


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 Accredited to ISO 15189:2012	Bolton NHS Foundation Trust	
	Issue No: 002 Issue date: 05 October 2022	
	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>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 Thermo-Shandon Cassette printer SOP:HY-SOP-CU-0004</p> <p>Tissue processing using Excelsior and Leica Tissue processors SOPs;HY-SW-PROC-0013; HY-PROC-SW-1</p> <p>Decalcification SOP: HY-SOP-CU-0021 HY-PROC-SOP-1</p> <p>Leica Tissue Embedding centres SOP: HY-SOP-MLAB-0010</p> <p>Leica / Thermo-Shandon 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-SW-6</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 slides and frozen sections	<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
	Elastic fibres, muscle, collagen	Millers elastic stain SOP: HY-SOP-SS-0007
	Amyloid	Improved 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
	Differentiation of Gram positive and Gram negative organisms	Gram stain SOP: HY-SOP-SS-0014



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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 (cont'd)</u></p> <p>Special stains for the detection of: (cont'd)</p> <p>Melanin, Argentaffin, Chromaffin and some Lipofuscins,</p> <p>Fibrin</p> <p>Connective tissue, Muscle, Collagen</p> <p>Hepatitis B affected cells</p> <p>Haemosiderin</p> <p>Reticular fibres</p> <p>Mast cells</p> <p>Muscle, collagen, connective tissue</p> <p>Tubercle bacilli</p> <p>Amyloid</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>Masson Fontana SOP: HY-SOP-SS-0015</p> <p>Martius Scarlet Blue, MSB SOP: HY-SOP-SS-0017</p> <p>Mason Trichrome SOP: HY-SOP-SS-0018</p> <p>Shikata's Orcein SOP: HY-SOP-SS-0019</p> <p>Perl's Prussian Blue SOP: HY-SOP-SS-0021</p> <p>Gordon & Sweet's Reticulin SOP: HY-SOP-SS-0022</p> <p>Toluidine Blue SOP: HY-SOP-SS-0023</p> <p>Van Gieson SOP: HY-SOP-SS-0024</p> <p>Ziehl Nielson modified SOP: HY-SOP-SS-0027</p> <p>Sirius Red SOP: HY-SOP-SS-0032</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 slides	Immunocytochemistry examination activities to detect the following:	Roche Benchmark Ultra SOP: HY-SOP-ICC-0009
	Squamous epithelium, follicular epithelia in thyroid, epithelia and mesothelium in small and large bowel	34 beta E 12
	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
	Granulocytes, Reed-Sternberg cells	CD15, Granular Ass Antigen
	Follicular dendritic cells	CD21 Follicular Dendritic Cell



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<p>HUMAN BODY TISSUE (cont'd)</p> <p>FFPE slides</p>	<p><u>Histopathological examination activities for the purposes of clinical diagnosis (cont'd)</u></p> <p>Immunocytochemistry examination activities to detect the following (cont'd):</p> <p>Small B cell lymphocytic lymphoma</p> <p>Normal and neoplastic T cells from thymocytes to mature T cells</p> <p>T and B cell lymphomas</p> <p>T cell lymphomas and mantle cell lymphoma</p> <p>Neural / neuroendocrine tissue and natural killer cells</p> <p>Macrophages</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>Mantle cell lymphomas and breast</p> <p>Squamous epithelium</p> <p>Columnar cell epithelium</p> <p>Myoepithelial cells of the prostate / breast. Squamous cell carcinoma</p>	<p>In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:</p> <p>Roche Benchmark Ultra SOP: HY-SOP-ICC-0009</p> <p>CD23 Sub population of B Lymphocytes</p> <p>CD3, T Cell</p> <p>CD43, T Cell</p> <p>CD5, T Cell</p> <p>CD56, NCAM, Neural Adhesion</p> <p>CD68, Macrophage</p> <p>CD79a, B Cell</p> <p>CDX2</p> <p>CEA, Carcinoembryonic Antigen</p> <p>Chromogranin</p> <p>CK7, Cytokeratin 7</p> <p>Cyclin D1</p> <p>CK14, Cytokeratin 14</p> <p>CK20, Cytokeratin 20</p> <p>CK 5/6, Cytokeratin 5/6</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 slides	Immunocytochemistry examination activities to detect the following (cont'd):	Roche Benchmark Ultra SOP: HY-SOP-ICC-0009
	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
	Endothelia cells	F.VIII R. Ag, Factor VIII Antigen
	Breast carcinoma and urothelial carcinoma	GATA3
	Placental secreting trophoblasts	HCG, Human Chorionic Gonadotrophin
	HER-2 expressing cells in breast cancer	HER-2
	Melanoma cells	HMB45
	Endothelial cells. Benign and malignant vascular disorders	JC70A or CD31
	B cells and plasma cells	Kappa
	B cells	L26, B Cell, CD20
	B cells and plasma cells	Lambda
	All Leucocytes	LCA, CD45
	Melanomas and angiomyolipomas	MART-1 (Melan A)



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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 slides	Immunocytochemistry examination activities to detect the following (cont'd):	Roche Benchmark Ultra SOP: HY-SOP-ICC-0009
	Proliferating cells	MIB-1 Proliferating Cell Marker
	Central and peripheral neuroendocrine cells	NSE (neuron specific enolase)
	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)
	Prostate secretory and ductal epithelium	PSA, Prostate Specific Antigen
	Vascular and leucocyte differentiation	QBend10 (CD34)
	Malignant melanocytic tumors of the skin and metastases of human malignant melanomas	S100



