


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 UKAS MEDICAL 9927 Accredited to ISO 15189:2022	Bolton NHS Foundation Trust	
	Issue No: 008 Issue date: 11 December 2025	
	Cellular Pathology and Andrology Bolton Royal Hospital Minerva Road Farnworth Bolton BL4 0JR	Contact: Lewis Hurley Tel: +44 (0)1204 390 390 E-Mail: lewis.hurley@boltonft.nhs.uk Website: www.boltonhospitals.nhs.uk
Testing performed at the above address only		

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>FFPE slides</p> <p>FFPE (Formalin fixed paraffin embedded) 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>Routine morphological staining for the detection of:</p> <p>Identification of nuclei, cell cytoplasm and most connective tissues in cells and tissues</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>Decalcification Pathvision Faxitron SOP: HY-SOP-CU-0021 HY-PROC-SOP-1</p> <p>Leica/Epredia Tissue Sectioning Microtomes SOP: HY-SOP-MLAB-0011</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> <p>Sakura Tissue Tek DRS 2000 stainer Haematoxylin & Eosin stain Manual and Automated SOPs: HY-SOP-MLAB-0003; HY-SOP-SS-0029</p>



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<p>HUMAN BODY TISSUE (cont'd)</p> <p>FFPE (Formalin fixed paraffin embedded) slides</p>	<p><u>Histopathological examination activities for the purposes of clinical diagnosis</u> (cont'd)</p> <p>Special stains for the detection of:</p> <p>Acid mucopolysaccharides</p> <p>Acid and Neutral Mucopolysaccharides</p> <p>Acid and Neutral Mucopolysaccharides, no glycogen</p> <p>Differentiation of glycogen from mucin</p> <p>Neural Mucins/glycogen</p> <p>Elastic fibres, muscle, collagen</p> <p>Amyloid</p> <p>Fungal hyphae / yeast bodies</p> <p>Pneumocysts</p> <p>H. pylori, connective tissue</p>	<p>In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:</p> <p>Documented in-house procedures for manual special stains</p> <p>Alcian Blue, Ph 2.5, SOP: HY-SOP-SS-0001</p> <p>Alcian Blue/PAS SOP: HY-SOP-SS-0002</p> <p>Alcia Blue/PAS Diastase SOP: HY-SOP-SS-0003</p> <p>PAS + Diastase digestion SOP: HY-SOP-SS-0005</p> <p>PAS SOP: HY-SOP-SS-0012</p> <p>Millers elastic stain SOP: HY-SOP-SS-0007</p> <p>Congo Red SOP: HY-SOP-SS-0008</p> <p>Grocott-Gomori Methanamine Silver SOP: HY-SOP-SS-0009</p> <p>Grocott Modified for Pneumocystis, SOP: HY-SOP-SS-0010</p> <p>Giemsa stain, Gurr's Improved SOP: HY-SOP-SS-0013</p>



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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 (cont'd)	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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<p>HUMAN BODY TISSUE (cont'd)</p> <p>FFPE (Formalin fixed paraffin embedded) slides (cont'd)</p>	<p><u>Histopathological examination activities for the purposes of clinical diagnosis</u> (cont'd)</p> <p>Immunocytochemistry examination activities to detect the following (cont'd):</p> <p>B cells all stages</p> <p>Loss of differentiation in colorectal cancers</p> <p>Adenocarcinoma</p> <p>Neuroendocrine cells</p> <p>Adenocarcinomas of breast, lung, endometrium, ovary, thyroid and carcinomas of bladder and renal cell</p> <p>Columnar cell epithelium</p> <p>Myoepithelial cells of the prostate / breast. Squamous cell carcinoma</p> <p>Cytomegalovirus infected cells</p> <p>Smooth and striated muscle tumours</p> <p>Adenocarcinoma from mesothelioma and ductal vs lobular cancer of the breast</p> <p>Variety of normal and neoplastic epithelia</p> <p>Breast carcinoma and urothelial carcinoma</p> <p>HER-2 expressing cells in breast cancer</p> <p>Melanoma cells</p>	<p>In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:</p> <p>Roche Ventana Benchmark Ultra SOP: HY-SOP-ICC-0009</p> <p>CD79a, B Cell</p> <p>CDX2</p> <p>CEA, Carcinoembryonic Antigen</p> <p>Chromogranin</p> <p>CK7, Cytokeratin 7</p> <p>CK20, Cytokeratin 20</p> <p>CK 5/6, Cytolkeratin 5/6</p> <p>Cytomegalovirus, CMEG</p> <p>Desmin</p> <p>E-Cadherin</p> <p>EMA, Epithelial Membrane Antigen</p> <p>GATA3</p> <p>HER-2</p> <p>HMB45</p>



