


# Schedule of Accreditation

issued by

## United Kingdom Accreditation Service

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

 <p><b>8608</b></p> <p>Accredited to ISO 15189:2012</p>	<b>University Hospitals of Leicester NHS Trust</b>	
	<b>Issue No: 005    Issue date: 18 October 2021</b>	
<b>Department of Cellular Pathology</b> <b>Sandringham Building</b> <b>Leicester Royal Infirmary</b> <b>Infirmary Square</b> <b>Leicester</b> <b>LE1 5WW</b>	<b>Contact: Diana Cullen</b> <b>Tel: +44 (0) 116 258 6591</b> <b>E-Mail: <a href="mailto:diana.cullen@uhl-tr.nhs.uk">diana.cullen@uhl-tr.nhs.uk</a></b> <b>Website: <a href="http://www.leicestershospitals.nhs.uk">http://www.leicestershospitals.nhs.uk</a></b>	
<b>Testing performed by the Organisation at the locations specified below</b>		

### Locations covered by the organisation and their relevant activities

#### Laboratory locations:

Location details	Activity	Location code
<b>Address:</b> Department of Cellular Pathology Sandringham Building Leicester Royal Infirmary Infirmary Square Leicester LE1 5WW  <b>Local contact</b> Diana Cullen	Histology sample preparation and reporting  Non-Gynaecological Cytology Sample Preparation and Reporting	LRI
<b>Address:</b> Department of Cellular Pathology Glenfield Hospital Groby Road Leicester LE3 9QP  <b>Local contact</b> Diana Cullen	Histology sample preparation and reporting	GH
Robert Kilpatrick Clinical Sciences Building Leicester Royal Infirmary Infirmary Square Leicester LE1 5WW  <b>Local contact</b> Diana Cullen	Electron Microscopy	RKCSB
Cytogenetics Laboratory Leicester Royal Infirmary Infirmary Square Leicester LE1 5WW  <b>Local contact</b> Diana Cullen	FISH	CYG
Mohs Lab Dermatology Leicester Royal Infirmary Infirmary Square Leicester LE1 5WW  <b>Local contact</b> Diana Cullen	Intraoperative and Mohs Cryotomy and Staining	MOHS



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**Site activities performed away from the locations listed above:**

<b>Location details</b>	<b>Activity</b>
On site mortuary and body store Leicester Royal Infirmary Infirmary Square Leicester LE1 5WW	Storage of bodies Retrieval of tissue via post mortem Record keeping (body identification and audit trail)
On site body store Glenfield Hospital Groby Road Leicester LE3 9QP	Storage of bodies
On site body store Leicester General Hospital Gwendolen Road Leicester LE5 4PW	Storage of bodies



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DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY TISSUE	<u>Histopathological examination activities for the purposes of clinical diagnosis</u>	Documented in house methods incorporating manufacturers' instructions where relevant:	
Formalin-fixed tissue samples	Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis	Specimen Dissection  Key SOPs PR3851 Sample Handling and Dissection	LRI GH
Formalin-fixed tissue		Tissue Processing ThermoShandon Excelsior Tissue processors  Key SOPs PR3868 Processing of Tissue for Histopathology	LRI
Formalin-fixed tissue		Embedding using Sakura Tissue Tek Embedding Centres  Key SOPs PR2969 Production of a Routine H&E Stained Section	LRI
Formalin Fixed paraffin wax blocks of processed tissue		Microtomy  Microm Ergostar HM340E microtome  Key SOPs PR2969 Production of a Routine H&E Stained Section	LRI
FFPE slides (Formalin fixed paraffin embedded) and frozen sections	Routine morphological staining for the detection of basophilic and eosinophilic structures	H&E staining and coverslipping using automated stainer  Leica Autostainer XL Gemini Autostainer Key SOP: PR2969 Production of a Routine H&E Stained Section	LRI



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HUMAN BODY TISSUE (cont'd)	<u>Histopathological examination activities for the purposes of clinical diagnosis (cont'd)</u>	Documented in house methods incorporating manufacturers' instructions where relevant:	
Fresh/frozen tissue	Intraoperative examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis	Frozen sections slide production using Thermo Shandon FSE cryotomes Leica CM1950 Cryotome  Key Management of Fresh Tissue and Frozen Sections	LRI GH
Frozen sections	Routine morphological staining for the detection of basophilic and eosinophilic structures	Manual H & E Staining  Key SOP PR2963 Management of Fresh Tissue and Frozen Sections	LRI GH
FFPE slides (Formalin fixed paraffin embedded)	Special stains for the detection of:	Documented in-house procedures for manual special stains  Key SOP PR3636 Special Stains Procedures	LRI
	Lymphoid cells helicobacteria like organisms	Modified Giemsa	
	Non-acid fact bacteria	Gram stain	
	Gram positive and gram-negative bacteria	Gram Twort	
	Atrophy pigment	Long Ziehl Neelsen	
	Fibrosis, differentiation of muscle and collagen	Martius scarlet blue trichrome (MSB)	
	Atrophy pigment	Modified Ziehl Neelsen	



