


# Schedule of Accreditation

issued by

## United Kingdom Accreditation Service

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

 <b>8136</b> <b>Accredited to ISO 15189:2012</b>	<b>East Lancashire Hospitals NHS Trust</b>	
	<b>Issue No: 003    Issue date: 28 September 2021</b>	
	<b>Cellular Pathology Department</b> <b>Royal Blackburn Teaching Hospital</b> <b>Haslingden Road</b> <b>Blackburn</b> <b>BB2 3HH</b> <b>United Kingdom</b>	<b>Contact: Dayle Squires</b> <b>Tel: +44 (0) 1254734162</b> <b>Fax: +44 (0) 1254733668</b> <b>E-Mail: dayle.squires@elht.nhs.uk</b> <b>Website: www.elht.nhs.uk</b>

**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
<b>Address</b> Cellular Pathology Department Royal Blackburn Teaching Hospital Haslingden Road Blackburn BB2 3HH United Kingdom	<b>Local contact</b> Dayle Squires	Histopathology Cytology (Non-Gynae) Andrology
Cellular Pathology Department Burnley General Teaching Hospital Casterton Avenue Burnley BB10 2PQ United Kingdom	Dayle Squires	Andrology



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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><b>HUMAN BODY TISSUE AND FLUIDS</b></p> <p>Fixed, fresh and frozen tissue; excisional and incisional biopsies and surgical resection specimens</p> <p>Formalin fixed tissues samples (as above)</p> <p>Processed tissue samples (as above)</p> <p>Paraffin waxed tissue samples (as above)</p> <p>Frozen tissues</p>	<p><u>Routine Histopathology</u></p> <p>Examination of tissues to identify or exclude morphological and cytological abnormalities for the purposes of diagnosis</p>	<p>Macroscopic and Microscopic examination. In house documented procedures in conjunction with equipment as specified below:</p> <p><u>Specimen dissection</u></p> <p>Documented in-house procedure CP/P1 by manual methods</p>	A
		<p><u>Tissue Processing</u></p> <p>Documented in-house procedure CP-H8 in conjunction with manufacturers instructions using Leica Peloris</p>	A
		<p><u>Tissue Embedding</u></p> <p>Documented in-house procedure CP/H9 by manual methods</p>	A
		<p><u>Tissue Sectioning (microtomy)</u></p> <p>Documented in-house procedure CP/H10 using Leica RM2235 microtomes</p>	A
		<p><u>Tissue Sectioning (microtomy)</u></p> <p>Documented in-house procedure CP/H5 using Leica CM1860UV manual cryostat</p>	



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<p>HUMAN BODY TISSUE AND FLUIDS (cont'd)</p> <p>Fixed, fresh and frozen tissue; excisional and incisional biopsies and surgical resection specimens</p>	<p><u>Routine Staining</u></p> <p>Detection of:</p> <p>Identification of basophilic and eosinophilic structures</p>	<p>Documented in-house procedures for manual and automated staining using Leica ST5020 stainer &amp; CV5030 coverslipper.</p> <p>Haematoxylin &amp; Eosin (SOP CP/H11 (automated) ,CP/H37 (manual) and CP/H96 (for frozen sections)</p>	A
	<p><u>Special Staining</u></p> <p>Examination of tissues to identify or exclude morphological and cytological abnormalities for the purposes of diagnosis</p> <p>Detection of:</p> <p>Amyloid</p> <p>Fungi</p> <p>Connective tissue</p> <p>Diastase Digestion</p> <p>Haemosiderin and ferric iron</p> <p>Reticulin fibres</p> <p>Acid Mucopolysaccharides</p> <p>Acid Mucopolysaccharides</p>	<p>Documented in-house procedures for automated staining using Roche Benchmark and with reference to:</p> <p>Congo Red (CP/H26)</p> <p>Grocott (CP/H35)</p> <p>Masson Trichrome (CP/H41)</p> <p>PAS +/- Diastase (CP/H47)</p> <p>Perls (CP/H48)</p> <p>Reticulin (CP/H51)</p> <p>Documented in-house procedures for manual staining:</p> <p>Alcian Blue (CP/H23)</p> <p>Alcian Blue PAS (CP/H24)</p>	A



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<p><b>HUMAN BODY TISSUE AND FLUIDS (cont'd)</b></p> <p>Fixed, fresh and frozen tissue; excisional and incisional biopsies and surgical resection specimens</p>	<p><u>Special Staining (cont'd)</u></p> <p>Examination of tissues to identify or exclude morphological and cytological abnormalities for the purposes of diagnosis (cont'd)</p> <p>Detection of: (cont'd)</p> <p>Elastic fibres and connective tissue</p> <p>Gram +/- organisms</p> <p>Connective tissue and fibrin</p> <p>Melanin pigment</p> <p>Helicobacter pylori</p> <p>Copper-associated protein and Hepatitis B-affected cells</p> <p>Mast cells</p> <p>Connective tissue, collagen, fibrin</p> <p>Tubercle bacilli</p>	<p>Documented in-house procedures for automated staining using Roche Benchmark and with reference to:</p> <p>Elastin Van Gieson (CP/H30)</p> <p>Gram stain (CP/H33)</p> <p>Martius, Scarlet &amp; Blue stain (MSB) (CP/H39)</p> <p>Masson Fontana (CP/H40)</p> <p>Modified Giemsa (CP/H70)</p> <p>Shikata (CP/H45)</p> <p>Toluidine Blue (CP/H65)</p> <p>Haematoxylin Van Gieson (CP/H38)</p> <p>Ziehl Neelsen (SOP CP/H59)</p>	<p>A</p>



