


# Schedule of Accreditation

issued by

## United Kingdom Accreditation Service

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

 <p><b>UKAS</b> MEDICAL 8638</p> <p>Accredited to ISO 15189:2012</p>	<h3>Belfast Health and Social Care Trust</h3> <p>Issue No: 004    Issue date: 22 December 2021</p>	
	<p>Royal Hospitals Cellular Pathology Institute of Pathology Grosvenor Road Belfast BT12 6BA</p>	<p>Contact: Leona Grant Tel: +44 (0)2890 637513 E-Mail: <a href="mailto:Leona.grant@belfasttrust.hscni.net">Leona.grant@belfasttrust.hscni.net</a> Website: <a href="http://www.belfasttrust.hscni.net/Laboratory-MortuaryServices.htm">www.belfasttrust.hscni.net/Laboratory-MortuaryServices.htm</a></p>
<p>Testing performed by the Organisation at the locations specified below</p>		

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

#### Laboratory locations:

Location details	Activity	Location code
<p>Royal Hospitals Cellular Pathology Institute of Pathology Grosvenor Road Belfast BT12 6BA</p> <p style="text-align: right;">Shauna McAuley 07917880333</p>	<p>Histopathology Diagnostic Cytology</p>	RH
<p>Royal Hospitals Microbiology Laboratory Kelvin Building Grosvenor Road Belfast BT12 6BA</p> <p style="text-align: right;">Robbie Wilson 02890632670</p>	<p>Electron microscopy</p>	RHMic
<p>Royal Hospitals Mohs Laboratory Level 5 Dermatology Department Outpatient Centre Falls Road Belfast BT12 6BA</p> <p style="text-align: right;">Robbie Wilson 02895045785</p>		Mohs



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

Location details	Activity	Location code
On-site Mortuary and Body Store Royal Hospitals Grosvenor Road Belfast BT12 6BA	Storage of bodies Retrieval of tissue via post-mortem Record keeping (body identification and audit trail)	RHMort
FNA Breast Clinic Outpatients Mammography Suite Belfast City Hospital	Slide preparation, Staining by Giemsa method, Screening and provisional reporting	BCHbc
ROSE Head and Neck Clinic Belfast Royal Hospital	Slide preparation, Staining by Giemsa method, ROSE, Rapid onsite evaluation of adequacy	HNC
Ultrasound ROSE Level 4 Ultra Sound Department Belfast Royal Hospital	Slide preparation, Staining by Giemsa method. ROSE - adequacy advice given	RHus
Ultrasound ROSE Lorimer Suite Ground Floor Belfast City Hospital	Slide preparation, Staining by Giemsa method. ROSE - adequacy advice given	BCHus
Ultrasound ROSE Belfast Royal Hospital, Level 3, Intervention Suite	Slide preparation, Staining by Giemsa method. ROSE - adequacy advice given	RHusi
EUS ROSE Belfast Royal Hospital Level 3 Endoscopy Day Unit	Slide preparation, Staining by Giemsa method. ROSE - adequacy advice given	RHeus
EUS ROSE Ground Floor, Tower Block Endoscopy Unit Belfast City Hospital	Slide preparation, Staining by Giemsa method. ROSE - adequacy advice given	BCHeus
CT ROSE Belfast Royal Hospital Level 2 and Level 3 X-ray Dept and CT Dept	Slide preparation, Staining by Giemsa method. ROSE - adequacy advice given	RHct



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Location details	Activity	Location code
EBUS ROSE Ground Floor, Tower Block Endoscopy Unit Belfast City Hospital	Slide preparation, Staining by Giemsa method. ROSE - adequacy advice given	BCHebu



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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 AND FLUIDS  Systemic body fluid samples including fine needle aspirations.	<u>Cytopathological examination of fluids for the purpose of diagnosis</u>  Examination of fluids in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis	Documented in house methods incorporating manufacturers' instructions where relevant:  Samples centrifuged and processed using Hologic ThinPrep technique – T2000  Conventional sample preparation using centrifuge and cytocentrifuge  Automated papanicolaou and H&E staining using Tissue Tek Prisma plus automated slide stainer and Tissue Tek Glas G2 Coverslipper  <ul style="list-style-type: none"> <li>• LP 402 001 (TP-81)</li> <li>• LP 402 008 (TP-88)</li> <li>• LP 400 005 (TP-46)</li> </ul>	RH
Cervical LBC Samples (Thinprep).	Preparation of samples in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis/screening	Hologic T5000 auto LBC processor  <ul style="list-style-type: none"> <li>• LP 412 007 (TP-114)</li> <li>• PD 400 003 (TP-288)</li> </ul>	RH
Glass slides from cervical LBC samples	Staining of samples in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis/screening	Automated papanicolaou staining using Tissue Tek Prisma Plus and Tissue Tek Glas G2 Coverslipper  <ul style="list-style-type: none"> <li>• LP 412 100 (TP-115)</li> </ul>	RH
Slides prepared as above	Morphological assessment and interpretation/diagnosis	Interpretive microscopy using microscopes  <ul style="list-style-type: none"> <li>• LP 400 007 (TP-48)</li> </ul>	RH



