


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 8509 Accredited to ISO 15189:2012	Sheffield Teaching Hospitals NHS Foundation Trust	
	Issue No: 005 Issue date: 04 April 2022	
	Department of Cellular and Infectious Sciences Royal Hallamshire Hospital Glossop Road Sheffield S10 2JF	Contact: Duncan Whittaker Tel: +44 (0) 114 2714964 E-Mail: duncan.whittaker2@nhs.net Website: www.sth.nhs.uk

Testing performed by the Organisation at the locations specified below

Locations covered by the organisation and their relevant activities

Laboratory locations:

Location details	Activity	Location code
Address Royal Hallamshire Hospital Glossop Road Sheffield S10 2JF	Local contact Histopathology Diagnostic Cytopathology	A
Address Laboratory Medicine Centre (North Lane) Northern General Hospital Herries Road Sheffield S5 7AU	Local contact Rapid frozen section for intraoperative reporting Microbiology Department	B

Site activities performed away from the locations listed above:

Location details	Activity	Location code
Dermatology Clinic, Royal Hallamshire Hospital	Mohs' rapid frozen section service	C



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Histopathology (cont'd)</u>		
	Preparation and examination to identify or exclude morphological and cytological abnormalities	Macroscopic and Microscopic examination using in-house procedures in conjunction with manufacturer's instructions for the following methods (where relevant)	
Fresh and frozen tissue	Intraoperative diagnosis	Rapid frozen section: Cryotomy and manual H&E staining using a Bright Cryostat and HIML 131, HIMED067, HISL003, HIML 077, HISL007	B
Stained tissue section on glass slide	Intraoperative diagnosis	Scanning of glass slides using Hamamatsu Nanozoomer 2.0RS Scanner and HISL003, HIMED056	B
Scanned image of frozen section on glass slide	Intraoperative diagnosis	Viewing slide image using Dell monitor and primary reporting using HMED067, Reporting for Primary Digital Reporting	A
Fresh and frozen tissue	Intraoperative diagnosis	Rapid frozen section Moh's micrographic technique: Cryotomy and manual H&E using a Bright microscope and HIML048	C
Skin	Detection of inflammatory skin disease	Direct Immunofluorescence using Bright cryostat and HIML039, 036	A
Formalin fixed paraffin embedded (FFPE) tissue	Basophilic and eosinophilic tissue structures	Routine Haematoxylin and eosin (H&E) staining and coverslipping: Automated method using HIML090 and Dako Coverstainer and TissueTek coverslipper	A
	Detection of the following:	Special staining: Manual methods and the following stains	A
	Acid mucins	Alcian Blue HISM006	



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Histopathology (cont'd)</u> Preparation and examination to identify or exclude morphological and cytological abnormalities	Macroscopic and Microscopic examination using in-house procedures in conjunction with manufacturer's instructions for the following methods (where relevant)	A
	Detection of the following:	Special staining: Manual methods and the following stains	A
	Acid and neutral mucopolysaccharides	Alcian Blue PAS HISM006	
	Calcium deposits	Alizarin Red HISM076	
	Amyloid	Congo Red HISM007	
	Acid and neutral mucopolysaccharides	Diastase Alcian Blue PAS HISM006	
	Basement membranes, neutral mucins	Diastase PAS HISM011, 034	
	Differentiation of haematopoietic cell lineages and mast cells	Giemsa (Lennert's) HISM001	
	Helicobacter pylori	Giemsa (Modified) HISM015	
	Reticulin	Gordon and Sweets Reticulin HISM008	
	Gram positive and Gram negative bacteria	Gram Twort HISM061	
	Glomerular basement membrane	Grocotts Methenamine Silver for renal basement membranes HISM027	
	Fungi	Grocotts Methenamine Silver HISM025	
Myelin	Luxol Fast Blue HINP030		



