

# Schedule of Accreditation

issued by

## United Kingdom Accreditation Service

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



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ISO 15189:2012

### University Hospitals Birmingham NHS Foundation Trust

Issue No: 004 Issue date: 03 September 2020

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Testing performed by the Organisation at the locations specified below

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

##### Laboratory locations:

Location details	Activity
<p><b>Address</b> Department of Musculoskeletal Pathology Royal Orthopaedic Hospital NHS Foundation Trust Robert Aitken Institute for Clinical Research University of Birmingham Birmingham B15 2TT</p> <p><b>Local contact</b> Satveer Kaur Tel: +44 (0)121 414 7642</p>	<p>Molecular Biology Histopathology</p>

#### 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>Fixed, fresh and frozen tissue including biopsy/open biopsy, curettage, resections and amputations</p> <p>Fixed, fresh and frozen tissue including biopsy/open biopsy, curettage, resections and amputations</p>	<p><u>Histopathology examination activities for the purpose of clinical diagnosis</u></p> <p>Examination of tissues to identify or exclude morphological abnormalities for the purpose of clinical diagnosis</p>	<p>Documented in-house methods and manufacturer's operating instructions as specified:</p> <p>Specimen Dissection:</p> <p>TR02 Pre- Examination Processes TR15 Dissection of Soft Tissue Tumour Resection Specimens TR16 Dissection of Bone Tumour Resection Specimens TR35 Specimen Disposal and Storage TR50 Loading Biopsies</p> <p>Bone Dissection using: AEW350 Bandsaw TR11 Use and Maintenance of the AEW350 Bandsaw</p>



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<p>HUMAN BODY TISSUE (cont'd)</p> <p>Fixed, fresh and frozen tissue including biopsy/open biopsy, curettage, resections and amputations</p> <p>Fresh tissue including biopsy/open biopsy, curettage, resections and amputations</p> <p>Fixed, fresh and frozen tissue including biopsy/open biopsy, curettage, resections and amputations</p> <p>Formalin- fixed and processed tissue (to paraffin wax) including biopsy/open biopsy, curettage, resections and amputations</p> <p>Formalin- fixed paraffin embedded tissue in tissue blocks</p>	<p><u>Histopathology examination activities for the purpose of clinical diagnosis (cont'd)</u></p>	<p>Documented in-house methods and manufacturer's operating instructions as specified:</p> <p>Decalcification of Bone using: Faxitron LX-60 AGFA CR-30X S1300R Refrigerated Shaking Incubator TR17 Decalcification TR68 Use and Maintenance of the Faxitron LX-60 TR69 Use and maintenance of the CR30X Specimen Radiography System TR79 Use and maintenance of the S1300R Refrigerated Shaking Incubator</p> <p>Frozen Sections and manual H&amp;E staining using: Leica CM1850 UV Cryostat LAB10 Use and maintenance of the Leica CM1850 UV Cryostat LAB52 Performing frozen sections</p> <p>Tissue Processing using : Leica ASP300 Leica ASP300s</p> <p>TR23 Use and maintenance of the Leica ASP 300 and ASP 300s</p> <p>Tissue Embedding using : Leica EG 1160 Embedding Centre</p> <p>LAB14 Embedding</p> <p>Microtomy using: Leica RM2245 LAB35 Microtomy</p>



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HUMAN BODY TISSUE (cont'd)	<u>Histopathology examination activities for the purpose of clinical diagnosis (cont'd)</u>	Documented in-house methods and manufacturer's operating instructions as specified:
Formalin- fixed paraffin wax-embedded tissue sections on microscope slides	Demonstration of general tissue architecture	Haematoxylin and Eosin Stain using: Thermo Shandon Gemini Varistainer LAB21 Haematoxylin and Eosin Staining LAB48 Use and maintenance of the Thermo Shandon Gemini Varistainer
Formalin- fixed paraffin wax-embedded tissue sections on microscope slides	Demonstration of:	Special Stains:
	PAS positive substances	LAB01 Special Stains LAB07 Control Tissue
	Glycogen	Periodic Acid Schiff (PAS)
	Iron	Periodic Acid Schiff + Diastase (PASD)
	Mycobacterium Tuberculosis (TB)	Perl's Prussian Blue
	Gram positive and negative bacteria	Ziehl- Neelsen
	Fungi	Gram's Stain
	Elastic fibres	Grocott
	Melanin	Elastic Van Gieson
	Amyloid	Masson Fontana
	Reticulin fibres	Congo Red
		Reticulin



