


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 <p>UKAS MEDICAL</p> <p>9890</p> <p>Accredited to ISO 15189:2012</p>	<p>Birmingham Women's and Children's Hospital NHS Foundation Trust</p> <p>Issue No: 005 Issue date: 14 June 2021</p>	
	<p>Diana, Princess of Wales Children's Hospital Steelhouse Lane Birmingham B4 6NH</p>	<p>Contact: Susan Cavanagh Tel: +44 (0)121 333 9833 E-Mail: Susan.cavanagh@nhs.net Website: www.bwc.nhs.uk</p>
<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
HUMAN BODY TISSUE AND FLUIDS	<u>Histology examination activities in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis</u>	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified: Surgipath RS481118 Rough Cutting Microtome, Leica CM1950 Microtome
Biopsy, excision, resection and post mortem specimens	Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis	Specimen dissection: REC025 – Specimen Trimming REC026 – Receipt and handling of tumour specimens in the laboratory Gall Bladder Hilar Plate Trimming MED001 Appendix Trimming MED002 Bone Trimming MED003
Biopsy, excision, resection and post mortem specimens	Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis	Specimen dissection: Bowel Resection Trimming MED004 REC009 – Fresh Tissue Trimming REC012 – Hirschsprung's Disease – Diagnosis and Resection REC014 – Kidney needle biopsy REC020 – Small biopsies (other than tumours) not requiring incision Brain (non Tumour) Trimming MED005 Hirschsprung Trimming MED006



9890
Accredited to
ISO 15189:2012

Schedule of Accreditation
issued by
United Kingdom Accreditation Service
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

Birmingham Women's and Children's Hospital NHS Foundation Trust
Issue No: 005 Issue date: 14 June 2021

Testing performed at main address only

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
<p>HUMAN BODY TISSUE AND FLUIDS (cont'd):</p> <p>Biopsy, excision, resection and post mortem specimens</p>	<p><u>Histology examination activities in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd):</u></p> <p>Examination of tissues in order 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>Intra-operative Procedures MED007 Lymph node Trimming MED008 Ovary, Salpinx, Uterus Trimming MED009 Paediatric Solid Tumour Trimming MED011 Retinoblastoma Trimming MED014 Spleen Trimming MED015 Thyroid Trimming MED016 Hepatectomy (Non Tumour) Trimming MED017 Kidney (Non Tumour) Ureter, PUJ Trimming MED018 Meckel Trimming MED019 Skin Trimming MED020 Specimen dissection:Surgical Specimen Trim (Non-otherwise specified) MED021 Testicle Adnexal Structures Trimming MED022 Tonsil Trimming MED023</p> <p>REC005 – Decalcification of tissue</p>



9890

Accredited to
ISO 15189:2012

Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

Birmingham Women's and Children's Hospital NHS Foundation Trust

Issue No: 005 Issue date: 14 June 2021

Testing performed at main address only

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
<p>HUMAN BODY TISSUE AND FLUIDS (cont'd):</p> <p>Biopsy, excision, and resection specimens</p> <p>Formalin Fixed Paraffin wax blocks of processed tissue.</p>	<p><u>Histology examination activities in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd):</u></p> <p>Examination of tissues in order 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>Using Bright Cryostat OFT5000 LS-001 for frozen sections: Cryostat Sectioning of frozen tissue – LAB010 REC003 – Snap freezing for cryomicrotomy REC010 – Frozen section for rapid diagnosis, HISEXT/LAB051 HISLAB010 – Cutting frozen sections HISLAB031 – H&E staining</p> <p>Tissue processed using Excelsior Tissue Processors (LAB070, LAB071, HISEXT/REC010, HISEXT/REC013) Rapid Manual Paraffin Wax Processing LAB033 Eye Processing, section cutting and staining LAB087 LAB011 Trim and Section cutting of Routine Paraffin Wax Blocks LAB036, LAB037</p>



9890
Accredited to
ISO 15189:2012

Schedule of Accreditation
issued by
United Kingdom Accreditation Service
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

Birmingham Women's and Children's Hospital NHS Foundation Trust
Issue No: 005 Issue date: 14 June 2021

