Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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



8680

Accredited to ISO 15189:2022

Royal National Orthopaedic Hospital NHS Trust

Issue No: 007 Issue date: 15 August 2025

Royal National Orthopaedic Hospital NHS Trust

Brockley Hill

Stanmore

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Testing performed at the above address only

DETAIL OF ACCREDITATION

| | Type of test/Properties | Standard specifications/ |
|---------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Materials/Products tested | measured/Range of measurement | Equipment/Techniques used |
| HUMAN BODY TISSUE | Histological examinations for the purpose of clinical diagnosis | In-house documented procedures based on equipment manuals as relevant |
| Fixed and fresh tissue; biopsies, excisional and surgical resection | Examination of tissues to identify or exclude morphological abnormalities for the purposes of clinical diagnosis. | Specimen Dissection |
| Biopsy / open biopsy Resections Curettage | | SOPTRI1 – Trimming Room Procedures |
| Amputation | | SOPSCU1 – Surgical Cut-up |
| Fixed tissue | | Saws SOPL46 – EXakt saw Decalcification of bone SOPL16-decalcification SOPL5-faxitron Pathvision Tissue Processing Leica Histocore Pegasus Plus tissue processors SOPL54 |

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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 | | Tissue Embedding SOPL14 – embedding procedures Myr EC 500 embedding machine and cold plate |
| Formalin fixed paraffin embedded tissue | | Microtomy SOPL15 – Microtomy Leica RM2245 microtomes |
| Formalin fixed paraffin embedded tissue | Identification of basophilic and eosinophilic structures | Haematoxylin and Eosin stain Automated SOPL20 – Leica Histocore Spectra ST & CT |
| | Special Stains to detect the following | Special staining MP3 – Manual Staining |
| Imprints – fixed | Osteosarcoma | Alkaline phosphatase |
| Formalin-fixed paraffin embedded tissue | PAS +ve substances | Periodic acid Schiff (PAS) reaction |
| | Mycobacterium tuberculosis (TB) | Ziehl Neelsen |
| | Amyloid | Congo Red (Highman's) |
| | | Automated SOPL10 –Immunohistochemistry SOPL 31 Leica Bond III |
| | Epithelial cells | AE1/AE3 |
| | Inflammary 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> |
| lissue | Tollowing | Automated SOPL10 –Immunohistochemistry SOPL 31 Leica Bond III |
| | Chordoma | Brachyury |
| | Smooth muscle cells | Caldesmon |
| | Myoepithelial cells | Calponin Cyclin D1 |
| | 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 |
| | | CD23 |
| | Activated lymphocytes and plasma cells. RS cells in hodgkins lymphoma | CD30 |
| | Endothelial cells, activated B and T lymphocytes | CD31 |
| | Endothelial cells | CD34 |
| | All leucocytes | CD45 |
| | Macrophages | CD68 |
| | MIC2 gene products | CD99 |
| | Mast cell and GIST | CD117 |
| | Plasma cells | CD138 |

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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> |
| | 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 |
| | | H3K27me3 |
| | Absence of expression on epitheliod sarcoma cells | INI/BAF47 |
| | Proliferating cells in germinal centre B cells | Ki67 |
| | Melanocytes | Melan A |
| | Cytokeratins | MNF116 |
| | Low grade myxoid fibrosarcoma | MUC-4 |
| | Rhadomyosarcoma | Myogenin MYOD1 |
| | | |

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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> |
| | Progesterone receptor | PR |
| | Squamous epithelium | P63 |
| | Prostate | PSA Pan-TRK |
| | Schwannoma, malignant melanoma | S100 |
| | Leiomyosarcoma | SMA |
| | Solitary fibrous tumour | STAT-6 |
| | Neuroendocrine | Synaptophysin SMARCA4 SOX-10 |
| | Acute lymphoblastic lymphoma | TdT |
| | Thyroid transcription factor-1 | TTF1 |
| | Epithelioid haemangioendothelioma (EHE) | CAMTA1 |
| | Pseudo myogenic haemangioendothelioma | FOSB |
| | Histone H3.3G34W mutant cells | H3.3G34W |
| | Alveolar soft part sarcoma (ASPS), renal cell carcinoma, PEComas and Epithelioid haemangioendothelioma (EHE) | TFE3 |
| | Epithelioid haemangiomas, osteoblastoma and osteoid osteoma | FOS |
| | | |

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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 | Morphological assessment and interpretation/diagnosis | Interpretive Microscopy SOPSCU7 –microscopic reporting of cases |
| HUMAN BODY TISSUE | Molecular examinations for the purpose of clinical diagnosis | In-house documented procedures based on equipment manuals as relevant |
| Formalin-fixed paraffin-embedded tissue | Detection of specific gene rearrangements in solid tumours | Molecular Biology - Fluorescence in situ hybridisation (interphase FISH) SOPM1 - interphase FISH SOPM2 - Molecular Pathology Laboratory org. SOPM5- Using the fluorescent microscope. Olympus BX61 SOPM6 - Preparing samples or molecular genetic studies |
| | Alveolar Rhabdomyosarcoma: FOXO1 gene rearrangement using break-apart probes. PAX3/FOXO1 gene rearrangement using fusion probes PAX7/FOXO1 gene rearrangement using fusion probes Aneurysmal bone cyst / Nodular Fasciitis: USP6 gene rearrangement using break-apart probes. | |
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| HUMAN BODY TISSUE | Molecular examinations for the purpose of clinical diagnosis | In-house documented procedures based on equipment manuals as relevant Molecular Biology - Fluorescence in situ hybridisation (interphase FISH) SOPM1 - interphase FISH SOPM2 - Molecular Pathology Laboratory org. SOPM5- Using the fluorescent microscope. Olympus BX61 SOPM6 - Preparing samples or molecular genetic studies |
| | Angiomatoid fibrous histiocytoma, Clear cell sarcoma, Desmoplastic small round cell tumour, Extraskeletal myxoid chondrosarcoma and PNET/ Ewing's sarcoma: EWSR1 gene rearrangement using break-apart probes. Atypical lipomatous tumour / well-differentiated liposarcoma, Dedifferentiated liposarcoma, Parosteal osteosarcoma MDM2 gene amplification analysis | |

