


# Schedule of Accreditation

issued by

## United Kingdom Accreditation Service

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

|  |   |  |
|--|---|--|
| <br><b>UKAS</b><br>MEDICAL<br><b>8062</b><br><br>Accredited to<br><b>ISO 15189:2012</b> | <b>Maidstone and Tunbridge Wells NHS Trust</b>  |  |
|  | Issue No: 005    Issue date: 20 February 2023   |  |
|  | <b>Cellular Pathology Department</b><br><b>Maidstone Hospital</b><br><b>Hermitage Lane</b><br><b>Maidstone</b><br><b>ME16 9QQ</b> | <b>Contact: Mrs Theresa Welfare</b><br><b>Tel: +44 (0)1622 227238</b><br><b>E-Mail: <a href="mailto:theresa.welfare@nhs.net">theresa.welfare@nhs.net</a></b> |
| <b>Testing performed at the above address only</b>   |   |  |

### Activities performed away from the location listed above:

| Location details   |   | Activity                                     |
|--|---|--|
| <b>Address</b><br>Maidstone Hospital<br>Hermitage Lane<br>Maidstone<br>ME16 9QQ            | <b>Local Contact</b><br>Theresa Welfare | Body Store: body storage, and release        |
| <b>Address</b><br>Tunbridge Wells Hospital<br>Tonbridge Road<br>Tunbridge Wells<br>TN2 4QJ | <b>Local Contact</b><br>Theresa Welfare | Mortuary services: body storage, and release |



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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>Fresh tissue</p> <p>Formalin fixed tissue unless specified</p> <p>Formalin fixed tissue</p> <p>Formalin fixed tissue</p> | <p><u>Histopathological examination activities for the purposes of clinical diagnosis</u></p> <p>Preparation and examination to identify or exclude morphological &amp; cytological abnormalities</p> <p>Rapid intra-operative for rapid examination of tissues to identify or exclude morphological abnormalities for the purpose of clinical diagnosis</p> <p>Examination of tissues to identify or exclude morphological abnormalities for the purpose of clinical diagnosis</p> | <p>Macroscopic and Microscopic examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant)</p> <p><u>Rapid frozen section</u></p> <p>Cryotomy using Cryostat CM1850 UV.<br/>RWF-CP-HIS- SOP9</p> <p>Manual Haematoxylin &amp; Eosin (H&amp;E) staining method using:</p> <p><u>Macroanalysis and dissection</u></p> <p>Manual method using:<br/>SOP's:<br/>RWF-CP-HIS-SOP3, HIS-SOP4, RWF-CP-HIS-SOP5, HIS-SOP26</p> <p><u>Decalcification</u></p> <p>Manual method using:<br/>RWF-CP-HIS-SOP6</p> <p><u>Tissue Processing</u></p> <p>Automated method using:<br/>Sakura VIP6<br/>Sakura VIP5<br/>Sakura VIP6AI tissue processor<br/>RWF-CP-HIS-SOP72<br/>RWF-CP-HIS-SOP29</p> |



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| <p>HUMAN BODY TISSUE (cont'd)</p> <p>Formalin fixed tissue, processed to paraffin wax</p> <p>Formalin fixed, paraffin embedded (FFPE) Tissue</p> <p>Formalin fixed, paraffin embedded (FFPE) tissue</p> <p>Formalin fixed, paraffin embedded (FFPE) tissue</p> | <p><u>Histopathology</u> (cont'd)</p> <p>Nuclei and connective tissue</p> <p>Detection of acid and neutral mucins</p> | <p>Documented in-house procedures</p> <p><u>Embedding</u></p> <p>Manual method using:<br/>Leica Embedding Centre EG1160,<br/>Leica HistoCore Arcadia H<br/>Embedding Centre and HistoCore<br/>Arcadia C Coldplate<br/>RWF-CP-HIS-SOP36</p> <p><u>Microtomy</u></p> <p>Manual method using:<br/>Leica RM2135,<br/>Leica RM2235 and Ergostar<br/>microtomes<br/>RWF-CP-HIS-SOP37</p> <p><u>Routine Haematoxylin &amp; Eosin (H&amp;E) staining and coverslipping</u></p> <p>Automated method using:<br/>Sakura Tissue-Tek Prisma Stainer,<br/>Sakura Tissue-Tek Film<br/>Coverslipper.<br/>RWF-CP-HIS-SOP41</p> <p>Manual haematoxylin and eosin<br/>staining H&amp;E<br/>RWF-CP-HIS-SOP22</p> <p>Manual method using:<br/>RWF-CP-HIS-SOP43</p> <p><u>Special stains</u></p> <p>PAS, PASD, ABPAS and ABPASD<br/>stains and automated method<br/>using:<br/>Sakura Tissue-Tek Prisma Stainer,<br/>Sakura Tissue-Tek Film<br/>Coverslipper<br/>RWF-CP-HIS-SOP41</p> |