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Histopathology (cont'd)</u> Preparation and examination to identify or exclude morphological and cytological abnormalities	Macroscopic and Microscopic examination using in-house procedures in conjunction with manufacturer's instructions for the following methods (where relevant)	A
	Detection of the following:	Special staining: Manual methods and the following stains	A
	Myelin	Luxol Fast Blue/Cresyl Fast Violet HINP030	
	Melanin	Masson Fontana HSMP030	
	Collagen	Masson Trichrome HISMP010	
	Collagen	Masson Trichrome (Goldner's) HISM063	
	Elastin and collagen	Miller's Elastic Van Gieson HISM031	
	Acid glycoproteins	MILAB HISM066	
	Fibrin deposits	MSB HISM004	
	Acid mucins	Mucicarmine HISM022	
	Hepatitis B surface antigen	Orcein (Shikata) HISM067	
	Basement membranes, neutral mucins, glycogen	Periodic Acid Schiff (PAS) HISM011	
	Fungi	PAS for fungi HISM011	
	Iron	Perls' Prussian Blue HISM005	
	Copper associated protein	Rhodanine HISM065	
Amyloid	Sirius Red HISM019		
Neutral triglycerides	Sudan Black HISM041		



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HUMAN TISSUES AND FLUIDS (cont'd)	Histopathology (cont'd) Preparation and examination to identify or exclude morphological and cytological abnormalities	Macroscopic and Microscopic examination using in-house procedures in conjunction with manufacturer's instructions for the following methods (where relevant)	A
	Detection of the following: Mast cells Calcium salts Acid fast bacilli Spirochetes Acid fast bacilli	Special staining: Manual methods and the following stains Toluidine Blue HISM048 Von Kossa HISM020 Wade Fite HISM055 Warthin Starry HISM024 Ziehl Neelsen HISM021	A
FFPE tissue	Detection of the following Extra cellular beta-amyloid Corticotrophs Squamous and columnar epithelium Hepatocytes ALK protein Myeloid cells, macrophages	Immunohistochemistry: Automated methods using Ventana Benchmark Ultra**** Dako Omnis autostainer* Dako 48 Link Autostainer** Manual staining*** and SOPs HIIC002, HIIC003, HIIC009, HIIC010, HIIC015, HIIC016, HIIC017, HIIC018, HIIC019, HIIC041, HIML036, HIIC046 A4 (beta amyloid) ** ACTH** AE1/AE3* AFP* ALK-1* , **** Annexin*	A



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Histopathology (cont'd)</u> Preparation and examination to identify or exclude morphological and cytological abnormalities	Macroscopic and Microscopic examination using in-house procedures in conjunction with manufacturer's instructions for the following methods (where relevant)	A
FFPE tissue	Detection of the following	Immunohistochemistry cont'd: Automated methods using Ventana Benchmark Ultra**** Dako Omnis autostainer* Dako 48 Link Autostainer** Manual staining***	A
	Lewy bodies	Alpha-Synuclein***	
	Phosphatase sensitive epitope	AT8**	
	Marker of Alzheimer's disease	BAPP*	
	Desmoid tumour, colorectal cancer	Beta-Catenin*	
	Lymphocytes	BCL-2*	
	Lymphoma	BCL-6*	
	Adenocarcinoma	BEREP4*	
	Trophoblasts	Beta HCG	
	Renal allograft rejection	C4d***, ****	
	Ovarian carcinoma	Ca125*	
	Gastrointestinal cancer	Ca19.9*	
	C-cell hyperplasia	Calcitonin*	
	Malignant mesotheliomas	Calretinin*	
	Malignant epithelial cells	CAM 5.2*	
	Burkett lymphoma	CD10*	



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Histopathology (cont'd)</u> Preparation and examination to identify or exclude morphological and cytological abnormalities	Macroscopic and Microscopic examination using in-house procedures in conjunction with manufacturer's instructions for the following methods (where relevant)	A
	Multiple myelomas	CD138*	
	Hodgkin's lymphoma	CD15*	
	Thyomas	CD1a*	
	T-cell lymphoma	CD2*	
	Neoplasms of B-cell derivation	CD20*	
	Malignant lymphomas	CD21*	
	Differentiation of lymphomas	CD23*	
	T cells	CD3*	
	Large cell lymphoma	CD30**	
	Endothelial cells	CD31*	
	Vascular and lymphatic tumours	CD34*	
	Plasma cells	CD38*	
	Thymocytes and T helper cells	CD4*	
	B cell lymphomas	CD43*	
	Tumour cells of lymphoid origin	CD45*	
T cell lymphomas	CD45Ro*		
B and T cell malignancies	CD5*		
T/NK cell lymphomas	CD56*		



