Pecan, Peppertree Pine Privet	Thermo Fisher Unicap 250	



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HUMAN BODY FLUIDS (cont'd)	Immunological examinations for the purpose of clinical diagnosis (cont'd)		A
	Detection and quantification of specific IgE to the following allergens: (cont'd)	Chemiluminescence using in house procedures BI/S/508.BI/S/509, BI/S/611 in conjunction with manufacturer's instruction using	
Serum (cont'd)	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 flavus Aspergillus flavus Aspergillus terreus Aureobasidium pullulans Botrytis cinerea Candida albicans Chaetomium globosum Cladosporium herbarum Curvularia lunata 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	Thermo Fisher Unicap 250	



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HUMAN BODY FLUIDS (cont'd)	Immunological examinations for the purpose of clinical diagnosis (cont'd)		A
	Detection and quantification of specific IgE to the following allergens: (cont'd)	Chemiluminescence using in house procedures BI/S/508.BI/S/509, BI/S/611 in conjunction with manufacturer's instruction using Thermo Fisher Unicap 250	
Serum (cont'd)	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 feathers Canary bird feathers Cat dander Chicken droppings Chicken feathers Chicken, serum proteins Chinchilla epithelium Cow dander Deer epithelium Dog dander Duck feathers Ferret epithelium Finch feathers Fox epithelium Goat epithelium Goose feathers Guinea pig epithelium Hamster epithelium Horse dander Horse, serum proteins		



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HUMAN BODY FLUIDS (cont'd)	Immunological examinations for the purpose of clinical diagnosis (cont'd)		A
	Detection and quantification of specific IgE to the following allergens: (cont'd)	Chemiluminescence using in house procedures BI/S/508.BI/S/509, BI/S/611 in conjunction with manufacturer's instruction using	
Serum (cont'd)	Mink 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 Rat epithelium, serum proteins and urine proteins Rat serum proteins Rat serum proteins Rat serum proteins Rat serum proteins Rat serum proteins Rat serum proteins Sheep epithelium Swine epithelium Turkey feathers Storage mite House dust mite Berlin beetle Blood worm Cockroach Fire ant Green nimitti Horse fly Mediterranean flour moth	Thermo Fisher Unicap 250	



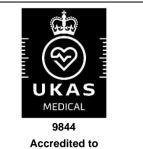
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HUMAN BODY FLUIDS (cont'd)	Immunological examinations for the purpose of clinical diagnosis (cont'd)		A
	Detection and quantification of specific IgE to the following allergens: (cont'd)	Chemiluminescence using in house procedures BI/S/508.BI/S/509, BI/S/611 in conjunction with manufacturer's instruction using	
Serum (cont'd)	Moth Bumble bee venom European paper wasp White faced hornet Amoxicilloyl Ampicilloyl Cefaclor Chlorhexidine Chymopapain Gelatin bovine Insulin bovine Insulin bovine Insulin porcine Penicilloyl G Penicilloyl V Pholcodine Morphine Suxamethonium (succinylcholine) Abachi wood dust Bougainvillea Castor bean Chloramin T Cotton seed Ethylene oxide Ficus Formaldehyde/Formalin Green coffee bean Hexahydrophtalic anhydrid Isocyanate HDI Isocyanate HDI Isocyanate TDI Ispaghula Methyltetrahydrophtalic anhydrid Phthalic anhydride Silk	Thermo Fisher Unicap 250	



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HUMAN BODY FLUIDS (cont'd)	Immunological examinations for the purpose of clinical diagnosis (cont'd)		A
	Detection and quantification of specific IgE to the following allergens: (cont'd)	Chemiluminescence using in house procedures BI/S/508.BI/S/509, BI/S/611 in conjunction with manufacturer's instruction using	
Serum (cont'd)	Silk waste Sunflower seed Trimellitic anhydride fish feed Cotton Daphni Seminal fluid Streptavidin Tobacco loof	Thermo Fisher Unicap 250	
Serum (cont'd)	Tobacco leaf Anisakis Ascaris Apple Apricot Asparagus Aubergine Avocado Persea americana Bamboo shoot Banana Beetroot Blackberry Blueberry Broccoli Brussel sprouts Cabbage Carambola Carrott Cauliflower Cherry Cucumber Fennel Fig Garlic Grape Grapefruit Guava Jack fruit Jujube		