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| HUMAN BODY TISSUE (cont'd)<br>Formalin fixed, paraffin embedded (FFPE) tissue | <u>Histopathology</u> (cont'd)<br>Detection of:<br><br>Acid and neutral mucins<br><br>Amyloid<br><br>Calcium deposits<br><br>Elastic fibres and connective tissue<br><br>Haematopoietic cells<br><br>Helicobacter<br><br>Bacteria<br><br>Nuclei and connective tissue<br><br>Mucins and glycogen<br><br>Fungi and pneumocystis<br><br>Melanin<br><br>Connective tissue<br><br>Fibrin<br><br>Hepatitis B surface antigen and copper associated protein<br><br>Iron (ferric) | Documented in-house procedures<br><br><u>Special staining</u><br><br>Manual methods using documented in-house procedures and stains as indicated:<br><br>Alcian blue (HIS-SOP10)<br>ABPAS (RWF-CP-HIS-SOP11)<br>ABPASD (RWF-CP-HIS-SOP12)<br><br>Congo Red (RWF-CP-HIS-SOP13)<br><br>Von Kossa (RWF-CP-HIS-SOP57)<br><br>EVG (HIS-SOP15)<br><br>Modified Giemsa (RWF-CP-HIS-SOP17)<br><br>Giemsa for helicobacter (RWF-CP-HIS-SOP16)<br><br>Gram (RWF-CP-HIS-SOP20)<br><br>HVG (RWF-CP-HIS-SOP46)<br><br>PAS (HIS-SOP52) and DPAS (RWF-CP-HIS-SOP53)<br><br>Grocott (RWF-CP-HIS-SOP21)<br><br>Masson Fontana (RWF-CP-HIS-SOP47)<br>Melanin bleach (RWF-CP-HIS-SOP48)<br><br>Masson Trichrome (RWF-CP-HIS-SOP49)<br><br>MSB (HIS-SOP50)<br><br>Orcein (RWF-CP-HIS-SOP51)<br><br>Perls RWF-CP-HIS-SOP54 |



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| HUMAN BODY TISSUE (cont'd)<br>Formalin fixed, paraffin embedded (FFPE) tissue (cont'd) | <u>Histopathology</u> (cont'd)<br>Detection of: (cont'd)<br>Reticulin fibres<br>Mast cells<br>Mycobacterium leprae<br>Spirochetes<br>Mycobacterium spp inc.tuberculosis<br>Detection of:<br><br>Broad spectrum cytokeratins<br>Foetal liver cells<br>Anaplastic large-cell lymphomas<br>Tumours of epithelial origin<br>Lymphocytes from mantle zone<br>Follicular centre cells<br>Epithelial cells<br>Epithelial cell membrane<br>Luminal cells of fallopian tubes<br>Mesothelial cell lining<br>Parafollicular (c-cells) | Documented in-house procedures<br><u>Special staining</u><br>Reticulin (RWF-CP-HIS-SOP55)<br>Toluidine Blue (HIS-SOP56)<br>Wade Fite (RWF-CP-HIS-SOP58)<br>Warthin Starry (RWF-CP-HIS-SOP59)<br>ZN (RWF-CP-HIS-SOP60)<br><u>Immunocytochemistry</u><br>Documented in house procedures in conjunction with manufacturer's instructions for Ventana Ultra Immunostainer, procedures: RWF-CP-HIS-SOP61, , RWF-CP-HIS-L1288 and incorporating the following antibodies:<br>AE1/AE3<br>AFP<br>ALK-1<br>AUA-1<br>Bcl-2<br>Bcl-6<br>Ber EP4<br>$\beta$ -Catenin<br>Ca125<br>Calretinin<br>Calcitonin |



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



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| HUMAN BODY TISSUE (cont'd)<br><br>Formalin fixed, paraffin embedded (FFPE) tissue (cont'd) | <u>Histopathology</u> (cont'd)<br><br>Detection of: (cont'd)<br><br>Platelets, megakaryocytes and platelet thrombi<br><br>Macrophages<br><br>B cells<br>Leukocytes and thymocytes<br><br>c-kit<br><br>Plasma cells<br><br>Intestinal epithelial cells<br><br>Carcinoembryonic antigen<br><br>Neuroendocrine<br><br>Epithelial and mesothelial cells<br><br>Stratified squamous epithelia; basal cells of complex epithelia.<br><br>Glandular and transitional epithelia<br><br>Epithelial cells<br><br>Gastrointestinal epithelia<br><br>CMV<br><br>Mantel cell lymphoma<br><br>Intermediate filament<br><br>GIST<br><br>Cell adhesion molecule<br><br>EBV<br><br>Epithelial membrane antigen | Documented in-house procedures<br><br><u>Immunocytochemistry</u><br><br>CD61<br><br>CD68<br><br>CD79a<br>CD99<br><br>CD117<br><br>CD138<br><br>CD-x2<br><br>CEA<br><br>Chromogranin A<br><br>CK5<br><br>CK5/6<br><br>CK7<br><br>CK19<br><br>CK20<br><br>CMV<br><br>Cyclin D1<br><br>Desmin<br><br>DOG-1<br><br>E-cadherin<br><br>EBV<br><br>EMA |