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	Myelodysplastic syndrome	CD61*	
	Myeloid neoplasms	CD68 (KP1)*	
	AML	CD68 (PGM1)*	
	T cell lymphoma	CD7*	
	B cell neoplasm	CD79a*	
	Infectious colitis, Crohn's	CD8*	
	Ewing's sarcoma	CD99***, ****	
	Adenocarcinoma	CDX2*	
	Histiogenesis of epithelial tumours	CEA**	
	Neuroendocrine derived tumour	Chromogranin*	
	Labels corneal epithelial cells	CK12***	
	Labels corneal epithelial cells	CK13***	
	Squamous cell carcinoma	CK14*	
	Epithelial tumours	CK19*	
Gastrointestinal epithelium	CK20*		
Differentiation of corneal/conjunctival cells	CK3***		



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HUMAN TISSUES AND FLUIDS (cont'd)	<p><u>Histopathology (cont'd)</u> Preparation and examination to identify or exclude morphological and cytological abnormalities</p> <p>Differentiate squamous cell carcinoma and adenocarcinoma</p> <p>Adenocarcinomas</p> <p>Adenocarcinomas</p> <p>Cytomegalovirus</p> <p>Labels basement membranes</p> <p>Mantle cell lymphomas</p> <p>Rhabdomyosarcomas</p> <p>Gastrointestinal tumour</p> <p>Epithelial cells of tissues</p> <p>Epithelial cells of tissues</p> <p>Oestrogen receptor alpha status</p> <p>Labels platelets</p> <p>Labels cells expressing von Willebrand factor</p> <p>Labels gonadotrophs</p> <p>Labels Apocrine epithelia</p> <p>Metastases from breast carcinoma</p> <p>GATA binding protein 3</p>	<p>Macroscopic and Microscopic examination using in-house procedures in conjunction with manufacturer's instructions for the following methods (where relevant)</p> <p>CK5/6*</p> <p>CK7*</p> <p>Claudin 4**</p> <p>CMV*</p> <p>Collagen IV*</p> <p>Cyclin D1*</p> <p>D33**</p> <p>DOG1*</p> <p>E-Cadherin*</p> <p>EMA*</p> <p>ER**</p> <p>Factor 13A*</p> <p>Factor 8*</p> <p>FSH*</p> <p>GCDFP*</p> <p>GFAP*</p> <p>GATA 3****</p>	A



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Histopathology (cont'd)</u> Preparation and examination to identify or exclude morphological and cytological abnormalities	Macroscopic and Microscopic examination using in-house procedures in conjunction with manufacturer's instructions for the following methods (where relevant)	A
	Labels Somatotroph cells	GH**	
	Labels erythrocytes	Glycophorin*	
	T cell lymphomas	Gran*	
	Mesotheliomas	HBME1**	
	Hepatocellular tumours	Hep1*	
	Human Her2 gene	Her2**, ****	
	Human Herpes type 8	HHV8, ****	
	Melanocytes	HMB45*	
	Basal and squamous epithelium	HMCK*	
	Breast epithelial marker	HMFG1*	
	Choriocarcinoma	HPL*	
	Herpes simplex virus	HSV1*	
	Discrimination of various tumours	IDH**	
	Multiple myelomas	IgA***, ****	
	Lymphoma	IgD*	
	Labels plasma cells containing IgG	IgG***, ****	
Labels plasma cells containing IgG4	IgG4***, ****		
Labels plasma cells containing IgG	IgM***, ****		
Ovarian tumours	Inhibin*		



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	Medulloblastomas	INI-1**	
	B cell lymphomas	KAPPA***, ****	
	Neoplastic cells	KI67*	
	B cell lymphoma	LAMBDA***, ****	
	Basement membranes	LAMININ	
	Pituitary adenomas	LH**	
	Labels dendrites of neurons	MAP-2*	
	Melanomas	MEL-A*	
	Mesotheliomas	Mesothelin**	
	Mismatch repair	MLH1 (MMR)****	
	Mismatch repair	MSH2 (MMR)****	
	Mismatch repair	MSH6 (MMR)****	
	HLA-ABC expression	MHC***	
	Epithelial tissue	MNF116*	
	Labels mucin secreting cells	MUC1	
	Lymphoid malignancies	MUM1**	
	Lymphoid and myeloid disorder	MYELO*	
	Myoblasts	MYO D1***	
	Labels neurons	Neurofilament*	
Malignant melanoma	NK1-C3*		