Testing performed at main address only

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
<p>HUMAN BODY TISSUE AND FLUIDS (cont'd);</p> <p>Formalin Fixed Paraffin Embedded Tissue (FFPE) sections on glass slides</p>	<p><u>Histology examination activities in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd):</u></p> <p>Identification of basophilic and eosinophilic structures</p> <p>Acid Mucins</p> <p>Acid and neutral mucins</p> <p>Ganglion cells</p> <p>H. Pylori</p> <p>Amyloid</p> <p>Copper</p> <p>Elastic and connective tissues</p> <p>H Pylori/microorganisms & Haemopoietic cells</p> <p>Fungi</p>	<p>Macroscopic and Microscopic examination:</p> <p>In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:</p> <p>Thermo HistoCentre 3 Embedding Centre : Embedding of routine paraffin Wax Blocks LAB014</p> <p>Manual and automated (Lini-stainer (Ski)) Haematoxylin and Eosin staining LAB031, HISEXT/LAB017</p> <p>Manual staining using the following SOPs:</p> <p>REC030 – Staining procedures on Non Tumour tissue</p> <p>Alcian Blue LAB001</p> <p>Alcian Blue / PAS technique LAB086</p> <p>Acetylcholinesterase Method for Rectal Biopsies? Hirschsprung's Disease LAB002</p> <p>Cresyl Fast Violet LAB006</p> <p>Congo Red LAB009</p> <p>Modified Rhodanine Method LAB013</p> <p>Elastic Van Gieson (EVG) LAB016 Orcein LAB040</p> <p>Giemsa LAB024</p> <p>Grocott – Gomori Methenamine Silver Method for Fungi LAB027</p>



9890

Accredited to
ISO 15189:2012

Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

Birmingham Women's and Children's Hospital NHS Foundation Trust

Issue No: 005 Issue date: 14 June 2021

Testing performed at main address only

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY TISSUE AND FLUIDS (cont'd); Formalin Fixed Paraffin Embedded Tissue (FFPE) sections on glass slides (cont'd)	<u>Histology examination activities in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd):</u> Melanin Demonstration of fibrin Connective tissues Copper associated protein, Hepatitis B surface antigen (HBSAg), and Elastic fibres Carbohydrates Glycogen Demonstration of basement membranes Iron Reticulin Fibres Mast Cells and general cytological appearance Tubercle Bacilli Calcium Gram positive and negative organisms	Macroscopic and Microscopic examination: In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified: Masson Fontana LAB034 Martius Scarlet Blue (MSB) LAB038 Masson Trichrome LAB039 Van Gieson LAB108 Orcein for copper associated protein, Hep B, and Elastin fibres LAB040 Periodic Acid Schiff (PAS) for carbohydrates LAB046 Periodic Acid Schiff Diastase/Amylase (PASD) for the identification of glycogen LAB047 Periodic Acid Methenamine Silver for Basement Membranes (LAB048) Perls Method for ferric iron LAB048 Gordon and Sweet's Silver Impregnation for Reticulin Fibres LAB054 Toluidine Blue for Mast Cells and General Cytology LAB059 Ziel-Neelson (ZN) Stain for Tubercle Bacilli LAB064 Silver Nitrate / Rubeanic Acid Technique for Calcium LAB084 Gram Method for Gram Positive Organisms LAB107



9890

Accredited to
ISO 15189:2012

Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

Birmingham Women's and Children's Hospital NHS Foundation Trust

Issue No: 005 Issue date: 14 June 2021

Testing performed at main address only

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
<p>HUMAN BODY TISSUE AND FLUIDS (cont'd):</p> <p>Fine needle aspirations (various sites), Serous effusions (pleural, ascetic) Respiratory fluids Urine Cyst fluids</p>	<p><u>Diagnostic Cytopathology</u> <u>Examination of non-gynaecological specimens in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis</u></p>	<p>HIS/REC004 The Preparation of Non Gynae Cytology Specimens, HISEXT/LAB084</p>
	<p>Staining for cellular architecture and nuclear detail (identification of basophilic and eosinophilic structures)</p>	<p>Papanicolaou staining for cytology LAB045</p>
BAL	Lipids	Oil Red O Staining LAB041
BAL	Fat Laden Macrophages	Demonstration of fat laden macrophages (Oil Red O) LAB018
All sample types as above	Morphological assessment and interpretation/diagnosis	HISREC004 – Preparation of NG Cytology Samples MED013 – reporting Histopath samples



9890
Accredited to
ISO 15189:2012

Schedule of Accreditation
issued by
United Kingdom Accreditation Service
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

Birmingham Women's and Children's Hospital NHS Foundation Trust
Issue No: 005 Issue date: 14 June 2021

