


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

| | | |
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|  <p>Accredited to ISO 15189:2022</p> | <h3>Maidstone and Tunbridge Wells NHS Trust</h3> | |
| | <p>Issue No: 010 Issue date: 23 February 2025</p> | |
| | <p>Cellular Pathology Department Maidstone Hospital Hermitage Lane Maidstone ME16 9QQ</p> | <p>Contact: Hayley Williams Tel: +44 (0)1622 224040 E-Mail: Hayley.williams15@nhs.net</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 | <p><u>Histopathological examination activities for the purposes of clinical diagnosis</u></p> <p>Preparation and examination to identify or exclude morphological & cytological abnormalities</p> | <p>Documented in-house procedures</p> <p>Macroscopic and Microscopic examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant)</p> |
| Fresh tissue | <p>Rapid intra-operative for rapid examination of tissues to identify or exclude morphological abnormalities for the purpose of clinical diagnosis</p> | <p><u>Rapid frozen section</u></p> <p>Cryotomy using Cryostat CM1850 UV. RWF-CP-HIS- SOP9 RWF-CP-HIS-LI104</p> |
| Formalin fixed tissue unless specified | <p>Macroscopic examination of tissues to identify or exclude morphological abnormalities for the purpose of clinical diagnosis</p> | <p><u>Macroanalysis and dissection</u></p> <p>Manual method using: SOP's: RWF-CP-HIS-SOP2 RWF-CP-HIS-SOP3 RWF-CP-HIS-SOP4 RWF-CP-HIS-SOP5</p> |
| Formalin fixed tissue | | <p><u>Decalcification</u></p> <p>Manual method using: RWF-CP-HIS-SOP6</p> |



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| HUMAN BODY TISSUE (cont'd) Formalin fixed tissue (cont'd) | <u>Histopathology</u> (cont'd) Tissue Processing | Documented in-house procedures <u>Tissue Processing</u> Automated method using: Leica Histocore Peloris III tissue processor RWF-CP-HIS-SOP73 |
| Formalin fixed tissue, processed to paraffin wax | Embedding | <u>Embedding</u> Manual method using: Leica HistoCore Arcadia H Embedding Centre and HistoCore Arcadia C Coldplate RWF-CP-HIS-SOP36 |
| Formalin fixed, paraffin embedded (FFPE) Tissue | Microtomy | <u>Microtomy</u> Manual method using: Leica RM2135, Leica RM2235 and Ergostar microtomes RWF-CP-HIS-SOP37 |
| Formalin fixed, paraffin embedded (FFPE) tissue | Demonstration of tissue morphology including nuclei and connective tissue | <u>Routine Haematoxylin & Eosin (H&E) staining and coverslipping</u> Automated method using: Sakura Tissue-Tek Prisma Stainer, Sakura Tissue-Tek Film Coverslipper. RWF-CP-HIS-SOP41 |
| Formalin fixed, paraffin embedded (FFPE) tissue | Detection of acid and neutral mucins | <u>Special stains</u> PAS, PASD, ABPAS and ABPASD stains and automated method using: Sakura Tissue-Tek Prisma Stainer, Sakura Tissue-Tek Film Coverslipper RWF-CP-HIS-SOP41 |



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| HUMAN BODY TISSUE (cont'd) Formalin fixed, paraffin embedded (FFPE) tissue | <u>Histopathology</u> (cont'd) Detection of: Acid and neutral mucins Amyloid Calcium deposits Elastic fibres and connective tissue Haematopoeiectic cells <i>Helicobacter pylori</i> Bacteria Nuclei and connective tissue Mucins and glycogen Fungi and pneumocystis Melanin Connective tissue, muscle and fibrin Fibrin Hepatitis B surface antigen and copper associated protein Iron (ferric) | Documented in-house procedures <u>Special staining</u> Manual methods using documented in-house procedures (RWF-CP-HIS-SOP71 and stains as indicated: Alcian blue (RWF-CP-HIS-LI34) ABPAS, ABPASD(RWF-CP-HIS-LI127) Congo Red (RWF-CP-HIS-LI37) Von Kossa (RWF-CP-LI139) EVG (RWF-CP-HIS-LI40) Modified Giemsa (RWF-CP-HIS-LI43) Giemsa for helicobacter (RWF-CP-HIS-LI41) Gram (RWF-CP-HIS-LI44) HVG (RWF-CP-LI108) PAS and DPAS (RWF-CP-HIS-LI127) Grocott (RWF-CP-HIS-LI45) Masson Fontana (RWF-CP-HIS-LI111) Melanin bleach (RWF-CP-HIS-LI111) Masson Trichrome (RWF-CP-HIS-LI124) MSB (RWF-CP-HIS-LI125) Orcein (RWF-CP-HIS-LI129) Perls' (RWF-CP-HIS-LI129) |