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<p>HUMAN BODY TISSUE (cont'd)</p> <p>FFPE slides</p> <p>Slides prepared as above</p>	<p><u>Histopathological examination activities for the purposes of clinical diagnosis (cont'd)</u></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>Mature, activated T cells and thymocytes</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 Benchmark Ultra SOP: HY-SOP-ICC-0009</p> <p>Smooth Muscle Actin (SMA)</p> <p>Thyroid Transcription Factor (TTF1)</p> <p>UCLH-1, T Cell (CD45RO)</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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HUMAN BODY FLUIDS (cont'd)	<u>Cytopathology (Non-Gynae) examination activities for the purposes of clinical diagnosis</u>	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:
Fine needle aspirates –Breast, sputum, urine CSF, oesophageal washings and brushings, Conventional Bronchial Brushings, Serous fluids, Bronchial washings and Bronchial Alveolar lavage samples.	Preparation and examination of cellular material to identify or exclude morphological and cytological abnormalities	In-house procedures in conjunction with manufacturer's instructions using: Jouan centrifuge, Thermo Shandon Cytospin, Class I Biological Safety cabinet , Leica Linear Stainer, Thermo Shandon MiniStainMate, Light microscopes
Cerebrospinal fluid		Non-gynae specimen preparation, examination and reporting SOPs: NC-SOP-LAB-0007; CY-NG-SOP-2; CY-NG-SOP-3; NC-SOP-LAB-0012
Serous Fluids including Pleural fluids		Specimen Preparation SOPs: NC-SOP-LAB-0009 Cerebrospinal Fluid; CY-NG-SOP-2, Non-Gynae Reporting Protocols
Sputum		CY-NG-SOP-3, Specimen Preparation – FNA, Brushings and Direct smears. CY-NG-SOP-2, Non-Gynae Reporting Protocols
Urine		NC-SOP-LAB-0013 - Specimen Preparation - Sputum, CY-NG-SOP-2, Non-Gynae Reporting Protocols
Broncho-alveolar lavage		NC-SOP-LAB-0015 - Specimen Preparation - Urines, CY-NG-SOP-2, Non-Gynae Reporting Protocols
		NC-SOP-LAB-0008 - Specimen Preparation - Bronchoalveolar Lavage (BAL), CY-NG-SOP-2, Non-Gynae Reporting Protocols



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HUMAN BODY FLUIDS (cont'd)	<u>Cytopathology (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:
Synovial fluid		NC-SOP-LAB-0014 - Specimen Preparation - Synovial Fluid, CY-NG-SOP-2, Non-Gynae Reporting Protocols
Body cavity fluids and FNAs	Demonstration of Cells (nuclei and cytoplasm) and micro organisms	Preparation of cell blocks for histology processing and staining SOP: NC-SOP-LAB-0001
Non-gynae cytology preparations on glass slides	Cellular morphological abnormalities	Papanicolaou stain SOP: NC-SOP-STAIN-0001 Leica Linear ST4020 (operating and staining)
Non-gynae cytology preparations on glass slides - Non fixed body cavity fluids, CSF BAL and Synovial fluids.	Malignant Cells	Giemsa Staining (Hema-Gurr) SOP: NC-SOP-STAIN-0011
BAL and synovial fluid	Malignant Cells	Differential cell count SOPs: NC-SOP-LAB-0008 NC-SOP-LAB-0014 NC-SOP-RPT-0006 NC-SOP-RPT-0013
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 FLUID (cont'd)	<u>Andrology examination activities for the purposes of clinical diagnosis</u>	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions and following the following guidelines:
	Fertility Semen Analysis:	WHO Laboratory Manual for the Examination of Human Semen and Sperm-Cervical Mucus Interaction 5th Edition.
		Jouan centrifuge, Class I Biological Safety Cabinet , Leica Linear stainer, Thermo Shandon StainMate Mini, Haematoxylin, Eosin and Nigrosin stain, light microscopes, Phase contrast microscope with heated stage, Neubauer counting chambers.
Semen	pH, volume	Infertility Semen Analysis - Volume, Appearance, Viscosity and pH SOP: NC-SOP-AND-0002
Semen	Concentration and count	Infertility Semen Analysis - Sperm Concentration SOP: NC-SOP-AND-0005
Semen	Motility	Infertility Semen Analysis - Assessment of Motility and Agglutination SOP: NC-SOP-AND-0003
Semen	Morphology	Infertility Semen Analysis - Sperm Morphology SOP: NC-SOP-AND-0006
Semen	Vitality	Infertility Semen Analysis - Sperm Vitality SOP: NC-SOP-AND-0004



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HUMAN BODY FLUID (cont'd) Semen Semen Semen Semen Semen	<u>Andrology examination activities for the purposes of clinical diagnosis (cont'd)</u> Post Vasectomy Semen Analysis: Absence/presence of sperm Sperm concentration pH and volume Morphology Motility	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified: Post Vasectomy Semen Analysis SOP: CY-AND-SOP -1 Warm Post Vasectomy Semen Analysis, Specimen Reception, NC-SOP-AND-0014 - Warm Post Vasectomy Semen Analysis, Sperm Concentration SOP: NC-SOP-AND-019 Warm Post Vasectomy Semen Analysis, Volume, Viscosity, Appearance and pH SOP: NC-SOP-AND-0015 Warm Post Vasectomy Semen Analysis, Volume, Viscosity, Appearance and pH SOP: NC-SOP-AND-0015 Warm Post Vasectomy Semen Analysis, Assessment of Motility SOP: NC-SOP-AND-0016
END		