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| HUMAN BODY TISSUE (cont'd)<br><br>Formalin fixed, paraffin embedded (FFPE) tissue (cont'd) | <u>Histopathology</u> (cont'd)<br><br>Detection of: (cont'd)<br><br>Oestrogen receptor<br><br>Gross cystic disease fluid protein - 15<br><br>Trophoblasts<br><br>Epidermal growth factor<br><br>Melanoma<br><br>Human herpes virus 8<br><br>Normal adult human hepatocytes<br><br>Mu-chains of human IgM<br><br>Leydig, sertoli cells<br><br>Ig Light chain<br><br>High molecular weight cytokeratin<br><br>Proliferation marker<br><br>Ig light chain<br><br>Melanoma<br><br>Broad spectrum cytokeratin<br><br>B cells and plasma cells<br><br>Human myeloperoxidase<br><br>Oct 3/4 protein in germ cell tumours<br><br>HPV marker<br><br>Neoplastic prostate glands | Documented in-house procedures<br><br><u>Immunocytochemistry</u><br><br>ER<br><br>GCDFP-15<br><br>HCG (beta)<br><br>Her-2<br><br>HMB45<br><br>HHV8<br><br>HSA<br><br>IgM<br><br>Inhibin<br><br>Kappa<br><br>Ker903<br><br>MIB-1 (Ki67)<br><br>Lambda<br><br>Melan A<br><br>MNF116<br><br>MUM-1<br><br>Myeloperoxidase<br><br>Oct 3/4<br><br>P16<br><br>P504S |





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| HUMAN BODY TISSUE (cont'd)<br>Formalin fixed, paraffin embedded (FFPE) tissue (cont'd) | <u>Histopathology</u> (cont'd)<br>Detection of: (cont'd)<br>Tumour suppressor gene<br>p57 protein (Kip 2)<br>Basal cell marker<br>Placental alkaline phosphatase<br>Progesterone receptor<br>Prostate specific antigen<br>Prostatic acid phosphatase<br>Melanoma and neuroendocrine<br>Mesenchymal marker<br>Neuroendocrine marker<br>Bone marrow Lymphocytes & immature lymphoid cells<br>Thyroid follicles<br>Thyroid transcription factor 1<br>Mesenchymal marker<br>Wilms tumour protein<br>MOC-31<br>Naspin-A<br>PAX-5<br>PAX-8 | Documented in-house procedures<br><u>Immunocytochemistry</u><br>P53<br>P57<br>P63<br>PLAP<br>PR<br>PSA<br>PSAP<br>S100<br>SMA<br>Synaptophysin<br>Tdt<br>Thyroglobulin<br>TTF-1<br>Vimentin<br>WT1<br>adenocarcinoma and malignant mesothelioma<br>lung adenocarcinoma, SCC and mesothelioma<br>B-cell lymphomas<br>renal cell carcinoma, thyroid carcinoma and ovarian carcinoma |



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| <p>HUMAN BODY TISSUE (cont'd)</p> <p>Formalin fixed, paraffin embedded (FFPE) tissue (cont'd)</p> <p>Slides prepared in-house from sample types specified above</p> | <p><u>Histopathology</u> (cont'd)</p> <p>Detection of: (cont'd)</p> <p>GATA3</p> <p>P40</p> <p>NKX3.1</p> <p>Morphological assessment and interpretation/ diagnosis</p> | <p>Documented in-house procedures</p> <p><u>Immunocytochemistry</u></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><u>Microscopy/ qualitative analysis</u></p> <p>In house procedures:<br/>RWF-CP-SOP22<br/>RWF-CP-HIS-SOP32<br/>RWF-CP-SOP20<br/>RWF-CP-HIS-SOP25<br/>Using microscopes as follows:<br/>Olympus BX40<br/>Olympus BX41<br/>Olympus BX45TF<br/>Olympus BX50<br/>Olympus BX51<br/>Leica DM400B<br/>Leica DMR<br/>Zeiss Axioplan<br/>Zeiss Axioscope<br/>Zeiss Eurostar<br/>Nikon Eclipse E800<br/>Nikon Eclipse 80i<br/>Nikon Eclipse E400<br/>Nikon Eclipse 50i<br/>Laborlux S</p> |



