


# Schedule of Accreditation

issued by

## United Kingdom Accreditation Service

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

 <p><b>UKAS</b> MEDICAL</p> <p>8680</p> <p>Accredited to ISO 15189:2012</p>	<h3>Royal National Orthopaedic Hospital NHS Trust</h3> <p>Issue No: 003    Issue date: 30 June 2021</p>	
	<p>Royal National Orthopaedic Hospital NHS Trust Brockley Hill Stanmore Middlesex HA7 4LP</p>	<p>Contact: Professor Adrienne Flanagan Tel: +44 (0)20 8909 5354</p> <p>E-Mail: <a href="mailto:adrienne.flanagan@rnoh.nhs.uk">adrienne.flanagan@rnoh.nhs.uk</a> Website: <a href="https://www.rnoh.nhs.uk/">https://www.rnoh.nhs.uk/</a></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
<p>HUMAN BODY TISSUE</p> <p>Fixed and fresh tissue; biopsies, excisional and surgical resection</p> <p>Biopsy / open biopsy Resections Curettage</p> <p>Amputation</p> <p>Fixed tissue</p>	<p>Histological examinations for the purpose of clinical diagnosis</p> <p>Examination of tissues to identify or exclude morphological abnormalities for the purposes of clinical diagnosis.</p>	<p>In-house documented procedures based on equipment manuals as relevant</p> <p><u>Specimen Dissection</u></p> <p>SOPTRI1 – Trimming Room Procedures</p> <p>SOPSCU1 – Surgical Cut-up</p> <p><u>Saws</u></p> <p>SOPL46 – EXakt saw</p> <p><u>Decalcification of bone</u> SOPL16-decalcification SOPL5-faxitron Biovision faxitron</p> <p><u>Tissue Processing</u> SOPL23 – for Leica ASP 300 Processor SOPL43 for Excelsior AS Processor x 2</p>



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HUMAN BODY TISSUE	Histological examinations for the purpose of clinical diagnosis	In-house documented procedures based on equipment manuals as relevant
Formalin Fixed tissue		<u>Tissue Embedding</u> SOPL14 – embedding procedures Leica embedding machine and cold plate
Formalin fixed paraffin embedded tissue		<u>Microtomy</u> SOPL15 – Microtomy Leica RM2245 microtomes
Formalin fixed paraffin embedded tissue	Identification of basophilic and eosinophilic structures	<u>Haematoxylin and Eosin stain</u> Automated and manual SOPL20 – Leica XL autostainer
Imprints – fixed	Special Stains to detect the following  Osteosarcoma	<u>Special staining</u> MP3 – Manual Staining  Alkaline phosphatase
Formalin-fixed paraffin embedded tissue	PAS +ve substances  Glycogen  Mycobacterium tuberculosis (TB)  Amyloid	Periodic acid Schiff (PAS) reaction  Diastase/Periodic Acid Schiff (PAS)  Ziehl Neelsen  Congo Red (Highman's)
	Epithelial cells	Automated SOPL10 –Immunohistochemistry SOPL 31 Leica Bond III  AE1/AE3
	Inflammatory myofibroblastic	ALK
	Scattered T cells in germinal centres and mantle zone B cells	BCI2



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HUMAN BODY TISSUE	Histological examinations for the purpose of clinical diagnosis	In-house documented procedures based on equipment manuals as relevant
Formalin-fixed paraffin-embedded tissue	Immunohistochemistry to detect the following	<u>Immunohistochemistry</u> Automated SOPL10 –Immunohistochemistry SOPL 31 Leica Bond III
	Chordoma	Brachyury
	Smooth muscle cells Myoepithelial cells	Caldesmon Calponin
	Dendritic cells and thymocytes	CD1a
	T cells	CD3
	All germinal centre cells	CD10
	Germinal mantle zone B lymphocytes	CD20
	Mature B cells and follicular dendritic cells	CD21
	Activated lymphocytes and plasma cells. RS cells in hodgkins lymphoma	CD30
	Endothelial cells, activated B and T lymphocytes	CD31
	Endothelial cells	CD34
	Dendritic cells	CD35
	All leucocytes	CD45
	Macrophages	CD68
	MIC2 gene products	CD99
	Mast cell and GIST	CD117
	Plasma cells	CD138