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HUMAN BODY FLUIDS (cont'd)	Immunological examinations for the purpose of clinical diagnosis (cont'd)		A
	Detection and quantification of specific IgE to the following allergens: (cont'd)	Chemiluminescence using in house procedures BI/S/508.BI/S/509, BI/S/611 in conjunction with manufacturer's instruction using Thermo Fisher Unicap 250	
Serum (cont'd)	Kiwi Lemon Lettuce Lime Litchi Mandarin (tangerine, clementine, satsumas) Mango Melon Olive (black, fresh) Onion Orange Papaya Passion fruit Pear 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		



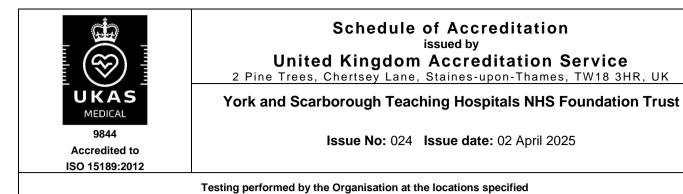
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HUMAN BODY FLUIDS (cont'd)	Immunological examinations for the purpose of clinical diagnosis (cont'd)		A
	Detection and quantification of specific IgE to the following allergens: (cont'd)	Chemiluminescence using in house procedures BI/S/508.BI/S/509, BI/S/611 in conjunction with manufacturer's instruction using	
Serum (cont'd)	Gluten Green bean Japanese millet Lentil Lima bean Linseed Lupin seed Macadamia Pea Peanut Pecan nut Pistachio 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	Thermo Fisher Unicap 250	



Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd)	Immunological examinations for the purpose of clinical diagnosis (cont'd) Detection and quantification of specific IgE to the following allergens: (cont'd)	Chemiluminescence using in house procedures BI/S/508.BI/S/509, BI/S/611 in conjunction with manufacturer's instruction using	A
Serum (cont'd)	Dill Fennel seed Ginger Green pepper Lovage Mace Marjoram Mint Mustard Oregano Paprika 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	Thermo Fisher Unicap 250	



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HUMAN BODY FLUIDS (cont'd)	Immunological examinations for the purpose of clinical diagnosis (cont'd)		A
	Detection and quantification of specific IgE to the following allergens: (cont'd)	Chemiluminescence using in house procedures BI/S/508.BI/S/509, BI/S/611 in conjunction with manufacturer's instruction using Thermo Fisher Unicap 250	
Serum (cont'd)	Octopus Orange roughy Oyster Pacific squid Plaice Pollock Red snapper Salmon Sardine Japanese Pilchard Sardinops melanosticta Scallop Shrimp Snail		
Serum (cont'd)	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, boiled Sheep milk Sheep whey Carob (E410)		



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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)	Immunological examinations for the purpose of clinical diagnosis (cont'd)		A
	Detection and quantification of specific IgE to the following allergens: (cont'd)	Chemiluminescence using in house procedures BI/S/508.BI/S/509, BI/S/611 in conjunction with manufacturer's instruction using	
Serum (cont'd)	Guar, guar gum (E412) Gum arabic (E414) Tragacanth (E413) Cochineal extract (Carmine red) (E120) Cacao Coffee Honey Hop Malt Mushroom Tea Yeast <u>Food mixes of:</u> Peanut, Hazel nut, Brazil nut, Almond, Coconut Fish, Shrimp, Blue mussel, Tuna, Salmon Wheat, Oat, Maize, Sesame seed, Buckwheat Egg white, Milk, Fish, Wheat, Peanut, Soybean Tomato, Yeast, Garlic, Onion, Celery Hazel nut, Brazil nut, Orange, Apple, Cacao Almond, Kiwi, Melon, Banana, Grape	Thermo Fisher Unicap 250	



