


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

2 Pine Trees, Chertsey Lane, Staines, Middlesex, TW18 3HR, UK

 <p>UKAS MEDICAL</p> <p>8366</p> <p>Accredited to ISO 15189:2012</p>	<p>The Royal Wolverhampton NHS Trust operating as Black Country Pathology Services</p> <p>Issue No: 004 Issue date: 21 July 2020</p>	
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<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
<p>HUMAN TISSUES</p> <p>Fixed and fresh tissue, excisional and incisional biopsies and surgical resection specimens</p> <p>Formalin fixed paraffin wax blocks of processed tissue</p> <p>Fresh human tissue</p>	<p><u>Histopathology</u></p> <p>Examination to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis</p> <p>Identification of nuclei, cell cytoplasm and connective tissues in cells and tissues</p>	<p>Macroscopic and Microscopic examination using in house procedures in conjunction with manufacturer's instructions for the following methods (where relevant):</p> <p>Specimen dissection Specimen trimming and reporting SOPs/CP/H55-H73, H83-H84, H95, H99-H100 Organisation of work in the trimming room SOP/CP/H91</p> <p>Decalcification of bone specimens SOP/CP/H83</p> <p>Tissue processing Using ThermoFisher Excelsior AS Tissue Processing Machines SOP/CP/H51</p> <p>Tissue embedding Using ThermoScientific HistoStar embedding centres SOP/CP/H49</p> <p>Tissue sectioning (microtomy) ThermoScientific Finesse ME+, Anglia Scientific Sledge, Reichert-Jung 2030, ThermoScientific Finesse 325, Reichert-Jung 1130/Biocut, ThermoScientific Microm HM355S, ThermoScientific HM325.SOP/CP/H02</p> <p>Cryotomy, frozen sections using Thermocryostat SOP/CP/H85 and manual H&E (SOP/CP/H22)</p>



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<p>HUMAN TISSUES (cont'd)</p> <p>Formalin fixed paraffin embedded (FFPE) sections prepared as above</p> <p>FFPE sections (unless otherwise stated)</p>	<p><u>Histopathology</u></p> <p>Examination to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis</p> <p>Identification of nuclei, cell cytoplasm and connective tissues in cells and tissues</p> <p>Special staining to detect the following:</p> <p>Acid and Neutral Mucopolysaccharides</p> <p>Acid Mucopolysaccharides</p> <p>Amyloid</p> <p>Elastic Fibres and connective tissue</p> <p>Helicobacter/Microorganisms</p> <p>Gram +ve & Gram -ve microorganisms</p> <p>Fungi</p> <p>Melanin</p> <p>Copper Associated Protein & Hepatitis B</p> <p>Glycogen/Neutral Mucins/Fungi</p> <p>Iron, Haemosiderin, asbestos body presence</p>	<p>Macroscopic and Microscopic examination using in house procedures in conjunction with manufacturer's instructions for the following methods (where relevant):</p> <p>Routine Haematoxylin and Eosin staining SOP/CP/H22 Haematoxylin & Eosin stain Gemini AS stainer SOP/CP/N44</p> <p>Manual staining of histopathology examinations to assist in detection of clinical abnormalities:</p> <p>Alcian Blue/PAS: SOP/CP/H12</p> <p>Alcian Blue: SOP/CP/H12</p> <p>Congo Red: SOP/CP/H24</p> <p>Elastin Van Gieson: SOP/CP/H30</p> <p>Giemsa: SOP/CP/H16</p> <p>Gram Stain: SOP/CP/H18</p> <p>Grocott Stain: SOP/CP/H20</p> <p>Melanin Bleach Stain: SOP/CP/H39</p> <p>Orcein: SOP/CP/H40</p> <p>PAS/PAS Diastase: SOP/CP/H34</p> <p>Perls: SOP/CP/H35</p>



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HUMAN TISSUES	<u>Histopathology</u> Examination to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis	Macroscopic and Microscopic examination using in house procedures in conjunction with manufacturer's instructions for the following methods (where relevant):
FFPE sections	Special staining to detect the following: (cont'd)	Manual staining of histopathology examinations to assist in detection of clinical abnormalities:
	Reticulin fibre architecture	Reticulin: SOP/CP/H17
	Connective tissue/Collagen/Muscle	Van Gieson: SOP/CP/H46
	Calcium	Von Kossa: SOP/CP/H47
	Spirochaetes	Warthin-Starry: SOP/CP/H87
	Tubercle and Leprosy Bacilli	Ziehl Neelsen: SOP/CP/H48
HUMAN TISSUES	<u>Histopathology</u> Examination to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis	Macroscopic and Microscopic examination using in house procedures in conjunction with manufacturer's instructions for the following methods (where relevant):
FFPE sections	Special staining to detect the following:	Automated staining using SOP/CP/H111 Ventana Benchmark special Stainer I/CP/299
	Acid Mucopolysaccharides	Alcian Blue
	Amyloid	Congo Red
	Helicobacter/Microorganisms	Giemsa
	Fungi	Grocott stain
	Connective tissue	Masson Trichrome
	Iron, Haemosiderin, asbestos body presence	Perls
	Reticulin fibre architecture	Reticulin



