Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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



Locations covered by the organisation and their relevant activities

Laboratory locations:

Location details		Activity	Location code
Address: Department of Cellular Pathology Sandringham Building Leicester Royal Infirmary Infirmary Square Leicester LE1 5WW	Local contact Diana Cullen	Histology sample preparation and reporting Electron Microscopy sample preparation and reporting Non-Gynaecological Cytology Sample Preparation and Reporting	LRI
Address: Department of Cellular Pathology Glenfield Hospital Groby Road Leicester LE3 9QP	Local contact Diana Cullen	Histology sample preparation and reporting	GH
Address: Leicester General Hospital Gwendolen Road Leicester LE5 4PW	Local contact Diana Cullen	Sample receipt and transportation	LGH
Address: Robert Kilpatrick Clinical Sciences Building Leicester Royal Infirmary Infirmary Square Leicester LE1 5WW	Local contact Diana Cullen	Electron Microscopy analysis	RKCSB
Address: Mohs Lab Dermatology outpatient's department Balmoral building Leicester Royal Infirmary Infirmary Square Leicester LE1 5WW	Local contact Diana Cullen	Intraoperative and Mohs Cryotomy and Staining	монѕ

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UKAS MEDICAL 8608 Accredited to ISO 15189:2022	University Hospitals of Leicester NHS Trust Issue No: 011 Issue date: 02 July 2025
	Testing performed by the Organisation at the locations specified

Site activities performed away from the locations listed above:

Location details	Activity
On site mortuary and body store Leicester Royal Infirmary Infirmary Square Leicester LE1 5WW	Storage and release 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 and release of bodies
On site body store Leicester General Hospital Gwendolen Road Leicester LE5 4PW	Storage and release 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	Histopathological examination activities for the purposes of clinical diagnosis	Documented in house methods incorporating manufacturers' instructions where relevant:	
Formalin-fixed tissue and fresh 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	LRI
		Key SOPs PR3868 Processing of Tissue for Histopathology	
Formalin-fixed tissue		Embedding using ThermoScientific Histostar Embedding Centres	LRI
		Key SOPs PR2969 Production of a Routine H&E Stained Section	
FFPE blocks		Microtomy	LRI
		Microm Ergostar HM340E and Leica Histocore microtomes	
		Key SOPs PR2969 Production of a Routine H&E Stained Section	
FFPE slides	Routine morphological staining for the detection of basophilic and eosinophilic structures	H&E staining and coverslipping using manual methods and automated stainer	LRI
		DAKO coverstainer Gemini Autostainer Key SOP: PR2969 Production of a Routine H&E Stained Section	



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HUMAN BODY TISSUE (cont'd)	Histopathological examination activities for the purposes of clinical diagnosis (cont'd)	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 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	Special stains for the detection of:	Documented in-house procedures for manual special stains	LRI
		Key SOP PR3636 Special Stains Procedures	
	Lymphoid cells helicobacteria like organisms	Modified Giemsa	
	Non-acid bacteria	Gram stain	
	Fibrosis, differentiation of muscle and collagen	Martius scarlet blue trichrome (MSB)	
	Leprosy	Modified Ziehl Neelsen	
Frozen Sections	Neutral Lipids	Oil red O	LRI
	Mast cells	Toluidine blue	



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HUMAN BODY TISSUE (cont'd)	Histopathological examination activities for the purposes of clinical diagnosis (cont'd)	Documented in house methods incorporating manufacturers' instructions where relevant:	
FFPE slides		Automated special stains using the Dako Artisan Autostainer PR3636 Special stains procedures	LRI
	Acid mucins	Alcian blue	
	Glycogen, basement membranes, and other PAS-positive structures	Diastase/Alcian blue/Periodic acid Schiff (PAS)	
	Glycogen, basement membranes, and other PAS-positive structures	Diastase / Periodic acid Schiff (PASD)	
	Reticulin	Gordon and Sweets	
	Fungi including pneumocystis	Grocotts	
	Amyloid	Puchtler's Congo red	
	Basement membranes	Jones' methenamine silver	
	Acid fast bacilli	Ziehl Neelsen	
	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 Detection of copper-associated protein	Orcein (Shikatas method)	
	Haemosiderin and asbestos bodies	Perls prussian blue	
	Spirochetes	Warthin Faulkner	



