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Sheffield Teaching Hospitals NHS Foundation Trust

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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** Stephanie Parr stephanie.parr3@nhs.net	Histopathology Diagnostic Cytopathology	A
Address Laboratory Medicine Centre (North Lane) Northern General Hospital Herries Road Sheffield S5 7AU	**Local contact** Stephanie Parr stephanie.parr3@nhs.net Leeanne Tovey leeanne.tovey@nhs.net	Rapid frozen section for intraoperative reporting Microbiology Department	B
Address Department of Histopathology Chesterfield Royal Hospital Calow S44 5BL	**Local contact** Melanie Hulbert Melanie.hulbert@nhs.net	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

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	Histopathology		
Fresh tissue samples and Formalin fixed tissues	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	A
		Tissue Dissection: Manual methods using documented procedures CRHHIS-HIST007	C
		Decalcification: Manual method using HIRD 027	A
		Decalcification: Manual using CRHHIS-HIST009	C
		Tissue Processing: Automated method using HIML086 and Sakura VIP5 & 6, and Leica Peloris tissue processors	A
		Tissue Processing: Automated method using the Leica ASP300 and Epredia Excelsior AS CRHHIS-HIST059	C
		Embedding: Manual method using HIML075 and Sakura, Leica and Thermo embedding centres.	A
		Embedding: Manual method using Leica EG1150 and Thermo Histostar CRHHIS-HIST013	C

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN TISSUES AND FLUIDS (cont'd)	Histopathology (cont'd)		
Fresh tissue samples and Formalin fixed tissues (cont'd)	Preparation and examination to identify or exclude morphological and cytological abnormalities (cont'd)	Macroscopic and Microscopic examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant)	
		Microtomy: Manual method using HIML093 and Leica RM2235 and Microm HM 325 microtomes	A
		Microtomy: CRHHIS-HIST060 Using LeicaHistoCore BioCut , 2235, 2255 microtomes CRHHIS-HIST060	C
Tooth		Preparing ground tooth sections using EXACT 300/30 Diamond Band Saw and HIML125	A
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
Fresh and frozen tissue	Intraoperative diagnosis	Cryotomy: Thermo Cryostar cryostat CRHHIS-HIST030	C
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

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN TISSUES AND FLUIDS (cont'd)	Histopathology (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 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
Fixed, fresh and frozen tissue, excisional and incisional biopsies and surgical resection specimens Non-gynae cytology cell blocks	Identification of nuclei, cell cytoplasm and connective tissues in cells and tissues	Haematoxylin and Eosin staining-Manual and automated methods-Rapid H&E stain for frozen sections: Leica Spectra ST Stainer Leica Spectra CV CV5030 CRHHIS-HIST073	C
Formalin fixed paraffin embedded (FFPE) tissue	Detection of the following:	Special staining: Manual methods and the following stains	
	Acid mucins	Alcian Blue HISM006 (A) and CRHHIS-HIS-STAIN3 (C)	A, C
	Acid and neutral mucopolysaccharides	Alcian Blue PAS HISM006 (A) and CRHHIS-STAIN4 (C)	A, C
	Calcium deposits	Alizarin Red HISM076	A

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN TISSUES AND FLUIDS (cont'd)	Histopathology (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)	
Formalin fixed paraffin embedded (FFPE) tissue (cont'd)	Detection of the following: (cont'd)	Special staining: Manual methods and the following stains	
	Amyloid	Congo Red HISM007 (A) and CRHHIS-STAIN5 (C)	A, C
	Acid and neutral mucopolysaccharides	Diastase Alcian Blue PAS HISM006 (A) and CRHHIS-STAIN4 (C)	A, C
	Basement membranes, neutral mucins	Diastase PAS HISM011 (A) and CRHHIS-STAIN19 (C)	A, C
	Morphological inspection of blood cells	Giemsa Diff Quick CRHHIS-STAIN7	C
	Differentiation of haematopoietic cell linages and mast cells	Giemsa (Lennert's) HISM001	A
	Helicobacter pylori	Giemsa (Modified) HISM015 (A) and CRHHIS-STAIN8 (C)	A, C
	Reticulin	Reticulin HISM008 (A) and CRHHIS-STAIN21 (C)	A, C
	Gram positive and Gram negative bacteria	Gram HISM061 (A) and CRHHIS-STAIN9 (C)	A, C
	Glomerular basement membrane	Grocotts Methenamine Silver for renal basement membranes HISM027	A
	Fungi	Grocotts Methenamine Silver HISM025 (A) and Methenamine Silver Technique MST CRHHIS-STAIN10 (C)	A, C