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<p>HUMAN BODY TISSUE (cont'd)</p> <p>FFPE (Formalin fixed paraffin embedded) slides (cont'd)</p>	<p><u>Histopathological examination activities for the purposes of clinical diagnosis</u> (cont'd)</p> <p>Immunocytochemistry examination activities to detect the following (cont'd):</p> <p>Endothelial cells. Benign and malignant vascular disorders</p> <p>B cells</p> <p>All Leucocytes</p> <p>Melanomas and angiomyolipomas</p> <p>Proliferating cells</p> <p>Oestrogen receptors breast carcinoma</p> <p>Prostatic carcinoma</p> <p>Malignant change in cervical epithelium, HPV</p> <p>Cell proliferation</p> <p>Ovarian carcinoma, renal cell carcinoma and thyroid carcinoma</p> <p>P40 protein</p> <p>Wild type mutant p53</p> <p>Breast carcinoma</p> <p>Vascular and leucocyte differentiation</p> <p>Malignant melanocytic tumours of the skin and metastases of human malignant melanomas</p>	<p>In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:</p> <p>Roche Ventana Benchmark Ultra SOP: HY-SOP-ICC-0009</p> <p>JC70A or CD31</p> <p>L26, B Cell, CD20</p> <p>LCA, CD45</p> <p>MART-1 (Melan A)</p> <p>MIB-1 Proliferating Cell Marker</p> <p>Oestrogen Receptor (OR)</p> <p>P504S, Clone 13H4</p> <p>P16</p> <p>P63</p> <p>PAX8</p> <p>P40</p> <p>P53</p> <p>Progesterone Receptor (PR)</p> <p>QBend10 (CD34)</p> <p>S100</p>



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<p>HUMAN BODY TISSUE (cont'd)</p> <p>FFPE (Formalin fixed paraffin embedded) slides (cont'd)</p> <p>Slides prepared as above</p>	<p><u>Histopathological examination activities for the purposes of clinical diagnosis</u> (cont'd)</p> <p>Immunocytochemistry examination activities to detect the following (cont'd):</p> <p>Smooth muscle cells, myofibroblasts and myoepithelial cells</p> <p>Follicular epithelial cells of thyroid, Type II pneumocytes ie; smooth muscle, endothelium, lymphocytes</p> <p>Cells of mesenchymal origin</p> <p>Mesenchymal cells, Wilms tumour, Serous ovarian adenocarcinoma</p> <p>Morphological assessments and interpretation/diagnosis</p>	<p>In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:</p> <p>Roche Ventana Benchmark Ultra SOP: HY-SOP-ICC-0009</p> <p>Smooth Muscle Actin (SMA)</p> <p>Thyroid Transcription Factor (TTF1)</p> <p>Vimentin</p> <p>WT-1</p> <p>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</p>



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<p>HUMAN BODY FLUIDS</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>FNAs and Brushings</p> <p>Non-gynae Cytology Preparations and Staining</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>Demonstration of Cells (nuclei and cytoplasm) and micro-organisms</p> <p>Cellular morphological 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> <p>CY-NG-SOP-3 Specimen Preparation FNA, Brushings and Direct Smears</p> <p>Papanicolaou stain using the Gemini AS stainer SOP: CY-SW-2 Preparing an Agar Block NC-SOP-LAB-0001</p>



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<p>HUMAN BODY FLUIDS (cont'd)</p> <p>Non-gynae cytology preparations on glass slides</p> <p>Slides prepared as above</p>	<p><u>Cytology (Non-Gynae) examination activities for the purposes of clinical diagnosis (cont'd)</u></p> <p>Malignant Cells</p> <p>Morphological assessments and interpretation/diagnosis</p>	<p>In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:</p> <p>Giemsa Staining (Hema-Gurr) SOP: NC-SOP-STAIN-0011</p> <p>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</p>
<p>HUMAN BODY FLUIDS</p> <p>Semen</p>	<p><u>Andrological examination activities for the purposes of clinical diagnosis</u></p> <p><u>Post vasectomy:</u></p> <p>Detection of sperm</p> <p>1-hour Post Vasectomy: Detection of sperm Sperm concentration Sperm motility</p>	<p>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)</p> <p>Manual method using large volume chambers/manual microscopy and documented in-house procedure: Post Vasectomy Semen Analysis SOP: CY-AND-SOP -1</p> <p>Manual method using large volume chambers/manual microscopy and documented in-house procedure: 1hour Post Vasectomy Semen Analysis CY-AND-SOP-2</p>



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<p>HUMAN BODY FLUIDS (cont'd)</p> <p>Semen (cont'd)</p>	<p><u>Andrological examination activities for the purposes of clinical diagnosis (cont'd)</u></p> <p><u>Fertility testing:</u></p> <p>Volume</p> <p>pH</p> <p>Sperm morphology including TZI scoring</p> <p>Sperm concentration</p> <p>Sperm motility</p> <p>Sperm vitality</p>	<p>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</p> <p>Volume/weight</p> <p>Colorimetric strips</p> <p>Stained slides (Papanicolau) using the Gemini AS stainer and microscopy (Bright field) SOP: CY-SW-2</p> <p>Improved Neubauer counting chambers and Microscopy (Phase contrast)</p> <p>Microscopy (Phase contrast)</p> <p>Stained slide (Eosin/Nigrosin dye exclusion test) microscopy (Bright field)</p>
END		