Testing performed at main address only

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
<p>HUMAN BODY TISSUE AND FLUIDS (cont'd):</p> <p>Formalin Fixed Paraffin Embedded Tissue (FFPE) sections on glass slides and non gynae cytology preparations:</p>	<p><u>Immunohistochemistry examination activities for the purposes of clinical diagnosis</u></p> <p>Smooth muscle cells</p> <p>Adenovirus</p> <p>Alpha fetoprotein</p> <p>Anaplastic large cell lymphoma / inflammatory myofibroblastic tumour</p> <p>Various carcinomas</p> <p>Used to aid classification of lymphomas/bone marrow biopsies</p> <p>Used to aid classification of lymphomas/bone marrow biopsies</p> <p>B cell marker</p> <p>Antibody mediated rejection</p> <p>Parafollicular cells in thyroid and medullary thyroid carcinomas</p> <p>Muscular marker</p> <p>Muscular marker</p> <p>Neuroanatomical marker</p> <p>Langerhan's cell histiocytosis</p> <p>T cell marker</p> <p>T cell marker</p> <p>T-cell subset</p>	<p>Documented in-house methods and Roche Ultra Immunostainer manufacturer's instructions for:</p> <p>Automated Immunohistochemistry Methods LAB110, HISEXT/LAB029</p> <p>Actin</p> <p>Adenovirus</p> <p>AFP</p> <p>ALK</p> <p>B Catenin</p> <p>BCL2</p> <p>BCL6</p> <p>BOB-1</p> <p>C4d</p> <p>Calcitonin</p> <p>Caldesmon</p> <p>Calponin</p> <p>Calretinin</p> <p>CD1a</p> <p>CD2</p> <p>CD3</p> <p>CD4</p>



9890
Accredited to
ISO 15189:2012

Schedule of Accreditation
issued by
United Kingdom Accreditation Service
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

Birmingham Women's and Children's Hospital NHS Foundation Trust
Issue No: 005 Issue date: 14 June 2021

Testing performed at main address only

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
<p>HUMAN BODY TISSUE AND FLUIDS (cont'd):</p> <p>Formalin Fixed Paraffin Embedded Tissue (FFPE) sections on glass slides and non gynae cytology preparations: (cont'd)</p>	<p><u>Immunohistochemistry examination activities for the purposes of clinical diagnosis (cont'd):</u></p> <p>T cell marker</p> <p>T cell marker</p> <p>T-cell subset</p> <p>Used to aid classification of lymphomas/bone marrow biopsies</p> <p>Used to aid classification of lymphomas/bone marrow biopsies</p> <p>Demonstration of Reed-Sternberg and other cells</p> <p>Ag on B Lymphocytes</p> <p>Dendritic cell marker</p> <p>Reed-Sternberg cells</p> <p>Endothelial marker</p> <p>Endothelial cells / classification of soft tissue lesions</p> <p>T cell marker</p> <p>Lymphocytes</p> <p>Nerve and neuroendocrine cells</p> <p>Neural marker</p> <p>Megakaryocytes</p> <p>Macrophages and mononuclear cells</p>	<p>Documented in-house methods and Roche Ultra Immunostainer manufacturer's instructions for:</p> <p>Automated Immunohistochemistry Methods LAB110, HISXT/LAB029</p> <p>CD5</p> <p>CD7</p> <p>CD8</p> <p>CD10</p> <p>CD14</p> <p>CD15</p> <p>CD20</p> <p>CD21</p> <p>CD30</p> <p>CD31</p> <p>CD34</p> <p>CD43</p> <p>CD45</p> <p>CD56</p> <p>CD57</p> <p>CD61</p> <p>CD68</p>



9890
Accredited to
ISO 15189:2012

Schedule of Accreditation
issued by
United Kingdom Accreditation Service
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

Birmingham Women's and Children's Hospital NHS Foundation Trust
Issue No: 005 Issue date: 14 June 2021

Testing performed at main address only

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
<p>HUMAN BODY TISSUE AND FLUIDS (cont'd):</p> <p>Formalin Fixed Paraffin Embedded Tissue (FFPE) sections on glass slides and non gynae cytology preparations: (cont'd)</p>	<p><u>Immunohistochemistry examination activities for the purposes of clinical diagnosis (cont'd):</u></p> <p>Used to aid classification of B-cell lymphomas</p> <p>Used to aid classification of lymphomas/bone marrow biopsies Ewing's Sarcoma marker</p> <p>GIST, Haematopoietic progenitor, mast cells</p> <p>Langerhan's cells / soft tissue markers</p> <p>Haematopoietic progenitor</p> <p>Protein in gastro-intestinal cells</p> <p>Granules in neuroendocrine cells</p> <p>Used to aid classification of lymphomas</p> <p>Cytokeratin</p> <p>Cytokeratin in specific epithelium</p> <p>Cytokeratin in specific epithelium</p> <p>Pan cytokeratin marker</p> <p>Lymphatic endothelium</p> <p>Smooth and striated muscle cells</p> <p>Epstein-Barr virus</p> <p>Protein in epithelial cells</p>	<p>Documented in-house methods and Roche Ultra Immunostainer manufacturer's instructions for:</p> <p>Automated Immunohistochemistry Methods LAB110, HISEXT/LAB029</p> <p>CD79a</p> <p>CD99</p> <p>CD117</p> <p>CD163</p> <p>CD235a</p> <p>CEA</p> <p>Chromagranin A</p> <p>Cyclin D1</p> <p>CK AE1/AE3</p> <p>CK7</p> <p>CK19</p> <p>CK Pan</p> <p>D240</p> <p>Desmin</p> <p>EBER</p> <p>EMA</p>



