


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

| | | |
|--|--|---|
|  Accredited to ISO 15189:2022 | Great Western Hospitals NHS Foundation Trust | |
| | Issue No: 007 Issue date: 10 February 2025 | |
| | Department of Cellular Pathology Great Western Hospitals NHS Foundation Trust The Great Western Hospital Marlborough Road Swindon SN3 6BB | Contact: Matthew Long Tel: +44 (0) 1793 60(4277) E-Mail: Matthew.long1@nhs.net |
| Testing performed at the above address only | | |

Locations covered by the organisation and their relevant activities

Laboratory locations:

| Location details | | Activity |
|--|--|--|
| Address Department of Cellular Pathology Great Western Hospitals NHS Foundation Trust The Great Western Hospital Marlborough Road Swindon SN3 6BB | Local contact Andrea Taibi (contact detail above) | Diagnostic cytopathology Histopathology (inc routine and special staining) Immunohistochemistry Mortuary services (inc Body receipt, 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 |
|---------------------------|---|--|
| HUMAN TISSUES | <u>Histopathological examination activities for the purposes of clinical diagnosis</u> | Macroscopic and Microscopic examination supported by in-house documented procedures based on equipment manuals as relevant |
| Tissues | Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis | <u>Specimen Dissection:</u> BMS Specimen dissection (HIS-S-151) Tissue Preparation – Transfers (CP-S-039) |
| | | <u>Decalcification:</u> Decalcification (HIS-S-125) |
| | | <u>Tissue processing:</u> Sakura VIP6 A1 tissue processor (CP-S-010) |
| | | <u>Embedding:</u> Sakura Tissue Tek 6 embedding centre (CP-S-035) |
| | | <u>Microtomy:</u> Leica Histocore Biocut microtome SOP: CP-S-039 |
| | Identification of nuclei, cell cytoplasm and connective tissues in cells and tissues for the purposes of clinical diagnosis | <u>Haematoxylin and Eosin (H&E) staining:</u> Sakura Tissue Tek Prisma Plus stainer (SOP: CP-S-062) with integrated Sakura Tissue Tek Film coverslipper (SOP: CP-S-063) |
| | Examination to identify or exclude morphological and cytological abnormalities for purpose of diagnosis | <u>Special Staining</u> |
| | <u>Special staining of histopathology examinations to assist in detection of clinical abnormalities:</u> | <u>Manual methods for Special stains:</u> |
| | Acid and Neutral Mucopolysaccharides and Glycogen | Alcian Blue PAS (+/- Diastase) - HIS-S-002, HIS-S-006 |



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| HUMAN TISSUES (cont'd) | <p><u>Histopathology</u> (cont'd)</p> <p>Examination to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis</p> <p><u>Special Stains</u> (cont'd)</p> <p>Asbestos fibres, Haemosiderin, Ferric Iron</p> <p>Amyloid</p> <p>Elastic Fibres, connective tissue and Fibrin</p> <p>Reticulin Fibres</p> <p>Helicobacter/Microorganisms</p> <p>Acid Alcohol Fast Bacilli</p> <p>Spirochaetes</p> <p>Acid Fast Bacilli</p> <p>Fungi</p> <p>Gram +ve & Gram -ve microorganisms</p> <p>Haemopoietic cells</p> <p>Melanin</p> <p>Hepatitis B Surface Antigen, Copper Associated Protein</p> <p>Mast Cells</p> | <p>Macroscopic and Microscopic examination using in house procedures in conjunction with manufacturer's instructions for the following methods (where relevant)</p> <p>Perls' Prussian Blue - HIS-S-040</p> <p>Congo Red - HIS-S-004</p> <p>Miller's Elastin Stain - HIS-S-012 Masson Trichrome - HIS-S-131 Martius Scarlet Blue - HIS-S-011 Haematoxylin Van Gieson - HIS-S-010</p> <p>Gordon and Sweet's Reticulin - HIS-S-074</p> <p>Modified Giemsa - HIS-S-148</p> <p>Ziehl Neelsen - HIS-S-072</p> <p>Warthin Starry - HIS-S-133</p> <p>Wade Fite - HIS-S-132</p> <p>Grocott's Hexamine Silver - HIS-S-128</p> <p>Gram Stain - HIS-S-127</p> <p>Giemsa - HIS-S-007</p> <p>Masson Fontana - HIS-S-130 Melanin Bleach - HIS-S-028</p> <p>Shikata's Orcein - HIS-S-043</p> <p>Toluidine Blue - HIS-S-155</p> |