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HUMAN BODY TISSUE (cont'd)	Histopathological examination activities for the purposes of clinical diagnosis (cont'd)	Documented in house methods incorporating manufacturers' instructions where relevant:	
	Examination of tissues to identify or exclude enzymatic abnormalities for the purpose of diagnosis	Microscopic examination	LRI
Rectal biopsies frozen slides	Detection of ganglion cells	Manual Enzyme Histochemistry method – PR3635 Handling Rectal Biopsies for Hirschsprungs Disease	LRI
FFPE slides	Immunohistochemistry to detect the following:	Automated Immunohistochemical staining using DAKO Envision Flex Autostainers	LRI
		Key SOP: PR3069 Immunohistochemistry Procedures	
	Lymphoma/Carcinoma	Bcl 2	
	B Cells	BOB-1	
	Complement (renal disease)	C4d	
	Thyroid disease	Calcitonin	
	Smooth muscle and sarcoma	Caldesmon	
	Calponin (calcium building) protein (Vascular and peripheral smooth muscle; other contractile cells)	Calponin	
	Neuroanatomical marker	Calretinin	
	Gastrointestinal tumours/Pancreas	CA19.9	
	Histiocytes/Langerhan cell	CD 1a	
	Pan T-lymphocytes	CD 2	



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	measured/Range of measurement	Equipment/Techniques used	Code
HUMAN BODY TISSUE (cont'd)	Histopathological examination activities for the purposes of clinical diagnosis (cont'd)	Documented in house methods incorporating manufacturers' instructions where relevant:	
FFPE slides (Formalin fixed paraffin embedded) (cont'd)	Immunohistochemistry to detect the following (cont'd):	Automated Immunohistochemical staining using DAKO Envision Flex Autostainers	LRI
		Key SOP: PR3069 Immunohistochemistry Procedures	
	Differentiation of carcinoids and metastatic adenocarcinomas	CD X2	
	T-cell subset	CD 4	
	Pan T-cell marker	CD 5	
	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)	
	Lymphomas	CD 25	
	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)	
	Nerve and neuroendocrine cells	CD 56 (NCAM)	



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HUMAN BODY TISSUE (cont'd)	Histopathological examination activities for the purposes of clinical diagnosis (cont'd)	Documented in house methods incorporating manufacturers' instructions where relevant:	
FFPE slides (Formalin fixed paraffin embedded) (cont'd)	Immunohistochemistry to detect the following (cont'd):	Automated Immunohistochemical staining using DAKO Envision Flex Autostainers	LRI
		Key SOP: PR3069 Immunohistochemistry Procedures	
	NK cells, neuroendocrine cells	CD 57	
	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	
	Smooth and striated muscle cells	Desmin	
	Lymphatic endothelium	D2-40 (Podoplanin)	
	Distinguish lobular from ductal carcinoma	E-Cadherin	
	Epstein-Barr virus	EBV	
	Breast carcinoma	GCDFP-15	
	Activated human cytotoxic T lymphocytes (CTL) and natural killer (NK) cells	Granzyme B	
	Melanocytes (Melanoma)	HMB 45	
	Detection of HPV-infected cells	HPV	



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HUMAN BODY TISSUE (cont'd)	Histopathological examination activities for the purposes of clinical diagnosis (cont'd)	Documented in house methods incorporating manufacturers' instructions where relevant:	
FFPE slides (Formalin fixed paraffin embedded) (cont'd)	Immunohistochemistry to detect the following: (cont'd)	Automated Immunohistochemical staining using DAKO Envision Flex Autostainers	LRI
		Key SOP: PR3069 Immunohistochemistry Procedures	
	Immunoglobulin M	lgM	
	Immunoglobulin G4	lgG4	
	Melanocytes	Melan-A	
	Germ cell tumours	Oct 3/4	
	Nuclei of tumour cells. A cell growth regulator. Used in conjunction with P53.	P21	
	PD-L1 protein expression in NSCLC	PD-L1 (clone 22C3)	
	Progesterone receptor expression in tumours	Progesterone Receptor (PR)	
	Smooth muscle myosin	SMM	
	BKV infected cells	SV40	
	Immature T cells	TdT	
	Nuclear Protein in Lung and Thyroid	TTF-1	
	Tumour marker Wilms	WT1	
	Epidermal differentiation	AE1/AE3	