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Histopathology (cont'd)</u> Preparation and examination to identify or exclude morphological and cytological abnormalities	Macroscopic and Microscopic examination using in-house procedures in conjunction with manufacturer's instructions for the following methods (where relevant)	A
	Neuroendocrine tumours	NSE***, ****	
	Germ cell tumour	OCT4**	
	Cervical carcinoma	P16*, ****	
	Prostate adenocarcinoma	P504S*	
	Neoplasia	P53*	
	Wilm's tumour and Beckwith-Wiedemann Syndrome	P57**	
	Alzheimer and Parkinson disease	P62**	
	Squamous cell carcinoma	P63*	
	Prostate carcinoma	PAP**	
	Parathyroid tumour	Parafibromin***	
	Classification of lymphoma	PAX 5*	
	Carcinoma marker	PAX 8****	
	Pan-neuronal marker	PGP 9.5*	
	Seminomas and desmoplastic small round cell tumours	PLAP**	
	Mismatch repair	PMS2 (MMR)****	
Progesterone receptor alpha status	PR**		
Lactotrophic cells	Prolactin*		
Prostatic adenocarcinoma	PSA*		
Renal cell carcinoma	RCC*		



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<p>HUMAN TISSUES AND FLUIDS (cont'd)</p>	<p><u>Histopathology (cont'd)</u> Preparation and examination to identify or exclude morphological and cytological abnormalities</p> <p>S100 positive neoplasms</p> <p>Leiomyomas, leiomyosarcomas and pleomorphic adenovirus</p> <p>Labels myoepithelial cells in breast</p> <p>Polyoma virus</p> <p>Neuroendocrine neoplasms</p> <p>Differentiation of frontotemporal dementia</p> <p>Vascular tumours, mesothelial cells and peripheral nerves</p> <p>Tumours of thyroid origin</p> <p>T cell lymphomas</p> <p>Classification of pituitary tumours</p> <p>Tumours from lung and thyroid</p> <p>B-cell chronic lymphocytic leukaemia/small lymphocytic lymphoma</p> <p>Labels nucleus of ovary and kidney cells</p>	<p>Macroscopic and Microscopic examination using in-house procedures in conjunction with manufacturer's instructions for the following methods (where relevant)</p> <p>S100*</p> <p>SMA*</p> <p>SMM**</p> <p>SV40*</p> <p>SYNAP*</p> <p>TDP43**</p> <p>Thrombomodulin**</p> <p>Thyroglobulin*</p> <p>TIA1*</p> <p>TSH**</p> <p>TTF1*</p> <p>VIMENTIN*</p> <p>WT1**, ****</p>	<p>A</p>



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Formalin fixed paraffin embedded tissue samples	Detection of: EGFR mutation analysis in lung. BRAF for melanoma KRAS for colorectal cancer NRAS/BRAF in second line Lynch screening	Using in-house procedures in conjunction with manufacturer's instructions (where relevant) Real-time PCR using the Biocartis Idylla™ SOP HIIC048	A
Post mortem lung tissue	Microscopic analysis and counting of asbestos fibres	Manual in-house procedure using HIML114	
Surgical biopsies	Examination of tissues to identify or exclude ultrastructural morphological abnormalities or diagnosis	Electron Microscopy using Philips Electron Microscopes and the following: Processing EM tissue Cutting of EM specimens Embedding EM specimens Operation of electron microscope	
Lymph node tissue	Detect the expression level of Cytokeratin 19 normally not present in lymph node tissue.	One Step Nucleic Acid Amplification (OSNA) using Sysmex RD210 analyser and HIML114	
Scanned images of glass slides tissue sections (provided by UKAS ISO 15189 accredited laboratory customer reference 8264)		Viewing slide image using Dell monitor and primary reporting using HMED067, Reporting for Primary Digital Reporting	A