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HUMAN BODY TISSUE (cont'd)	<u>Histopathological examination activities for the purposes of clinical diagnosis</u> (cont'd)	Documented in house methods incorporating manufacturers' instructions where relevant:	
FFPE slides (cont'd) (Formalin fixed paraffin embedded) unless otherwise stated	Special stains for the detection of: (cont'd)	Documented in-house procedures for manual special stains  Key SOP: PR3636 Special Stains Procedures	LRI
Frozen Sections	Lipids  Amyloid  Mast cells	Oil red O  Stokes Congo Red  Toluidine blue	
Formalin Fixed Paraffin Embedded Tissue (FFPE) sections on glass slides	Acid mucins  Glycogen, basement membranes, and other PAS-positive structures  Glycogen, basement membranes, and other PAS-positive structures  Reticulin  Fungi including pneumocystis  Amyloid  Basement membranes  Atrophy pigment	Automated special stains using the Dako Artisan Autostainer  SOP: HL3 049 Use of DAKO Artisan for Special Stains  Alcian blue  Diastase/Alcian blue/Periodic acid Schiff (PAS)  Diastase / Periodic acid Schiff (PAS)  Gordon and Sweets  Grocotts  Highmans Congo red  Jones' methenamine silver  Long Ziehl Neelsen	LRI



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HUMAN BODY TISSUE (cont'd)	<u>Histopathological examination activities for the purposes of clinical diagnosis</u> (cont'd)	Documented in house methods incorporating manufacturers' instructions where relevant:	LRI
FFPE slides (cont'd) (Formalin fixed paraffin embedded)	Special stains for the detection of: (cont'd)	Automated special stains using the Dako Artisan Autostainer	
		SOP: PR3636 Special Stains Procedures	
	Fibrosis, differentiation of muscle and collagen	Martius scarlet blue trichrome (MSB)	
	Fibrosis, differentiation of muscle and collagen	Massons trichrome	
	Elastin	Millers/Van Gieson (EVG)	
	Hep B surface antigen	Orcein (Shikatas method)	
	Haemosiderin and asbestos bodies	Perls prussian blue	
	Spirochetes	Warthin Faulkner	
	<u>Examination of tissues to identify or exclude enzymatic abnormalities for the purpose of diagnosis</u>	Microscopic examination	
Frozen sections muscle tissue and FFPE muscle sections on glass slides	Detection of ganglion cells	Manual Enzyme Histochemistry method – PR3635 Handling Rectal Biopsies for Hirschsprungs Disease	LRI



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HUMAN BODY TISSUE AND FLUIDS  FFPE slides (Formalin fixed paraffin embedded)	<u>Histopathological examination of tissues for the purpose of diagnosis (cont'd)</u>  <u>Immunohistochemistry to detect the following:</u>  Epidermal differentiation  Embryonic cell in normal tissues and germ tumours  Identification of anaplastic large cell lymphomas  Amyloid  Prostate  Malignant mesothelioma  Lymphoma/Carcinoma  Lymphomas  Epithelial cells  B Cells  Cytoplasmic protein  GIST Tumours  C-Myc Oncogene protein  Complement (renal disease)  Gastrointestinal and pulmonary disease  Smooth muscle and sarcoma	Documented in house methods incorporating manufacturers' instructions where relevant:  Automated Immunohistochemical staining using DAKO Envision Flex Autostainers  Key SOP: PR3069 Immunohistochemistry Procedures  AE1 / AE3  $\alpha$ -Feto protein  Alk 1  $\beta$ - Amyloid Precursor Protein  34 $\beta$ E12  BAP-1  Bcl-2  Bcl-6  BerEp4  BOB-1  $\beta$ - Catenin  C Kit  C-Myc  C4d  Calcitonin  Caldesmon	LRI



