


# Schedule of Accreditation

issued by

## United Kingdom Accreditation Service

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

 <b>Accredited to ISO 15189:2012</b>	<b>Bolton NHS Foundation Trust</b>  <b>Issue No: 006   Issue date: 01 April 2025</b>	
	<b>Cellular Pathology and Andrology</b> <b>Bolton Royal Hospital</b> <b>Minerva Road</b> <b>Farnworth</b> <b>Bolton</b> <b>BL4 0JR</b>	<b>Contact: Lewis Hurley</b> <b>Tel: +44 (0)1204 390 390</b> <b>E-Mail: lewis.hurley@boltonft.nhs.uk</b> <b>Website: www.boltonhospitals.nhs.uk</b>
<b>Testing performed at the above address only</b>		

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

#### Site activities performed away from the laboratory:

Location details	Activity
Mortuary Bolton Royal Hospital Minerva Road Farnworth Bolton BL4 0JR United Kingdom	Mortuary Services (body receipt, storage and release)



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DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
<p>HUMAN BODY TISSUE</p> <p>Tissue: biopsy, excision, resection and post-mortem specimens</p> <p>Femoral head, bone reamings</p> <p>Formalin Fixed Paraffin Embedded (FFPE) wax blocks of processed tissue.</p> <p>Frozen sections: Parathyroid and other excisional/resection tissue removed from body</p> <p>FFPE slides</p>	<p><u>Histopathological examination activities for the purposes of clinical diagnosis</u></p> <p>Examination of tissues 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>Specimen dissection SOP:HY-SOP-PATH-100, HY-SOP-CU-0013, AFOS Downdraft benches SOP: HY-SW-CU-008</p> <p>Tissue processing using Leica Tissue processors SOPs;HY-PROC-SW-1</p> <p>Decalcification Pathvision Faxitron SOP: HY-SOP-CU-0021 HY-PROC-SOP-1</p> <p>Leica Tissue Embedding centres SOP: HY-SOP-MLAB-0010</p> <p>Leica/Epredia Tissue Sectioning Microtomes SOP: HY-SOP-MLAB-0011</p> <p>Cryotomy Intra-operative Frozen sections Leica CM1850 Cryostat SOP: HY-SOP-CU-0010</p> <p>Interpretive/diagnostic microscopy SOP: HY-MAIN-SW-7, HY-MAIN-SOP-4, HY-MLAB-DOC-20, HY-MLAB-DOC-28, HM-ESD-11</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:
FFPE (Formalin fixed paraffin embedded) slides	<u>Routine morphological staining for the detection of:</u>  Identification of nuclei, cell cytoplasm and most connective tissues in cells and tissues	Sakura Tissue Tek DRS 2000 stainer Haematoxylin & Eosin stain Manual and Automated SOPs: HY-SOP-MLAB-0003; HY-SOP-SS-0029
FFPE (Formalin fixed paraffin embedded) slides	Special stains for the detection of:	Documented in-house procedures for manual special stains
	Acid mucopolysaccharides	Alcian Blue, Ph 2.5, SOP: HY-SOP-SS-0001
	Acid and Neutral Mucopolysaccharides	Alcian Blue/PAS SOP: HY-SOP-SS-0002
	Acid and Neutral Mucopolysaccharides, no glycogen	Alcia Blue/PAS Diastase SOP: HY-SOP-SS-0003
	Differentiation of glycogen from mucin	PAS + Diastase digestion SOP: HY-SOP-SS-0005
	Neural Mucins/glycogen	PAS SOP: HY-SOP-SS-0012
	Elastic fibres, muscle, collagen	Millers elastic stain SOP: HY-SOP-SS-0007
	Amyloid	Congo Red SOP: HY-SOP-SS-0008
	Fungal hyphae / yeast bodies	Grocott-Gomori Methanamine Silver SOP: HY-SOP-SS-0009
	Pneumocysts	Grocott Modified for Pneumocystis, SOP: HY-SOP-SS-0010
	H. pylori, connective tissue	Giemsa stain, Gurr's Improved SOP: HY-SOP-SS-0013