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FFPE sections	Special staining to detect the following: (cont'd)	Automated staining using SOP/CP/H111 Ventana Benchmark special Stainer I/CP/299
FFPE sections	Tubercle and Leprosy Bacilli	Ziehl Neelsen
FFPE sections	Immunohistochemistry to detect the following: alpha-1-antitrypsin (A1AT) accumulation in the hepatocytes of A1AT deficient liver	Automated method using SOP/CP/IM013 Ventana Benchmark Ultra staining machines SOP/CP/IM015 SOP/CP/IM016 A1 Anti-trypsin
	Heptocellular carcinomas, Endodermal sinus tumor (EST) or Yolk sac tumours (YST)	AFP
	ALK-positive anaplastic large cell lymphoma.	ALK
	Identification of prostate adenocarcinoma	AMACR
	Diffuse lymph-proliferative disease and neoplastic cells of follicular lymphomas.	BCL-2
	Classification of diffuse large B-cell lymphomas, follicular lymphomas and Burkitt lymphoma/leukemia	BCL-6
	Differential diagnosis of adenocarcinoma vs. malignant mesothelioma and basal cell carcinoma vs. squamous cell carcinoma of the skin.	BER EP4



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FFPE sections	Immunohistochemistry to detect the following: (cont'd)	Automated method using SOP/CP/IM013 Ventana Benchmark Ultra staining machines SOP/CP/IM015 SOP/CP/IM016
	Epithelium cells (Adenocarcinomas)	CA19.9
	Serous ovarian carcinoma and mesothelioma.	CA125
	Identification of smooth muscle and tumors with smooth muscle origin such as leiomyosarcoma, leiomyoma, angioleiomyoma and glomus tumor.	Caldesmon
	Marker for mesotheliomas	Calretinin
	T cells	CD3
	T cells (helper and mature)	CD4
	Mature T cells, T cell lymphomas	CD5
	T cells (cytotoxic / suppressor)	CD8
	Mature B cells, follicular dendritic cells, CALLA	CD10
	Granulocytes, Reed-Sternberg cells	CD15
	B Cells	CD20
	follicular dendritic cells (FDC) and mature B cells	CD21
	B cells, some T cells (small B cell lymphomas)	CD23



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FFPE sections	Immunohistochemistry to detect the following: (cont'd)	Automated method using SOP/CP/IM013 Ventana Benchmark Ultra staining machines SOP/CP/IM015 SOP/CP/IM016
	Reed-Sternberg cells, plasma cells	CD30
	Endothelial cells	CD31
	Haematopoietic cells, vascular endothelium	CD34
	T cells and myeloid lineage cells, B cells	CD43
	Haemopoietic, epithelial +mesenchymal cells marker. Tracks early T-cell development in Thymus	CD44
	Identifying tumors of lymphoid origin. B cells, T cells, monocytes, macrophages	CD45 (LCA)
	Natural killer cells, neuroendocrine tissues Macrophages, monocytes, myeloid cells	CD56
	B cells	CD68
	Mast cells, gastrointestinal stromal tumour (GIST)	CD79a
	Differentiating B cells	CD117
	Adenocarcinomas of the GI tract	CDX2
	CEA glycoproteins, carcinomas of the GI tract, lung and breast	CEA
	Tissues of neuroendocrine origin	Chromogranin
	Cytomegalovirus marker	CMV



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FFPE sections	Immunohistochemistry to detect the following: (cont'd)	Automated method using SOP/CP/IM013 Ventana Benchmark Ultra staining machines SOP/CP/IM015 SOP/CP/IM016
	Epithelial cells	CK AE1/AE3
	Epithelial cells	CK (CAM5.2)
	Differential diagnosis of poorly differentiated squamous cell carcinoma vs. adenocarcinoma, epithelioid mesothelioma vs. lung carcinoma, ductal hyperplasia vs. ductal carcinoma in situ of the breast, and prostate carcinoma vs. its benign mimics.	CK5
	Adenocarcinomas, columnar epithelial cells, lung, breast endometria	CK7
	Basal Cells marker used in Identifying basal-like carcinoma breast	CK14
	Carcinomas of urothelium, GI and Merkel	CK20
	Mantle cell lymphoma	Cyclin D1
	Tumours of myogenic origin. Smooth muscle, striated muscle.	DESMIN
	Gastrointestinal stromal tumors	DOG-1



