


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 8509 Accredited to ISO 15189:2022	Sheffield Teaching Hospitals NHS Foundation Trust	
	Issue No: 010 Issue date: 23 May 2024	
	Department of Cellular and Infectious Sciences Royal Hallamshire Hospital Glossop Road Sheffield S10 2JF	Contact: Richard Fleming Tel: +44 (0) 114 2715319 E-Mail: richard.fleming1@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
Address Department of Histopathology Chesterfield Royal Hospital Calow S44 5BL	Local contact Greg Zardin Histopathology Department	C

Site activities performed away from the locations listed above:

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



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DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN TISSUES AND FLUIDS Formalin fixed tissues Bone biopsy Tooth	<u>Histopathology</u> Preparation and examination to identify or exclude morphological and cytological abnormalities	Macroscopic and Microscopic examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant) Macroanalysis and dissection: Manual method using: HIRD 015 and 017 Decalcification: Manual method using HIRD 027 Tissue Processing: Automated method using HIML075 and Sakura VIP5 & 6, and Leica Peloris tissue processors Embedding: Manual method using HIML075 and Sakura, Leica and Thermo embedding centres. Microtomy: Manual method using HIML093 and Leica RM2235 and Microm HM 325 microtomes Microtomy: Manual method using HIML049 and Leica RM2255 microtome Preparing ground tooth sections using EXACT 300/30 Diamond Band Saw and HIML125	A



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Histopathology</u> (cont'd)		
	Preparation and examination to identify or exclude morphological and cytological abnormalities (cont'd)	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 Leica CM1950 Cryostat and HIML 131, HIMED067, HISL003, HIML 077, HISL007	A, 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 Leica CM1950 Cryostat and HIML048	D
Skin	Detection of inflammatory skin disease	Direct Immunofluorescence using Bright cryostat and HIML039, 036	A
Formalin fixed paraffin embedded (FFPE) tissue and/or prepared diagnostic cytology slides	Basophilic and eosinophilic tissue structures	Routine Haematoxylin and eosin (H&E) staining and coverslipping: Automated method using HIML090 Leica HistoCore Spectra ST autostainers, Leica HistoCore Spectra CV coverslippers	A
Formalin fixed paraffin embedded (FFPE) tissue	Detection of the following:	Special staining: Manual methods and the following stains	A
	Acid mucins	Alcian Blue HISM006	



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



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Formalin fixed paraffin embedded (FFPE) tissue (cont'd)	Detection of the following: (cont'd)	Special staining: Manual methods and the following stains	
	Myelin	Luxol Fast Blue/Cresyl Fast Violet HINP030	A
	Melanin	Masson Fontana HSMP030	A
	Collagen	Masson Trichrome HISMP010	A
	Collagen	Masson Trichrome (Goldner's) HISM063	A
	Elastin and collagen	Miller's Elastic Van Gieson HISM031	A
	Acid glycoproteins	MILAB HISM066	A
	Fibrin deposits	MSB HISM004	A
	Acid mucins	Mucicarmine HISM022	A
	Hepatitis B surface antigen	Orcein (Shikata) HISM067 (A) and CRHHIS-HIST022 (C)	A, C
	Basement membranes, neutral mucins, glycogen	Periodic Acid Schiff (PAS) HISM011 (A) and CRHHIS-HIST022 (C)	A, C
	Fungi	PAS for fungi HISM011 (A) and CRHHIS-HIST022 (C)	A, C
	Iron	Perls' Prussian Blue HISM005(A) and CRHHIS-HIST022 (C)	A, C
	Amyloid	Sirius Red HISM019 (A) and CRHHIS-HIST022 (C)	A, C



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Formalin fixed paraffin embedded (FFPE) tissue (cont'd)	Detection of the following: (cont'd)	Special staining: Manual methods and the following stains	
	Neutral triglycerides	Sudan Black HISM041	A
	Mast cells	Toluidine Blue HISM048	A
	Calcium salts	Von Kossa HISM020	A
	Acid fast bacilli	Wade Fite HISM055	A
	Spirochetes	Warthin Starry HISM024	A
	Acid fast bacilli	Ziehl-Neelsen HISM021	A, C
	Elastin and Copper Protein	Orecin (Shikata) CRHHIS-HIST022	C
	Reticulin	Reticulin CRHHIS-HIST022	C
Cytology cell blocks	Differentiate cells in cytology preparations	Papanicolaou CRHHIS-HIST022	C
Frozen sections only	Neutral triglycerides and lipids	Oil Red O	C
	Heparin Rich mast cells	Toluidine Blue	
	Calcium Salts	Von Kossa	
	Acid fast Bacilli	Wade Fite	
	Spirochetes	Warthin Starry	