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HUMAN BODY TISSUE (cont'd)	<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:
FFPE (Formalin fixed paraffin embedded) slides	Special stains for the detection of: (cont'd)	Documented in-house procedures for manual special stains
	Differentiation of Gram positive and Gram negative organisms	Gram stain SOP: HY-SOP-SS-0014
	Melanin, Argentaffin, Chromaffin and some Lipofuscins,	Masson Fontana SOP: HY-SOP-SS-0015
	Copper Associated Protein	Shikata's Orcein SOP: HY-SOP-SS-0019
	Haemosiderin	Perl's Prussian Blue SOP: HY-SOP-SS-0021
	Reticular fibres	Gordon & Sweet's Reticulin SOP: HY-SOP-SS-0022
	Mast cells	Toluidine Blue SOP: HY-SOP-SS-0023
	M. leprae	Ziehl Nielson modified SOP: HY-SOP-SS-0027
	Tubercle bacilli	Ziehl Nielson SOP: HY-SOP-SS-0026



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HUMAN BODY TISSUE (cont'd)	<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:
FFPE (Formalin fixed paraffin embedded) slides	Immunocytochemistry examination activities to detect the following:	Roche Ventana Benchmark Ultra SOP: HY-SOP-ICC-0009
	Glandular and stratified squamous epithelium	AE1/AE3
	Embryonic Cells in normal tissue and germ tumours	AFP, Alpha -1-Fetoprotein
	Follicular and diffused large cell lymphomas from reactive lymph nodes	bcl-2 Oncoprotein
	Reed Sternberg cells in Hodgkin's lymphoma, anaplastic large cell lymphoma and plasma cells	Ber H2, CD30
	Epithelial Cells of the Colon	Ber EP4
	Classification of mesothelial cells and malignant mesothelioma of the epithelial type	Calretinin
	Carcinomas from malignant tumours of non-epithelial origin	CAM 5.2
	All germinal centre cells – tonsil Renal cell carcinoma	CD10 CALLA
	KIT protein in gastro-intestinal stromal tumours	CD117, c-KIT, GIST tumour marker,
	CD138, B cell differentiation	CD138
	Normal and neoplastic T cells from thymocytes to mature T cells	CD3, T Cell
	Neural / neuroendocrine tissue and natural killer cells	CD56, NCAM, Neural Adhesion
	Macrophages	CD68, Macrophage



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FFPE slides (cont'd)	Immunocytochemistry examination activities to detect the following (cont'd):	Roche Ventana Benchmark Ultra SOP: HY-SOP-ICC-0009
	B cells all stages	CD79a, B Cell
	Loss of differentiation in colorectal cancers	CDX2
	Adenocarcinoma	CEA, Carcinoembryonic Antigen
	Neuroendocrine cells	Chromogranin
	Adenocarcinomas of breast, lung, endometrium, ovary, thyroid and carcinomas of bladder and renal cell	CK7, Cytokeratin 7
	Columnar cell epithelium	CK20, Cytokeratin 20
	Myoepithelial cells of the prostate / breast. Squamous cell carcinoma	CK 5/6, Cytokeratin 5/6
	Cytomegalovirus infected cells	Cytomegalovirus, CMEG
	Smooth and striated muscle tumours	Desmin
	Adenocarcinoma from mesothelioma and ductal vs lobular cancer of the breast	E-Cadherin
	Variety of normal and neoplastic epithelia	EMA, Epithelial Membrane Antigen
	Breast carcinoma and urothelial carcinoma	GATA3
	HER-2 expressing cells in breast cancer	HER-2
	Melanoma cells	HMB45



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FFPE slides (cont'd)	Immunocytochemistry examination activities to detect the following (cont'd):	Roche Ventana Benchmark Ultra SOP: HY-SOP-ICC-0009
	Endothelial cells. Benign and malignant vascular disorders	JC70A or CD31
	B cells	L26, B Cell, CD20
	All Leucocytes	LCA, CD45
	Melanomas and angiomyolipomas	MART-1 (Melan A)
	Proliferating cells	MIB-1 Proliferating Cell Marker
	Oestrogen receptors breast carcinoma	Oestrogen Receptor (OR)
	Prostatic carcinoma	P504S, Clone 13H4
	Malignant change in cervical epithelium, HPV	P16
	Cell proliferation	P63
	Ovarian carcinoma, renal cell carcinoma and thyroid carcinoma	PAX8
	P40 protein	P40
	Wild type mutant p53	P53
	Breast carcinoma	Progesterone Receptor (PR)
	Vascular and leucocyte differentiation	QBend10 (CD34)
	Malignant melanocytic tumours of the skin and metastases of human malignant melanomas	S100