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HUMAN BODY TISSUE (cont'd)	Histopathological examination activities for the purposes of clinical diagnosis (cont'd)	Documented in house methods incorporating manufacturers' instructions where relevant:	
FFPE slides (Formalin fixed paraffin embedded) (cont'd)	Immunohistochemistry to detect the following: (cont'd)	Automated Immunohistochemical staining using Agilent DAKO OMNIS stainer:	LRI
		Key SOP: PR3069 Immunohistochemistry Procedures	
	Embryonic cell in normal tissues and germ tumours	α-Feto protein	
	Identification of anaplastic large cell lymphomas	Alk1	
	Prostate adenocarcinoma	p504s (AMACR)	
	Malignant mesothelioma	BAP-1	
	Amyloid	β- Amyloid Precursor Protein	
	Cytoplasmic protein	β - Catenin	
	Lymphoma/Carcinoma	Bcl-2	
	Lymphomas	Bcl-6	
	Epithelial cells	BerEp4	
	Complement (renal disease)	C4d	
	GI Tumours/Pancreas	CA19.9	
	Ovarian Tumour	CA 125	
	Thyroid disease	Calcitonin	
	Smooth muscle and sarcoma	Caldesmon	



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HUMAN BODY TISSUE AND FLUIDS	Histopathological examination of tissues for the purpose of diagnosis (cont'd):	Documented in house methods incorporating manufacturers' instructions where relevant:	
FFPE slides (Formalin fixed paraffin embedded) (cont'd)	Immunohistochemistry to detect the following (cont'd):	Automated Immunohistochemical staining using Agilent DAKO OMNIS stainer:	LRI
		Key SOP: PR3069	
	Calponin (calcium binding) protein (Vascular & peripheral smooth muscle; other contractile cells)	Calponin	
	Neuroanatomical marker	Calretinin	
	Epithelial cell marker	Cam 5.2	
	Renal carcinoma/Lymphoma	CD 10 (calla)	
	CD11 antigen	CD 11	
	Lymphoma/Plasmacytoma	CD 138	
	Reed Sterberg and other cell types	CD 15 (leuM1)	
	B cells	CD 19	
	Histiocytes/Langerhan cells	CD 1a	
	Pan T-lymphocytes	CD 2	
	Antigen of B Lymphocytes	CD 20 (L26)	
	Follicular dendritic cells	CD 21	
	Aid in the classification of Lymphoma	CD 23	
	Lymphomas	CD 25	
	T Antigen on Lymphocytes	CD 3	



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HUMAN BODY TISSUE AND FLUIDS (cont'd)	Histopathological examination of tissues for the purpose of diagnosis (cont'd):	Documented in house methods incorporating manufacturers' instructions where relevant:	
FFPE slides (Formalin fixed paraffin embedded) (cont'd)	Immunohistochemistry to detect the following (cont'd):	Automated Immunohistochemical staining using Agilent DAKO OMNIS stainer:	LRI
		Key SOP: PR3069	
	Reed Sterberg cells	CD 30 (Ber H2)	
	Endothelial marker	CD 31 (PECAM)	
	Stem cell/endothelium sarcoma	CD 34 (Qbend 10)	
	Dendritic cell marker	CD 35	
	T-cell subset	CD 4	
	Pan T-cell marker	CD 43 (MT1)	
	Pan Leukocyte marker (T&B)	CD 45 (LCA)	
	Pan T-cell marker	CD 5	
	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)	
	T-cell marker	CD 7	
	Useful for identification of B-cell lymphomas	CD 79a	
	T-cell subset	CD 8	
	Ewings sarcoma	CD 99 (mic2)	



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HUMAN BODY TISSUE AND FLUIDS (cont'd)	Histopathological examination of tissues for the purpose of diagnosis (cont'd):	Documented in house methods incorporating manufacturers' instructions where relevant:	
FFPE slides (Formalin fixed paraffin embedded) (cont'd)	Immunohistochemistry to detect the following (cont'd):	Automated Immunohistochemical staining using Agilent DAKO OMNIS stainer:	LRI
		Key SOP: PR3069	
	Differentiation of carcinoids and metastatic adenocarcinoma	CD X2	
	Neuroendocrine	Chromogranin A	
	Demonstration of cytokeratins	CK 14	
		СК 19	
		CK 5/6	
		CK 20	
	T-cell marker	CD 7	
	GIST Tumours	C Kit	
	Cytomegalovirus	CMV	
	C-Myc Oncogene protein	С-Мус	
	Mantle cell lymphoma	Cyclin D1	
	Lymphatic endothelium	D2-40 (Podolplanin)	
	Smooth and striated muscle cells	Desmin	
	GIST	DOG-1	
	Distinguish lobular from ductal carcinoma	E-Cadherin	
	Protein in epithelial cells	ЕМА	