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| HUMAN BODY TISSUE | Molecular examinations for the purpose of clinical diagnosis | In-house documented procedures based on equipment manuals as relevant |
| Formalin-fixed paraffin-embedded tissue | Detection of specific gene rearrangements in solid tumours | Molecular Biology - Fluorescence in situ hybridisation (interphase FISH) SOPM1 - interphase FISH SOPM2 - Molecular Pathology Laboratory org. SOPM5- Using the fluorescent microscope. Olympus BX61 SOPM6 - Preparing samples or molecular genetic studies |
| | Desmoplastic small round cell tumour: WT1 gene rearrangement using break-apart probes. | |
| | Extraskeletal myxoid chondrosarcoma: NR4A3gene rearrangement using break-apart probes | |
| | Low-grade fibromyxoid sarcoma and Myxoid liposarcoma: FUS gene rearrangement using break apart probes | |
| | Myxoid liposarcoma: DDIT3 gene rearrangement using break-apart probes | |
| | Radiation-induced Angiosarcoma: c-MYC gene amplification analysis | |
| | Synvovial sarcoma: SS18 gene rearrangement using break-apart probes | |
| | Round cell carcinomas: | |
| | C/C gene rearrangement using break apart probes | |

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| HUMAN BODY TISSUE | Molecular examinations for the purpose of clinical diagnosis | In-house documented procedures based on equipment manuals as relevant |
| Formalin-fixed paraffin-embedded tissue | Detection of specific gene rearrangements in solid tumours | Molecular Biology - Fluorescence in situ hybridisation (interphase FISH) SOPM1 - interphase FISH SOPM2 - Molecular Pathology Laboratory org. SOPM5- Using the fluorescent microscope. Olympus BX61 SOPM6 - Preparing samples or molecular genetic studies |
| | Dermatofibrosarcoma protuberans: | molecular genetic statics |
| | COL1A1-PDGFB rearrangement using break apart probes | |
| | Alveolar Rhabdomyosarcoma: PAX3-FOXO1 gene rearrangement and PAX7-FOXO1 using fusion probes | |
| | | Nucleic Acid Extraction manual method using in house procedures SOPM3- |
| | Detection of specific fusion transcripts in solid tumours | Reverse Transcription-PCR RT-PCR SOPM4 -PCR |
| | | SOPM6 – Preparing samples or molecular genetic studies. |
| | Alveolar Rhabdomyosarcoma: PAX3/FOXO1 PAX7/FOXO1 | |
| | Angiomatoid fibrous histiocytoma EWSR1/CREB1 EWSR1/ATF1 | |
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| HUMAN BODY TISSUE | Molecular examinations for the purpose of clinical diagnosis | In-house documented procedures based on equipment manuals as relevant | |
| | | Nucleic Acid Extraction manual method using in house procedures SOPM3- | |
| | Detection of specific fusion transcripts in solid tumours | Reverse Transcription-PCR RT-PCR SOPM4 –PCR | |
| | | SOPM6 – Preparing samples or molecular genetic studies. | |
| | Alveolar soft part sarcoma ASPSCR1/TFE3 | | |
| | Clear cell sarcoma, EWSR1/ATF1 EWSR1/CREB1 | | |
| | Desmoplastic small round cell tumour: EWSR1/WT1 | | |
| | Extraskeletal myxoid chondrosarcoma: EWSR1/NR4A3 TAF15/NR4A3 | | |
| | Low-grade fibromyxoid sarcoma: FUS/CREB3L2 | | |
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| HUMAN BODY TISSUE | Molecular examinations for the purpose of clinical diagnosis | In-house documented procedures based on equipment manuals as relevant |
| Formalin-fixed paraffin-embedded tissue | Detection of specific fusion transcripts in solid tumours | Reverse Transcription-PCR RT-PCR SOPM4 –PCR Epperdorf Nexus SOPM6 – Preparing samples or molecular genetic studies. |
| | Mesenchymal chondrosarcoma: HEY1/NCOA2 | |
| | Myxoid liposarcoma: FUS/DDIT3 | |
| | Nodular Fasciitis: MYH9/USP6 | |
| | PNET/ Ewing's sarcoma: EWSR1/FLI1 EWSR1/ERG | |
| | Synvovial sarcoma: SS18/SSX1 SS18/SSX2 | |
| | Small round cell sarcomas: BCOR/CCNB3 | |
| | Epithelioid haemangioendothelioma: WWTR1/CAMTA1 | |
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| HUMAN BODY TISSUE | Molecular examinations for the purpose of clinical diagnosis | In-house documented procedures based on equipment manuals as relevant |
| Formalin-fixed paraffin-embedded tissue | Detection of specific point mutations in solid tumours for detection of specific fusion transcripts in solid tumours | PCR and Restriction enzyme digestion PCR SOPM4 –PCR Techne TC4000 SOPM6 – Preparing samples or molecular genetic studies. |
| | Desmoid-type fibromatosis: CTNNB1 mutation analysis – exon3- p.T41A, p.S45P and p.S34F substitutions | |
| | Fibrous dysplasia / intramuscular myxoma: GNAS1 mutation analysis p.R201H p.R201C and p.Q227L | |
| END | | |

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