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN TISSUES AND FLUIDS (cont'd)	Histopathology (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)	
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 HINP030	A
	Melanin	Masson Fontana HISM012 (A) and CRHHIS-STAIN13 (C)	A, C
	Collagen and connective tissues	Masson Trichrome HISM010 (A) and CRHHIS-STAIN14 (C)	A, C
	Collagen	Masson Trichrome (Goldner's) HISM063	A
	Elastin and collagen	Miller's Elastic Van Gieson HISM031 (A) and CRHHIS-STAIN6 (C)	A, C
	Acid glycoproteins	Millers Alcian Blue MILAB HISM066	A
	Fibrin deposits	MSB HISM004 (A) and CRHHIS-STAIN16 (C)	A, C
	Acid mucins	MucicarmineHISM022	A
	Hepatitis B surface antigen and copper associated protein	Orcein (Shikata) HISM067 (A) and CRHHIS-STAIN18 (C)	A, C
	Basement membranes, neutral mucins, glycogen	Periodic Acid Schiff (PAS) HISM011 (A) and CRHHIS-STAIN19 (C)	A, C
	Fungi	PAS for fungi HISM011 (A) and CRHHIS-STAIN19 (C)	A, C
	Iron	Perls' Prussian Blue HISM005(A) and CRHHIS-STAIN20 (C)	A, C

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN TISSUES AND FLUIDS (cont'd)	Histopathology (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)	
Formalin fixed paraffin embedded (FFPE) tissue (cont'd)	Detection of the following: (cont'd)	Special staining: Manual methods and the following stains	
	Amyloid	Sirius Red HISM019 (A) and CRHHIS-STAIN22 (C)	A, C
	Mast cells	Toluidine Blue HISM048 (A) and CRHHIS-STAIN23 (C)	A, C
	Calcium salts	Von Kossa HISM020 (A) and CRHHIS-STAIN24 (C)	A, C
	Acid fast bacilli	Wade Fite HISM055 (A) and CRHHIS-STAIN25 (C)	A, C
	Spirochetes	Warthin Starry HISM024 (A) and CRHHIS-STAIN26 (C)	A, C
	Acid fast bacilli	Ziehl-Neelsen HISM021 (A) and CRHHIS-STAIN27 (C)	A, C

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN TISSUES AND FLUIDS (cont'd)	Histopathology (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)	
Formalin fixed paraffin embedded (FFPE) tissue and/or prepared diagnostic cytology slides	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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HUMAN TISSUES AND FLUIDS (cont'd)	Histopathology (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)	
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
	Lympocytes	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, C
	Thyomas	CD1a*	A
	T-cell lymphoma	CD2*	A

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HUMAN TISSUES AND FLUIDS (cont'd)	Histopathology (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)	
Formalin fixed paraffin embedded (FFPE) tissue and/or prepared diagnostic cytology slides (cont'd)	Detection of the following: (cont'd)	Immunohistochemistry:	
	Neoplasms of B-cell derivation	CD20*/^	A, C
	Malignant lymphomas	CD21*	A
	Differentiation of lymphomas	CD23*	A
	T cells	CD3*/^	A, C
	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
	B and T cell malignancies	CD5*	A
	T/NK cell lymphomas	CD56*/^	A, C
	Myelodysplastic syndrome	CD61*	A
	Myeloid neoplasms	CD68 (KP1)*	A
	AML	CD68 (PGM1)* /^	A, C