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	Detection of the following:	Immunohistochemistry: Manual staining*** Leica ST5020 stainer and CV5030 coverslipper HIIC028	A
		Automated methods using Ventana Benchmark Ultra**** Dako Omnis autostainer* Dako 48 Link Autostainer** and SOPs HIIC002, HIIC003, HIIC009, HIIC010, HIIC015, HIIC016, HIIC017, HIIC018, HIIC019, HIIC041, HIML036, HIIC046	A
		Dako Auto immunostainer and DAKO PT link machines as relevant CRHHIS-HIST042^	C
	Extra cellular beta-amyloid	A4 (beta amyloid) **	A
	Corticotrophs	ACTH**	A
	Squamous and columnar epithelium	AE1/AE3*/^	A, C
	Hepatocytes	AFP*	A
	ALK protein	ALK-1*, ****	A
	Myeloid cells, macrophages	Annexin*	A
	Lewy bodies	Alpha-Synuclein***	A
	Androgen Receptors	AR****	A
Phosphatase sensitive epitope	AT8**	A	
Marker of Alzheimer's disease	BAPP*	A	



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Formalin fixed paraffin embedded (FFPE) tissue and/or prepared diagnostic cytology slides (cont'd)	Detection of the following: (cont'd)	Immunohistochemistry:	
	Benign melanocytic nevi	BAP1	A
	Desmoid tumour, colorectal cancer	Beta-Catenin*	A
	Lymphocytes	BCL-2*/^	A, C
	Lymphoma	BCL-6*	A
	Adenocarcinoma	BEREP4*/^	A, C
	Trophoblasts	Beta HCG	A
	Renal allograft rejection	C4d,****	A
	Ovarian carcinoma	Ca125*	A
	Gastrointestinal cancer	Ca19.9*	A
	C-cell hyperplasia	Calcitonin*	A
	Malignant mesotheliomas	Calretinin*/^	A, C
	Lymphomas	c-MYC****	A
	Malignant epithelial cells	CAM 5.2*	A
	Burkett lymphoma	CD10*/^	A, C
	Multiple myelomas	CD138*	A
	Kit Protein Receptors	CD117 (CKIT)**	A
	Hodgkin's lymphoma	CD15*/^	A
	Thyomas	CD1a*	A
	T-cell lymphoma	CD2*	A



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	Detection of the following: (cont'd)	Immunohistochemistry:	
	Neoplasms of B-cell derivation	CD20*/^	A
	Malignant lymphomas	CD21*	A
	Differentiation of lymphomas	CD23*	A
	T cells	CD3*/^	A
	Large cell lymphoma	CD30**/^	A, C
	Endothelial cells	CD31*/^	A, C
	Vascular and lymphatic tumours	CD34*/^	A, C
	Plasma cells	CD38*	A
	Thymocytes and T helper cells	CD4*/^	A, C
	B cell lymphomas	CD43*	A
	Tumour cells of lymphoid origin	CD45*/^	A, C
	T cell lymphomas	CD45Ro*	A
	B and T cell malignancies	CD5*	A
	T/NK cell lymphomas	CD56*/^	A, C
	Myelodysplastic syndrome	CD61*	A
	Myeloid neoplasms	CD68 (KP1)* /^	A, C
AML	CD68 (PGM1)* /^	A, C	



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	Detection of the following: (cont'd)	Immunohistochemistry:	
	T cell lymphoma	CD7*	A
	B cell neoplasm	CD79a*/^	A, C
	Infectious colitis, Crohn's	CD8*	A
	Ewing's sarcoma	CD99****	A
	Adenocarcinoma	CDX2*	A
	Histiogenesis of epithelial tumours	CEAp**	A
	Histiogenesis of epithelial tumours	CEAm*	A
	Neuroendocrine derived tumour	Chromogranin*/^	A, C
	Epithelial cells of corneal type differentiation	CK3****	A
	Labels corneal epithelial cells	CK12***	A
	Labels corneal epithelial cells	CK13***	A
	Squamous cell carcinoma	CK14*	A
	Epithelial tumours	CK19*	A
Gastrointestinal epithelium	CK20*/^	A, C	
Differentiation of corneal/conjunctival cells	CK3***	A	