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HUMAN BODY TISSUE AND FLUIDS (cont'd)	<u>Histopathological examination of tissues for the purpose of diagnosis</u> (cont'd)	Documented in house methods incorporating manufacturers' instructions where relevant:	LRI
FFPE slides (cont'd) (Formalin fixed paraffin embedded)	<u>Immunohistochemistry to detect the following:</u> (cont'd)	Automated Immunohistochemical staining using DAKO Envision Flex Autostainers  Key SOP: PR3069 Immunohistochemistry Procedures	
	Calponin (calcium binding) protein (Vascular & peripheral smooth muscle; other contractile cells)	Calponin	
	Neuroanatomical marker	Calretinin	
	Epithelial cell marker	Cam 5.2	
	Ovarian Tumour	CA 125	
	GI Tumours/Pancreas	CA19.9	
	Histiocytes/Langerhan cell	CD 1a	
	Pan t-lymphocytes	CD 2	
	Differentiation of carcinoids and metastatic adenoCa	CD X2	
	T Antigen on Lymphocytes	CD 3	
	T-cell subset	CD 4	
	Pan T-cell marker	CD 5	
	T-cell marker	CD 7	





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HUMAN BODY TISSUE AND FLUIDS (cont'd)	<u>Histopathological examination of tissues for the purpose of diagnosis (cont'd)</u>	Documented in house methods incorporating manufacturers' instructions where relevant:	LRI
FFPE slides (cont'd) (Formalin fixed paraffin embedded)	<u>Immunohistochemistry to detect the following: (cont'd)</u>	Automated Immunohistochemical staining using DAKO Envision Flex Autostainers	
		Key SOP: PR3069 Immunohistochemistry Procedures	
	T-cell subset	CD 8	
	Renal carcinoma/Lymphoma	CD 10 (calla)	
	CD11 antigen	CD 11	
	Reed Sterberg and other cell types	CD 15 (leuM1)	
	B cell	CD 19	
	Antigen of B Lymphocytes	CD 20 (L26)	
	Follicular dendritic cells	CD 21	
	Aid in the classification of Lymphoma	CD 23	
	Lymphomas	CD 25	
	Reed Sterberg cells	CD 30 (Ber H2)	
	Endothelial marker	CD 31 (PECAM)	
	Stem cell/endothelium sarcoma	CD 34 (Qbend 10)	
	Dendritic cell marker	CD35	
	Pan T-cell marker	CD 43 (MT1)	
	Pan Leukocyte marker (T&B)	CD 45 (LCA)	



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FFPE slides (cont'd) (Formalin fixed paraffin embedded)	<u>Immunohistochemistry to detect the following:</u> (cont'd)	Automated Immunohistochemical staining using DAKO Envision Flex Autostainers	
		Key SOP: PR3069 Immunohistochemistry Procedures	
	Nerve and neuroendocrine cells	CD 56 (NCAM)	
	NK cells, neuroendocrine cells	CD 57	
	Megakaryocytes in trephines	CD 61	
	Macrophages and mononuclear cells	CD 68 (PGM1)	
	Useful for identification of B-cell lymphomas	CD 79a	
	Ewings sarcoma	CD 99 (mic2)	
	Lymphoma/Plasmacytoma	CD 138	
	GI carcinoma	CEA	
	Neuroendocrine	Chromogranin A	
	CK in epithelium	CK 5/6	
	CK in epithelium	CK 7	
	Ck for Carcinoma	CK 14	
	Ck for Carcinoma	CK 19	
	CK for gastro-intestinal cells	CK 20	
	Cytomegalovirus	CMV	



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FFPE slides (cont'd) (Formalin fixed paraffin embedded)	<u>Immunohistochemistry to detect the following:</u> (cont'd)	Automated Immunohistochemical staining using DAKO Envision Flex Autostainers	
		Key SOP: PR3069 Immunohistochemistry Procedures	
	Mantle cell lymphoma	Cyclin D1	
	Smooth and striated muscle cells	Desmin	
	B cells but not plasma cells, lymphatic endothelium	D-240	
	GIST	DOG-1	
	Distinguish lobular from ductal carcinoma	E-Cadherin	
	Epstein-Barr virus	EBV	
	Protein in epithelial cells	EMA	
	Endothelial cells and megakaryocytes	Factor 8	
	Urothelial Carcinoma	GATA 3	
	Breast carcinoma	GCDF	
	Glial fibrillary acide protein	GFAP	
	Intrinsic membrane protein of erythrocytes	Glycophorin A	
	Activated human cytotoxic T lymphocytes (CTL) and natural killer (NK) cells	Granzyme B	