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HUMAN BODY TISSUE AND FLUIDS (cont'd)	<u>Histopathological examination of tissues for the purpose of 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 Also utilising Pathvision Faxitron <ul style="list-style-type: none"> <li>Cat A – LP 401 601 (TP-76)</li> <li>Cat B – LP 401 602 (TP-77)</li> <li>Cat C – LP 401 603 (TP-78)</li> <li>Cat D – LP 401 604 (TP-79)</li> <li>Cat E – LP 401 605 (TP-80)</li> <li>Examination of Early Miscarriages - LP 429 013 (TP-159)</li> </ul>	RH
Formalin-fixed tissue samples including thrombin clots prepared by systemic cytology service		Tissue Processing 2 x VIP-6 AL 2 x Xpress X120 2 x VIP-6 E2 1 x VIP-6 E2 (Neuropathology) <ul style="list-style-type: none"> <li>TP-55</li> <li>TP-56</li> </ul>	RH
Formalin-fixed tissue samples including thrombin clots prepared by systemic cytology service		Embedding using: Manual: 2 x Tec 5 Tissue Embedding Console <ul style="list-style-type: none"> <li>TP-57</li> </ul> Automatic: 2 xa120 Autoembedder <ul style="list-style-type: none"> <li>TP-57</li> </ul>	RH
Bone and calcified tissue		Decalcification using formic acid <ul style="list-style-type: none"> <li>TP-69</li> </ul>	RH



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<p>HUMAN BODY TISSUE AND FLUIDS (cont'd)</p> <p>Fresh/frozen tissue</p> <p>Formalin Fixed paraffin wax blocks of processed tissue, including thrombin clots prepared by systemic cytology service</p>	<p><u>Histopathological examination of tissues for the purpose of diagnosis</u> (cont'd)</p> <p>Intraoperative examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis</p> <p>Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis</p>	<p>Documented in house methods incorporating manufacturers' instructions where relevant:</p> <p>Frozen sections using:</p> <p>Leica CM1950 cryostat</p> <p>Manual H&amp;E staining</p> <ul style="list-style-type: none"> <li>• LP 401 113 (TP-53)</li> <li>• LP 421 120 (TP-121)</li> </ul> <p>Microtomy using:</p> <p>Microm HM325 Tissue Tek Autosection Gaileo SEMI-automatic Leica Histocore Autocut (Bone and calcified tissue) Leica RM2235 Leica RM2135</p> <ul style="list-style-type: none"> <li>• LP 401 019 (TP-58)</li> </ul>	<p>RH</p> <p>Mohs</p> <p>RH</p>



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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:	
FFPE slides (Formalin fixed paraffin embedded) and frozen sections	Routine morphological staining for the detection of basophilic and eosinophilic structures	H&E staining using: 2 x HE600 Thermo Linear	Mohs
		<ul style="list-style-type: none"> <li>• LP 401 120 (TP-59) (H&amp;E)</li> <li>• LP 401 121 (TP-60) (Maintenance of Staining machines)</li> <li>• LP 421 120 (TP-121)</li> <li>• LP 401 122 (TP-61) (Coverslippers)</li> </ul>	RH RH Mohs RH
FFPE slides (Formalin fixed paraffin embedded)	Special stains for the detection of:	Documented in-house procedures for manual special stains	RH
	TB bacilli	Auramine O	
	Nissl Substance	Cresyl Fast Violet Method	
	Fibrosis	Haematoxylin and van Gieson	
	Myelin in peripheral nerves	Modification of Kultschitsky's Stain	
	Myelin	Luxol Fast Blue/Haematoxylin	
	Fibrin deposition, fibrinosis, fibrosis of liver	Martius Scarlet Blue	
	Melanin	Masson Fontana	
	Helicobacter	Modified May-Grunwald Giemsa	
	Hep B surface antigen Copper-associated protein	Orcein	



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HUMAN BODY TISSUE AND FLUIDS (cont'd)	<u>Histopathological examination of tissues for the purpose of diagnosis</u> (cont'd)	<u>Documented in house methods incorporating manufacturers' instructions where relevant:</u>	RH
FFPE slides (cont'd) (Formalin fixed paraffin embedded)	Special stains for the detection of: (cont'd)		
	Mast cells	Toluidine Blue	
	Calcium	von Kossa	
FFPE slides (Formalin fixed paraffin embedded)	Special stains for the detection of:	Automatic special staining using: 3 x Benchmark Special Stainer TP-67	
	Acid mucins	Alcian Blue	
	All Mucins	Alcian Blue PAS ± Diastase	
	H.Pylori	Alcian Yellow	
	Amyloid	Congo Red	
	Gram positive and negative bacteria	Gram	
	Fungi	Methenamine Silver (Grocott)	
	Basement membrane (renal)		
	Fibrosis, differentiation of muscle and collagen	Masson Trichrome	
	Helicobacter	Modified May-Grunwald Giemsa	
	Fungus	Mucicarmine	
	Glycogen, basement membranes, and other PAS-positive structures	Periodic Acid Schiff (PAS +/- Diastase)	
	Haemosiderin	Perls' Prussian Blue	
	Reticulin	Reticulin	
	Spirochetes	Steiner II	
	Acid-Alcohol fast bacilli	Ziehl Neelsen	