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FFPE sections	Immunohistochemistry to detect the following: (cont'd)	Automated method using SOP/CP/IM013 Ventana Benchmark Ultra staining machines SOP/CP/IM015 SOP/CP/IM016
	Expression of E-Cadherin in Ductal and lobular breast carcinomas Normal and neoplastic epithelium V.W factor in endothelial cells	E-CAD
	Mesothelial Cells and epithelial cells	EMA
	Estrogen receptor status in breast carcinomas.	ER
	Breast carcinoma, urothelial carcinoma marker	GATA-3
	Metastases from breast carcinoma.	GCDFP-15
	Placental trophoblasts	HCG
	Heopatoocytes marker used for Hepatocellular carcinoma classification	HerPar-1
	Confirms the absence of basal cells	HMWCK
	Melanocytes with immature melanosome formation	HMB45
	Plasma cells and related lymphoid cells containing IgA, and for the classification of B-cell neoplasias	IgA
	Plasma cells and related lymphoid cells containing IgG, and for IgG plasma cell neoplasia	IgG
	Human IgD (delta-chains)	IgD



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FFPE sections	Immunohistochemistry to detect the following: (cont'd)	Automated method using SOP/CP/IM013 Ventana Benchmark Ultra staining machines SOP/CP/IM015 SOP/CP/IM016
	Plasma cells and lymphoid cells containing IgM.	IgM
	Peptide hormone used to differentiate between adrenal cortical tumours and RCC	Inhibin
	Proliferating cells	Ki67
	Proliferating cells / HPV infected cells	Ki67/P16
	B cells and plasma cells	KAPPA
	B cell tumours	LAMBDA
	Melanoma marker	Melan A
	Alveolar macrophages, plasma cells, lung adenocarcinoma	Myelo
	Lung adenocarcinoma diagnosis	Napsin
	Adenocarcinomas and most squamous cell carcinomas (SCC)	NCL-5D3 (CK8/18)
	Pro/pre B cells, mature B cells	OCT 2
	Early embryonic cells and germ cells marker. Used as a specific germ cell tumour marker	OCT 3/4



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	Pro/pre B cells, mature B cells	PAX-5
	Ovarian serous tumour marker	PAX-8
	HPC associated SCC	P16
	Pulmonary SCC	P40
	Wild-type and mutant-type p53 protein and accumulation in human neoplasia.	P53
	Basal cells	P63
	Differential diagnosis between prostatic adenocarcinoma and prostatic intraepithelial neoplasia (PIN) or its benign mimics such as atypical hyperplasia	P63/Racemase
	Tumors of prostatic origin	PSA
	Germ cell tumours	PLAP
	Measuring of the relative level of expression for progesterone receptor in breast cancer tissue	PGR
	Renal cell carcinoma	RCC
	Smooth muscle cells, myoepithelial cells	SMA
	Smooth Muscle cells marker used for Myoepithelial cells breast	SMMS-1



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FFPE sections	Immunohistochemistry to detect the following: (cont'd)	Automated method using SOP/CP/IM013 Ventana Benchmark Ultra staining machines SOP/CP/IM015 SOP/CP/IM016
	S100-positive neoplasms	S100
	Neuroendocrine cells	Synapto
	Vascular tumors, meningiomas and choriocarcinomas, mesotheliomas	Thrombomodulin
	Metastatic tumors in the lung and thyroid	TTF-1
	Thyroid carcinomas	Thyroglobulin
	Sarcoma tumour marker	Vimentin
	Plasma cells	VS38
	Epithelial cells and smooth muscle in fallopian tube. Wilms tumour	WT1
HUMAN TISSUES	<u>Histopathology</u> Examination to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis	Macroscopic and Microscopic examination using in house procedures in conjunction with manufacturer's instructions for the following methods (where relevant):
Slides prepared in house from samples listed above	Morphological assessment and interpretation/diagnosis	Microscopy (qualitative analysis) Light Microscopes-Nikon, Olympus, Leica SOP/CP/D25 Specimen trimming and reporting SOPs/CP/H55-H73, H83-H84, H95, H99-H100



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<p>HUMAN TISSUES AND FLUIDS</p> <p>Fine needle aspirations (various sites) Serous effusions (pleural, ascetic, pericardial) Respiratory fluids and brushings Urine Gastrointestinal brushings Cyst Fluids Synovial Fluid</p> <p>Slides prepared in house from samples listed above</p>	<p><u>Diagnostic Cytopathology</u></p> <p>Examination of non-gynaecological tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis:</p> <p>Basic cellular components Morphological inspection and differential counting of blood cells</p> <p>Morphological assessment and interpretation/diagnosis</p>	<p>Documented in-house Methods and Manufacturer's instructions using Papanicolaou and Diff Quick-rapid Giemsa Stain:</p> <p>Preparation and processing SOPs: SOP/CP/N05, N07, N09-N12, N20-N21, N24-N25, N27. Rapid Giemsa Manual Staining Technique (Diff Quick) SOP/CP/N22 Remounts and Restains Procedure SOP/CP/N28 Eppendorf 5810 Centrifuge, Operation and Maintenance SOP/CP/N08 Papanicolaou taining using Thermo Scientific Gemini AS Stainer SOP/CP/N44 T2000 ThinPrep Machine Preparation of gynae and non-gynae specimens SOP/CP/N31 Procedure for Handling Urgent Gynae and non-Gynae specimens SOP/CP/N33</p> <p>Microscopy (qualitative analysis) Light Microscopes-Nikon, Olympus, Leica SOP/CP/D25</p>
END		