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HUMAN BODY TISSUE AND FLUIDS (cont'd)	<u>Histopathological examination of tissues for the purpose of diagnosis</u> (cont'd)	Documented in house methods incorporating manufacturers' instructions where relevant:	LRI
FFPE slides (cont'd) (Formalin fixed paraffin embedded)	<u>Immunohistochemistry to detect the following:</u> (cont'd)	Automated Immunohistochemical staining using DAKO Envision Flex Autostainers	
	Mesothelial marker	Key SOP: PR3069 Immunohistochemistry Procedures HBME-1	
	Human chronic gonadotrophin	HCG	
	Identification of hairy cell leukaemia and lymphomas	HCL	
	Antibody labels hepatocytes and is a useful tool for the differential diagnosis of hepatocellular tumors in general	Hepatocyte (Hepar-1)	
	Melanocytes (Melanoma)	HMB 45	
	Detection of HPV infected cells	HPV	
	Detection of HSV in human cellular material	HSV 1	
	Detection of HSV in human cellular material	HSV 2	
	Immunoglobulin M	IgM	
	Immunoglobulin G4	IgG4	
	Carcinoma vs Germ cell tumour	Inhibin $\alpha$	



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FFPE slides (cont'd) (Formalin fixed paraffin embedded)	<u>Immunohistochemistry to detect the following:</u> (cont'd)	Automated Immunohistochemical staining using DAKO Envision Flex Autostainers Key SOP: PR3069 Immunohistochemistry Procedures	
	Kappa light chains	Kappa	
	Lambda light chains	Lambda	
	Proliferating cells	Mib 1	
	Melanocytes	Melan-a	
	MLH-1 mismatch repair protein	MLH1	
	MSH-2 mismatch repair protein	MSH2	
	MSH6 mismatch repair protein	MSH6	
	Epithelial tissues from simple glandular to stratified squamous epithelium and identification of normal and neoplastic cells of epithelial origin	MNF116	
	B cell marker used to aid classification of lymphomas	MUM-1 (IRF4)	
	Myeloid leukaemia	Muramidase(lysozyme)	
	Myeloperoxidase-positive cells in normal and neoplastic tissues and discrimination between lymphoid and myeloid disorders	Myeloperoxidase	
	Serves as a reserve supply of oxygen within muscles	Myoglobin	
	Skeletal muscle – classification of rhabdosarcomas / Wilms tumour	Myogenin/Myf 4	



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FFPE slides (cont'd) (Formalin fixed paraffin embedded)	<u>Immunohistochemistry to detect the following:</u> (cont'd)	Automated Immunohistochemical staining using DAKO Envision Flex Autostainers Key SOP: PR3069 Immunohistochemistry Procedures	
	Neuronal cells, merkel cell tumour of skin, pancreatic endocrine neoplasm, carcinoid tumour and parathyroid tumour	Neurofilament	
	B-Cell marker	Oct-02	
	Germ cell tumours	Oct 3/4	
	Oestrogen receptors	ER	
	B Cell Marker	PAX5-BSAP	
	Ovarian cancer/HPV	P16	
	Nuclei of tumour cells. A cell growth regulator. Used in conjunction with P53.	P21	
	Cell proliferation marker	P53	
	Beckwith-Wiedemann syndrome (BWS)	P57	
	Lymphoma	Pax 8	
	PD-L1 protein expression in NSCLC	PD-L1 (clone 22C3)	
	Enzyme produced by trophoblasts	PLAP	
	PMS2 mismatch repair protein	PMS2	



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FFPE slides (cont'd) (Formalin fixed paraffin embedded)	<u>Immunohistochemistry to detect the following:</u> (cont'd)	Automated Immunohistochemical staining using DAKO Envision Flex Autostainers Key SOP: PR3069 Immunohistochemistry Procedures	
	Progesterone receptor expression in tumours	Progesterone Receptor	
	Marker for prostatic carcinoma	PSA	
	Used to aid classification metastatic PR carcinoma	PSAP	
	Prostate adenocarcinoma	P504s (AMACR)	
	Prostate adenocarcinoma	P504s/P63 (pcock)	
	Tumour suppressor gene	P63	
	Renal carcinoma marker	Renal Cell Carcinoma	
	Schwann cells, nerve processes, S100 positive neoplasm	S100	
	Smooth muscle actin	SMA	
	Classification of breast tumours	SMM	
	Sympathetic nerves, mucosal cells, myenteric nerves of the gastrointestinal tract, salivary glands some thyroid	Somatostatin	
	Melanoma	SOX-10	
	Solitary fibrous tumours	STAT-6	
	BKV infected cells	SV40	