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HUMAN BODY TISSUE AND FLUIDS (cont'd)	<u>Histopathological examination of tissues for the purpose of diagnosis (cont'd)</u>	<u>Documented in house methods incorporating manufacturers' instructions where relevant:</u>	RH
FFPE slides (cont'd) (Formalin fixed paraffin embedded)	Immunohistochemistry to detect the following:	Automated Immunohistochemical staining using Leica Bond III and the following antibodies	
Unfixed diagnostic cytology slides (cont'd)		<ul style="list-style-type: none"> <li>• LP 404 005 (TP-94)</li> <li>• LP 404 006 (TP-95)</li> <li>• PD 400 002 (TP 287)</li> </ul>	
	Smooth muscle	Actin (Smooth muscle)	
	Pituitary hormone	ACTH	
	Muscle dystrophy panel	Adhalin	
	For the identification of anaplastic large cell lymphomas	ALK protein	
	Alpha-1-antitrypsin	Alpha-1-antitrypsin	
	Embryonic cell in normal tissues and germ tumours	Alpha fetoprotein	
	Amyloid marker	Amyloid A component	
	Hairy cell leukaemia	Annexin-1	
	Axonal swelling and damage (neuro)	APP	
	Dementia profile (neuro)	βAmyloid	
	Glioma panel (neuro)	ATRX	
	Detects syncytiotrophoblasts	Beta-hCG	
	Beta-Catenin	Beta-Catenin	
	Epithelial cells	Ber EP4	
	Lymphoma/Carcinoma	BCL-2	
	Lymphomas	BCL-6	



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FFPE slides (cont'd) (Formalin fixed paraffin embedded)	Immunohistochemistry to detect the following: (cont'd)	Automated Immunohistochemical staining using Leica Bond III and the following antibodies	
Unfixed diagnostic cytology slides (cont'd)		<ul style="list-style-type: none"> <li>• LP 404 005 (TP-94)</li> <li>• LP 404 006 (TP-95)</li> <li>• PD 400 002 (TP 287)</li> </ul>	
	Autoimmune and immunodeficiency disorders	BETA F1	
	B-cells	BOB 1	
	BRAF mutations	BRAF	
	Rhabdoid tumours	BRG1	
	Pancreatic tumour/	CA 19-9	
	Ovarian tumour	CA 125	
	Gastrointestinal and pulmonary disease	Calcitonin	
	Protein involved in smooth muscle and non-muscle contraction	Caldesmon H	
	Myoepithelial cells in benign and malignant breast lesions	Calponin	
	Neuroanatomical marker	Calretinin	
	Histiocytes/Langerhan cell	CD1a	
	Pan t-lymphocytes	CD2	
	Pan T-cell marker	CD3	
	T-cell subset	CD4	



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HUMAN BODY TISSUE AND FLUIDS (cont'd)	<u>Histopathological examination of tissues for the purpose of diagnosis (cont'd)</u>	<u>Documented in house methods incorporating manufacturers' instructions where relevant:</u>	RH
FFPE slides (cont'd) (Formalin fixed paraffin embedded)	Immunohistochemistry to detect the following: (cont'd)	Automated Immunohistochemical staining using Leica Bond III and the following antibodies	
Unfixed diagnostic cytology slides (cont'd)		<ul style="list-style-type: none"> <li>• LP 404 005 (TP-94)</li> <li>• LP 404 006 (TP-95)</li> <li>• PD 400 002 (TP 287)</li> </ul>	
	Pan T-cell marker	CD5	
	T-cell marker	CD7	
	T-cell subset	CD8	
	Renal carcinoma/Lymphoma	CD10* RTU	
	Renal carcinoma/Lymphoma	cCD10 (CYTO)	
	Renal carcinoma/Lymphoma	CD11c	
	Hairy cell leukaemia	CD13	
	Hepatocellular carcinoma Breast tumours Renal cell carcinoma Prostate tumour Most Acute myeloid leukaemias A proportion of acute lymphoid leukaemias	cCD15 (CYTO)	
	Reed-Sterberg and other cell types	CD15* RTU	
	NK cells, activated macrophages and a subset of T cells	CD16	
	Antigen of B lymphocytes	CD20 (B-cell L26)	



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FFPE slides (cont'd) (Formalin fixed paraffin embedded)	Immunohistochemistry to detect the following: (cont'd)	Automated Immunohistochemical staining using Leica Bond III and the following antibodies	
Unfixed diagnostic cytology slides (cont'd)		<ul style="list-style-type: none"> <li>• LP 404 005 (TP-94)</li> <li>• LP 404 006 (TP-95)</li> <li>• PD 400 002 (TP 287)</li> </ul>	
	Follicular Dendritic cells	CD21	
	Aid in the classification of Lymphoma	CD23	
	Reed-Sterberg cells	cCD30 Ber H2 (CYTO)	
	Reed-Sterberg cells	CD30* RTU	
	Endothelial marker	CD31	
	Stem cell/endothelium Sarcoma	CD34* RTU	
	Dendritic cell marker	CD35	
	Plasma cells	CD38	
	Pan T-cell marker	CD43(MT1)	
	Pan Leukocyte marker (T&B)	CD45 (LCA)	
	Neuroendocrine	cCD56 (CYTO)	
	Neuroendocrine	CD56 * RTU (ROUTINE)	
	NK cells, neuroendocrine cells	CD57* RTU	
	Megakaryocytic leukaemias	CD61	
	Macrophages and mononuclear cells	CD68 (KPI)	