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<p>HUMAN TISSUES AND FLUIDS (cont'd)</p> <p>Nerve biopsy</p> <p>Tissue samples, predominantly from the central nervous system on FFPE slides (Formalin fixed paraffin embedded)</p> <p>Frozen sections of muscle tissue</p>	<p><u>Neuropathology examination activities to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis</u></p> <p><u>Detection of myelinated nerve fibres</u></p> <p>Detection of the following:</p> <p>Neuronal architecture or the Nissl Substance</p> <p>Senile plaques and neurofibrillary tangles</p> <p>Senile plaques and neurofibrillary tangles</p> <p>Myelin</p> <p>Myelin</p> <p>Detection of the following:</p> <p>Basophilic and eosinophilic structures</p> <p>Acid phosphatase activity</p> <p>Fibre types</p>	<p>Macroscopic and Microscopic examination using in-house procedures in conjunction with manufacturer's instructions for the following methods (where relevant)</p> <p>Nerve Tease preparation using the Olympus SZX12 dissection microscope and KL1500 LCD light source, HINP032</p> <p>Manual staining using the following stains:</p> <p>Cresyl Fast Violet, HINP023</p> <p>Gallyas, HINP009</p> <p>Modified Bielschowsky, HINP048</p> <p>Luxol Fast Blue, HINP030</p> <p>LFB/Cresyl Fast Violet, HINP030</p> <p>Cryotomy using the Leica CM3050S Cryostat and HIN035 followed by manual staining using the following:</p> <p>Rapid H&E HINP052</p> <p>Acid Phosphatase HINP027</p> <p>ATPase at pH 4.3, 4.6, 9.4 HINP036</p>	<p>A</p>



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HUMAN TISSUES AND FLUIDS (cont'd) Frozen sections of muscle tissue	<u>Neuropathology (cont'd)</u> Preparation and examination to identify or exclude morphological and cytological abnormalities Detection of the following: Cytochrome oxidase activity Cytochrome oxidase positive fibres and Cytochrome oxidase negative fibres Nuclei, muscle fibres, mitochondria, sarcoplasmic reticulum, connective tissue, sarcolemma. Myoadenylate deaminase activity Phosphorylase activity Mitochondria and sarcoplasmic reticulum Glycogen Phosphofructokinase activity	Macroscopic and Microscopic examination using in-house procedures in conjunction with manufacturer's instructions for the following methods (where relevant) Cryotomy using the Leica CM3050S Cryostat and HIN035 followed by manual staining using the following: Cytochrome oxidase HINP028 Cytochrome oxidase/SDH HINP033 Engels Gomori Trichrome HINP031 Myoadenylate Deaminase HINP043 Myophosphorylase HINP010 NADH-TR HINP024 PAS/DPAS HINP034 Phosphofructokinase HINP042 Succinate Dehydrogenase HINP019 Sudan Black HINP042	A



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<p>HUMAN TISSUES AND FLUIDS (cont'd)</p> <p>Fresh brain tissue</p> <p>Urine, fluids, aspirates, sputum</p>	<p><u>Neuropathology (cont'd)</u> Preparation and examination to identify or exclude morphological and cytological abnormalities</p> <p>Detection of the following</p> <p>Basophilic and eosinic structures</p> <p>Nuclei cytoplasm</p> <p><u>Non-gynae Cytology</u></p> <p>Examination of cellular material to identify or exclude morphological and cytological abnormalities</p>	<p>Macroscopic and Microscopic examination using in-house procedures in conjunction with manufacturer's instructions for the following methods (where relevant)</p> <p>Brain smear preparation HINP004 and manual staining using the following:</p> <p>Rapid H&E HIM105</p> <p>Rapid Toluidine blue HINP053</p> <p>TriMat class1 microbiological safety cabinet, HIHID062, HISC037.</p> <p>Thermo IEC CL30 centrifuge Boeco U-320 centrifuge, Thermo scientific Cytospin 4, Thermo scientific HISC040.</p> <p>Lini stain Papanicolaou stain HISC020, May-Grunwald stain HISC018, H&E stain HISC008</p>	A
<p>Slides prepared in house as above</p>	<p>Morphological assessment and interpretation/diagnosis</p>	<p>Light microscopy using the Olympus BX45 or Nikon Eclipse E400, RCYSR001 Pre-screening; RCYSR002 Primary Screening; RCYSR005 Pathologist / ABMSP reporting RCYSR025 Negative/Inadequate reporting phrases; RCYSR026 Abnormal cytology reporting phrases</p>	