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HUMAN BODY TISSUE (cont'd)	<u>Histopathology examination activities for the purpose of clinical diagnosis (cont'd)</u>	Documented in-house methods and manufacturer's operating instructions as specified:
Formalin- fixed paraffin embedded tissue sections on microscope slides	Demonstration of:	Roche Ventana Benchmark Ultra LAB 027 Immunohistochemistry using the antibodies below:
	Epithelial cells	AE1/AE3
	Yolk sac tumours	AFP
	Anaplastic large cell lymphoma, Inflammatory myofibroblastic tumour	ALK-1
	Scattered T cells in germinal centres and mantle zone B cells	Bcl-2
	Desmoid tumours	Beta- Catenin
	Epithelial cells	Ber-EP4
	Chordoma	Brachyury
	GI and Pancreatic carcinoma	CA19.9
	Serous ovarian carcinoma	CA125
	Medullary carcinoma	Calcitonin
	Smooth muscle cells	Caldesmon
	Mesothelial cells	Calretinin
	Ewing- like sarcoma BCOR-CCNB3	CCNB-3
	Dendritic cells and thymocytes	CD1a
	T cells	CD3
	T cells	CD4
	T cells	CD5
	All germinal centre cells	CD10



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HUMAN BODY TISSUE (cont'd)	<u>Histopathology examination activities for the purpose of clinical diagnosis (cont'd)</u>	Documented in-house methods and manufacturer's operating instructions as specified:
Formalin- fixed paraffin embedded tissue sections on microscope slides (cont'd)	Demonstration of: (cont'd)	Roche Ventana Benchmark Ultra LAB 027 Immunohistochemistry using the antibodies below:
	Hodgkin's lymphoma	CD15
	Germinal mantle zone B lymphocytes	CD20
	Mature B cells and follicular dendritic cells	CD21
	B cells	CD23
	Activated lymphocytes and plasma cells. RS cells in Hodgkin's lymphoma	CD30
	Endothelial cells, activated B and T lymphocytes	CD31
	Endothelial cells	CD34
	Low grade B cell lymphoma	CD43
	All leucocytes	CD45
	Neuroendocrine cells and plasma cells	CD56
	Macrophages	CD68
	B lymphocytes	CD79a
	MIC2 gene products	CD99
	Mast cell and GIST	CD117
	Plasma cells	CD138
	Carcinoma	CEA



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HUMAN BODY TISSUE (cont'd)	<u>Histopathology examination activities for the purpose of clinical diagnosis (cont'd)</u>	Documented in-house methods and manufacturer's operating instructions as specified:
Formalin- fixed paraffin embedded tissue sections on microscope slides (cont'd)	Demonstration of: (cont'd)	Roche Ventana Benchmark Ultra LAB 027 Immunohistochemistry using the antibodies below:
	Neuroendocrine	Chromogranin
	Mesothelial and epithelial cells	CK5
	Glandular and transitional epithelial cells	CK7
	Gastric and intestinal epithelium, urothelium and merkel cells	CK20
	Epithelial cells	CK MNF116
	Endothelial cells	COX-2
	Mantle cells (lymphocytes)	CyclinD1
	Smooth and striated muscle cells	Desmin
	T cells, macrophages	ERG
	Oestrogen receptor	Oestrogen Receptor
	Ewing's sarcoma	EYA3
	Ewing's sarcoma	Fli-1
	Kaposi sarcoma	HHV8
	Melanoma cells	HMB45
	Absence of expression on epithelioid sarcoma cells	Ini-1
	Proliferating cells in germinal centre B cells	Ki-67
	Melanocytes	Melan-A



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HUMAN BODY TISSUE (cont'd)	<u>Histopathology examination activities for the purpose of clinical diagnosis (cont'd)</u>	Documented in-house methods and manufacturer's operating instructions as specified:
Formalin- fixed paraffin embedded tissue sections on microscope slides (cont'd)	Demonstration of: (cont'd)	Roche Ventana Benchmark Ultra LAB 027 Immunohistochemistry using the antibodies below:
	Liposarcoma	MDM-2
	Acute myeloid leukaemia / granulocytic sarcoma	Myeloperoxidase
	Low grade myxoid fibrosarcoma	Muc-4
	Rhabdomyosarcoma	Myf-4
	Rhabdomyosarcoma	Myo-D1
	Rhadomyosarcoma	Myogenin
	Rhabdomyosarcoma	Myoglobin
	Neuroblastoma	NB84
	Neurons of the nervous system	NF
	Normal and neoplastic cells of neuronal and neuroendocrine origin	NSE
	Germ cell tumours, myoepitheliomas	Oct-04
	P53 protein	P53
	Squamous epithelium	P63
	Glandular epithelium of the prostate	PAP
	Renal cell carcinoma	PAX-8
	Germ cell tumours	PLAP
	Progesterone Receptor	PR



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HUMAN BODY TISSUE (cont'd)	<u>Histopathology examination activities for the purpose of clinical diagnosis (cont'd)</u>	Documented in-house methods and manufacturer's operating instructions as specified:
Formalin- fixed paraffin embedded tissue sections on microscope slides (cont'd)	Demonstration of: (cont'd)	Roche Ventana Benchmark Ultra LAB 027 Immunohistochemistry using the antibodies below:
	Prostate carcinoma	PSA
	Schwannoma, malignant melanoma	S100
	Osteoblast differentiation	SATB2
	Leiomyosarcoma	SMA
	Solitary fibrous tumour	STAT6
	Neuroendocrine	Synaptophysin
	Acute lymphoblastic lymphoma	TdT
	Alveolar soft part sarcoma	TFE-3
	Thyroid transcription factor - 1	TTF-1
	Lung and thyroid carcinoma	Thyroglobulin
	Thyroid carcinoma Synovial sarcoma	TLE-1
	Cytoskeleton and connective tissue Marker	Vimentin
	Acute myeloid leukaemia and angiosarcoma	VWF
	Wilms' tumour	WTI(C-19)
Formalin-fixed tissue sections of microscope slides	Morphological assessment and interpretation/ diagnosis	Light microscopy using Olympus BX51 (AST86) Olympus BX51TF (AST22). LAB08 Post Examination Processes