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FFPE slides (cont'd) (Formalin fixed paraffin embedded)	<u>Immunohistochemistry to detect the following:</u> (cont'd)	Automated Immunohistochemical staining using DAKO Envision Flex Autostainers Key SOP: PR3069 Immunohistochemistry Procedures	
	Identification of neuroendocrine neoplasms, including neoplasms of epithelial type, ID of nervous system neoplasms with neuronal differentiation and ID of adrenocortical neoplasm	Synaptophysin	
	Immature T cells	TdT	
	b TCR bearing T lymphocytes	TCR-β	
	Well differentiated thyroid carcinomas	Thyroglobulin	
	Involved in apoptosis	TIA-1	
	Nuclear Protein in Lung and Thyroid	TTF	
	Identification of basement membranes	Type 4 Collagen	
	Tumours of urothelial origin	Uroplakin II	
	Filaments in mesenchymal cells	Vim	
	Tumour marker Wilms	WT1	
	ALK protein in NSCLC	ALK (clone D5F3)	
	HER2 amplification in breast and gastric tumours	Her 2 (Clone 4b5)	
	ROS-1 protein in NSCLC	ROS-1 (clone SP384)	





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HUMAN BODY TISSUE AND FLUIDS (cont'd)	<u>Histopathological examination of tissues for the purpose of diagnosis (cont'd)</u>	Documented in house methods incorporating manufacturers' instructions where relevant:	
Fresh Frozen tissue	Basophilic and Eosinophilic tissue structures	Frozen sections (intraoperative and Mohs) using Leica CM1950 Sectioning Cryostat and Leica Autostainer ST4040 H & E staining using: documented in house procedure – PR2963	MOHS
FFPE Slides	Identification of Her 2 DNA/RNA sequences	FISH (Fluorescence <i>in-situ</i> Hybridisation) using documented -in house procedure by means of hybridization of a complimentary DNA/RNA (probes). – PR2970 Fluorescence In Situ Hybridisation	CYG
FFPE Slides	Detection of: EBV Kappa Light Chains Lambda Light Chains	Manual ISH using Key SOP PR3527	LRI
Slides prepared as above	Morphological assessment and interpretation/diagnosis	Interpretive microscopy: Microscopes: Leica DM2000 Nikon Microscopes Olympus Microscopes Key SOPs PR3850 Reporting of Cellular Pathology Samples	LRI GH



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<p>HUMAN BODY TISSUE AND FLUIDS (cont'd)</p> <p>Tissue, fluids</p>	<p><u>Histopathological examination of tissues for the purpose of diagnosis (cont'd)</u></p> <p><u>Electron Microscopy examinations to assist in detection of clinical abnormalities</u></p> <p>Demonstration of general tissue architecture</p> <p>Contrast enhancement of tissue architecture of ultrathin sections</p> <p>Detection of abnormal cells</p>	<p>Documented in house methods incorporating manufacturers' instructions where relevant:</p> <p>In house documented procedure &amp; manufacturer's instructions using</p> <p>Tissue processing &amp; embedding Leica EM TP Tissue processor, Gen lab oven, MSE Microfuges Key SOP PR2968 Electron Microscopy</p> <p>Tissue sectioning for light and electron microscopy using Leica EM UC6 and UC7 microtomes Key SOPs PR2968 Electron Microscopy</p> <p>Tissue staining for light microscopy manual methods -Toluidine blue</p> <p>Contrast enhancement; -manual methods and microscopy :- Uranyl acetate and Reynold lead citrate Key SOP PR2968 Electron Microscopy</p> <p>Electron microscopic analysis using Jeol 100CX Electron Microscopes Key SOP PR2968 Electron Microscopy</p>	<p>RKCSB</p>



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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY TISSUE AND FLUIDS (cont'd)	<u>Cytopathological examination of fluids for the purpose of diagnosis</u>	Documented in house methods incorporating manufacturers' instructions where relevant:	
HUMAN BODY FLUIDS	<u>Non-Gynaecological (Diagnostic) Cytopathology</u> <u>Preparation and screening for detection or exclusion of pathological abnormalities</u>	Macroscopic and Microscopic examination:  Documented in house methods incorporating manufacturers' instructions where relevant:	
Systemic body fluid samples	Examination of fluids in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis	Sample preparation using Leica Autostainer XL staining machine for Haematoxylin and Eosin and Papanicolaou Staining Heraeus Megafuge centrifuge Thermo Shandon cytospin Labnet Spectrafuge 16M Bioquell Class 1 safety cabinet Leica Microscopes  Manual stain – Romanowsky  PR3068 Preparation of Non-Gynaecological Cytology Samples	GH
FNA	Examination of fluids in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis	Manual - Diff Quick rapid Romanowsky stain using HL8 – PR3068 Preparation of Non-Gynaecological Cytology Samples	GH
Slides prepared as above	Morphological assessment and interpretation/diagnosis	Interpretive microscopy using Leica microscopes Key SOP PR3850 Reporting of Cellular Pathology Samples	GH
END			