9890
Accredited to
ISO 15189:2012

Schedule of Accreditation
issued by
United Kingdom Accreditation Service
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

Birmingham Women's and Children's Hospital NHS Foundation Trust
Issue No: 005 Issue date: 14 June 2021

Testing performed at main address only

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
<p>HUMAN BODY TISSUE AND FLUIDS (cont'd):</p> <p>Formalin Fixed Paraffin Embedded Tissue (FFPE) sections on glass slides and non gynae cytology preparations: (cont'd)</p>	<p><u>Immunohistochemistry examination activities for the purposes of clinical diagnosis (cont'd):</u></p>	<p>Documented in-house methods and Roche Ultra Immunostainer manufacturer's instructions for:</p>
		Automated Immunohistochemistry Methods LAB110, HISEXT/LAB029
	Dermal dendrocytes (skin / soft tissue markers)	Factor XIIIa
	Astrocytes, Schwann cells and peripheral nerve tumours	GFAP
	Infantile haemangioma	GLUT1
	B cell marker	Granzyme B
	Human Chorionic Gonadatrophin	HCG
	Hepatocyte differentiation	Hepatocyte
	Herpes	HSV
	Used to aid identification of melanomas	HMB45
	Juvenile granuloma cell	Inhibin
	Epitheliod sarcoma, atypical teratois / rhabdoid tumour	INI1
	Nuclear protein in proliferating cells	Ki67
	Langerhan's cell Histiocytosis	Langerin
	Lysosomes	Lysosome
Myeloma oncogene marker	MUM-1	
Neutrophils, granulocytic sarcoma	Myeloperoxidase	
Skeletal muscle	Myogenin	
Skeletal muscle differentiation	Myo D1	



9890
Accredited to
ISO 15189:2012

Schedule of Accreditation
issued by
United Kingdom Accreditation Service
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

Birmingham Women's and Children's Hospital NHS Foundation Trust
Issue No: 005 Issue date: 14 June 2021

Testing performed at main address only

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
<p>HUMAN BODY TISSUE AND FLUIDS (cont'd):</p> <p>Formalin Fixed Paraffin Embedded Tissue (FFPE) sections on glass slides and non gynae cytology preparations: (cont'd)</p>	<p><u>Immunohistochemistry examination activities for the purposes of clinical diagnosis (cont'd):</u></p> <p>Neuronal cell types</p> <p>Nerve fibres</p> <p>Neuronal cell marker</p> <p>B Cell marker</p> <p>B Cell marker</p> <p>Cell proliferation</p> <p>Demonstration of small nerve fibres in skin biopsies / neuroendocrine differentiation / neuroblastoma</p> <p>Expressed in neuroblastomas</p> <p>Enzyme produced by trophoblasts</p> <p>Expressed in a range of cell types</p> <p>SV40 virus</p> <p>Smooth muscle cells</p> <p>Demonstration of synaptophysin producing cells</p> <p>Differential leukaemia / lymphomas</p> <p>Nuclear protein in lung and thyroid</p> <p>Filament in mesenchymal cells</p> <p>Wilm's Tumour</p> <p>Vascular marker</p> <p>T cell subset</p>	<p>Documented in-house methods and Roche Ultra Immunostainer manufacturer's instructions for:</p> <p>Automated Immunohistochemistry Methods LAB110, HISEXT/LAB029</p> <p>NEUN</p> <p>Neurofilament</p> <p>NSE</p> <p>OCT-2</p> <p>PAX5</p> <p>P53</p> <p>PGP 9.5</p> <p>PHO2XB</p> <p>PLAP</p> <p>S100</p> <p>SV40</p> <p>SMA</p> <p>Synaptophysin</p> <p>TDT</p> <p>TTF1</p> <p>Vimentin</p> <p>WT1 Dako (N-Term)</p> <p>WT1 Dako (Vasc)</p> <p>UCHL1 (CD45RO)</p>



9890

Accredited to
ISO 15189:2012

Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

Birmingham Women's and Children's Hospital NHS Foundation Trust

Issue No: 005 Issue date: 14 June 2021

Testing performed at main address only

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY TISSUE AND FLUIDS: (cont'd) Slides prepared in house from samples listed above	<u>Histology examination activities for the purposes of clinical diagnosis.</u> Morphological assessment and interpretation/diagnosis	Microscopy (qualitative analysis) Light microscopes – Reporting Histopathology Specimens MED013, HISEXT/MED001, HISEXT/MED006, HISEXT/MED008, HISEXT/MED012
END		