


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 <p>UKAS MEDICAL 10209</p> <p>Accredited to ISO 15189:2012</p>	<p>Ulster Independent Clinic Ltd</p> <p>Issue No: 004 Issue date: 16 April 2021</p>	
	<p>Cellular Pathology Laboratory Ulster Independent Clinic 245 Stranmillis Road Belfast United Kingdom BT9 5JH</p>	<p>Contact: Kathryn Kennedy Tel: +44 (0) 2890686505 Fax: +44 (0) 2890381704 E-Mail: cpl@uic.org.uk Website: http://ulsterindependentclinic.com/Departments/cellular-pathology/</p>
<p>Testing performed at the above address only</p>		

DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY TISSUE	<u>Histopathological and Non-gynae Cytological examination activities for the purposes of clinical diagnosis</u>	Documented in-house methods and manufacturer's operating instructions as specified to support clinical diagnosis:
Fixed tissue, excisional and incisional biopsies and surgical resection specimens	Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis	Tissue Dissection and decalcification Dissection Manuals - Category A, B, C, D, E, CPL-H-MN-001, CPL-H-MN-002, CPL-H-MN-003, CPL-H-MN-004, CPL-H-MN-005, CPL-H-LP-007 and CPL-H-LP-011
		Preparation of fresh tissue for processing using Class II Microflow Biological Safety Cabinet – SOP's CPL-G-LP-007, CPL-H-LP-006
		Processing specimens using Tissue-Tek Autowrite Cassette Printer - SOP CPL-H-LP-010
		<u>Tissue Processing</u> Tissue Tek VIP 6 tissue processors SOP: CPL-H-LP-002 CPL-H-LP-004



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		<u>Tissue Embedding</u> Production of paraffin blocks using Tissue -Tek TEC V Complete Embedding Centre - SOP CPL-H-LP-003
		<u>Tissue Microtomy</u> Production of sections from formalin fixed paraffin embedded tissues using Tissue Tek Autosection automated Microtome and rotary Accu-Cut SRM 200 Microtome SOP: CPL-H-LP-008
HUMAN BODY TISSUE (cont'd)	<u>Histopathological and Non-gynae Cytological examination activities for the purposes of clinical diagnosis (cont'd)</u>	Documented in-house methods and manufacturer's operating instructions as specified to support clinical diagnosis:
Formalin-fixed paraffin embedded tissue slides	Demonstration of basophilic and eosinophilic structures	Automated H&E staining using Tissue-Tek Prisma Autostainer and Tissue-Tek Film Coverslipper - SOP's CPL-G-LP-001, CPL-G-LP-002, CPL-G-LP-013
HUMAN BODY TISSUE AND FLUIDS	Histopathological examination activities for the purposes of clinical diagnosis (cont'd)	Special Tinctorial Histochemical Staining Methods Stained sections on slides using Tissue-Tek Prisma Autostainer and Tissue-Tek Film Coverslipper – SOP's CPL-G-LP-001, CPL-G-LP-004
Formalin-fixed paraffin embedded tissue slides	Helicobacter	Cresyl Violet
	Glycogen - Acid and Neutral mucins	Periodic Acid Schiff (PAS +/- Diastase)
	Amyloid	Congo Red
	M Tuberculosis	Ziehl Neelsen
		Manual Staining:



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	<u>Elastin</u>	EVG (Millers) CPL-H-LP-012
HUMAN BODY TISSUE (cont'd)	<u>Histopathological and Non-gynae Cytological examination activities for the purposes of clinical diagnosis</u> (cont'd)	Documented in-house methods and manufacturer's operating instructions as specified to support clinical diagnosis:
Stained tissue slides	Morphological assessment and interpretation / diagnosis	Microscopic examination: Assorted range of diagnostic bright-field microscopes CPL-G-LP-009 CPL-M-MP-001 – Pathologist Reporting Procedure
HUMAN BODY TISSUE (cont'd)	<u>Examination of fluids in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis</u>	
Body cavity fluids, urine, respiratory specimens, cyst fluids, FNA needle washings		Processing of diagnostic cytology specimens using ThinPrep 2000 processor, Labofuge 400 Centrifuge, CytoTek Cytospin, Biological Safety Cabinet – SOP's CPL-C-LP-001, CPL-C-LP-003 CPL-C-LP-004, CPL-C-LP-005, CPL-G-LP-007
Formalin- fixed, paraffin- embedded tissue sections or cytological preparations on microscope slides		Staining of diagnostic cytology slides using Tissue-Tek Prisma Autostainer and Tissue-Tek Film Coverslipper – SOP's CPL-G-LP-001, CPL-G-LP-002
	Nuclei and other cellular components	, Papanicolaou, Haematoxylin & Eosin
		Manual technique CPL-C-LP-002 Giemsa