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN TISSUES AND FLUIDS (cont'd)	Histopathology (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)	
Formalin fixed paraffin embedded (FFPE) tissue and/or prepared diagnostic cytology slides (cont'd)	Detection of the following: (cont'd)	Immunohistochemistry:	
	T cell lymphoma	CD7*	A
	B cell neoplasm	CD79a*/^	A, C
	Infectious colitis, Crohn's	CD8*/^	A, C
	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
	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

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HUMAN TISSUES AND FLUIDS (cont'd)	Histopathology (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)	
Formalin fixed paraffin embedded (FFPE) tissue and/or prepared diagnostic cytology slides (cont'd)	Detection of the following: (cont'd)	Immunohistochemistry:	
	Differentiate squamous cell carcinoma and adenocarcinoma	CK5/6*/^	A, C
	Adenocarcinomas	CK7*/^	A, C
	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

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN TISSUES AND FLUIDS (cont'd)	Histopathology (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)	
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
	Basel and squamous epithelium	HMCK*	A
	Choriocarcinoma	HPL*	A
	Herpes simplex virus	HSV1*	A
	Discrimination of various tumours	IDH**	A

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN TISSUES AND FLUIDS (cont'd)	Histopathology (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)	
Formalin fixed paraffin embedded (FFPE) tissue and/or prepared diagnostic cytology slides (cont'd)	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
	Melanomas	MEL-A*/^	A, C
	Mesotheliomas	Mesothelin**	A
	Mismatch repair	MLH1 (MMR)****	A

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN TISSUES AND FLUIDS (cont'd)	Histopathology (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)	
Formalin fixed paraffin embedded (FFPE) tissue and/or prepared diagnostic cytology slides (cont'd)	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
	Labels neurons	Neurofilament*	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

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN TISSUES AND FLUIDS (cont'd)	Histopathology (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)	
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
	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 and Head and Neck cancers	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

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN TISSUES AND FLUIDS (cont'd)	Histopathology (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)	
Formalin fixed paraffin embedded (FFPE) tissue and/or prepared diagnostic cytology slides (cont'd)	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

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN TISSUES AND FLUIDS (cont'd)	Histopathology (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)	
Formalin fixed paraffin embedded (FFPE) tissue and/or prepared diagnostic cytology slides (cont'd)	Detection of the following: (cont'd)	Immunohistochemistry:	
	Tumours from lung and thyroid	TTF1*/^	A, C
	B-cell chronic lymphocytic leukaemia/small lymphocytic lymphoma	VIMENTIN*	A
	Labels nucleus of ovary and kidney cells	WT1**,****	A
Slides produced from location C processes listed above	Microscopic Examination for the purposes of clinical diagnosis	Interpretive Microscopy (qualitative analysis) CRH-PATH001 and CRH-PATH018. Light microscopy using Nikon microscopes	C

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
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)	
Formalin fixed paraffin embedded tissue samples	Detection of the following:	Using in-house procedures in conjunction with manufacturer's instructions (where relevant) Real-time PCR using the Biocartis Idylla™ SOP HIIC048 and HIMED074	A, C
	EGFR mutation analysis in lung.	EGFR Mutation Test	A
	BRAF for melanoma	BRAF Mutation Test	A
	KRAS for colorectal cancer	KRAS Mutation Test	A, C
	NRAS/BRAF mutations in colorectal cancer	NRAS-BRAF Mutation Test	A, C
	KRAS for lung cancer	KRAS Mutation Test	A
	Braf for lung cancer	BRAF Mutation Test	A
	Non-Small Cell Lung Cancers	Gene Fusion PCR based Test	A
	MSI mutations for 1st line screening in Lynch syndrome	MSI Test	A, C
	NRAS/BRAF in second line Lynch screening	NRAS-BRAF Mutation Test	A
Post-mortem lung tissue	Microscopic analysis and counting of asbestos fibres	Manual in-house procedure using HIML114	A