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HUMAN BODY FLUIDS (cont'd)	Immunological examinations for the purpose of clinical diagnosis (cont'd)		A
	Detection and quantification of specific IgE to the following allergens: (cont'd)	Chemiluminescence using in house procedures BI/S/508.BI/S/509, BI/S/611 in conjunction with manufacturer's instruction using	
	Food mixes of: (cont'd)	Thermo Fisher Unicap 250	
Serum (cont'd)	Pork, Beef, Egg yolk, Chicken, Turkey		
	Maize, Pea, White bean, Carrot, Broccoli		
	Rye, Rice, Potato, Mushroom, Pumpkin		
	Pea, White bean, Carrot, Potato		
	Tomato, Spinach, Cabbage, Paprika		
	Orange, Apple, Banana, Peach		
	Strawberry, Pear, Lemon, Pineapple		
	Apple, Banana, Pear, Peach		
	Pea, Peanut, Soybean		
	Carrot, Potato, Spinach, Cucumber		
	Wheat, Rye, Barley, Rice		
	Kiwi, Melon, Banana, Peach, Pineapple		
	Pecan nut, Cashew nut, Pistachio, Walnut		



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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)	Immunological examinations for the purpose of clinical diagnosis (cont'd)		A
	Detection and quantification of specific IgE to the following allergens: (cont'd)	Chemiluminescence using in house procedures BI/S/508.BI/S/509, BI/S/611 in conjunction with manufacturer's instruction using	
	Food mixes of: (cont'd)	Thermo Fisher Unicap 250	
Serum (cont'd)	Pork, Beef, Chicken meat, Turkey meat		
	Hazel nut, Shrimp, Kiwi, Banana		
	Sesame seed, Yeast, Garlic, Celery		
HUMAN BODY FLUIDS AND TISSUES	Microbiology examination for the purposes of clinical diagnosis	In house documented methods based on related UK Standards for Microbiology investigations (UKHSA SMIs):	A
	General isolation of microorganisms of clinical significance.	Manual inoculation followed by culture using:	
Aspirates Cellular and fluid material contained on swabs and cannulae	Significance.	Ears examination MI/655 Eye examination MI/368 General bench SOP MI/012	
Faeces		Enteric processing MI/380 Campylobacter MI/382 E.coli O157 MI/654 Yersinia MI/657 Vibrio/Pleisiomonas/Aeromonas MI/659 Salmonella MI/660 Shigella MI/665	
Fluids (incl. contact lenses fluid)		MI/039 CAPD MI/010 CSF MI/012 ascitic fluids	



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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 AND TISSUES (cont'd)	Microbiology examination for the purposes of clinical diagnosis (cont'd)	In house documented methods based on related UK Standards for Microbiology investigations (UKHSA SMIs):	A
Genital samples		Genital bench specimen processing MI/662	
Samples from sterile sites		Prosthetic joint associated tissue samples MI/363	
Tissues		Clinical and hot bench specimen processing MI/662	
Urine		General urine methods MI/008 Urine sample processing MI /378	
	Detection, identification and quantification of:	Staining (inc Gram) and microscopic examination using: MI/02	
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		
Whole blood	General isolation of microorganisms of clinical significance.	Automated culture using BD BACTEC FX continuous monitoring system MI/009	
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 MI/1030	
Urine	Quantification of white and red blood cells, bacteria and epithelial cells	Manual Inverted Microscopy/enumeration and manual inoculation using MI/008 general urine methods MI/378 urine sample processing	



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	Type of test/Properties		
Materials/Products tested	measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Microbiology examination for</u> <u>the purposes of clinical</u> <u>diagnosis</u> (cont'd)	In house documented methods based on related UK Standards for Microbiology investigations (UKHSA SMIs):	A
Cerebral fluid samples	Quantification of white and red blood cells and bacteria	Microscopy (inc. Gram Stain) using MI/010 CSF MI/012 Gram stain	
Female genital tract swabs	Microscopic diagnosis of bacterial vaginosis	Microscopy examination (Hay's criteria) using: MI/011 MI/662 Genital bench specimen processing	
Swabs	Screening for Methicillin resistant <i>Staphylococcus</i> <i>aureus</i> (MRSA)	Manual inoculation and culture using MI/014 Resistance screening MI/667 MRSA/MSSA screening	
	General isolation of microorganisms of clinical significance	Manual inoculation and culture using:	
Sputum	olg.mod.loo	Culture media, growth SOP MI/1025	
Bronchial lavage		Respiratory investigations MI/1026	
		Manual inoculation and culture using MI/661 resistance screening and:	
Rectal swabs	Screening for Vancomycin resistant enterococci (VRE)	MI/672	
Faeces	Screening for Extended spectrum betalactamases (ESBL)	MI/706	
Rectal swabs	Screening for Extended spectrum betalactamases (ESBL)	MI/014	
Faeces and rectal swabs	Screening for Carbapenamase producing Enterobacteriaceae (CPE)	MI/705	



