

Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 <p>Accredited to ISO 15189:2012</p>	Cardiff and Vale University Health Board Issue No: 005 Issue date: 13 August 2020	
	Cellular Pathology Department Cardiff and Vale University Health Board University Hospital of Wales Heath Park Cardiff CF14 4XW	Contact: Mr Scott Gable Tel: +44(0)2920744277 E-Mail: Scott.gable@wales.nhs.uk Website: http://www.cardiffandvaleuhb.wales.nhs.uk/home

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				
<table border="0" style="width: 100%;"> <tr> <td style="width: 30%;">Address</td> <td>Local contact</td> </tr> <tr> <td>Cellular Pathology Department Cardiff and Vale University Health Board University Hospital of Wales Heath Park Cardiff CF14 4XW</td> <td>Contact: Mr Scott Gable Tel: +44(0)2920744277 Fax: +44 (0) TBC E-Mail: Scott.gable@wales.nhs.uk Website: www.cardiffandvaleuhb.wales.nhs.uk/home</td> </tr> </table>	Address	Local contact	Cellular Pathology Department Cardiff and Vale University Health Board University Hospital of Wales Heath Park Cardiff CF14 4XW	Contact: Mr Scott Gable Tel: +44(0)2920744277 Fax: +44 (0) TBC E-Mail: Scott.gable@wales.nhs.uk Website: www.cardiffandvaleuhb.wales.nhs.uk/home	Routine Histopathology Special Stains Immunohistochemistry Diagnostic Cytology (Non-Gynae) Electron microscopy Interpretation and reporting Intra-operative Frozen sections Neuropathology	A
Address	Local contact					
Cellular Pathology Department Cardiff and Vale University Health Board University Hospital of Wales Heath Park Cardiff CF14 4XW	Contact: Mr Scott Gable Tel: +44(0)2920744277 Fax: +44 (0) TBC E-Mail: Scott.gable@wales.nhs.uk Website: www.cardiffandvaleuhb.wales.nhs.uk/home					

Site activities performed away from the locations listed above:

Location details	Activity	Location code
Mortuary / Body Store University Hospital of Wales Heath Park Cardiff CF14 4XW	Mortuary Services	B
Mortuary / Body Store University Hospital Llandough Penlan Road Penarth Cardiff	Body Store	C



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Location details	Activity	Location code
Mohs Micrographic Surgery clinic Glamorgan House Cardiff and Vale University Health Board University Hospital of Wales Heath Park Cardiff CF14 4XW	Mohs rapid frozen section service	D
Ultrasound Clinic University Hospital of Wales Heath Park Cardiff CF14 4XW	Renal biopsy adequacy check	E



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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
<p>HUMAN BODY TISSUE</p> <p>Formalin-fixed tissue samples</p>	<p><u>Histopathological examination activities for the purposes of clinical diagnosis</u></p> <p>Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis</p>	<p>In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:</p> <p>Supported by:</p> <p>Specimen Dissection using Macropath Dissection camera system</p> <p>SOPs LP-CPY-DISSECTGUIDE LI-CPY-BMSDiss, LI-CPY-DISSECTION</p> <p>Tissue processing Excelsior ASTissue processors (x5)</p> <p>Leica TP1020 carousel processor (neuropathology samples only)</p> <p>LP-CPY-ExcelsiorAS</p> <p>Embedding using Sakura Tissue-tec V embedding units (x3) LP-CPY-Embed LP-CPY-EmbedGuide,</p>	<p>A</p> <p>A</p> <p>A</p>



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HUMAN BODY TISSUE (cont'd)	<u>Histopathological examination activities for the purposes of clinical diagnosis (cont'd)</u>	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:	
Formalin Fixed paraffin wax blocks of processed tissue,		Microtomy using Thermofisher and Leica microtomes	A
Fresh frozen tissue	Intraoperative examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis	Cryotomy - Intra-operative Frozen sections and manual H&E stain Thermofisher FSE cryostat SOP LI-CPT-H&EHand SOP LP-CPY-Surgfrozen sec	A
Fresh frozen skin tissue	Intraoperative examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis	ThermoFisher NX70 Cryostar ThermoFisher Stainmate: H&E and Toluidine Blue stains LP-CPY-FrozSecMOHs LI-CPY-MOHsFreezTis LI-CPY-MOHsInking LI-CPY-MOHsSetUp LI-CPY-Stainmate	D