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

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN TISSUES AND FLUIDS (cont'd)	Neuropathology (cont'd)		A
	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)	
Frozen sections of muscle tissue	Detection of the following:	Cryotomy using the Leica CM3050S Cryostat and HIN035 followed by manual staining using the following:	A
	Cytochrome oxidase positive fibres and Cytochrome oxidase negative fibres	Cytochrome oxidase/SDH HINP033	A
	Nuclei, muscle fibres, mitochondria, sarcoplasmic reticulum, connective tissue, sarcolemma.	Engels Gomori Trichrome HINP031	A
	Myoadenylate deaminase activity	Myoadenylate Deaminase HINP043	A
	Phosphorylase activity	Myophosphorylase HINP010	A
	Mitochondria and sarcoplasmic reticulum	NADH-TR HINP024	A
	Glycogen	PAS/DPAS HINP034	A
	Phosphofructokinase activity	Phosphofructokinase HINP042	A
		Succinate Dehydrogenase HINP019	A
		Sudan Black HINP042	A
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

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY TISSUE AND FLUIDS (cont'd)	Cytopathological examination activities for the purposes of clinical diagnosis	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
		Papanicolaou stain HISC020, May-Grunwald stain HISC018 and, H&E stain HISC008 performed on the MYREVA SS-30 autostainer SOP HISC047	A
Body fluids, Aspirates, FNA, brushings, washings	Detection of abnormal cells	Using Leica stainer and cytospin stains used are PAP, H&E and Romanowsky -SOP: CRHHIS-NGY013	C
Slides produced from processes listed above	Microscopic Examination for the purposes of clinical diagnosis	Interpretive Light microscopy using: Nikon microscopes (qualitative analysis) SOPs: CRH-PATH001 and CRH-PATH018	C
		Pathologist reporting of Histopathology slides HIMED066 Final Authorisation of Reports HIMED051	A
Stained tissue section on glass slide	Primary reporting of Histopathology slides	Scanning and Primary reporting from Digital images of Upper & Lower GI, Skin, Urology, Breast, Gynae using 3DHistech P1000 digital slide scanner SOP HIML137 and HIML136, HIMED067, HIMED069	A

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</u>	Documented in-house methods based on related UK SMIs 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 Serum and Plasma Serum and Plasma Serum and Plasma Serum and Plasma Serum and Plasma Serum, Dry Blood Spot and Plasma Serum, Dry Blood Spot and Plasma Serum, Dry Blood Spot and Plasma Serum and Plasma Serum and Plasma	Detection of the following: Hep A IgM Antibody Hep A Total Antibody Hep B Total Core Antibody Hep B Core IgM Antibody Hep B Surface Antibody Hep B s Antigen Neutralisation Hep B Surface Antigen Hep C Antibody HIV Ag/Antibody combo Rubella IgG Antibody Syphilis Antibody Total	Roche Cobas 8000 immunoassay, and SOP VIAS044	B
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 Syphilis Total Hepatitis E IgM Hepatitis E IgG	Diasorin Liaison XL automated immunoassay analyser and SOP VIAS045	B

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)	Serology examinations for the purposes of clinical diagnosis (cont'd)	In-house documented procedures based on equipment manuals as relevant	
Serum and plasma	Detection of the following : EBV NA IgG HSV IgG HTLV I + II Measles IgG Mumps IgG Parvovirus IgG Parvovirus IgM Rubella IgM Toxoplasma IgG Toxoplasma IgM VZV Immunity IgG	Diasorin Liaison XL automated immunoassay analyser and SOP VIAS045	B
Faeces	Detection of *Helicobacter Pylori*	Diasorin Liaison XL automated immunoassay analyser and SOP VIAS045	B
Serum	Detection of Hepatitis D	Diasorin Liaison XL automated immunoassay analyser and SOP VIAS045	B