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| HUMAN TISSUES (cont'd) | <u>Immunohistochemistry examination activities for detection of clinical abnormalities:</u> | <u>Immunohistochemistry</u> Microscopic examination supported by in-house documented procedures based on equipment manuals as relevant: |
| Tissues | Immunohistochemistry to detect the following: | Documented in house methods used in accordance with the manufacturers operating instructions for the use of Agilent Dako Omnis IHC automated immunostainers Incorporating the following antibodies. |
| | Hepatocellular carcinomas, Endodermal sinus tumor (EST) or Yolk sac tumours (YST) | Alpha FetoProtein |
| | Prostate ca | AMACR/Racemase |
| | Follicular lymphomas | BCL2 |
| | Germinal centre lymphocytes, Non Hodgkins lymphoma / DLBCL | BCL6 |
| | High molecular weight cytokeratin | 34βe12 |
| | Epithelial cells | BER EP4 |
| | Ovarian epithelial malignancies | CA125 |
| | Secretory epithelia | CK8/18 |
| | T cells | CD3 |
| | Tcells , subset of B cells in mantle zone | CD5 |
| | Lymphoblastic, Burkitts, follicular lymphomas. Germinal centres, perineurium, breast myoepithelial cells etc | CD10 |
| | Reed Sternberg cells, granulocytes, monocytes | CD15 |
| | B cells | CD20 |
| | B cells, monocytes, FDCs | CD23 |
| | RS cells, Hodgkin cells, ALCL | CD30 |



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| Tissues (cont'd) | Immunohistochemistry to detect the following: (cont'd) | Documented in house methods used in accordance with the manufacturers operating instructions for the use of Agilent Dako Omnis IHC automated immunostainers and SOP-CP-S-091 Incorporating the following antibodies: |
| | Endothelial cells, platelets, monocytes, granulocytes, some B cells | CD31 |
| | Vascular endothelium. Lymphoid and myeloid progenitor cells | CD34 |
| | Majority of leucocytes | CD45 |
| | Neurons, astrocytes, schwann cells, NK cells, | CD56 |
| | Macrophages, monocytes, neutrophils, basophils, large lymphocytes | CD68 PG-M1 KP1 |
| | B cells | CD79a |
| | GIST, Mast cells etc | CD117 |
| | Intestinal epithelial cells | CDX2 |
| | Cell surface glycoprotein, overexpressed in colonic and other tumours | CEA (MONO) |
| | Neuroendocrine cells and tumours | CHROMOGRANIN A |
| | Epithelium | CK (AE1/AE3) |
| | Non keratinising stratified squamous and basal epithelia | CK5/6 |
| | Plasma cells | Was CD 138 change to V538C |
| | Glandular and transitional epithelia | CK7 |
| | Ductal and glandular epithelia | CK19 |