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FFPE slides (cont'd) (Formalin fixed paraffin embedded)	Immunohistochemistry to detect the following: (cont'd)	Automated Immunohistochemical staining using Leica Bond III and the following antibodies	
Unfixed diagnostic cytology slides (cont'd)		<ul style="list-style-type: none"> <li>• LP 404 005 (TP-94)</li> <li>• LP 404 006 (TP-95)</li> <li>• PD 400 002 (TP 287)</li> </ul>	
	Useful for identification of B-cell lymphomas	CD79 $\alpha$	
	Ewings sarcoma	CD99/MIC 2	
	GIST,RCC,Germ cell tumor	CD117	
	Human CD123	CD123	
	Lymphoma/Plasmacytoma	CD138	
	Antigen in intestinal epithelium	CDX2* RTU	
	GI carcinoma	CEAm	
	Hepatocellular carcinoma	CEAp	
	Axonal swelling and damage (neuro)	Clusterin	
	Neuroendocrine	Chromogranin A* RTU	
	Cytomegalovirus	CMV	
	Mantle cell lymphoma	Cyclin D1	
	Haematopoietic tumours	CYMC	
	Pan cytokeratin	Cytokeratin AE1/AE3	
	Pan cytokeratin	Cytokeratin CAM 5.2	



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HUMAN BODY TISSUE AND FLUIDS (cont'd)	<u>Histopathological examination of tissues for the purpose of diagnosis (cont'd)</u>	<u>Documented in house methods incorporating manufacturers' instructions where relevant:</u>	RH
FFPE slides (cont'd) (Formalin fixed paraffin embedded)	Immunohistochemistry to detect the following: (cont'd)	Automated Immunohistochemical staining using Leica Bond III and the following antibodies	
Unfixed diagnostic cytology slides (cont'd)		<ul style="list-style-type: none"> <li>• LP 404 005 (TP-94)</li> <li>• LP 404 006 (TP-95)</li> <li>• PD 400 002 (TP 287)</li> </ul>	
	CK in epithelium	CK5/6	
	Cytokeratin in epithelium	CK7	
	Ck for Carcinoma	CK14	
	Ck for Carcinoma	CK19	
	CK in gastro-intestinal cells	CK20	
	High MW cytokeratin, complex epithelia	CK 34BE12	
	Certain types of T-cell lymphomas. Follicular Dendritic tumours.	CXCL13	
	Lymphatic endothelium	D2-40	
	Smooth and striated muscle cells	Desmin	
	GIST	DOG-1	
Frozen sections of muscle tissue	Muscular dystrophy panel	Dystrophin 1	
Frozen sections of muscle tissue	Muscular dystrophy panel	Dystrophin 2	
Frozen sections of muscle tissue	Muscular dystrophy panel	Dystrophin 3	



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FFPE slides (cont'd) (Formalin fixed paraffin embedded)	Immunohistochemistry to detect the following: (cont'd)	Automated Immunohistochemical staining using Leica Bond III and the following antibodies	
Unfixed diagnostic cytology slides (cont'd)		<ul style="list-style-type: none"> <li>• LP 404 005 (TP-94)</li> <li>• LP 404 006 (TP-95)</li> <li>• PD 400 002 (TP 287)</li> </ul>	
Frozen sections of muscle tissue	Muscular dystrophy panel	Dysferlin	
	Epstein-Barr virus	EBV	
	Distinguish Lobular from Ductal carcinoma	E-Cadherin	
	Protein in epithelial cells	EMA	
	Vascular neoplasms	ERG	
	Endothelial cells	Factor VIII	
	Lymphoma (Hodgkins)	Fascin	
	Ewings sarcoma	FLI-1	
	Pituitary hormone	FSH	
	Stomach hormone	Gastrin	
	Breast and urothelial carcinoma	Gata-3	
	Glycoprotein in epithelium	GCDFP	
	Astrocytes and astrocytic cells in brain	GFAP	
	Pancreatic hormone	Glucagon	



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Unfixed diagnostic cytology slides (cont'd)		<ul style="list-style-type: none"> <li>• LP 404 005 (TP-94)</li> <li>• LP 404 006 (TP-95)</li> <li>• PD 400 002 (TP 287)</li> </ul>	
	Marker of malignancy	Glut 1	
	Erythroid leukaemias	Glycophorin A	
	Hepatocellular carcinoma	Glypican 3	
	Cytotoxic T lymphocytes and NK Cells	Granzyme B	
	Pituitary hormone	GH	
	Mesothelial marker	HBME-1	
	Hepatitis B infected tissue	Hepatitis B(surface)	
	Hepatitis B infected tissue	Hepatitis B(Core)	
	Benign and malignant liver derived tissues	Hepatocyte	
	Transmembrane glycoprotein	HER-2 ORACLE	
	Transmembrane glycoprotein	c-erB-2 (her-2) (CYTO)	
	HSV infected tissue	Herpes Simplex 1	
	HSV infected tissue	Herpes Simplex 2	
	For identification of Kaposi's sarcoma	HHV8	
	Muscle myopathies	HLA-ABC	