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| HUMAN BODY TISSUE (cont'd)<br><br>Fresh and frozen tissue  | <u>Histopathology</u> (cont'd)<br><br>Detection of:<br><br>Fibrinogen<br><br>IgM<br><br>C3C<br><br>IgG<br><br>IgM<br><br>IgA | Documented in-house procedures<br><br><u>Immunofluorescence</u><br><br>Manual methods using documented in-house procedures HIS-SOP32 and conjugated antibodies as follows:<br><br>Anti-human Fibrinogen FITC<br><br>Anti-human IgG/AM FITC<br><br>Anti-human C3CFITC<br><br>Anti-human IgG FITC<br><br>Anti-human IgM FITC<br><br>Anti-human IgA FITC  |
| Slides prepared in-house from sample types specified above | Morphological assessment and interpretation/ diagnosis   | <u>Microscopy/ qualitative analysis</u><br><br>In house procedures:<br>RWF-CP-SOP22<br>RWF-CP-HIS-SOP32<br>RWF-CP-SOP20<br>RWF-CP-HIS-SOP25<br><br>Using microscopes as follows:<br>Olympus BX40<br>Olympus BX41<br>Olympus BX45TF<br>Olympus BX50<br>Olympus BX51<br>Leica DM400B<br>Leica DMR<br>Zeiss Axioplan<br>Zeiss Axioscope<br>Zeiss Eurostar<br>Nikon Eclipse E800<br>Nikon Eclipse 80i<br>Nikon Eclipse E400<br>Nikon Eclipse 50i<br>Laborlux S |



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| <p>HUMAN BODY FLUIDS</p> <p>Body fluids:<br/>CSF, urine, body cavity fluids,<br/>bronchial brushings, washings,<br/>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:<br/>Heraeus Megafuge 1.0 Centrifuge<br/>Shandon Cytospin 3<br/>RWF-CP-CYT-SOP1<br/>RWF-CP-CYT-SOP14<br/>RWF-CP-CYT-SOP16</p> <p><u>Papanicolaou staining</u></p> <p>Documented in house procedures in conjunction with manufacturer's instructions using:<br/>Leica stainer/coverslipper<br/>ST5020/CV5030<br/>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:<br/>Leica stainer ST5020<br/>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>Detection of:</p> <p>Her-2 overexpression</p> <p>MMR</p> <p>ALK in NSCLC</p> <p>PD-L1 in NSCLC</p> | <p>Documented in-house procedures</p> <p><u>Microscopy/ qualitative analysis</u></p> <p>In house procedures:<br/>RWF-CP-SOP22<br/>RWF-CP-HIS-SOP32<br/>RWF-CP-SOP20<br/>RWF-CP-HIS-SOP25</p> <p>Using microscopes as follows:<br/>Olympus BX40<br/>Olympus BX41<br/>Olympus BX45TF<br/>Olympus BX50<br/>Olympus BX51<br/>Leica DM400B<br/>Leica DMR<br/>Zeiss Axioplan<br/>Zeiss Axioscope<br/>Zeiss Eurostar<br/>Nikon Eclipse E800<br/>Nikon Eclipse 80i<br/>Nikon Eclipse E400<br/>Nikon Eclipse 50i<br/>Laborlux S</p> <p><u>Immunohistochemistry</u></p> <p>Documented in house procedures in conjunction with manufacturer's instructions for Ventana Benchmark XT</p> <p>4B5 (RWF-CP-MOL-SOP23)</p> <p>Mismatch repair protein</p> <p>Anaplastic Lymphoma Kinase protein in NSCLC.</p> <p>Programmed Death Ligand 1 protein expression in the NSCLC tumours.</p> |



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| HUMAN BODY FLUIDS (cont'd)               | <u>Cytopathology (Non-Gynae) examination activities for the purposes of clinical diagnosis</u> (cont'd) | Documented in-house procedures  |
| Formalin fixed, paraffin embedded tissue | Fluorescent in-situ Hybridisation for the detection of:   | <u>Fluorescent in-situ Hybridisation</u><br><br>Using documented in-house procedures in conjunction with manufacturer's instructions for VP2000 |
|  | HER-2 amplification   | HER-2 / CEP17 dual target probe (RWF-CP-MOL-SOP6)   |
| Formalin fixed, paraffin embedded tissue | Real-time PCR mutation testing for the presence of:   | <u>Real time PCR</u><br><br>Using documented in-house procedures in conjunction with manufacturer's instructions for Cobas 4800                 |
|  | KRAS mutations in codons 12/13 and 61   | RWF-CP-MOL-SOP30  |
|  | BRAF mutations at codon 600   | RWF-CP-MOL-SOP30  |
| END                                      |   |   |