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<p>HUMAN BODY TISSUE (cont'd)</p> <p>FFPE slides (Formalin fixed paraffin embedded)</p> <p>FFPE slides (Formalin fixed paraffin embedded)</p>	<p><u>Histopathological examination activities for the purposes of clinical diagnosis</u> (cont'd)</p> <p>DEMONSTRATION OF:</p> <p>Basophilic and eosinophilic structures</p> <p>Basement membrane</p> <p>Basement membrane, Fungi</p> <p>Diastase resistant Polysaccharides</p> <p>Polysaccharides including glycogen</p> <p>Connective tissue (reticulin fibres)</p>	<p>In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:</p> <p>Macroscopic and Microscopic examination</p> <p>Routine morphological Haematoxylin and Eosin (H & E) staining using Thermofisher Gemini AS Staining machine, Leica Autostainer, Thermo Varistain slide stainer, Artisan Pro Link Staining System (SOPs LI-CPY-Artisan, LP-CPY-LeicaStain)</p> <p>Hand staining H&E (SOP LI-CPY-H&Ehand)</p> <p>Special Tinctorial Histochemical Staining (using DAKO Artisan & Manual Techniques)</p> <p>Methanamine Silver (LI-CPY-MethAg, LP-CPY-Artisan)</p> <p>Grocott (LI-CPY-Grocott, LP-CPY-Artisan)</p> <p>DPAS (LI-CPY-DPAS, LP-CPY-Artisan)</p> <p>Periodic acid Schiff (PAS) (LI-CPY-PAS, LP-CPY-Artisan)</p> <p>Retic (LI-CPY-Retic, LP-CPY-Artisan)</p>	<p>A</p>



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HUMAN BODY TISSUE (cont'd) FFPE slides (Formalin fixed paraffin embedded)	<u>Histopathological examination activities for the purposes of clinical diagnosis</u> (cont'd)	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified: Special Tinctorial Histochemical Staining using Manual Techniques	A
	Acid Mucopolysaccharides	Alcian Blue pH 2.5 (LI-CPY-ABlue)	
	Acid and neutral mucins	Alcian blue-PAS (LI-CPY-ABPAS)	
	Calcium complexes	Alizarin Red S (LI-CPY-AlizRedS)	
	Amyloid	Congo red (Slidders) (LI-CPY-NrCRed)	
	<i>Helicobacter pylori</i>	Giemsa (LI-CPY-Giemsahp)	
	Gram positive and negative bacteria	Gram (LI-CPY-Gram)	
	Gram positive and negative bacteria	Gram Twort (LI-CPY-GramNeg)	
	Connective tissue (collagen/fibrin)	Martius scarlet blue (MSB) (LI-CPY-MSB)	
	Melanin	Masson Hamperl (LI-CPY-Hamp)	
	Connective tissue (collagen/muscle)	Masson Trichrome (LI-CPY-MTrich)	
	Elastic fibres & connective tissue	Miller's EVG (LI-CPY-EVG)	
	Elastic fibres & connective tissue (renal biopsies)	Miller's EVG (LI-CPY-RnBxEVG)	



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HUMAN BODY TISSUE (cont'd)	<u>Histopathological examination activities for the purposes of clinical diagnosis (cont'd)</u>	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:	A
FFPE slides (Formalin fixed paraffin embedded) (cont'd)	DEMONSTRATION OF: (cont'd)	Special Tinctorial Histochemical Staining using Manual Techniques (cont'd)	
	Hepatitis B surface antigen and copper associated protein	Orcein (LI-CPY-Orcein)	
	Haemosiderin	Perl's Prussian blue (LI-CPY-Perls)	
	Connective tissues (Muscle)	Van Gieson (LI-CPY-VG)	
	Spirochaetes	Warthin Starry (LI-CPY-WartStar)	
	<i>Mycobacterium spp</i> including <i>M. tuberculosis</i>	Ziehl Neelsen (ZN) (LI-CPY-ZN)	
	<i>Mycobacterium spp</i> including <i>M. leprae</i>	Modified ZN (LI-CPY-ZNLepros)	
	Amyloid	Sulphated Alcian Blue LI-CPY-SAB	
	Cellular components	Haematoxylin & Eosin LI-CPY-H&EHAND	
Frozen tissue section	Lipids	Oil red O (LI-CPY-ORO)	