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	Microbiology examination for the purposes of clinical diagnosis (cont'd)	In house documented methods based on related UK Standards for Microbiology investigations (UKHSA SMIs):	A
Faeces and rectal swabs	Trans-rectal screening for Carbapenamase producing Enterobacteriaceae (CPE) and Ciprofloxacin and Gentamicin resistance	MI/705	
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 MI/016	
Respiratory samples Urine Tissue Swabs (including endoscopy) Body fluids	Isolation and presumptive identification of Acid-alcohol fast bacilli (inc <i>Mycobacterium</i> <i>spp)</i>	Automated culture using BD MGIT continuous monitoring system. MI/009 Fluorescent microscopy as above.	
Whole Blood	Isolation and presumptive identification of Acid-alcohol fast bacilli (inc <i>Mycobacterium</i> <i>spp)</i>	Automated culture using BD BacTec 40 continuous monitoring system. MI/009 Fluorescent microscopy as above.	
Hair, skin, nail	General isolation and characterisation of clinically significant fungi.	Manual culture and Calcofluor white fluorescent microscopy using MI/013	
Cultures isolated in house from the above	Identification of clinically significant bacteria.	Biochemical profile determination using automated Matrix-assisted laser desorption/ionisation (MALDITOF) MI/674 Maldi Biotyper MI/095 VITEK MI/1011 API	
Whole blood – positive blood culture specimens	Direct identification of clinically significant bacteria.	Matrix-assisted laser desorption/ionisation (MALDITOF) MI/674 MaldiBiotyper	



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	Microbiology examination for the purposes of clinical diagnosis (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 MI/670 EUCAST method of disc diffusion	
		Gradient MIC determination by E- test using MI/1010 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 MIM068	
Culture isolated in house from the above	Identification of Staphylococcal isolates	Prolab Staphylococcal Latex Agglutination kit MI/003	
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 MI/696	
Urine	Detection of Legionella antigen	Binax NOW Legionella Urinary Antigen Test kit by Alere MI/677	
Culture isolated in house from the above	Detection of <i>Salmonella</i> polyvalent 'O' (PSO) and 'H' (PSH); <i>Shigella spp. Vibrio</i> <i>spp</i>	Salmonella MI/660, Shigella MI/665- Vibrio/Pleisiomonas/Aeromonas MI/659	
Female genital swabs	Detection of <i>Trichomonas</i> vaginalis	Broth culture and light microscopy MI/662	
Faeces	Detection of <i>Helicobacter</i> pylori antigen	Pro-flow Lateral flow kit MI/066	
	Identification of <i>E.coli</i> 0157	Prolex latex kit using E coli O157 MI/654	



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	Microbiology examination for the purposes of clinical diagnosis (cont'd)	In house documented methods based on related UK Standards for Microbiology investigations (UKHSA SMIs):	A
Faeces	Detection of ova, cysts and parasites (OCP)	Concentration and light microscopic examination using MI/017	
Faeces	Detection of <i>Cryptosporidium</i> oocysts	Fluorescent microscopy (Auramine stain) using MI/679	
	Identification of Cyclospora by microscopy		
Faeces	Detection of <i>C.difficile</i> GDH antigen	DS2 automated EIA platform using MI/1016 Techlab Cdiff Check and manual lateral flow Techlab Cdiff chek complete MI/1023	
Faeces	Detection of <i>C.difficile</i> toxin A &B	Lateral flow Techlab Cdiff Chek complete using MI/062	
Faeces	Detection of Rotavirus antigen	DS2 automated EIA platform, EIA Rota Premier meridian, antigen kit using MI/063 and MI/062	
Blood	Detection of Gamma interferon antigen	DS2 automated EIA MI/064 and MI/062 4	
	Molecular examination activities for the purpose of clinical diagnosis	Documented in house methods incorporating manufacturer's' instructions where relevant using Cepheid GeneXpert real time PCR SOP MVI/226	A
Cultures isolated in house from the above	Detection of MRSA	MVI/230	
Faeces	Detection of Norovirus	MVI/376	
Faeces	Detection of C.difficile toxin	MVI/226	
Nasopharyngeal swabs, nose and throat swabs	Quad test - detection of RSV and Influenza A & B, RSV and SARS-CoV-2	MVI/226	