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| HUMAN BODY TISSUE (cont'd) | <u>Histopathology</u> (cont'd) | Documented in-house procedures |
| Formalin fixed, paraffin embedded (FFPE) tissue (cont'd) | Detection of: (cont'd) | <u>Special staining</u> |
| | Reticulin fibres | Reticulin (RWF-CP-HIS-LI131) |
| | Mast cells | Toluidine Blue (RWF-CP-HIS-LI138) |
| | <i>Mycobacterium leprae</i> | Wade Fite (RWF-CP_HISLI140) |
| | Spirochetes | Warthin Starry (RWF-CP-HIS-LI141) |
| | Mycobacterium spp inc.tuberculosis | ZN (RWF-CP-LI142) |
| Formalin fixed, paraffin embedded (FFPE) tissue | Detection of: | <u>Immunocytochemistry</u> |
| | | Documented in house procedures in conjunction with manufacturer's instructions for Ventana Benchmark Ultra procedure: RWF-CP-HIS-SOP61 and incorporating the following antibodies: |
| | Broad spectrum cytokeratins | AE1/AE3 |
| | Foetal liver cells | AFP |
| | Anaplastic large-cell lymphomas | ALK-1 |
| | Lymphocytes from mantle zone | Bcl-2 |
| | Follicular centre cells | Bcl-6 |
| | Epithelial cells | BerEp4 |
| | Epithelial cell membrane | β-Catenin |
| | Luminal cells of fallopian tubes | Ca125 |
| | Mesothelial cell lining | Calretinin |
| | Parafollicular (c-cells) | Calcitonin |
| | Smooth muscle | Caldesmon |



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| HUMAN BODY TISSUE (cont'd) Formalin fixed, paraffin embedded (FFPE) tissue (cont'd) | <u>Histopathology</u> (cont'd) Detection of: (cont'd) Low molecular weight cytokeratin Dendritic cells: cortical thymocytes: Langerhans cells Peripheral blood T cells T cell marker Helper/inducer sub-population of normal T cells T and B cells in mantle zone Mature T-cells Cytotoxic/suppressor T cells Immature B-cells Myeloid cells and RS cells B cells Follicular dendritic cells/mature B cells FDC and EBV transformed blasts RS cells Endothelial cells Vascular endothelial cells T cell activation Leukocytes Neurons, Schwann cells, NK cells and subset of activated T cells Platelets, megakaryocytes and platelet thrombi | Documented in-house procedures <u>Immunocytochemistry</u> Cam5.2 CD1a CD2 CD3 CD4 CD5 CD7 CD8 CD10 CD15 CD20 CD21 CD23 CD30 CD31 CD34 CD43 CD45 CD56 CD61 |



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| HUMAN BODY TISSUE (cont'd) Formalin fixed, paraffin embedded (FFPE) tissue (cont'd) | <u>Histopathology</u> (cont'd) Detection of: (cont'd) Macrophages Red blood and erythroid precursor cells Mature B cells Leukocytes and thymocytes Interstitial Cajal Cells Plasma cells Intestinal epithelial cells Carcinoembryonic antigen Neuroendocrine tumours Stratified squamous epithelia; basal cells of complex epithelia. Glandular and transitional epithelia Epithelial cells Gastrointestinal epithelia CMV Cellular proliferation marker, Mantel cell lymphoma Smooth muscle cells intermediate filament GIST Lymphatic vessels Cell adhesion molecule EBV | Documented in-house procedures <u>Immunocytochemistry</u> CD68 CD71 CD79a CD99 CD117 CD138 CD-X2 CEA Chromogranin A CK5/6 CK7 CK19 CK20 CMV Cyclin D1 Desmin DOG-1 D2-40/Podoplanin E-cadherin EBV |