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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>Histopathological examination of tissues for the purpose of diagnosis (cont'd)</u>	<u>Documented in house methods incorporating manufacturers' instructions where relevant:</u>	RH
FFPE slides (cont'd) (Formalin fixed paraffin embedded)	Immunohistochemistry to detect the following: (cont'd)	Automated Immunohistochemical staining using Leica Bond III and the following antibodies	
Unfixed diagnostic cytology slides (cont'd)		<ul style="list-style-type: none"> <li>• LP 404 005 (TP-94)</li> <li>• LP 404 006 (TP-95)</li> <li>• PD 400 002 (TP 287)</li> </ul>	
	Muscle myopathies	HLA-DR	
	Melanocytes (Melanoma)	HMB45	
	Benign and malignant tumour formation	HMG2	
	Ovarian clear cell carcinoma marker	HNF-1 $\beta$	
	Glioma marker	IDH1	
	Immunoglobulin A	IgA	
	Immunoglobulin D	IgD	
	Immunoglobulin G	IgG	
	Immunoglobulin G4	IgG4	
	Immunoglobulin M	IgM	
	Carcinoma vs Germ cell tumor	Inhibin A	
	Tumour marker	IMP3	
	Pancreatic hormone	Insulin	
	Malignant Rhabdoid tumours	INI-1	
	Kappa light chains	Kappa	



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HUMAN BODY TISSUE AND FLUIDS (cont'd)	<u>Histopathological examination of tissues for the purpose of diagnosis (cont'd)</u>	<u>Documented in house methods incorporating manufacturers' instructions where relevant:</u>	RH
FFPE slides (cont'd) (Formalin fixed paraffin embedded)	Immunohistochemistry to detect the following: (cont'd)	Automated Immunohistochemical staining using Leica Bond III and the following antibodies	
Unfixed diagnostic cytology slides (cont'd)		<ul style="list-style-type: none"> <li>• LP 404 005 (TP-94)</li> <li>• LP 404 006 (TP-95)</li> <li>• PD 400 002 (TP 287)</li> </ul>	
	Lambda light chains-used to identify tumor monoclonality	Lambda	
	Langerhans cell histiocytosis	Langerin	
	Lymphoid	LEF1	
	Pituitary hormone	LH	
	Mast cells	Mast Cell Tryptase	
	Melanocytes (Melanoma)	Melan-A	
Frozen sections of muscle tissue	Muscular dystrophy panel	Merosin	
	Cell proliferation marker	MIB-1 (Ki-67)	
	Mismatch repair protein	MLH1	
	Mismatch repair protein	MSH2	
	Mismatch repair protein	MSH6	
	Secretory epithelial/ Mesenchymal tumours	MUC-1	
	Human muc2glycoprotein/ Adenocarcinomas	MUC-2	



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HUMAN BODY TISSUE AND FLUIDS (cont'd)	<u>Histopathological examination of tissues for the purpose of diagnosis (cont'd)</u>	<u>Documented in house methods incorporating manufacturers' instructions where relevant:</u>	RH
FFPE slides (cont'd) (Formalin fixed paraffin embedded)	Immunohistochemistry to detect the following: (cont'd)	Automated Immunohistochemical staining using Leica Bond III and the following antibodies	
Unfixed diagnostic cytology slides (cont'd)		<ul style="list-style-type: none"> <li>• LP 404 005 (TP-94)</li> <li>• LP 404 006 (TP-95)</li> <li>• PD 400 002 (TP 287)</li> </ul>	
	Soft tissue neoplasms and carcinomas	MUC-4	
	Diffuse and infiltrative carcinomas	MUC-5AC* RTU	
	Human muc6glycoprotein	MUC-6	
	B cell marker used to aid classification of lymphomas	MUM1	
	Myeloid cells, histiocytes, granulocytes, macrophages and monocytes	Muramidase(Lysozyme)	
	Myeloid cell populations	Myeloperoxidase	
	Rhabdomyosarcoma	Myo D1	
	Rhabdomyosarcoma	Myogenin	
	Tumours of muscle origin	Myoglobin	
	Myosin heavy chain during muscle fibre development	Myosin heavy chain neonatal	
	Lung adenocarcinoma	Napsin A	
	Neuronal differentiation of neoplasms	Neurofilament Protein	