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HUMAN BODY TISSUE AND FLUIDS (cont'd)  Paraffin tissue section	<u>Immunocytochemistry</u>  Examination of tissues to identify or exclude morphological and cytological abnormalities for the purposes of diagnosis	Documented in-house procedures CP/H17, CP/H18 & CP/H22 in conjunction with manufacturers instructions using Roche Ventana ULTRA immunohistochemistry system and the following antibodies:	
	High molecular weight cytokeratins	34βE12	
	Cytokeratin cocktail for CK1-8, 10, 14-16 and 19	AE1/AE3	
	Alpha-methyl-CoA racemase enzyme	AMACR	
	B-catenin protein	B-catenin	
	Diffuse lymph-proliferative disease and neoplastic cells of follicular lymphomas	Bcl-2 Oncoprotein	
	Prognostic marker in some B-cell Non-Hodgkins lymphomas.	Bcl-6 oncoprotein	
	Epithelial cell types	BerEP4	
	CA-125 protein	CA-125	
	Calcitonin polypeptide	Calcitonin	
	Calretinin protein	Calretinin	
	Cytokeratin	Cam 5.2 (CK 8 & 18)	
	T-cells	CD3	
Mature T cells, T cell lymphomas	CD5		



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HUMAN BODY TISSUE AND FLUIDS (cont'd)  Paraffin tissue section (cont'd)	<u>Immunocytochemistry</u> (cont'd)		A
	Examination of tissues to identify or exclude morphological and cytological abnormalities for the purposes of diagnosis (cont'd)	Documented in-house procedures CP/H17, CP/H18 & CP/H22 in conjunction with manufacturers instructions using Roche Ventana ULTRA immunohistochemistry system and the following antibodies:	
	Mature B cells, follicular dendritic cells, CALLA	CD10	
	Granulocytes, Reed-Sternberg cells	CD15	
	B cells	CD20	
	B cells, some T cells	CD23	
	Reed-Sternberg cells, plasma cells	CD30	
	Endothelial cells	CD31	
	Haematopoietic cells, vascular endothelium	CD34	
	Leukocyte common antigen (LCA)	CD45	
	Natural killer cells, neuroendocrine tissues	CD56	
	Macrophages, monocytes, myeloid cells	CD68	
	B cells	CD79a	
Mast cells	CD117 (c-kit)		
Differentiating B cells	CD138		
CDX-2 protein	CDX2		



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HUMAN BODY TISSUE AND FLUIDS (cont'd)  Paraffin tissue section (cont'd)	<u>Immunocytochemistry</u> (cont'd)  Examination of tissues to identify or exclude morphological and cytological abnormalities for the purposes of diagnosis (cont'd)	Documented in-house procedures CP/H17, CP/H18 & CP/H22 in conjunction with manufacturers instructions using Roche Ventana ULTRA immunohistochemistry system and the following antibodies:	A
	Glycoprotein	CEA	
	Tissues of neuroendocrine origin	Chromogranin A	
	Cytomegalovirus	CMV	
	Cytokeratin 5	Cytokeratin 19	
	Adenocarcinomas, columnar epithelial cells	Cytokeratin 20	
	Stratified squamous epithelium, basal cells, mesotheliomas	Cytokeratin 5/6	
	Normal & neoplastic epithelia	Cytokeratin 7	
	Podoplanin	D2-40	
	Muscle specific protein	Desmin	
	DOG-1 protein	DOG-1	
	Normal duct epithelial cells, ductal carcinoma	E – cadherin	
	Normal and neoplastic epithelium	Epithelial membrane antigen	
	Oestrogen receptors	ER	
	GATA-3 protein	GATA-3	
	GCDFP-15 protein	GCDFP15	