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HUMAN BODY TISSUE (cont'd)	<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:
FFPE slides (cont'd)	Immunocytochemistry examination activities to detect the following (cont'd):	Roche Ventana Benchmark Ultra SOP: HY-SOP-ICC-0009
	Smooth muscle cells, myofibroblasts and myoepithelial cells	Smooth Muscle Actin (SMA)
	Follicular epithelial cells of thyroid, Type II pneumocytes ie; smooth muscle, endothelium, lymphocytes	Thyroid Transcription Factor (TTF1)
	Cells of mesenchymal origin	Vimentin
	Mesenchymal cells, Wilms tumour, Serous ovarian adenocarcinoma	WT-1
Slides prepared as above	Morphological assessments and interpretation/diagnosis	Leica DM4B/DMRB/DM2000, Olympus BX40/41 and Nikon Eclipse 80C microscopes SOPs: HY-SOP-PATH-0001, HY-MAIN-SOP-4, HY-MLAB-DOC-20, HY-MLAB-DOC-28, HM-ESD-11, HY-MAIN-SW-7, HY-MAIN-SW-6





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<p><b>HUMAN BODY FLUIDS</b></p> <p>Fine needle aspirates – Bronchial Brushings, Serous fluids, Sputum, Bronchial washings, Urine</p> <p>Serous Fluids including Pleural fluids</p> <p>Sputum and Bronchial Washings</p> <p>Urine</p>	<p><u>Cytology (Non-Gynae) examination activities for the purposes of clinical diagnosis</u></p> <p>Preparation and examination of cellular material 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>In-house procedures in conjunction with manufacturer's instructions using:</p> <p>Hettich Rotina 380 centrifuge SOP: CY-SW-1 Thermo Shandon Cytospin SOP: NC-SOP-STAIN-0003 Class I Biological Safety cabinet SOP: CY-NG-SW-3 Light microscopes SOPs: HY-MAIN-SW-6, HY-MAIN-SW-7</p> <p>Non-gynae specimen preparation, examination and reporting SOPs: NC-SOP-LAB-0007; CY-NG-SOP-2; CY-NG-SOP-3; NC-SOP-LAB-0012</p> <p>NC-SOP-LAB-0017 – Specimen Preparation – Aspirated Fluid.</p> <p>NC-SOP-LAB-0013 - Specimen Preparation - Sputum, NC-SOP-LAB-0007 – Specimen Preparation – Bronchial Washings</p> <p>NC-SOP-LAB-0015 - Specimen Preparation - Urines</p>



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HUMAN BODY FLUIDS (cont'd)	<u>Cytology (Non-Gynae) 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:
FNAs and Brushings	Demonstration of Cells (nuclei and cytoplasm) and micro-organisms	CY-NG-SOP-3 Specimen Preparation FNA, Brushings and Direct Smears
Non-gynae Cytology Preparations and Staining	Cellular morphological abnormalities	Papanicolaou stain using the Gemini AS stainer SOP: CY-SW-2 Preparing an Agar Block NC-SOP-LAB-0001
Non-gynae cytology preparations on glass slides	Malignant Cells	Giemsa Staining (Hema-Gurr) SOP: NC-SOP-STAIN-0011
Slides prepared as above	Morphological assessments and interpretation/diagnosis	Using light microscopy- Leica DM4B/DMRB/DM2000, Olympus BX40/41 and Nikon Eclipse 80C microscopes SOPs: HY-MAIN-SW-6, HY-MAIN-SOP-4, HY-MAIN-SW-7



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HUMAN BODY FLUIDS	<u>Andrological examination activities for the purposes of clinical diagnosis</u>	
Semen	<u>Post vasectomy:</u>	Based on 2016 Laboratory guidelines for post vasectomy semen analysis: Association of Biomedical Andrologists, the British Andrology Society and the British Association of Urological Surgeons)
	Detection of sperm	Manual method using large volume chambers/manual microscopy and documented in-house procedure: Post Vasectomy Semen Analysis SOP: CY-AND-SOP -1
	1-hour Post Vasectomy: Detection of sperm Sperm concentration Sperm motility	Manual method using large volume chambers/manual microscopy and documented in-house procedure: 1hour Post Vasectomy Semen Analysis CY-AND-SOP-2
Semen	<u>Fertility testing:</u>	Based on WHO laboratory manual for the examination and processing of human semen (Sixth edition 2021) and manual method / documented in-house procedure SOPs: NC-SOP-AND-0002, 0004, 0005, 0006
	Volume	Volume/weight
	pH	Colorimetric strips
	Sperm morphology including TZI scoring	Stained slides (Papanicolau) using the Gemini AS stainer and microscopy (Bright field) SOP: CY-SW-2
	Sperm concentration	Improved Neubauer counting chambers and Microscopy (Phase contrast)
	Sperm motility	Microscopy (Phase contrast)
	Sperm vitality	Stained slide (Eosin/Nigrosin dye exclusion test) microscopy (Bright field)
END		