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Formalin-fixed paraffin-embedded tissue	Immunohistochemistry to detect the following	<u>Immunohistochemistry</u>
	Low molecular weight marker	CAM 5.2
	Neuroendocrine	Chromogranin A
	Glandular and transitional epithelia	Cytokeratin 20
	Gastrointestinal epithelia	Cytokeratin 20
	Smooth and striated muscle cells	Desmin
	GIST	DOG1
	Epithelial membrane	EMA
	Oestrogen receptor	ER
	T cells, macrophages	ERG
	Glial fibrillary acidic protein	GFAP
	Melanoma cells	HMB45
	Chondroblastoma cells	H3-K36M
	Absence of expression on epithelioid sarcoma cells	INI/BAF47
	Proliferating cells in germinal centre B cells	Ki67
	Melanocytes	Melan A
	Cytokeratins	MNF116
	Low grade myxoid fibrosarcoma	MUC-4
	Rhabdomyosarcoma	Myogenin
	Progesterone receptor	PR



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Formalin-fixed paraffin-embedded tissue	Immunohistochemistry to detect the following  Squamous epithelium  Prostate  Schwannoma, malignant melanoma  Leiomyosarcoma  Solitary fibrous tumour  Neuroendocrine  Acute lymphoblastic lymphoma  Thyroid transcription factor-1  Epithelioid haemangioendothelioma (EHE)  Pseudo myogenic haemangioendothelioma  Histone H3.3G34W mutant cells  Alveolar soft part sarcoma (ASPS), renal cell carcinoma, PEComas and Epithelioid haemangioendothelioma (EHE)  Epithelioid haemangiomas, osteoblastoma and osteoid osteoma	<u>Immunohistochemistry</u>  P63  PSA  S100  SMA  STAT-6  Synaptophysin  TdT  TTF1  CAMTA1  FOSB  H3.3G34W  TFE3  FOS
Formalin-fixed paraffin-embedded tissue	Morphological assessment and interpretation/diagnosis	<u>Interpretive Microscopy</u>  SOPSCU7 –microscopic reporting of cases



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<p>HUMAN BODY TISSUE</p> <p>Formalin-fixed paraffin-embedded tissue</p>	<p>Molecular examinations for the purpose of clinical diagnosis</p> <p>Detection of specific gene rearrangements in solid tumours</p> <p><b>Alveolar Rhabdomyosarcoma:</b> <i>FOXO1</i> gene rearrangement using break-apart probes. <i>PAX3/FOXO1</i> gene rearrangement using fusion probes <i>PAX7/FOXO1</i> gene rearrangement using fusion probes</p> <p><b>Aneurysmal bone cyst / Nodular Fasciitis:</b> <i>USP6</i> gene rearrangement using break-apart probes.</p> <p><b>Angiomatoid fibrous histiocytoma, Clear cell sarcoma, Desmoplastic small round cell tumour, Extraskeletal myxoid chondrosarcoma and PNET/ Ewing's sarcoma:</b> <i>EWSR1</i> gene rearrangement using break-apart probes.</p> <p><b>Atypical lipomatous tumour / well-differentiated liposarcoma, Dedifferentiated liposarcoma, Parosteal osteosarcoma</b> <i>MDM2</i> gene amplification analysis</p>	<p>In-house documented procedures based on equipment manuals as relevant</p> <p><u>Molecular Biology - Fluorescence <i>in situ</i> hybridisation (interphase FISH)</u> SOPM1 – interphase FISH SOPM2 – Molecular Pathology Laboratory org. SOPM5- Using the fluorescent microscope. Olympus BX61 SOPM6 – Preparing samples or molecular genetic studies</p>



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<p>HUMAN BODY TISSUE</p> <p>Formalin-fixed paraffin-embedded tissue</p> <p>Formalin-fixed paraffin-embedded tissue</p>	<p>Molecular examinations for the purpose of clinical diagnosis</p> <p>Detection of specific fusion transcripts in solid tumours</p> <p><b>Alveolar Rhabdomyosarcoma:</b> PAX3/FOXO1 PAX7/FOXO1</p> <p><b>Angiomatoid fibrous histiocytoma</b> EWSR1/CREB1 EWSR1/ATF1</p> <p><b>Alveolar soft part sarcoma</b> ASPSCR1/TFE3</p> <p><b>Clear cell sarcoma,</b> EWSR1/ATF1 EWSR1/CREB1</p> <p><b>Desmoplastic small round cell tumour:</b> EWSR1/WT1</p> <p><b>Extraskeletal myxoid chondrosarcoma:</b> EWSR1/NR4A3 TAF15/NR4A3</p> <p><b>Low-grade fibromyxoid sarcoma:</b> FUS/CREB3L2</p>	<p>In-house documented procedures based on equipment manuals as relevant</p> <p><u>Nucleic Acid Extraction</u> manual method using in house procedures SOPM3-</p> <p><u>Reverse Transcription-PCR RT-PCR</u> SOPM4 –PCR</p> <p>SOPM6 – Preparing samples or molecular genetic studies.</p>



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END		