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| HUMAN BODY TISSUE (cont'd) Formalin fixed, paraffin embedded (FFPE) tissue (cont'd) | <u>Histopathology</u> (cont'd) Detection of: (cont'd) Epithelial membrane antigen Oestrogen receptor Gross cystic disease fluid protein - 15 Trophoblasts Melanoma Human herpes virus 8 Normal adult human hepatocytes Leydig, Sertoli cells Ig light chain High molecular weight cytokeratin Proliferation marker Ig light chain Melanoma Broad spectrum cytokeratin B cells and plasma cells Human myeloperoxidase Oct 3/4 protein in germ cell tumours HPV marker Neoplastic prostate glands Tumour suppressor gene p57 protein (Kip 2) Basal cell marker | Documented in-house procedures <u>Immunocytochemistry</u> EMA ER GCDFP-15 HCG (beta) HMB45 HHV8 HSA Inhibin Kappa Ker903 MIB-1 (Ki67) Lambda Melan A MNF116 MUM-1 Myeloperoxidase Oct 3/4 P16 P504S (AMACR) P53 P57 P63 |



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| HUMAN BODY TISSUE (cont'd) Formalin fixed, paraffin embedded (FFPE) tissue (cont'd) | <u>Histopathology</u> (cont'd) Detection of: (cont'd) Placental alkaline phosphatase Prostate adenocarcinoma versus BPH Progesterone receptor Prostate specific antigen Prostatic acid phosphatase NSCLC Melanoma and neuroendocrine Neural crest and Schwann cells Mantal cell lymphoma Mesenchymal marker Neuroendocrine marker Bone marrow lymphocytes and immature lymphoid cells Thyroid follicles Thyroid transcription factor 1 Mesenchymal marker Wilms tumour protein Adenocarcinoma and malignant mesothelioma Lung adenocarcinoma, SCC and mesothelioma B-cell lymphomas | Documented in-house procedures <u>Immunocytochemistry</u> PLAP PIN-4 cocktail PR PSA PSAP ROS-1 (SP384) S100 SOX10 SOX11 SMA Synaptophysin Tdt Thyroglobulin TTF-1 Vimentin WT1 MOC-31 Napsin-A PAX-5 |



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| <p>HUMAN BODY TISSUE (cont'd)</p> <p>Formalin fixed, paraffin embedded (FFPE) tissue (cont'd)</p> | <p><u>Histopathology</u> (cont'd)</p> <p>Detection of: (cont'd)</p> <p>Renal cell carcinoma, thyroid carcinoma and ovarian carcinoma</p> <p>Metastatic urothelial and breast carcinomas</p> <p>Squamous cell carcinomas, urothelial carcinomas and rare cases of lung adenocarcinomas.</p> <p>Prostate adenocarcinoma</p> <p>Breast cancer</p> <p>Mismatch repair proteins</p> <p>NSCLC</p> <p>NSCLC</p> | <p>Documented in-house procedures</p> <p><u>Immunocytochemistry</u></p> <p>PAX-8</p> <p>GATA3</p> <p>P40</p> <p>NKX3.1</p> <p>HER-2 (4B5)</p> <p>MLH-1 MSH-2 MSH-6 PMS-2</p> <p>ALK-1 (D5F3)</p> <p>PD-L1 (SP263)</p> |



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| <p>HUMAN BODY TISSUE (cont'd)</p> <p>Slides prepared in-house from sample types specified above</p> | <p><u>Histopathology</u> (cont'd)</p> <p>Morphological assessment and interpretation/ diagnosis</p> | <p>Documented in-house procedures</p> <p><u>Microscopy/ qualitative analysis</u></p> <p>In house procedures: RWF-CP-SOP22 RWF-CP-HIS-SOP32 RWF-CP-SOP20</p> <p>Using microscopes as follows: Olympus BX40 Olympus BX41 Olympus BX45TF Olympus BX50 Olympus BX51 Leica DM400B Leica DMR Zeiss Axioplan Zeiss Axioscope Zeiss Eurostar Nikon Eclipse E800 Nikon Eclipse 80i Nikon Eclipse E400 Nikon Eclipse 50i Laborlux S</p> |