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HUMAN BODY FLUIDS AND TISSUES	<u>Serology examinations for the purposes of clinical diagnosis</u>	In-house documented procedures based on related UK SMIs and equipment manuals as relevant	
Serum and Plasma	Detection of the following:	Roche Cobas 8000 immunoassay, and SOP VIAS044	B
Serum and Plasma	Hep A IgM Antibody		
Serum and Plasma	Hep A Total Antibody		
Serum and Plasma	Hep B Total Core Antibody		
Serum and Plasma	Hep B Core IgM Antibody		
Serum and Plasma	Hep B Surface Antibody		
Serum and Plasma	Hep B s Antigen Neutralisation		
Serum, Dry Blood Spot and Plasma	Hep B Surface Antigen		
Serum, Dry Blood Spot and Plasma	Hep C Antibody		
Serum, Dry Blood Spot and Plasma	HIV Ag/Antibody combo		
Serum, Dry Blood Spot and Plasma	Rubella IgG Antibody		
Serum and Plasma	Syphilis Antibody IgG		
Serum and Plasma	HIV Ab		
Oral fluid samples			
Serum and plasma	COVID-19 Antibody testing - Anti SARS CoV 2 total antibody (qualitative)	Roche Cobas 8000 Immunoassay and SOP QUGE014	B
Serum and plasma	Detection of the following :	Diasorin Liaison XL automated immunoassay analyser and SOP VIAS045	B
	HBe Ag		
	HBe Ab		
	HBsAg (2nd line)		
	HBsAg Quantitative		
	Hepatitis A Total Antibody		
	Hepatitis C Antibody (2nd line)		
	HIV Ab/Ag (2nd Line)		
	Borrelia IgG		
	CMV IgG		
	CMV IgM		
	CMV Avidity		
	EBV IgM (Clinical)		
	EBV VCA IgG		



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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)	<u>Serology examinations for the purposes of clinical diagnosis (cont'd)</u>	In-house documented procedures based on equipment manuals as relevant	
Serum and plasma	Detection of the following : EBV NA IgG HSV Immunity HTLV I + II Measles Immunity Measles Clinical Mumps Immunity Mumps Clinical Parvovirus Immunity Parvovirus Clinical Rubella IgM Toxoplasma IgG Toxoplasma IgM VZV Immunity	Diasorin Liaison XL automated immunoassay analyser and SOP VIAS045	B
Oral fluid samples	Detection of HIV Ab	Diasorin Liaison XL automated immunoassay analyser and SOP VIAS045, and the HIV Genscreen EIA using SOP VISE035	B
Serum and plasma	Detection of the following: HIV Ag/Ab, HCV Ag/Ab, Syphilis total antibody Syphilis IgM HEV IgM,HEV IgG, Mycoplasma pneumonia IgG, IgA and IgM, VZV glycoprotein IgG	BioRad Evolis Twin Plus (ETP) Automated EIA platform, using the following kits and SOPs: BioRad Genscreen Ultra BioRad Genscreen Enzygnost Syphilis NMT Syphilis IgM Fortress HEV IgM Fortress HEV IgG Launch Virion/Serion ELISA Classic: Mycoplasma pneumonia IgG, IgA and IgM VaccZyme VZV glycoprotein IgG low level EIA. SOP VISE067	B
Serum and plasma	Detction of VZV IgG	Manual ELISA using the following kit: VaccZyme VZV glycoprotein IgG low level EIA and SOP VISE058	B
Serum	Hepatitis E IgG Hepatitis E IgM	Una Fortress HEV IgG VISE038 Una Fortress IgM VISE037	B