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| Tissues (cont'd) | Immunohistochemistry to detect the following: (cont'd) | Documented in house methods used in accordance with manufacturers operating instructions for the use of Agilent Dako Omnis IHC automated immunostainers and SOP CP-S-091 Incorporating the following antibodies: |
| | Gastric and intestinal epithelium, urothelium, Merkel cells of skin | CK20 |
| | Mantle cell lymphomas, myelomas | CYCLIN D1 |
| | Desmin in striated and smooth muscle | DESMIN |
| | Gastro intestinal stromal tumours | DOG – 1 |
| | Epithelial cells | E CADHERIN |
| | Normal and neoplastic epithelia | EMA |
| | Estrogen receptors | ER |
| | Dermal dendritic cells, endothelial cells | FACTOR XIII |
| | Melanocytic tumours | HMB45 |
| | Hepatocellular carcinoma | HEPATOCYTE SURFACE AG |
| | Granulosa cell and Sertoli cell tumours | INHIBIN A |
| | G1,S,G2 and mitotic phase cells | KI67 |
| | Kappa immunoglobulin light chains | KAPPA |
| | Lambda immunoglobulin light chains | LAMBDA |
| | Melanocytes | MELAN A |
| | Prostatic glands | PSA |
| | P53 Protein | P53 |



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| Tissues (cont'd) | Immunohistochemistry to detect the following: (cont'd) | Documented in house methods used in accordance with manufacturers operating instructions for the use of Agilent Dako Omnis IHC automated immunostainers and SOP CP-S-091 Incorporating the following antibodies: (cont'd) |
| | P63 Protein | P63 |
| | Seminoma, some germ cell tumours | PLAP |
| | Progesterone receptor | PR |
| | Neuroectodermal tissues | S100 |
| | Smooth muscle cells | SMMHC (MYOSIN) |
| | Smooth muscle cells | SMMHC (MYOSIN) |
| | Neuroendocrine tumours, neurons | SYNAPTOPHYSIN |
| | Thyroid and lung cells | TTF1 |
| | Mesenchymal cells | VIMENTIN |
| | Ovarian tumours | WT1 |
| | Lynch Syndrome (Mismatch repair | MISMATCH REPAIR : MLH1 MSH2 MSH6 PMS2 |
| | Tumour suppressor protein | P16 |
| | Calcium binding protein | CALRETININ |
| | Tcells: T cell surface antigen | CD1A |
| | Mesothelin protein | MESOTHELIN |



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| <p>HUMAN TISSUES (cont'd)</p> <p>Slides prepared in house from samples listed above</p> | <p><u>Immunohistochemistry examination activities for detection of clinical abnormalities: (cont'd)</u></p> <p>Morphological assessment and interpretation/diagnosis</p> | <p><u>Immunohistochemistry</u> Microscopic examination supported by in-house documented procedures based on equipment manuals as relevant:</p> <p>Microscopy (qualitative analysis) In-house procedure: Operation of microscopes (CP-S-038)</p> |
| <p>HUMAN BODY FLUIDS AND TISSUES</p> <p>Fine needle aspirations from: Lymph nodes Breast Thyroid Parotid Axilla Lung Pancreas</p> <p>Pleural Ascetic Pericardial Peritoneal Respiratory fluids and brushings Urine Peritoneal washings Ileal conduit Gastrointestinal brushings Cyst Fluids Synovial Fluid Sputum Cerebrospinal Fluid</p> | <p><u>Examination of non-gynaecological cytology specimens to assist in detection of clinical abnormalities</u></p> <p>Examination of tissues to identify or exclude cytological abnormalities for the purpose of clinical diagnosis</p> <p>Morphological assessment and interpretation/diagnosis</p> | <p>Microscopic examination supported by in-house documented procedures based on equipment manuals as relevant:</p> <p><u>Processing Non-gynae cytology specimens (CP-S-009)</u></p> <p><u>Staining:</u> Using in-house procedures for: Sakura Tissue Tek Prisma Plus stainer (SOP: CP-S-062) with integrated Sakura Tissue Tek Film coverslip (SOP: CP-S-063) Rapi-diff staining (CP-S-049), H&E (CP-S-011)</p> <p><u>Centrifugation:</u> Operation of centrifuges in Non-Gynae Cytology (CP-S-016)</p> <p><u>Microscopy:</u> Operation of microscopes (CP-S-038)</p> |
| END | | |