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HUMAN BODY TISSUE AND FLUIDS (cont'd)  Paraffin tissue section (cont'd)	<u>Immunocytochemistry</u> (cont'd)		A
	Examination of tissues to identify or exclude morphological and cytological abnormalities for the purposes of diagnosis (cont'd)	Documented in-house procedures CP/H17, CP/H18 & CP/H22 in conjunction with manufacturers instructions using Roche Ventana ULTRA system and the following antibodies:	
	Hepatocytes	Hepatocyte	
	Melanoma, melanocyte differentiation	HMB45	
	HMBE-1 protein	HMBE-1 mesothelioma	
	B cells and plasma cells	Kappa	
	Ki-67 protein	KI-67 ANTIGEN	
	B cell follicles	Lambda	
	Melanoma marker	Melan A	
	MNF116	MNF116	
	Adenocarcinoma	MOC-31	
	Myeloperoxidase	Myeloperoxidase	
	Aspartyl protease 4	Napsin	
	OCT 3/4 protein	OCT 3/4	
	Oestrogen receptor	Oestrogen receptor	
Paired box gene 8 protein	PAX-8		
P16 protein	P16		
P40 protein	P40		
P40 protein / CK 5/6 cytokeratin double stain	P40 / CK 5/6		





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HUMAN BODY TISSUE AND FLUIDS (cont'd)  Paraffin tissue section (cont'd)	<u>Immunocytochemistry</u> (cont'd)		A
	Examination of tissues to identify or exclude morphological and cytological abnormalities for the purposes of diagnosis (cont'd)	Documented in-house procedures CP/H17, CP/H18 & CP/H22 in conjunction with manufacturers instructions using Roche Ventana ULTRA system and the following antibodies:	
	P53 protein	P53	
	Prostate basal cells, proliferative cells	P63	
	Membrane associated sialoglycoprotein enzyme	Placental Alk Phosphatase	
	Prostate secretory and ductal epithelium	Prostate antigen specific	
	Renal cell carcinoma (RCC) antigen	Renal cell carcinoma	
	Schwann cells, nerve processes, S100 +ve neoplasms	S100	
	Smooth muscle cells, myoepithelial cells	Smooth muscle Actin	
	Smooth muscle protein	Smooth muscle myosin	
	Neuroendocrine cells	Synaptophysin	
	Thyroglobulin containing cells	Thyroglobulin	
	Lung and thyroid (thyroid follicular cells)	TTF-1	
Lung and thyroid (thyroid follicular cells) / Aspartyl protease double stain	TTF-1 / Napsin		
Cells of mesenchymal origin	Vimentin		



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<p>HUMAN BODY TISSUE AND FLUIDS (cont'd)</p> <p>Paraffin tissue section (cont'd)</p> <p>Formalin fixed paraffin embedded (FFPE) tissue on glass slides</p>	<p><u>Immunocytochemistry (cont'd)</u></p> <p>Examination of tissues to identify or exclude morphological and cytological abnormalities for the purposes of diagnosis (cont'd)</p> <p>Wilms tumour protein</p> <p><math>\alpha</math>-1-Fetoprotein</p> <p>Morphological assessment and interpretation / diagnosis</p>	<p>Documented in-house procedures CP/H17, CP/H18 &amp; CP/H22 in conjunction with manufacturers instructions using Roche Ventana ULTRA system and the following antibodies:</p> <p>Wt – 1</p> <p><math>\alpha</math>-1-Fetoprotein</p> <p>Microscopy using SOPs CP/P2 and CP/H18</p>	A
	<p><u>Cytology (Non-Gynae)</u></p> <p>Examination of tissues to identify or exclude morphological and cytological abnormalities for the purposes of diagnosis. Detection of:</p> <p>Cells (nuclei and cytoplasm) and micro organisms</p> <p>Cells (nuclei and cytoplasm) and micro organisms</p> <p>Microorganisms</p> <p>Morphological assessment and interpretation / diagnosis</p>	<p>In-house documented manual procedures CP/NG1 for preparation and manual staining</p> <p>Papanicolaou</p> <p>SOP CP/NG1 &amp; CP/NG3 in conjunction with manufacturers instructions using Hologic T2000</p> <p>Papanicolaou</p> <p>Rapid Giemsa</p> <p>Microscopy using SOP CP/NG7</p>	
<p>HUMAN BODY TISSUE AND FLUIDS</p> <p>Body fluids, urine, aspirates, washings &amp; oesophageal brushings</p> <p>Body fluids, urine, brushings, aspirates, washings, fine needle aspirates, EUSFNA</p> <p>Air-Dried Smears</p> <p>Prepared tissue and fluid samples on glass slides</p>			A



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HUMAN BODY FLUIDS	<u>Andrology</u> Andrological examination activities for the purposes of clinical diagnosis	In house documented procedures based on and in conjunction with the following guidelines	
Ejaculate	Post-Vasectomy: Detection of Spermatazoa	SOP CP/A7 by manual microscopy based on ABA Guidelines v3 2012	A & B
Ejaculate	Fertility Testing:  Volume Sperm motility pH Sperm concentration Sperm morphology Sperm viability Viscosity Appearance	SOP CP/A6 based on WHO Laboratory Manual for Examination and Processing of Human Semen 5 <sup>th</sup> Edition 2010  Volume / weight Manual microscopy pH paper Manual microscopy Stained slide assessment Stained slide assessment Visual observation Visual observation	A & B A & B A & B A & B A A A & B A & B
END			