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Molecular examinations for the purposes of clinical diagnosis</u>	In-house documented procedures based on equipment manuals as relevant	
Serum and plasma	Quantitative detection of HBV and HCV viral load	Quantitative PCR using the Hologic Panther Aptima and SOP VIMO0051	B
Dry blood spots	Qualitative detection of HCV	Qualitative PCR using Hologic Panther Aptima and SOP VIMO0051	B
Genital swabs and urine	Detection of DNA for Chlamydia trachomatis and Neisseria gonorrhoeae	Hologic Panther quantitative TMA and SOP VICH023	B
Genital swabs	Detection of DNA from Trichomonas vaginalis	Hologic Panther using quantitative TMA SOP VICH023	B
Serum and plasma	Quantitative detection of: HIV type 1 RNA	Quantitative assay using the Hologic Panther Aptima assay (VIMO051)	B
Serum, plasma, Roche PCR product	Hep C genotyping	Autoblot 3000 Immunoblot assay and SOP VIMO003	B
Blood, plasma, dry blood spot, urine, CSF	Quantitative detection of: CMV viral load EBV viral load	Roche Magnapure 96 extraction and Qiagen Rotorgene amplification using SOP VIMO035	B
Blood, plasma, swabs, CSF, NPA, sputum, BAL, urine	Quantitative detection of: BK virus HHV6	Roche Magnapure 96 extraction and Qiagen Rotorgene amplification	B
Blood, swabs, tissue	Quantitative detection of: Parvovirus	Roche Magnapure 96 extraction and Qiagen Rotorgene amplification	B



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Molecular examinations for the purposes of clinical diagnosis</u> (cont'd)	In-house documented procedures based on equipment manuals as relevant	
Blood, plasma, swabs, CSF, NPA, Sputum, BAL, faeces, vomit	Qualitative detection of the following: Respiratory virus (Influenza A, B, H1N1, RSV, Rhinovirus, Parainfluenza 1, 2, 3, 4, HMPV, Coronavirus, Adenovirus) Herpes simplex VZV Adenovirus Enterovirus Norovirus Measles	Qualitative PCE using Roche Magnapure 96 extraction and ABI 7500 amplification and SOPs: VIMO020 VIMO027 VIMO027 VIMO020 VIMO006 VIMO019 VIMO045	B
Swabs, CSF, sputum, urine	Qualitative detection of Mumps Quantitative detection of:	Qualitative PCR, using Roche Magnapure 96 extraction and ABI 7500 amplification SOP VIMO048 Quantitative PCR, using Roche Magnapure 96 extraction and ABI 7500 amplification	B
Blood, plasma Swabs, Induced sputum, BAL	Hepatitis E Pneumocystis jiroveci (PCP)	SOP VIMO049 SOP VIMO039	B
Swabs, sputum, NPA, BAL	Detection of Middle East Respiratory Syndrome Coronavirus (MERS-CoV)	PCR and Extraction using the Qiagen Qiacube platform and Amplification and detection using the ABI7500 SOP VIMO056	B
Swabs, sputum, BAL	Detection of Atypical respiratory organisms (Mycoplasma pneumoniae, Chlamydia pneumoniae & Chlamydia psittaci)	PCR and Extraction using the Roche MP96 and Amplification and Detection using the ABI7500 SOP VIMO046 and VIMO047	B
All respiratory samples (swabs, BAL, NPA, ETS)	Detection of respiratory viruses: Parainfluenza 1-4, Rhinovirus, Coronavirus, RSV A/B, Human Metapneumovirus and Adenovirus	PCR using the Roche FLOW system and MagnaPure 96 extraction system SOP VIMO052 and VIMO053	B



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Molecular examinations for the purposes of clinical diagnosis</u> (cont'd)	In-house documented procedures based on equipment manuals as relevant	
Faeces	Detection of C difficile toxin gene tcdA	Isothermal helicase method using QUIADEL Amplivue instrument and SOP BAEN004	B
Respiratory tract secretions	Detection of Mycobacterium tuberculosis (MTB) complex DNA and rifampicin-resistance associated mutations of the rpoB gene.	PCR and Cepheid GeneExpert System SOP BARE039	B
Nose swab, throat swab and combined Nose/Throat Swabs	Detection of SARS CoV2 PCR (qualitative)	Cepheid GeneXpert real-time PCR and SOP VIMO065	B
AAFB positive cultures	Identification of Mycobacterium tuberculosis complex	HAIN TB Check MPT64	B