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	Detection of the following: (cont'd)	Immunohistochemistry:	
	Differentiate squamous cell carcinoma and adenocarcinoma	CK5/6*/^	A, C
	Adenocarcinomas	CK7*	A
	Epithelial derived tissue	CK8/18^	C
	Claudin Proteins	Claudin 4**	A
	Cytomegalovirus	CMV*	A
	Labels basement membranes	Collagen IV*	A
	Mantle cell lymphomas	Cyclin D1*	A
	Rhabdomyosarcomas	D33**	A
	Gastrointestinal tumour	DOG1*	A
	Smooth and striated muscle cells, mesothelial cells	Desmin^	C
	Epithelial cells of tissues	E-Cadherin*/^	A, C
	Epithelial cells of tissues	EMA*/^	A, C
	Oestrogen receptor alpha status	ER**/^	A, C
	Vascular epithelia cells	ERG****	A
Labels platelets	Factor 13A*	A	
Labels cells expressing von Willebrand factor	Factor 8*	A	



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Formalin fixed paraffin embedded (FFPE) tissue and/or prepared diagnostic cytology slides (cont'd)	Detection of the following: (cont'd)	Immunohistochemistry:	
	Labels gonadotrophs	FSH*	A
	Labels Apocrine epithelia	GCDFP*	A
	Metastases from breast carcinoma	GFAP*	A
	GATA binding protein 3	GATA 3****	A
	Labels Somatotroph cells	GH**	A
	Labels erythrocytes	Glycophorin*	A
	T cell lymphomas	Gran*	A
	Mesotheliomas	HBME1**	A
	Hepatocellular tumours	Hep1*	A
	Human Her2 gene	Her2****	A
	Human Herpes type 8	HHV8,****	A
	Melanocytes	HMB45*	A
	Basal and squamous epithelium	HMCK*	A
	Breast epithelial marker	HMFG1*	A
	Choriocarcinoma	HPL*	A
	Herpes simplex virus	HSV1*	A
	Discrimination of various tumours	IDH**	A



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	Detection of the following: (cont'd)	Immunohistochemistry:	
	Multiple myelomas	IgA****	A
	Lymphoma	IgD*	A
	Labels plasma cells containing IgG	IgG***, ****	A
	Labels plasma cells containing IgG2	IgG2****	A
	Labels plasma cells containing IgG4	IgG4****	A
	Labels plasma cells containing IgG	IgM****	A
	Ovarian tumours	Inhibin*/^	A, C
	Medulloblastomas	INI-1**	A
	B cell lymphomas	KAPPA****	A
	Neoplastic cells	KI67*/^	A, C
	B cell lymphoma	LAMBDA***, ****	A
	Pituitary adenomas	LH**	A
	Labels dendrites of neurons	MAP-2*	A
	Melanomas	MEL-A*/^	A, C
Mesotheliomas	Mesothelin**	A	
Mismatch repair	MLH1 (MMR)****	A	



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	Detection of the following: (cont'd)	Immunohistochemistry:	
	Mismatch repair	MSH2 (MMR)****	A
	Mismatch repair	MSH6 (MMR)****	A
	HLA-ABC expression	MHC***	A
	Epithelial tissue	MNF116*	A
	Lymphoid malignancies	MUM1**	A
	Lymphoid and myeloid disorder	MYELO*	A
	Myoblasts	MYO D1***	A
	Labels neurons	Neurofilament*	A
	Malignant melanoma	NK1-C3*	A
	Prostate adenocarcinoma	NKX3.1****	A
	Neuroendocrine tumours	NSE***, ****	A
	Germ cell tumour	OCT4**	A
	Cervical carcinoma	P16*, ****	A
	Basal / Squamous cells	P40^	C
	Prostate adenocarcinoma	P504S*/^	A, C
Neoplasia	P53*	A	
Wilm's tumour and Beckwith-Wiedemann Syndrome	P57**	A	