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HUMAN BODY TISSUE AND FLUIDS (cont'd)	Histopathological examination of tissues for the purpose of diagnosis (cont'd):	Documented in house methods incorporating manufacturers' instructions where relevant:	
FFPE slides (Formalin fixed paraffin embedded) (cont'd)	Immunohistochemistry to detect the following (cont'd):	Automated Immunohistochemical staining using Agilent DAKO OMNIS stainer:	LRI
		Key SOP: PR3069	
	Oestrogen receptors	ER	
	Endothelial cells and megakaryocytes	Factor 8	
	Urothelial Carcinoma	GATA 3	
	Glial fibrillary acidic protein	GFAP	
	Intrinsic membrane protein of erythrocytes	Glycophorin A	
	Mesothelial marker	HBME-1	
	Human chronic gonadotrophin	HCG	
	Identification of hairy cell leukaemia and lymphomas	HCL	
	Demonstration of hepatocytes (including hepatocellular carcinoma)	Hepatocyte (Hepar-1)	
	Melanocytes (Melanoma)	HMB 45	
	Detection of HPV infected cells	HPV	
	Detection of HSV in human cells	HSV	
	Carcinoma vs Germ cell tumour	Inhibin α	
	Kappa light chains	Карра	



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HUMAN BODY TISSUE AND FLUIDS (cont'd)	Histopathological examination of tissues for the purpose of diagnosis (cont'd):	Documented in house methods incorporating manufacturers' instructions where relevant:	
FFPE slides (Formalin fixed paraffin embedded) (cont'd)	Immunohistochemistry to detect the following (cont'd):	Automated Immunohistochemical staining using Agilent DAKO OMNIS stainer:	LRI
		Key SOP: PR3069	
	Lambda light chains	Lambda	
	Myeloid leukaemia	Muramidase (lysozyme)	
	Melanocytes	Melan-a	
	Proliferating cells	Ki67 (Mib 1)	
	MLH1 mismatch repair protein	MLH1	
	Pan-cytokeratin	MNF116	
	MSH2 mismatch repair protein	MSH2	
	MSH6 mismatch repair protein	MSH6	
	B cell marker used to aid classification of lymphomas	MUM-1 (IRF4)	
	Myeloperoxidase-positive cells i	Myeloperoxidase	
	Reserve oxygen supply (muscles)	Myoglobin	
	Skeletal muscle – classification of rhabdosarcomas / Wilms tumour	Myogenin/Myf 4	



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HUMAN BODY TISSUE AND FLUIDS (cont'd)	Histopathological examination of tissues for the purpose of diagnosis (cont'd):	Documented in house methods incorporating manufacturers' instructions where relevant:	
FFPE slides (Formalin fixed paraffin embedded) (cont'd)	Immunohistochemistry to detect the following (cont'd):	Automated Immunohistochemical staining using Agilent DAKO OMNIS stainer:	LRI
		Key SOP: PR3069	
	Neuronal cells, Merkel cell tumour of skin, pancreatic endocrine neoplasm, carcinoid tumour and parathyroid tumour	Neurofilament	
	B-Cell marker	Oct-2	
	Germ cell tumours	Oct-3/4	
	Ovarian cancer/HPV	P16	
	Cell proliferation marker	P53	
	Beckwith-Wiedemann syndrome (BWS)	P57	
	Tumour suppressor gene	P63	
	B Cell Marker	PAX5-BSAP	
	Lymphoma/Thyroid disease	Pax 8	
	PD-L1 protein expression in NSCLC	PD-L1 (clone 22C3)	
	Enzyme produced by trophoblasts	PLAP	
	PMS2 mismatch repair protein	PMS2	
	Marker for prostatic carcinoma	PSA	
	Used to aid classification metastatic prostate carcinoma	PSAP	