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Molecular examination</u> <u>activities for the purpose of</u> <u>clinical diagnosis</u> (cont'd)	Documented in house methods incorporating manufacturer's' instructions where relevant using Cepheid GeneXpert real time PCR SOP MVI/226	A
EDTA Plasma	HIV virus RNA	VI/027, VI061	
EDTA Plasma	Hepatitis C virus RNA	VI/027, VI061	
EDTA Plasma	Hepatitis B virus DNA	VI/044, VI/061	
Sputum, bronchial lavage	Detection of <i>Mycobacterium</i> <i>tuberculosis</i> nucleic acid and	Cepheid GeneXpert real time PCR using SOP MI/375, MVI.226	
	rifampicin resistance.	Cepheid GeneXpert real time PCR using SOP MVI/226	
Pernasal aspirate/swab	RSV RNA	MVI/227	
	Influenza RNA	MVI/227	
Nasal swab	MRSA DNA	MVI/230	
		Elitech InGenius nucleic acid extraction and PCR system VI/158 and VI/128	
CSF, skin, eye, throat, vesicle & genital swabs	HSV I & II	VI/159	
CSF Urine	Adenovirus Varicella Zoster virus Enterovirus Parechovirus virus CMV (qualitative)	VI/159	
	Quantification of:		
EDTA/plasma	EBV viral load CMV viral load BKV viral load	VI/160	
Urine	<i>Mycoplasma genitalium</i> and associated macrolide resistance genes	VI/168	
	Mycoplasma genitalium DNA		



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	Molecular examination activities for the purpose of clinical diagnosis (cont'd)	Documented in house methods incorporating manufacturers' instructions where relevant using:	А
		Elitech InGenius nucleic acid extraction and PCR system VI/158 and VI/128	
Genital swabs, urine	C.trachomatis DNA	VI/007 VI/068	
Genital swabs, urine	N. gonorrhoeae DNA	VI/007 VI/068	
Genital swabs, urine	T. vaginalis DNA	VI/007	
		BioFire FilmArray Torch multiplex PCR technology	
Nasopharyngeal secretion	Respiratory Pathogens (RP2) plus Panel:	MI/1042	
	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		



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	Molecular examination activities for the purpose of clinical diagnosis (cont'd)	Documented in house methods incorporating manufacturers' instructions where relevant using:	A
Nasopharyngeal secretion (cont'd)	Respiratory Pathogens (RP2) plus Panel:	MI/1042	
	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>	BioFire FilmArray Torch multiplex PCR technology MI/1042	
	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		



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United Kingdom Accreditation Service 2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

York and Scarborough Teaching Hospitals NHS Foundation Trust

Issue No: 024 Issue date: 02 April 2025

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Molecular examination</u> <u>activities for the purpose of</u> <u>clinical diagnosis</u> (cont'd)	Documented in house methods incorporating manufacturers' instructions where relevant using:	A
Bronchoalveolar lavage, Sputum	Pneumonia panel plus (cont'd)	BioFire FilmArray Torch multiplex PCR technology using MI/1042	
	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 Mycoplasma pneumoniae Iuman 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		



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	Molecular examination activities for the purpose of clinical diagnosis (cont'd)	Documented in house methods incorporating manufacturers' instructions where relevant using:	А
CSF	Meningitis/Encephalitis Panel	MI/1050	
	Escherichia coli K1, Haemophilus influenzae, Listeria monocytogenes, Neisseria meningitidis, Streptococcus agalactiae, Streptococcus gneumoniae, Cryptococcus gattii/neoformans, Cytomegalovirus, Herpes simplex virus 1, Herpes simplex virus 2, Human herpesvirus 6, Enterovirus, Human parechovirus, Varicella zoster virus.		