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HUMAN BODY TISSUE (cont'd)	<u>Histopathological examination activities for the purposes of clinical diagnosis (cont'd)</u>	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:	A
FFPE slides (Formalin fixed paraffin embedded) (cont'd)	Immunohistochemistry to detect the following:	Automated Immunohistochemistry (cont'd) incorporating the following antibodies :	
	Immunohistochemistry to detect the following:	Automated Immunohistochemistry using Dako PT link (x3), Dako autostainer (x3), Dako Omnis (x2), Roche Benchmark Ultra	
		LI-CPY-ICDAKO48 LI-CPY-ICCPTLink	
		LP-CPY-OmnisUse LP-CPY-ICUltrUse LI-CPY-UltraHer2	
		Incorporating the following antibodies:	
	Gross Cystic Disease Protein	GCDFP	
	Alpha 1- Feto Protein	AFP	
	Alpha Inhibin Expression	Inhibin	
	T Cells/ B Cells Mantle Zone	Bcl-2	
	Follicular Center B Cells	Bcl-6	
	Follicular Dendritic Cells/ Mature B Cells	CD21	
	Follicular Dendritic Cells/Sub Population Of Mantle Zone B Cells	CD23	
	Kappa Light Chains	Kappa	
	Cell Proliferation Marker	Ki-67	



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HUMAN BODY TISSUE (cont'd)	<u>Histopathological examination activities for the purposes of clinical diagnosis (cont'd)</u>	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:	A
FFPE slides (Formalin fixed paraffin embedded) (cont'd)	Immunohistochemistry to detect the following: (cont'd)	Automated Immunohistochemistry (cont'd) incorporating the following antibodies :	
	Lambda Light Chains	Lambda	
	High Molecular Weight Cytokeratin	34 βE12	
	P 53 Expression	p53	
	Terminal Deoxynucleotidyl Transferase	TdT	
	Alk1 Protein (Anaplastic Large Cell Lymphoma)	ALK-1	
	Intermediate Filament	Desmin	
	Adreno Corticotrophic Hormone	ACTH	
	Calcitonin Expressing Cells	Calcitonin	
	Broad range cytokeratins	AE1/AE3	
	Epithelial cells	BerEP4	
	β Catenin expression	β Catenin	
	BK Virus	BKV	
	B-Cell sub groups	BOB1	
	Leutinising Hormone	LH	
	Neuroendocrine expression	Synaptophysin	
	Low Molecular Weight Cytokeratin	CAM5.2	
	Carcino Embryonic Antigen	CEA	



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HUMAN BODY TISSUE (cont'd)	<u>Histopathological examination activities for the purposes of clinical diagnosis (cont'd)</u>	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:	A
FFPE slides (Formalin fixed paraffin embedded) (cont'd)	Immunohistochemistry to detect the following: (cont'd)	Automated Immunohistochemistry (cont'd) incorporating the following antibodies :	
	Epithelial Membrane Antigen	EMA	
	Pan Muscle Actin	HMFGII	
	Gastrointestinal Stromal Tumours /Mast Cells	C-Kit Receptor (CD117)	
	Mic2 Gene Product	CD99 (mic2)	
	Fibrohistiocytic Tumour Marker	Factor XIIIa	
	Smooth Muscle	Calponin	
	C-Myc protein	c-MYC	
	CD4 Helper T cells	CD4	
	CD7 T cell subsets	CD7	
	CD8 T Cell subsets (Cytotoxic/Suppressor)	CD8	
	CD10 expression	CD10	
	CD15 expression	CD15	
	Reed Sternberg cells / CD30 expression	CD30	
	Endothelial cells	CD31	
	Melanosome/Melanoma	HMB45	
	Endothelial cells	CD34	
	T cell subset / Macrophages	CD43	