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HUMAN BODY TISSUE AND FLUIDS (cont'd)	Histopathological examination of tissues for the purpose of diagnosis (cont'd):	Documented in house methods incorporating manufacturers' instructions where relevant:	
FFPE slides (Formalin fixed paraffin embedded) (cont'd)	Immunohistochemistry to detect the following (cont'd):	Automated Immunohistochemical staining using Agilent DAKO OMNIS stainer:	LRI
		Key SOP: PR3069	
	Renal carcinoma marker	Renal Cell Carcinoma	
	Schwann cells, nerve processes, S100 positive neoplasm	S100	
	Smooth muscle actin	SMA	
	Melanoma	SOX-10	
	Solitary fibrous tumours	STAT-6	
	Neuroendocrine neoplasms	Synaptophysin	
	β TCR bearing T lymphocytes	TCR-β	
	Immature T cells	TdT	
	Well differentiated thyroid carcinomas	Thyroglobulin	
	Involved in apoptosis	TIA-1	
	Nuclear Protein in Lung and Thyroid	TTF-1	
	Identification of basement membranes	Type 4 Collagen	
	Tumours of urothelial origin	Uroplakin II	



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HUMAN BODY TISSUE AND FLUIDS (cont'd)	Histopathological examination of tissues for the purpose of diagnosis (cont'd):	Documented in house methods incorporating manufacturers' instructions where relevant:	
FFPE slides (Formalin fixed paraffin embedded) (cont'd)	Immunohistochemistry to detect the following (cont'd):	Automated Immunohistochemical staining using Agilent DAKO OMNIS stainer:	LRI
		Key SOP: PR3069	
	Filaments in mesenchymal cells	Vimentin	
	Tumour marker Wilms	WT1	
FFPE slides (Formalin fixed paraffin embedded)	Immunohistochemistry to detect the following:	Automated Immunohistochemical staining using Roche Ventana Benchmark Ultra	
		Key SOP: PR3069 Immunohistochemistry Procedures	
	HER2 amplification in breast and gastric tumours	Her 2 (Clone 4b5)	
Fresh Frozen tissue	Basophilic and Eosinophilic tissue structures	Frozen sections (intraoperative and Mohs) using Leica CM1950 Sectioning Cryostat and Myr autostainer H & E staining using: documented in house procedure – PR2963	MOHS



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HUMAN BODY TISSUE AND FLUIDS (cont'd)	Histopathological examination of tissues for the purpose of diagnosis (cont'd)	Documented in house methods incorporating manufacturers' instructions where relevant:	
FFPE Slides	Detection of: EBV Kappa Light Chains Lambda Light Chains	Automated chromogenic In-situ hybridisation staining on the Roche Ventana Benchmark, Key SOP PR3527 Chromogenic In Situ Hybridisation	LRI
FFPE slides	HER-2 amplification in breast and gastric tumours	Automated fluorescence in-situ hybridisation staining on the Agilent Dako OMNIS PR2970	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
	Electron Microscopy examinations to assist in detection of clinical abnormalities	In house documented procedure & manufacturer's instructions using	LRI
Tissue, fluids		Tissue processing and embedding Leica EM TP Tissue processor, Gen lab oven, MSE Microfuges Key SOP PR2968 Electron Microscopy	
		Tissue sectioning for light and electron microscopy using Leica EM UC6 and UC7 microtomes Key SOPs PR2968 Electron Microscopy	
	Demonstration of general tissue architecture	Tissue staining for light microscopy manual methods -Toluidine blue PR2968 Electron microscopy	



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HUMAN BODY TISSUE AND FLUIDS (cont'd)	Electron Microscopy examinations to assist in detection of clinical abnormalities (cont'd):	Documented in house methods incorporating manufacturers' instructions where relevant:	
	Contrast enhancement of tissue architecture of ultrathin sections	Contrast enhancement; -manual methods and microscopy:- Neodymium (III) Acetate and Reynold Lead Citrate Key SOP PR2968 Electron Microscopy	LRI
	Detection of abnormal cells	Electron microscopic analysis using Jeol 1400 Electron Microscopes Key SOP PR2968 Electron Microscopy	RKCSB



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HUMAN BODY TISSUE AND FLUIDS (cont'd)	Non-Gynaecological (Diagnostic) Cytopathology Preparation and screening for detection or exclusion of pathological abnormalities	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 Papanicolau Staining Heraeus Megafuge centrifuge Thermo Shandon cytospin Bioquell Class 1 safety cabinet Leica Microscopes Manual stain – Romanowsky PR3068 Preparation of Non- Gynaecological Cytology Samples	LRI
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 PR3068 Preparation of Non- Gynaecological Cytology Samples	LRI
Slides prepared as above	Morphological assessment and interpretation/diagnosis	Interpretive microscopy using Leica microscopes Key SOP PR3850 Reporting of Cellular Pathology Samples	LRI
	END		