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)	Serology examinations for the purposes of clinical diagnosis (cont'd)	In-house documented procedures based on equipment manuals as relevant	
Serum	Qualitative detection of the following: ASO	Latex agglutination using Rheumajet ASO and VISE046	B
Serum and CSF	Antibodies to VDRL antigen	Slide flocculation using Launch Diagnostics ASI RPR kit VISE017	B
Serum and Plasma	Detection of HIV antibody	Bio-Rad Geenius immunochromatographic and SOP VISE057	B
Serum	Qualitative detection of β-D-Glucan	Cape Cod Fungitell Stat, a protease zymogen-based colorimetric assay SOP VIAS050	B
Faeces	Clostridiodes 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

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)	Molecular examinations for the purposes of clinical diagnosis (cont'd)	In-house documented procedures based on equipment manuals as relevant	
CSF	Identification of pathogens in nucleic acid extracts Detection of: CMV EBV HSV1 HSV2 Adenovirus Enterovirus Paraechovirus HHV6 HHV7 VZV	Hologic Panther using Aus-diagnostics Viral 12-well Panel; CSF Viral (12-well) semi-automated IVD. SOP VIMO078	B
Serum, plasma, Roche PCR product	Hep C genotyping	Autoblot 3000 Immunoblot assay and SOP VIMO003	B

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)	Molecular examinations for the purposes of clinical diagnosis (cont'd)	In-house documented procedures based on equipment manuals as relevant	
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 MPox (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

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)	Molecular examinations for the purposes of clinical diagnosis (cont'd)	In-house documented procedures based on equipment manuals as relevant	
Combined nose/throat swabs	Detection of SARS CoV-2 virus RNA (COVID-19)	SAMBA II SARS-CoV-2 test following SOP, VIM068a	B
		Abbott ID following SOP, POCT23	A, B
Respiratory tract secretions	Detection of Mycobacterium tuberculosis (MTB) complex DNA and rifampicin-resistance associated mutations of the rpoB gene.	PCR and Cepheid GeneXpert System SOP BARE039	B
Rectal and perirectal swabs Bacterial isolates	Detection of Carbapenem Resistant Organisms	Cepheid GeneXpert System and SOP BAIC016	B
Nose swab, throat swab and combined Nose/Throat Swabs	Detection of SARS CoV2 PCR (qualitative) target genes N2 and E	Cepheid GeneXpert real-time PCR and SOP VIMO065	B

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)	Molecular examinations for the purposes of clinical diagnosis (cont'd)	In-house documented procedures based on equipment manuals as relevant	
Faeces	Detection of the following faecal pathogens:	PCR using the Roche FLOW system, and MagnaPure 96 extraction system, SOP BAEN027, and the following:	B
	Campylobacter species *Salmonella* species *Shigella* species Toxin producing *Escherichia coli* (including O157)	R-Biopharm RIDAGENE bacterial stool panel I	
	Rotavirus Adenovirus Norovirus Astrovirus	R-Biopharm RIDAGENE viral stool panel I	
	Giardia lamblia *Cryptosporidium* species Entamoeba histolytica	R-Biopharm RIDAGENE parasite stool panel II	
	Clostridiodes difficile toxin A/B	R-Biopharm RIDAGENE *Clostridiodes* toxin A/B stool panel	

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 examinations for the purposes of clinical diagnosis	In-house documented procedures based on equipment manuals as relevant	
Swabs from wounds, ulcers, genital sites, eyes, nose, throat, ears, respiratory and gastric fluids, CSF, faeces, sterile fluids, pus,	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: 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]	B
Skin, hair, nails Urine		Mycology by culture [BAMY001] Urine culture (BAUR001)	B

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 examinations for the purposes of clinical diagnosis (cont'd)	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
	Microscopic examination of for qualitative detection of the following:		
Urine	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

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 examinations for the purposes of clinical diagnosis (cont'd)	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			