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HUMAN BODY TISSUE AND FLUIDS (cont'd)	<u>Histopathological examination of tissues for the purpose of diagnosis (cont'd)</u>	<u>Documented in house methods incorporating manufacturers' instructions where relevant:</u>	RH
FFPE slides (cont'd) (Formalin fixed paraffin embedded)	Immunohistochemistry to detect the following: (cont'd)	Automated Immunohistochemical staining using Leica Bond III and the following antibodies	
Unfixed diagnostic cytology slides (cont'd)		<ul style="list-style-type: none"> <li>• LP 404 005 (TP-94)</li> <li>• LP 404 006 (TP-95)</li> <li>• PD 400 002 (TP 287)</li> </ul>	
	Breast hormone	Oestrogen Receptor (CYTOLOGY)	
	Breast hormone	Oestrogen receptor (EP1) * RTU	
	B-Cell marker	OCT2	
	Germ cell tumours	OCT3/4	
	Ovarian cancer/HPV	P16	
		P40	
	Prostate adenocarcinoma	P504S	
	Cell proliferation marker	P53(DO7)	
	Hydatidiform mole	p57 KIP2	
	Tumour suppressor gene	p63* RTU	
	Pancreatic lipase marker	Pancreatic lipase	
	Pancreatic hormone	Pancreatic Polypeptide	
	Differential diagnosis of parathyroid tumours	Parathyroid Hormone	
	Parvovirus infected tissue	Parvovirus	
	Lymphoma marker	PD1	



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HUMAN BODY TISSUE AND FLUIDS (cont'd)	<u>Histopathological examination of tissues for the purpose of diagnosis (cont'd)</u>	<u>Documented in house methods incorporating manufacturers' instructions where relevant:</u>	RH
FFPE slides (cont'd) (Formalin fixed paraffin embedded)	Immunohistochemistry to detect the following: (cont'd)	Automated Immunohistochemical staining using Leica Bond III and the following antibodies	
Unfixed diagnostic cytology slides (cont'd)		<ul style="list-style-type: none"> <li>• LP 404 005 (TP-94)</li> <li>• LP 404 006 (TP-95)</li> <li>• PD 400 002 (TP 287)</li> </ul>	
	Lymphoma	PAX-5	
	Ovarian, thyroid and renal cell carcinoma marker	PAX-8	
	Enzyme produced by trophoblasts	Placental alk phos(PLAP)	
	Mismatch repair protein	PMS2	
	Breast hormone	PgR636	
	Pituitary hormone	Prolactin	
	Used to aid classification metastatic PR carcinoma	PSA poly	
	Marker for prostatic carcinoma	PSA mono	
	Marker for prostatic carcinoma	P. Acid Phosphatase	
	Renal carcinoma marker	RCC	
	Germ cell tumours	Sall-4	
	Colorectal carcinomas	SATB2	
	Used to aid classification metastatic PR carcinoma	S-100* RTU	



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HUMAN BODY TISSUE AND FLUIDS (cont'd)	<u>Histopathological examination of tissues for the purpose of diagnosis (cont'd)</u>	<u>Documented in house methods incorporating manufacturers' instructions where relevant:</u>	RH
FFPE slides (cont'd) (Formalin fixed paraffin embedded)	Immunohistochemistry to detect the following: (cont'd)	Automated Immunohistochemical staining using Leica Bond III and the following antibodies	
Unfixed diagnostic cytology slides (cont'd)		<ul style="list-style-type: none"> <li>• LP 404 005 (TP-94)</li> <li>• LP 404 006 (TP-95)</li> <li>• PD 400 002 (TP 287)</li> </ul>	
	Adrenal and gonadal development marker	SF-1	
	Neurofilament protein (neuro)	SMI 32	
	Pancreatic hormone	Somatostatin	
	Mantle cell lymphoma	Sox-11	
Frozen sections of muscle tissue	Mantle cell lymphoma	Spectrin	
	Demonstration of synaptophysin producing cells	Synaptophysin	
	Dementia profile (neuro)	Alpha-synuclein	
	Immature T cells	TdT	
	Precursor of thyroid hormones	Thyroglobulin	
	Lymphoid marker	TIA-1	
	Soft tissue neoplasms	TLE	
	Nuclear protein in lung and thyroid	TTF-1 (CYTO)	
	Nuclear protein in lung and thyroid	TTF-1 * RTU	
	Trypsin levels in pancreas	TRYPSIN	



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HUMAN BODY TISSUE AND FLUIDS (cont'd)	<u>Histopathological examination of tissues for the purpose of diagnosis (cont'd)</u>	<u>Documented in house methods incorporating manufacturers' instructions where relevant:</u>	RH
FFPE slides (cont'd) (Formalin fixed paraffin embedded)	Immunohistochemistry to detect the following: (cont'd)	Automated Immunohistochemical staining using Leica Bond III and the following antibodies	
Unfixed diagnostic cytology slides (cont'd)		<ul style="list-style-type: none"> <li>• LP 404 005 (TP-94)</li> <li>• LP 404 006 (TP-95)</li> <li>• PD 400 002 (TP 287)</li> </ul>	
	Pituitary hormone	TSH	
	Dementia profile (neuro)	TAU	
	Toxoplasmosis gondii infected tissue	Toxoplasmosis gondii	
	Choroid plexus tumours	Transthyretin (TTR)	
	<i>Treponema pallidum</i> infected tissue	<i>Treponema pallidum</i> Ab	
	Dementia profile (neuro)	Ubiquitin	
Frozen sections of muscle tissue	Muscular dystrophy panel	Utrophin	
	Labels brush border in gastrointestinal mucosal epithelium	Villin	
	Filaments in mesenchymal cells	Vimentin	
	Tumour marker Wilms	WT1	