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Formalin- fixed, paraffin- embedded tissue sections on microscope slides	<u>Immunohistochemistry for the detection of:</u>	Leica Bond III Immunostainer – SOP's CPL-G-LP-008, CPL-G-LP-003
	Pan cytokeratin	Multi-Cytokeratin AE1/AE3 Leica PA0909
	Neuroanatomical marker	Calretinin (CAL6) Leica PA0346
	Pan cytokeratin	Cytokeratin CAM 5.2 BD 345779
	Basal cell epithelium in prostate, myoepithelium in breast, squamous cell carcinoma in lung	Cytokeratin 14 Leica PA0074
	Pan T-cell marker	CD3 (LN10) Leica PA0553
	Pan T-cell marker	CD5 (4C7) Leica PA0168
	Renal cell carcinoma (RCC) /Lymphoma	CD10 (56C6) Leica PA0270
	B Lymphocytes	CD20 (L26) Agilent M075529-2
	Follicular Dendritic cells	CD21 (2G9) Leica PA0171
	B cells and B cell lymphomas	CD23 (1B12) Leica PA0169
	Stem cell/endothelium Sarcoma	CD34 (QBEnd/10) Leica PA0212
	Pan Leukocyte marker (T&B)	CD45 LCA RTU IS751 Agilent
	Neuroendocrine	CD56 (CD564) Leica PA0191
	Macrophages and mononuclear	CD68 (514H12)



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	cells	Leica PA0273
Formalin- fixed, paraffin- embedded tissue sections on microscope slides (cont'd)	<u>Immunohistochemistry for the detection of:</u> (cont'd)	Leica Bond III Immunostainer – SOP's CPL-G-LP-008, CPL-G-LP-003
	GIST, RCC, Germ cell tumour	CD117 (c-kit) Agilent A450229-2
	Gastrointestinal tumours	CDX2 (DAK-CDX2) Agilent IS08030-2
	Neuroendocrine cells and tumours with neuroendocrine differentiation	Chromogranin A Leica PA0515
	Epithelium cytokeratin	Cytokeratin 5 (XM26) Leica PA0468
	Epithelium cytokeratin	Cytokeratin CK7 (RN7) Leica PA0942
	Gastro-intestinal cells cytokeratin	Cytokeratin CK20 (Ks20.8) Agilent IS77730-2
	Smooth and striated muscle	Desmin (DE-R-11) Leica PA0032
	Distinguish lobular from ductal carcinoma of breast	E-Cadherin (NCH-38) Agilent IS05930-2
	Protein in epithelial cells	Epith. Mem. Antigen (GP1.4) Leica PA0035
	Epithelial cells	Epithelial Antigen Ber EP4 Agilent IS63730-2
	Breast hormone	Estrogen Receptor α (EP1) Agilent IS08461-2
	Melanocytes (melanoma)	Melanoma Marker HMB45 Leica PA0027
	Cell proliferation marker	Ki67 (MIB1) Agilent IS62661-2
	Melanocytes (melanoma)	Melan A (A103)



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		Leica PA0233
	Ovarian cancer/HPV	p16 Roche 705-4713
Formalin- fixed, paraffin- embedded tissue sections on microscope slides (cont'd)	<u>Immunohistochemistry for the detection of:</u> (cont'd)	Leica Bond III Immunostainer – SOP's CPL-G-LP-008, CPL-G-LP-003
	Cell proliferation marker	p53 (DO-7) Leica PA0057
	Prostate adenocarcinoma	p504S /Racemase (AMACR) Leica AMACR(EPMU1) RTU
	Tumour suppressor gene	p63 (DAK-p63) Agilent IR66261-2
	Breast hormone	Progesterone Recpt. (PgR 636) Agilent IR06861-2
	Neuroectodermal tumours and melanoma	S-100 (poly) Leica PA0900
	Smooth muscle cells and their tumours	Smooth Muscle Actin (α sm-1) Leica PA0943
	Demonstration of synaptophysin producing cells	Synaptophysin (27G12) Leica PA0299
	Nuclear protein in lung and thyroid	Thyroid Trans. Factor-1 (SPT24) Leica PA0364
	Wilm's tumour	Wilm's Tumour 1 (6F-H2) Agilent IS52730-2
	Marker of melanocytic and schwannian neoplasms.	Sox10 Cell Marque 383R-18
	Marker of High Molecular Weight Cytokeratin, complex epithelia	HMW CK34Be12 Leica PA0134
END		