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HUMAN BODY TISSUE (cont'd)	<u>Histopathological examination activities for the purposes of clinical diagnosis (cont'd)</u>	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:	A
FFPE slides (Formalin fixed paraffin embedded) (cont'd)	Immunohistochemistry to detect the following: (cont'd)	Automated Immunohistochemistry (cont'd) incorporating the following antibodies :	
	NK cells / Neuroendocrine cells	CD56	
	T cell subset	CD57	
	B cell subset	CD79a	
	Plasma cells	CD138	
	Microphthalmia Transcription Factor	MITF	
	Melanoma /Neuroendocrine	S100	
	C4d expression (transplant rejection)	C4D	
	Neuro Specific Enolase	NSE	
	Neuroendocrine	PGP9.5	
	Cytokeratin 20 expression	CK20	
	Her2 Receptor	Her-2	
	Oestrogen Receptor	ER	
	Progesterone Receptor	PR	
	Placental Alkaline Phosphatase	PLAP	
	Human Chorionic Gonadotrophin	HCG	



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HUMAN BODY TISSUE (cont'd)	<u>Histopathological examination activities for the purposes of clinical diagnosis (cont'd)</u>	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:	A
FFPE slides (Formalin fixed paraffin embedded) (cont'd)	Immunohistochemistry to detect the following: (cont'd)	Automated Immunohistochemistry (cont'd) incorporating the following antibodies :	
	Hepatocyte Expression	HEPAR	
	Calretinin expression	Calretinin	
	Gastrointestinal metaplasia	CDx2	
	Cytokeratin 5/6	CK5/6	
	Cytokeratin 19	CK19	
	Cytomegalovirus	CMV	
	Hairy Cell Leukaemia / DbA44 expressing cells	DbA44	
	Gastrointestinal stromal tumours	DOG 1	
	Lymphatic endothelium	D2 40	
	Cell adhesion molecule (E-Cadherin)	E-cadherin	
	ETS regulated gene product	ERG	
	Granzyme B Granules	Granzyme B	



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HUMAN BODY TISSUE (cont'd)	<u>Histopathological examination activities for the purposes of clinical diagnosis (cont'd)</u>	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:	A
FFPE slides (Formalin fixed paraffin embedded) (cont'd)	Immunohistochemistry to detect the following: (cont'd)	Automated Immunohistochemistry (cont'd) incorporating the following antibodies :	
	LDH1 gene product	LDH1	
	Immunoglobulin A	IgA	
	Immunoglobulin G	IgG	
	Immunoglobulin D	IgD	
	Immunoglobulin M	IgM	
	Lambda light chains	Lambda	
	Lysozyme location	Lysozyme	
	B cell subset with MUM 1 expression	MUM 1	
	Melanomas	Mel-C	
	Melanomas with Melan A expression	Melan-A	
	Mesothelial cells	Mesothelin	
	Mismatch repair protein MLH1	MLH1	
	Mismatch repair protein MSH2	MSH2	
	Mismatch repair protein MSH6	MSH6	
	Mismatch repair protein PMS2	PMS2	
	Napsin A expression	Napsin	



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HUMAN BODY TISSUE (cont'd)	<u>Histopathological examination activities for the purposes of clinical diagnosis (cont'd)</u>	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:	
FFPE slides (Formalin fixed paraffin embedded) (cont'd)	Immunohistochemistry to detect the following: (cont'd)	Automated Immunohistochemistry (cont'd) incorporating the following antibodies :	A
	Germ cell centre/mantle aone B cells/Plasma cells	Oct2	
	Gene product protein p16	P16 Ink 4	
	Prostatic Acid Phospatase	PAPH	
	Alpha Methylacyl Co A Expression	Racemase (AMACR)	
	Smooth Muscle Actin	Smooth Muscle (SMA)	
	Thyroglobulin	Thyroglobulin	
	Cytotoxic granules	Tia1	
	Vimentin expression	Vimentin	
	Von Willebrand Factor expression (endothelial cells)	vWF	
	Wilms tumour protein expression	Wt1	
	Protein tyrosine kinase associated with the zeta chain of the T cell receptor	ZAP 70	
Glass slides prepared as above	Morphological assessment and interpretation/diagnosis	Interpretive/diagnostic microscopy Microscopes (Leica, Olympus, Nikon, Zeiss) LP-CPY-SURGREPGUIDE LI-CPY-ICErPrHerRep	A