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HUMAN BODY TISSUE AND FLUIDS (cont'd)	<u>Histopathological examination of tissues for the purpose of diagnosis (cont'd)</u>	<u>Documented in house methods incorporating manufacturers' instructions where relevant:</u>	RH
FFPE slides (cont'd) (Formalin fixed paraffin embedded)	Immunohistochemistry to detect the following: (cont'd)	Automated Immunohistochemical staining using Ventana Benchmark Ultra <ul style="list-style-type: none"> <li>• TP-173</li> </ul>	
Unfixed diagnostic cytology slides (cont'd)	Pan Cytokeratin	AE1/AE3	
	Epithelial Cells	BER-EP4	
	Ovarian Tumour	CA125	
	Pan Cytokeratin	CAM 5.2	
	Macrophages and mononuclear cells	CD68	
	GIST, RCC, Germ cell Tumour	CD117	
	Antigen in intestinal epithelium	CDX2	
	GI carcinoma	CEA (m)	
	CK for carcinoma	CK 19	
	CK in gastro-intestinal cells	CK 20	
	CK in epithelium	CK 5/6	
	Cytokeratin in epithelium	CK 7	
	Cytomegalovirus	CMV	
	Lymphatic endothelium	D2-40	
	GIST	DOG-1	
	Protein in epithelial cells	EMA	
	Endothelial cells	FACTOR VIII	
	Breast and urothelial carcinoma	GATA-3	





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<p>HUMAN BODY TISSUE AND FLUIDS (cont'd)</p> <p>FFPE slides (cont'd) (Formalin fixed paraffin embedded)</p>	<p><u>Histopathological examination of tissues for the purpose of diagnosis (cont'd)</u></p> <p>Immunohistochemistry to detect the following: (cont'd)</p> <p>Transmembrane glycoprotein</p> <p>For identification of Kaposi's sarcoma</p> <p>Carcinoma vs Germ Cell Tumour</p> <p>Cell proliferation marker</p> <p>Colorectal Cancer / Lynch Syndrome</p> <p>Lung adenocarcinoma</p> <p>Ovarian cancer / HPV</p> <p>Tumour suppressor marker</p> <p>Colorectal carcinoma</p> <p>Demonstration of synaptophysin producing cells</p> <p>Nuclear protein in lung and thyroid</p> <p>Filaments in mesenchymal cells</p> <p>Tumour marker Wilms</p>	<p><u>Documented in house methods incorporating manufacturers' instructions where relevant:</u></p> <p>Automated Immunohistochemical staining using Ventana Benchmark Ultra</p> <ul style="list-style-type: none"> <li>• TP-173</li> </ul> <p>HER-2</p> <p>HHV-8</p> <p>INHIBIN A</p> <p>KI-67</p> <p>MMR</p> <p>NAPSIN A</p> <p>P16</p> <p>P63</p> <p>SATB2</p> <p>SYNAPTOPHYSIN</p> <p>TTF-1</p> <p>VIMENTIN</p> <p>WT-1</p>	<p>RH</p>



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<p>HUMAN BODY TISSUE AND FLUIDS (cont'd)</p> <p>FFPE slides (Formalin fixed paraffin embedded)</p> <p>Frozen sections of Renal and Skin Biopsies</p> <p>Frozen tissue sections</p>	<p><u>Histopathological examination of tissues for the purpose of diagnosis (cont'd)</u></p> <p>Immunohistochemistry to detect the following:</p> <p>Neurofilament and myelin</p> <p>Endothelial cells and myelin</p> <p>Immunoglobulins and complement (IgA, Albumin, C1Q, c3, C4, Fibrinogen, IgG, IgM)</p> <p>Immunofluorescence to detect the following:</p> <p>Type IV Collagen for diagnosis of Alports syndrome</p> <p>Detection of AA amyloid</p>	<p><u>Documented in house methods incorporating manufacturers' instructions where relevant:</u></p> <p>Manual Immunohistochemical staining the following antibodies Stained on Bond III followed by Luxol Fast Blue Special stain</p> <p>Anti-Neurofilament Protein LFB Key SOP</p> <ul style="list-style-type: none"> <li>LP 423 206 (TP-132)</li> </ul> <p>Anti-CD34 LFB Key SOP</p> <ul style="list-style-type: none"> <li>LP 423 227 (TP-133)</li> </ul> <p>Direct immunofluorescence staining using Ventana Discovery Key SOP</p> <ul style="list-style-type: none"> <li>TP-148, TP-1643</li> </ul> <p>Manual indirect immunofluorescence staining for type IV collagen using Wielisa Kit from Eurodiagnostica using antibodies to alpha 1,3,5 chain of type IV collagen; rat and Mouse FITC Key SOP</p> <ul style="list-style-type: none"> <li>TP-145 (LP425 126)</li> </ul> <p>Manual indirect immunofluorescence using monoclonal AA antibody Key SOP</p> <ul style="list-style-type: none"> <li>TP-146 (LP425 127)</li> </ul>	<p>RH</p>