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Formalin fixed paraffin embedded (FFPE) tissue and/or prepared diagnostic cytology slides (cont'd)	Detection of the following: (cont'd)	Immunohistochemistry:	
	Alzheimer and Parkinson disease	P62**	A
	Squamous cell carcinoma	P63*/^	A, C
	Prostate carcinoma	PAP**	A
	Parathyroid tumour	Parafibromin***	A
	Renal tumours	PAX 2****	A
	Classification of lymphoma	PAX 5*	A
	Carcinoma marker	PAX 8****	A
	Labels follicular help T-cells	PD1****	A
	PD-L1 protein in non-small cell lung cancer, urothelial cancer, melanoma and Head and Neck SCC	PDL-1 (22C3)**	A
	Pan-neuronal marker	PGP 9.5*	A
	Seminomas and desmoplastic small round cell tumours	PLAP**	A
	Mismatch repair	PMS2 (MMR)****	A
	Progesterone receptor alpha status	PR**/^	A, C
	Lactotrophic cells	Prolactin*	A
	Prostatic adenocarcinoma	PSA****/^	A, C



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	Detection of the following: (cont'd)	Immunohistochemistry:	
	Renal cell carcinoma	RCC*	A
	S100 positive neoplasms	S100*/^	A, C
	Leiomyomas, leiomyosarcomas and pleomorphic adenovirus	SMA*/^	A, C
	Labels myoepithelial cells in breast	SMM**	A
	Melanocytes and myoepithelial cells	SOX10****	A
	Mantle cell lymphoma	SOX11****	A
	Solitary fibrous tumours	STAT6****	A
	Polyoma virus	SV40*	A
	Neuroendocrine neoplasms	SYNAP*/^	A, C
	Differentiation of frontotemporal dementia	TDP43**	A
	Thymic and Bone marrow cortical lymphocytes	TDT*	A
	Vascular tumours, mesothelial cells and peripheral nerves	Thrombomodulin**	A
	Tumours of thyroid origin	Thyroglobulin*	A
T cell lymphomas	TIA1*	A	
Classification of pituitary tumours	TSH**	A	



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<p>HUMAN TISSUES AND FLUIDS (cont'd)</p> <p>Formalin fixed paraffin embedded (FFPE) tissue and/or prepared diagnostic cytology slides (cont'd)</p> <p>Slides produced from location C processes listed above</p>	<p><u>Histopathology</u> (cont'd)</p> <p>Preparation and examination to identify or exclude morphological and cytological abnormalities (cont'd)</p> <p>Detection of the following: (cont'd)</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>Microscopic Examination for the purposes of clinical diagnosis</p>	<p>Macroscopic and Microscopic examination using in-house procedures in conjunction with manufacturer's instructions for the following methods (where relevant)</p> <p>Immunohistochemistry:</p> <p>TTF1*/^</p> <p>VIMENTIN*</p> <p>WT1**, ****</p> <p><u>Interpretive Microscopy (qualitative analysis)</u> CRH-PATH001 and CRH-PATH018. Light microscopy using Nikon microscopes</p>	<p>A, C</p> <p>A</p> <p>A</p> <p>C</p>



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Histopathology</u> (cont'd)	Macroscopic and Microscopic examination using in-house procedures in conjunction with manufacturer's instructions for the following methods (where relevant)	
Formalin fixed paraffin embedded tissue samples	Preparation and examination to identify or exclude morphological and cytological abnormalities	Using in-house procedures in conjunction with manufacturer's instructions (where relevant) Real-time PCR using the Biocartis Idylla™ SOP HIIC048 and HIMED074	A
	Detection of the following:		
	EGFR mutation analysis in lung.	EGFR Mutation Test	
	BRAF for melanoma	BRAF Mutation Test	
	KRAS for colorectal cancer	KRAS Mutation Test	
	NRAS/BRAF mutations in colorectal cancer	NRAS-BRAF Mutation Test	
	MSI mutations for 1 st line screening in Lynch syndrome	MSI Test	
	NRAS/BRAF in second line Lynch screening	NRAS-BRAF Mutation Test	
Post-mortem lung tissue	Microscopic analysis and counting of asbestos fibres	Manual in-house procedure using HIML114	A
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	A
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	



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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>Cytochrome oxidase activity</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>Cytochrome oxidase HINP028</p>	<p>A</p>