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| <p>HUMAN BODY TISSUE (cont'd)</p> <p>Formalin fixed, paraffin embedded tissues</p> | <p><u>Histopathology</u> (cont'd)</p> <p>Qualitative detection of mutations in codons 12, 13, 59, 61, 117 or 146 of the KRAS oncogene</p> <p>Qualitative detection of exon 18 (G719A/C/S), exon 21 (L858R, L861Q), exon 20 (T790M, S768I) mutations, exon 19 deletions and exon 20 insertions in the EGFR oncogene</p> <p>Qualitative detection of mutations in codons 12, 13, 59, 61, 117 and 146 of the NRAS gene and codon 600 of the BRAF gene</p> <p>Qualitative detection of specific gene fusions of ALK, ROS1, RET and MET exon 14 skipping</p> <p>Qualitative detection of V600E/E2/D and V600K/R/M mutations in codon 600 of the BRAF gene</p> | <p>Documented in-house procedures</p> <p>Biocartis Idylla™ console, instrument and associated test cartridges (RWF-CP-MOL-SOP31)</p> |



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| <p>HUMAN BODY FLUIDS</p> <p>Body fluids: CSF, urine, body cavity fluids, bronchial brushings, washings, serous fluids, FNA</p> | <p><u>Cytopathology (Non-Gynae) examination activities for the purposes of clinical diagnosis</u></p> <p>Non-gynae cytology examination of cellular material in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis</p> | <p>Documented in-house procedures</p> <p>Macroscopic and microscopic examination</p> <p><u>Preparation/ centrifugation</u></p> <p>Documented in house procedures in conjunction with manufacturer's instructions using: Heraeus megafuge 1.0 and Hettich Rotina 380 centrifuge, Hettich 32 Cytocentrifug, class I safety cabinet, Heraeus</p> <p>Shandon Cytospin 3 RWF-CP-CYT-SOP1 RWF-CP-CYT-SOP14</p> <p>RWF-CP-CYT-SOP3</p> <p><u>Papanicolaou staining</u></p> <p>Documented in house procedures in conjunction with manufacturer's instructions using: Leica stainer/coverslipper ST5020/CV5030 RWF-CP-CYT-SOP14</p> <p><u>May Grunwald Giemsa staining</u></p> <p>Documented in house procedures in conjunction with manufacturer's instructions using: Leica stainer ST5020 RWF-CP-CYT-SOP14</p> |



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| <p>HUMAN BODY FLUIDS (cont'd)</p> <p>Slides prepared in-house from sample types specified above</p> <p>Formalin fixed, paraffin embedded tissue</p> | <p><u>Cytopathology (Non-Gynae) examination activities for the purposes of clinical diagnosis</u> (cont'd)</p> <p>Morphological assessment and interpretation/ diagnosis</p> <p>Fluorescent in-situ Hybridisation for the detection of:</p> <p>HER-2 amplification</p> | <p>Documented in-house procedures</p> <p><u>Microscopy/ qualitative analysis</u></p> <p>In house procedures: RWF-CP-SOP22 RWF-CP-HIS-SOP32 RWF-CP-SOP20 Using microscopes as follows: Olympus BX40 Olympus BX41 Olympus BX45TF Olympus BX50 Olympus BX51 Leica DM400B Leica DMR Zeiss Axioplan Zeiss Axioscope Zeiss Eurostar Nikon Eclipse E800 Nikon Eclipse 80i Nikon Eclipse E400 Nikon Eclipse 50i Laborlux S</p> <p><u>Fluorescent in-situ Hybridisation</u></p> <p>Using documented in-house procedures in conjunction with manufacturer's instructions for VP2000</p> <p>HER-2 / CEP17 dual target probe (RWF-CP-MOL-SOP6)</p> <p>Using Fluorescence microscope Olympus BX41</p> |
| END | | |