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<p>HUMAN BODY TISSUE AND FLUIDS (cont'd)</p> <p>Frozen tissue sections (cont'd)</p> <p>Frozen sections of transplant renal biopsies</p> <p>Frozen sections of skin</p>	<p><u>Histopathological examination of tissues for the purpose of diagnosis (cont'd)</u></p> <p>Immunofluorescence to detect the following: (cont'd)</p> <p>Kappa light chains</p> <p>Lambda light chains</p> <p>Detection of C4d</p> <p>Detection of BK virus</p> <p>Detection of Herpes gestationis factor</p>	<p><u>Documented in house methods incorporating manufacturers' instructions where relevant:</u></p> <p>Manual direct Immunofluorescence to detect Kappa antibodies</p> <p>Key SOP</p> <ul style="list-style-type: none"> <li>• TP-152</li> </ul> <p>Manual direct Immunofluorescence to detect Lambda antibodies</p> <p>Key SOP</p> <ul style="list-style-type: none"> <li>• TP-152</li> </ul> <p>Manual Indirect Immunofluorescence using monoclonal C4d</p> <p>Key SOP</p> <ul style="list-style-type: none"> <li>• TP-147 (LP425 128)</li> </ul> <p>Manual Indirect Immunofluorescence using monoclonal BKV</p> <p>Key SOP</p> <ul style="list-style-type: none"> <li>• TP-147 (LP425 128)</li> </ul> <p>Manual indirect immunofluorescence using C3 and IgG antibodies</p> <p>Key SOP</p> <ul style="list-style-type: none"> <li>• TP-148 (LP425 131)</li> </ul>	<p style="text-align: center;">RH</p>



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HUMAN BODY TISSUE AND FLUIDS (cont'd)	<u>Neuropathological examination of tissues for the purpose of diagnosis</u>	Documented in house methods incorporating manufacturers' instructions where relevant:	
Fresh muscle biopsy samples	Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis	Leica CM1950 cryostat <ul style="list-style-type: none"><li>• TP-53</li><li>• TP-124</li><li>• TP-128</li><li>• TP-136</li></ul>	RH
Frozen sections of muscle tissue	Special stains for the detection of:	Documented in-house procedures for manual special stains <ul style="list-style-type: none"><li>• Muscle Staining Manual LP 423 138 (TP-131)</li></ul> Manual H&E <ul style="list-style-type: none"><li>• TP-67</li></ul>	RH
	Lipid	Oil Red O	
	Cytochromoxidase enzyme	Cytochrome Oxidase	
	Fibre Typing	Modified Adenosine Triphosphatase	
	Abnormal mitochondria	Modified Gomori's Trichrome	
	NADH enzyme	NADH – Tetrazolium Reductase	
	Acid Phosphatase	Naphthol AS-Bi Phosphate – Acid Phosphatase	
	Atrophic Fibres	$\alpha$ -Naphthyl Acetate – Non-Specific Esterase	
	Phosphorylase	Phosphorylase	
	Succinase Dehydrogenase enzyme	Succinate Dehydrogenase	



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<p>HUMAN BODY TISSUE AND FLUIDS (cont'd)</p> <p>Tissue samples fixed in glutaraldehyde/formalin</p>	<p><u>Electron Microscopy examination of tissues for the purpose of diagnosis</u></p> <p>Assessment of ultrastructural features</p>	<p>Documented in house methods incorporating manufacturers' instructions where relevant:</p> <p>Processing and production of EM sections Ultramicrotome Reichert –Jung Ultra Cut E x 2</p> <ul style="list-style-type: none"> <li>• LP 426 010 (TP-155)</li> </ul> <p>Electron Microscope Philips CM10 Transmission</p> <ul style="list-style-type: none"> <li>• TP-610</li> </ul> <p>Digital camera AMT XR-80M</p> <ul style="list-style-type: none"> <li>• LP 426 010 (TP-155)</li> </ul>	<p>RHMic</p>
<p>Blood</p>	<p><u>Immunopathology examination of tissues for the purpose of diagnosis</u></p> <p>Diagnosis of Erythropoetic protoporphyria</p>	<p>Documented in house methods incorporating manufacturers' instructions where relevant:</p> <p>Fluorescence microscope DM2000 and camera, Leica DC 300F Key SOPs</p> <ul style="list-style-type: none"> <li>• LP 425 116 (TP-142)</li> <li>• LP 425 113 (TP-140)</li> </ul>	<p>RH</p>



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Blood	Miscellaneous examination of tissues for the purpose of diagnosis		
Blood	Herpes gestationis screening for presence of HGTV factor in pregnancy	Serum dilutions prepared from Clotted Blood specimens and cryostat sections of normal skin Leica CM1950 Cryostat, centrifuge Eppendorf	RH
Blood	Demonstration of circulating Antibodies - IgA, IgG	Manual Indirect immunofluorescence	RH
		<ul style="list-style-type: none"> <li>• LP 425 131 (TP-148)</li> <li>• LP 425 136 (TP-153)</li> </ul>	
END			