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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 AND TISSUES (cont'd)	Serological activities for the purpose of clinical diagnosis	Documented in house methods incorporating manufacturers' instructions where relevant using:	A
		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:	
Serum	Microbial serology for:	Beckman Coulter -UniCel Dxl 800 Procedures:VI/049 Hepatitis results protocol: VI/015 HIV results protocol: VI/014	
	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*		
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/008	



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	Serological activities for the purpose of clinical diagnosis (cont'd)	Documented in house methods incorporating manufacturers' instructions where relevant using:	A
		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:	
Serum	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	DiaSorin Liaison XL VI/048 (chemiluminescence)	
Nasopharyngeal swabs, nose and throat swabs	SARS-CoV-2	Perkin Elmer Chemagenic 360 extraction platform	
Nasopharyngeal swabs, nose and throat swabs	SARS-CoV-2	Samba II	



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	Serological activities for the purpose of clinical diagnosis (cont'd)	Documented in house methods incorporating manufacturers' instructions where relevant using:	A
Nose & Throat) Swabs in VTM	Nucleic acid extraction as below	Euroclone DuplicaPrep/Prepito D extraction platform and Euroclone Duplica NA body fluid kit and the below platforms	
	Detection of SARS-CoV-2 virus RNA (COVID-19) specifically RdRp, N and E gene	ABI 7500 TR PCR using the Gene finder COVID 19 plus Real AMP kit or	
	Detection of SARS-CoV-2 virus RNA (COVID-19) specifically Orf1ab/RdRp and E gene	the Anatolia Bosphore COVID-19 kit	
	Detection of SARS-CoV-2 virus RNA (COVID-19) specifically RdRp, N and E gene	ABI 7500 TR PCR using the Gene finder COVID 19 plus Real AMP kit	
END			<u>.</u>



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	Apper	ndix 1	
C Hull Royal Infirmary - Wards	Glucose	C Hull Royal Infirmary - Clinics/outpatient	Glucose
HRI Gastro	x	HRI Acute care, ambulatory	х
HRI Diabetes	x	HRI Respiratory	х
HRI Neurology	x	HRI General surgery	х
HRI Stroke	x	HRI Diabetes	х
HRI Orthopaedic	x	HRI Renal	х
HRI Medical	x	HRI Medical day unit	Х
HRI General medicine (COVID-19)	х	HRI Medical OPD	Х
HRI Ophthalmology	x	HRI Orthopaedic OPD	Х
HRI Respiratory (COVID-19)	x	HRI Xray	х
HRI General medicine (COVID-19)	x	HRI Surgical	х
HRI Neurology	x	HRI Acute care - ED	х
HRI Respiratory	x	HRI Endoscopy	х
HRI Winter ward	x	HRI Ophthalmology OP	х
HRI General surgery	x	HRI Ophthalmology Clinic	х
HRI Rheumatology	x	HRI Fracture Clinic	х
HRI Vascular	x	HRI discharge lounge	х
HRI Medical Elderly	x	HRI Antenatal clinic	х
HRI Acute Medical Unit	x	HRI occupational therapy	х
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	х		
HRI Surgical	x		
HRI Medical	х		
HRI NICU	х		
HRI OPD	х		
HRI SCBU	х		
HRI Paed assessment unit	х		



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Appendix 1				
D Castle Hill Hospital- Wards	Glucose	D Castle Hill Hospital - Clinics/outpatient	Glucose	
CHH Complex rehab	x	CHH Oncology	Х	
CHH Colorectal	x	CHH Cardiology	Х	
CHH Colorectal and gynae	x	CHH Dermatology	Х	
CHH Upper GI	x	CHH Endoscopy	Х	
CHH Urology	x	CHH Immunomodulatory Infusion Centre	Х	
CHH Breast / ENT	x	CHH Immunology	Х	
CHH Cardiac	x	CHH Oncology	Х	
CHH Oncology	x	CHH Urology Ambulatory Bay	Х	
CHH Surgical	x	CHH Day Surgery -recovery area post op	Х	
CHH Infectious diseases	x	CHH Breast / ENT-recovery area post op	Х	
CHH Medical Elderly	x	CHH Cardiac -recovery area post op	Х	
CHH intensive Care unit	x	CHH Plastics	Х	
CHH Max Fax theatre	x	CHH Preassessment	Х	
CHH Surgery theatre	x	CHH Xray	Х	
CHH Cardiology Catheter Lab theatre	x	CHH Surgical assessment	Х	
CHH Plastics theatre	x	CHH Breast care	Х	
CHH General medicine theatre	x	CHH ENT	Х	
CHH Gynae theatre	x			
E East Riding Hospital				
Adult Outpatients Clinic	x			
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