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<p>HUMAN BODY TISSUE (cont'd)</p> <p>Formalin- fixed paraffin embedded tissue and/or fresh frozen tissue</p> <p>RNA Extracted from formalin- fixed paraffin wax embedded tissue sections and/ or frozen tissue</p>	<p><u>Molecular Pathology examination activities for the purpose of clinical diagnosis</u></p> <p>Identification of:</p> <p>Alveolar Rhabdomyosarcoma: PAX3/FOXO1 PAX7/FOXO1</p> <p>Alveolar Sort Part Sarcoma: ASPCR1/TFE3</p> <p>Angiomatoid Fibrous Histiocytoma: EWSR1/ATF1 EWSR1/CREB1 FUS/ATF1</p> <p>Clear Cell Sarcoma: EWSR1/ATF1 EWSR1/CREB1 EWSR1/CREM</p> <p>Desmoplastic Small Round Cell Tumour: EXSR1/WT1</p>	<p>Documented in-house methods and manufacturer's operating instructions as specified:</p> <p>RNA Extraction using Qiagen RNeasy TCPCR01 RNA Extraction</p> <p>Thermal Cyclers – Bioer Life ECO Bioer Gene Touch</p> <p>Electrophoresis Equipment Consort EV243 Electrophoresis power supply Mini protean 3 system vertical tanks IBI horizontal tank Gel visualization – UVP BioDoc-it system Sony graphic printer UP-895CE</p> <p>TCPCR01 RNA Extraction TCPCR03 RT-PCR Technique TCPCR04 Gel Electrophoresis of PCR Products</p>



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<p>HUMAN BODY TISSUE (cont'd)</p> <p>RNA Extracted from formalin- fixed paraffin wax embedded tissue sections and/ or frozen tissue (cont'd)</p>	<p><u>Molecular Pathology examination activities for the purpose of clinical diagnosis</u></p> <p>Identification of: (cont'd)</p> <p>High Grade Endometrial Stromal Sarcoma: YWHAE/NUTM2A/B (FAM22)</p> <p>Low Grade Endometrial Stromal Sarcoma: JAZF1/SUZ12 MEAF6/PHF1</p> <p>Ewing's Sarcoma: EWSR1/FLI-1 EWSR1/ERG FUS/ERG</p> <p>Ewing's-like Sarcoma: BCOR/CCNB3 CIC/DUX4</p> <p>Extraskeletal Myxoid Chondrosarcoma: EWSR1/NR4A3 TAF2N/NR4A3</p>	<p>Documented in-house methods and manufacturer's operating instructions as specified:</p> <p>Thermal Cyclers - Bioer Life ECO - Bioer Gene Touch</p> <p>Electrophoresis Equipment Consort EV243 Electrophoresis power supply Mini protean 3 system vertical tanks IBI horizontal tank Gel visualization – UVP BioDoc-it system Sony graphic printer UP-895CE</p> <p>TCPCR01 RNA Extraction TCPCR03 RT-PCR Technique TCPCR04 Gel Electrophoresis of PCR Products</p>



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<p>HUMAN BODY TISSUE (cont'd)</p> <p>RNA Extracted from formalin- fixed paraffin wax embedded tissue sections and/ or frozen tissue (cont'd)</p>	<p><u>Molecular Pathology examination activities for the purpose of clinical diagnosis (cont'd)</u></p> <p>Identification of: (cont'd)</p> <p>Low Grade Fibromyxoid Sarcoma/ Sclerosing Epithelioid Fibrosarcoma: FUS/CREB3L2 FUS/CREB3L1 EWSR1/CREB3L2 EWSR1/CREB3L1</p> <p>Mesenchymal Chondrosarcoma: HEY1/NCOA2</p> <p>Myxoid Liposarcoma: FUS/DDIT3 EWSR1/DDIT3</p> <p>Synovial Sarcoma: SS18/SSX1 SS18/SSX2 SS18/SSX4</p>	<p>Documented in-house methods and manufacturer's operating instructions as specified:</p> <p>PCR Method (cont') using Thermal Cyclers:</p> <ul style="list-style-type: none"> <li>• Bioer Life ECO</li> <li>• Bioer Gene Touch</li> </ul> <p>Electrophoresis Equipment Consort EV243 Electrophoresis power supply Mini protean 3 system vertical tanks IBI horizontal tank Gel visualization – UVP BioDoc-it system Sony graphic printer UP-895CE TCPCR03 RT-PCR Technique TCPCR04 Gel Electrophoresis of PCR Products</p>
END		