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<p>HUMAN BODY FLUIDS AND TISSUES (cont'd)</p> <p>Swabs from wounds, ulcers, genital sites, eyes, nose, throat, ears, respiratory and gastric fluids, CSF, faeces, sterile fluids, pus,</p> <p>Skin, hair, nails Urine</p>	<p><u>Microbiology examinations for the purposes of clinical diagnosis</u></p> <p>Isolation and identification of microorganisms of clinical significance</p>	<p>In-house documented procedures based on equipment manuals as relevant</p> <p>Manual culture using non-selective selective, differential and chromogenic agar plates and liquid enrichment broth as indicated by SOPs: Wound swabs (inc. T/S, N/S, etc), fluids and tissues from sites not expected to be sterile and Neonate screens [BAWS001, BAWS002 &BAWS003] Genital tract swabs [BAGE001] N.gonorrhoeae [BAGE001] CSF culture and shunts [BASF003] Fluid from sites expected to be sterile CAPD fluid [BASF011] Corneal scrape and anterior chamber and vitreous taps [BAMI002] Contact lenses and fluid and corneal grafts [BAMI001] Heart valve culture [BAMI010] intra-venous lines and pacing wire tips [BAMI003] Bordetella culture [BARE011] Faecal culture [BABC016] H pylori culture [BAEN012] Orthopaedic tissue culture [BATI002] MSSA by culture [BAIC004] Multi-resistant Gram Negatives by culture [BAIC001] MRSA by culture [BAIC006] Vancomycin resistant enterococci (VRE) [BAIC002] Respiratory bacterial pathogens by culture [BARE003, BARE006] Cystic fibrosis respiratory culture [BARE001]</p> <p>Mycology by culture [BAMY001] Urine culture (BAUR001)</p>	<p>B</p> <p>B</p>



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Microbiology examinations for the purposes of clinical diagnosis (cont'd)</u>	In-house documented procedures based on equipment manuals as relevant	
Respiratory fluids, CSF, sterile fluids, pus, tissue, urine	Isolation and identification of microorganisms of clinical significance	Manual culture using non-selective selective, differential and chromogenic agar plates and liquid enrichment broth as indicated by SOPs:	B
Urine	Detection of WBC, RBC, epithelial cells, casts	IQ Sprint urine analyser using flow cytometry and BAUR003	B
Urine	Microscopic examination of for qualitative detection of the following: White and red blood cells, casts, epithelial cells	Light microscopy using inverted microscope and SOP BAUR001	B
CSF	Cell count and differential cell count	Manual cell count using SOP BASF003	B
Faeces	Cryptosporidium oocysts	Stained auramine slides by epi-fluorescent microscopy, SOP BAEN022	B
	Ova, cysts and parasites	Wet preparation using light microscopy and concentration using Parasep(BARE022)	B
Skin, hair, nails	Fungal elements	Wet preparations on microscope slides using epi-fluorescent microscopy and SOP BAMY001	B
Vaginal swabs	Clue cells	Stained slides by epi-fluorescent microscopy and SOP BAGE004	B
Respiratory samples, fluids, tissues	Acid fast bacilli	Stained auramine slides and epi-fluorescent microscopy, BACP002	B
Blood	Detection of microbial growth	BD FX analyser using SOP BABC016	B
Blood	Detection and presumptive identification of acid fast bacilli, including Mycobacterium species	Bactec BDFX40 using SOP BARE037	B



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Microbiology examinations for the purposes of clinical diagnosis (cont'd)</u>	In-house documented procedures based on equipment manuals as relevant	
Sputum, tissues, urine, fluids	Detection and presumptive identification of acid fast bacilli, including Mycobacterium species	BD MGIT analyser using SOP BARE05	B
		Mycobacterium culture using LJ media and SOP BARE005	B
Isolates of bacteria and yeasts	Identification of bacteria and yeast	Bruker MalDI-tof Biotyper using mass spectrometry, and Bruker MALDI-SMART SOP BAAS024	B
Isolates of bacteria	Determination of antimicrobial susceptibility	Disc diffusion using EUCAST method and SOP BAAS001	B
		MIC by strip diffusion using E test and MICE, SOP BAAS003	B
		Breakpoint method using EUCAST breakpoints and multipoint inoculation SOP BAAS001	B
Isolates of yeast		MIC using Oxoid Yeastone Sensititre and SOP BAAS029	B
Isolates of bacteria	Detection of carbapenemases OXA-48, KPC, VIM, IMP and NDM	NG-Test CARBA 5 kit, EUCAST method and SOP BAAS055	B
END			