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Neuropathology</u> (cont'd)		A
Frozen sections of muscle tissue	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)	
	Detection of the following:	Cryotomy using the Leica CM3050S Cryostat and HINP035 followed by manual staining using the following:	
	Cytochrome oxidase positive fibres and Cytochrome oxidase negative fibres	Cytochrome oxidase/SDH HINP033	
	Nuclei, muscle fibres, mitochondria, sarcoplasmic reticulum, connective tissue, sarcolemma.	Engels Gomori Trichrome HINP031	
	Myoadenylate deaminase activity	Myoadenylate Deaminase HINP043	
	Phosphorylase activity	Myophosphorylase HINP010	
	Mitochondria and sarcoplasmic reticulum	NADH-TR HINP024	
	Glycogen	PAS/DPAS HINP034	
	Phosphofructokinase activity	Phosphofructokinase HINP042	
		Succinate Dehydrogenase HINP019	
		Sudan Black HINP042	
Fresh brain tissue	Detection of the following	Brain smear preparation HINP004 and manual staining using the following:	A
	Basophilic and eosinic structures	Rapid H&E HIM105	A
	Nuclei cytoplasm	Rapid Toluidine blue HINP053	A



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HUMAN BODY TISSUE AND FLUIDS (cont'd)	<u>Cytopathological examination activities for the purposes of clinical diagnosis</u>	Macroscopic and Microscopic examination using in house procedures in conjunction with manufacturer's instructions for the following methods (where relevant):	
Urine, fluids, aspirates, sputum	Examination of cellular material to identify or exclude morphological and cytological abnormalities	TriMat class1 microbiological safety cabinet, HIHID062, HISC037. Thermo IEC CL30 centrifuge Boeco U-320 centrifuge, Thermo scientific Cytospin 4, Thermo scientific HISC040.	A
Body fluids, Aspirates, FNA, brushings, washings	Detection of abnormal cells	Papanicolaou stain HISC020, May-Grunwald stain HISC018 and, H&E stain HISC008 performed on the MYREVA SS-30 autostainer SOP HISC047	A
Slides produced from processes listed above	Microscopic Examination for the purposes of clinical diagnosis	Using Leica stainer and cytospin stains used are PAP, H&E and Romanowsky -SOP: CRHHIS-NGY013	C
		<u>Interpretive Light microscopy using: Nikon microscopes (qualitative analysis)</u> <u>SOPs: CRH-PATH001 and CRH-PATH018</u>	C
		Pathologist reporting of Histopathology slides HIMED066 Final Authorisation of Reports HIMED051	A



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Serology examinations for the purposes of clinical diagnosis</u>	Documented in-house methods based on related UK SMLs and equipment manuals as relevant to meet the requirements of the IDPS screening programme as defined in the laboratory QA evidence requirements	
Serum and Plasma	Detection of the following: Hep A IgM Antibody	Roche Cobas 8000 immunoassay, and SOP VIAS044	B
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 and Plasma	Rubella IgG Antibody		
Serum and Plasma	Syphilis Antibody IgG		
Oral fluid samples	HIV Ab		
Serum and plasma	COVID-19 Antibody testing - Anti SARS CoV 2 total antibody (qualitative)	Roche Cobas 8000 Immunoassay and SOP VIAS044	B
	Anti SARS CoV 2 spike antibody (qualitative)		
Serum and plasma	Detection of the following : HBe Ag HBe Ab HBsAg (2nd line) HBsAg Quantitative Hepatitis C Antibody (2nd line) HIV Ab/Ag (2nd Line) Borrelia IgG CMV IgG CMV IgM CMV Avidity EBV IgM (Clinical) EBV VCA IgG	Diasorin Liaison XL automated immunoassay analyser and SOP VIAS045	B
	Syphilis Hepatitis E IgM Hepatitis E IgG		



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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 Mumps Immunity 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 Antibody	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 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 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