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HUMAN BODY TISSUE (cont'd)	<u>Histopathological examination activities for the purposes of clinical diagnosis (cont'd)</u>	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:	A
Skin, muscle and renal biopsies	Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis	Electron Microscopy sample preparation, processing, staining (Tol Blue) and reporting using Leica EMTP - Processor Reichert Ultracut E and Leica ultramicrotome Phillips Microscope LI-EMOTPrep LP-CPY-EMProcEMTP LI-CPY-EMTEMUse LP-HIS-EMCutresin LI-CPY-EMTolBlue	
	<u>Neuropathological examination activities for the purposes of clinical diagnosis</u>	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:	
	DEMONSTRATION OF:	Specialist Post Mortem / Neuropathology Staining Index (Manual Techniques)	
Intraoperative smears (brain tissue)	Basophilic and eosinophilic structures	Haematoxylin and Eosin LI-CPY-H&Ehand	
FFPE slides of brain tissue (Formalin fixed paraffin embedded)	DNA and Nissl substance	Thionin (LI-CPY-Thionin)	
FFPE slides of brain tissue	Nerve fibres	Modified Bielschowsky (LI-CPY-NrBiel)	
FFPE slides of brain tissue	Nissl substance	Cresyl Fast Violet LI-CPY-NrCFV	



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<p>HUMAN BODY TISSUE (cont'd)</p> <p>FFPE slides of brain tissue</p> <p>Glass slides prepared as above</p> <p>Fluids, brushings, imprints, fine-needle aspirations from a diverse range of body sites Semen, Serous Fluid / Cyst Fluid, Bronchial Brushings, urine,</p>	<p><u>Neuropathological examination activities for the purposes of clinical diagnosis</u> (cont'd)</p> <p>DEMONSTRATION OF: (cont'd)</p> <p>Myelin</p> <p>Morphological assessment and interpretation/diagnosis</p> <p><u>Cytopathological (Non-Gynae) examination activities for the purposes of clinical diagnosis</u></p> <p>Examination of cellular material in order to identify or exclude morphological and cytological abnormalities</p>	<p>In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:</p> <p>Specialist Post Mortem / Neuropathology Staining Index (Manual Techniques)</p> <p>Luxol Fast Blue (LI-CPY-NrLFB)</p> <p>Interpretive / diagnostic microscopy Microscopes (Leica, Olympus, Nikon, Zeiss) LI-CPY-Microscope LP-CPY-SURGREGUIDE MP-CPY-CYTREP)</p> <p>In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:</p> <p>Diagnostic cytology (non-gynae) preparation and staining screening using ThinPrep 2000 processor, Cytospin, Gemini stainer Stains used: PAP MGG H&E</p> <p>LI-CPY-T2000 LP-CPY-CYTOSPIN</p> <p>LI-CPY-CytoCellBlocks LP-CPY-CytoPrep LI-CPY-GeminiOp LI-CPY-Handstaindestain</p>	<p>A</p>



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HUMAN BODY TISSUE (cont'd) Synovial fluid Glass slides prepared as above	<u>Cytopathological (Non-Gynae) examination activities for the purposes of clinical diagnosis (cont'd)</u> Detection of crystals of: Monosodium urate Calcium pyrophosphate Basic Calcium Phosphate Cholesterol Morphological assessment and interpretation/diagnosis	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified: Polarising crystallography Microscopes (Leica, Olympus, Nikon) Centrifuge Hettich 38 SOP LI-CPY-JF LI-CPY-Cent LI-CPY-Microscope Interpretive/diagnostic microscopy Microscopes (Leica, Olympus, Nikon, Zeiss) LI-CPY-PathrepNG LP-CPY-CYTREP	A
END			