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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: Mycoplasma IgA, IgM, IgG	Manual ELISA using Launch Virion/Sirion VISE060	B
Serum	Qualitative detection of the following: ASO Anti-DNase B	Latex agglutination using Rheumajet ASO and VISE046 bioMerieux Anti DNase B and VISE001	B
Serum and CSF	Treponema pallidum IgG	Particle agglutination using Serodia TPPA and VISE019	B
Serum and CSF	Antibodies to VDRL antigen	Slide flocculation using Axis Shield Syphilis Screen RPR and VISE017	B
Serum and Plasma	Detection of HIV antibody	Bio-Rad Geenius immunochromatographic and SOP VISE057	B
Faeces	Qualitative detection of the following: H pylori antigen	ELISA using Dynex DS2 analyser and the following kit and SOP: Oxoid IDEA Hp StAR, BAEN015	B
Faeces	C difficile GDH	RIDAQUICK lateral flow GDH BAEN002	B
Urine	Detection of Legionella urinary antigen	Sofia EIA and SOP BAUR011	B
Serum, CSF	Cryptococcal antigen	IMMY CrAg lateral flow assay (BASF014)	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
Throat swab and combined Nose/Throat Swabs in - Viral Transport Media - Universal Transport Media	Detection of SARS-CoV-2 virus RNA (COVID-19) specific gene sequence: ORF1ab	Hologic Aptima SARS-CoV-2 assay using the Hologic Panther system SOP VIVI004 and VICH023	B
Nasopharyngeal aspirate, Sputum			
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, RSV, Rhinovirus, Parainfluenza 1, 2, 3, 4, HMPV, Coronavirus, Adenovirus) Herpes simplex VZV Adenovirus Enterovirus Measles	Qualitative PCE using Roche Magnapure 96 extraction and ABI 7500 amplification and SOPs: VIMO020 VIMO027 VIMO027 VIMO020 VIMO006 VIMO019	B
Swabs, CSF, sputum, urine	Qualitative detection of Mumps	Qualitative PCR, using Roche Magnapure 96 extraction and ABI 7500 amplification SOP VIMO048	B
Skin swabs, penile swabs, nose and throat swabs	Quantitative detection of Monkey Pox (DNA) virus, specifically, G2R, F3L and C3L genes	Qualitative PCR using Roche Magnapure extraction and qualitative PCR by ABI 7500 following SOPs VIVO026 and VIMO073.	B
Nose swabs, throat swabs, nose/throat swabs	Detection of Mers CoV (RNA) virus specifically genes E (upE) and 1a (orf1a)	Qualitative PCR using Roche Magnapure extraction and ABI 7500 with Realstar MERS CoV RT PCR kit Altona following SOPs VIVO026 and VIMO056	B



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Molecular examinations for the purposes of clinical diagnosis (cont'd)</u>	In-house documented procedures based on equipment manuals as relevant	
Blood, plasma	Hepatitis E	Quantitative PCR using Qiacube Extraction and ABI 7500. SOP VIVI023 & VIMO042	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
Sputum, BAL	Detection of Pneumocystis jirovecii (PCP)	PCR and extraction using the Roche MP96 and amplification and detection using the ABI7500 SOP VIMO071	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
Nose swab, throat swab and combined Nose/Throat Swabs in - Viral Transport Media - Universal Transport Media	Detection of SARS CoV-2 virus RNA (COVID-19) specific gene sequences: RdRp gene and E gene	In-house real-time PCR assay using QuantaBio Custom XLT mastermix facilitated by MagNa Pure Extraction and the Hamilton PSH Liquid Handling Unti and ABI 7500, SOP VIVI004, VIVI026, VIMO052 and VIMO064.	B
Nasopharyngeal aspirate, Sputum, Bronchoalveolar lavage		Thermal extraction followed by ABIT 7500 SOP VIVI004, VIMO052 and VIMO064.	
Combined nose/throat swabs	Detection of SARS CoV-2 virus RNA (COVID-19)	SAMBA II SARS-CoV-2 test following SOP, VIM068a Abbott ID following SOP, POCT23	B A, B



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<p>HUMAN BODY FLUIDS AND TISSUES (cont'd)</p> <p>Respiratory tract secretions</p> <p>Rectal and perirectal swabs Bacterial isolates</p> <p>Nose swab, throat swab and combined Nose/Throat Swabs</p> <p>AAFB positive cultures</p>	<p><u>Molecular examinations for the purposes of clinical diagnosis</u> (cont'd)</p> <p>Detection of Mycobacterium tuberculosis (MTB) complex DNA and rifampicin-resistance associated mutations of the rpoB gene.</p> <p>Detection of Carbapenem Resistant Organisms</p> <p>Detection of SARS CoV2 PCR (qualitative) target genes N2 and E</p> <p>Identification of Mycobacterium tuberculosis complex</p>	<p>In-house documented procedures based on equipment manuals as relevant</p> <p>PCR and Cepheid GeneExpert System SOP BARE039</p> <p>Cepheid GeneXpert System and SOP BAIC016</p> <p>Cepheid GeneXpert real-time PCR and SOP VIMO065</p> <p>HAIN TB Check MPT64</p>	<p>B</p> <p>B</p> <p>B</p> <p>B</p>



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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] Faecal culture [BAEN001]] 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 automated microscopy 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	Ova, cysts and parasites	Wet preparation using light microscopy and concentration using Parasep(BAEN022)	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, BAGP002	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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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