


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

| | | |
|---|---|---|
|  <p>UKAS MEDICAL 9009</p> <p>Accredited to ISO 15189:2012</p> | Blackpool Teaching Hospitals NHS Foundation Trust | |
| | Issue No: 003 Issue date: 15 April 2020 | |
| | Department of Cellular Pathology Blackpool Teaching Hospitals NHS Foundation Trust Victoria Hospital Whinney Heys Road Blackpool FY3 8NR | Contact: Dr Patankar Tel: +44 (0) 1253 953 151 Fax: +44 (0) 1253 953 782 E-Mail: dr.patankar@nhs.net Website: http://www.bfwh.nhs.uk |
| Testing performed at the above address only | | |

Supporting activities performed at the location listed above:

| Location details | Activity |
|---|--|
| On-site Mortuary and Body Store Department of Cellular Pathology (as above) | Mortuary services (incl. body receipt, storage & release) for Coroner's deceased and hospital consented cases. Record keeping (body identification and audit trail) |



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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 AND FLUIDS</p> <p>Fixed, fresh and frozen tissue samples: excisional and incisional biopsies and surgical resection and post mortem specimens</p> | <p><u>Histopathological examination of tissues for the purpose of diagnosis</u></p> <p>Routine histopathology examination activities. Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of clinical diagnoses.</p> | <p>Macroscopic and Microscopic examination using in house procedures in conjunction with manufacturer's instructions for the following methods (where relevant):</p> <p><u>Macroanalysis, Specimen dissection</u> using: CPPM 003 CPPC 002,007,008,009,010</p> <p><u>Decalcification</u> using: CPPC 032, 033, 034</p> <p><u>Tissue processing</u> using: CPPC 035, 036 using the following tissue processors Thermo Excelsior Leica Peloris</p> <p><u>Embedding</u> using: CPPR 003 and Thermo Embedding Centre</p> <p><u>Frozen sections</u> using: CPPC 024, 025, 026 and Leica Microsystems CM1950 Cryostat</p> <p><u>Microtomy and slide production</u> using: CPPR 004 and Leica RM2135 and RM2235 Microtomes</p> |



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| HUMAN BODY TISSUE AND FLUIDS (cont'd) | <u>Histopathological examination of tissues for the purpose of diagnosis (cont'd)</u> | Macroscopic and Microscopic examination using in house procedures in conjunction with manufacturer's instructions for the following methods (where relevant): |
| Fresh skin biopsies | <u>Immunofluorescence</u> Detection of the following autoantibodies: IgM IgG IgA C ₃ (complement) | Cryotomy using documented in-house procedure: In conjunction with manufacturer's instructions for : Thermo Scientific Cryotome followed by direct immunofluorescence microscopy using documented in-house procedure: FITC labelled IgM FITC labelled IgG FITC labelled IgA FITC labelled C ₃ |
| FFPE tissue samples and cell blocks | All tissue components: Nuclei Cytoplasm Muscle fibres Red blood cells Fibrin | <u>Automated Routine Haematoxylin & Eosin staining</u> using: CPPC 002 and Thermo Gemini staining machine and Clearvue Coverslipper |
| FFPE tissue samples and cell blocks | All tissue components: Nuclei Cytoplasm Muscle fibres Red blood cells Fibrin | <u>Manual H&E staining</u> using: CPPC 026, CPPS005 |



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| <p>HUMAN BODY TISSUE AND FLUIDS (cont'd)</p> <p>FFPE tissue samples and cell blocks</p> | <p><u>Histopathological examination of tissues for the purpose of diagnosis</u> (cont'd)</p> <p>Special staining for identification of:</p> <p>Acid mucins</p> <p>Acid mucins and neutral mucins</p> <p>Amyloid</p> <p>Elastin and connective tissue</p> <p>Helicobacter Pylori</p> <p>Differentiate between gram positive and negative bacteria</p> <p>Fungi</p> <p>Mast cells</p> <p>Fibrin</p> <p>Connective tissue</p> <p>Melanin</p> <p>Tissue carbohydrates e.g. glycogen, mucins and fungal cell walls.</p> <p>Demonstration of iron</p> | <p>Macroscopic and Microscopic examination using in house procedures in conjunction with manufacturer's instructions for the following methods (where relevant):</p> <p><u>Special staining manual techniques</u>: using CPPS 005</p> <p>Alcian blue</p> <p>Alcian Blue Periodic Acid Schiff (AB PAS) +/- Diastase</p> <p>Congo Red</p> <p>EVG - Miller's Elastic Van Gieson</p> <p>Giemsa</p> <p>Gram</p> <p>Grocott's Hexamine Silver</p> <p>Hughesdens</p> <p>Martius Scarlet Blue (MSB)</p> <p>Masson Trichrome</p> <p>Masson – Fontana</p> <p>PAS +/- diastase</p> <p>Perls</p> |



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| HUMAN BODY TISSUE AND FLUIDS (cont'd) | <u>Histopathological examination of tissues for the purpose of diagnosis</u> (cont'd) | Macroscopic and Microscopic examination using in house procedures in conjunction with manufacturer's instructions for the following methods (where relevant): |
| FFPE tissue samples and cell blocks (cont'd) | Special staining for identification of: (cont'd) | Special staining manual techniques (cont'd): |
| | Reticulin | Reticulin - silver impregnation technique |
| | Copper associated protein / HepBsAg | Shikata's Orcein |
| | Differentiation of collagen from other connective tissues | Van Gieson Stain |
| | Acid fast Bacilli | Ziehl Neelsen (ZN) |
| FFPE tissue samples and cell blocks | Immunohistochemistry (using antibodies) to detect the following for the purposes of clinical diagnosis | <u>Automated</u> Immunohistochemical staining - Documented in house methods CPPI 003, CPPI 008, CPPST 0114, CPST 016 and Dako Link 48 Immunostainer and EnVision FLEX (High pH) kit |
| | Epithelial marker | AE1/AE3 |
| | Anaplastic lymphoma Kinase | ALK-1 |
| | Hepatocytes of foetal liver and hepatomas | Alpha fetoprotein |
| | Cytokeratins 1,5,10, and 14. | High Molecular weight CK34BE12 |
| | B cells in mantle zone and interfollicular T cells. | BCL-2 |
| | Epithelial marker | BerEP4 |
| | Associated with E-Cadherin. Fibromatous lesions of the breast and abdomen. | Beta-Catenin |



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| HUMAN BODY TISSUE AND FLUIDS (cont'd) | <u>Histopathological examination of tissues for the purpose of diagnosis</u> (cont'd) | Macroscopic and Microscopic examination using in house procedures in conjunction with manufacturer's instructions for the following methods (where relevant): |
| FFPE tissue samples and cell blocks (cont'd) | Immunohistochemistry to detect the following: (cont'd) | Immunohistochemical staining - Documented in house methods CPPI 003, CPPI 008, CPPST 0114, CPST 016 and Dako Link 48 Immunostainer and EnVision FLEX (High pH) kit (cont'd) CA125 |
| | High weight glycoprotein. Luminal cells of fallopian tube | |
| | Parafollicular C-cells in thyroid | Calcitonin |
| | Smooth muscle, smooth muscle tumours. | Caldesmon |
| | Mesothelial cell lining | Calretinin |
| | Low molecular weight cytokeratin 7 and 8 | CAM5.2 |
| | Dendritic cells, Langerhans cells, Thymocytes | CD1a |
| | T cell marker | CD3 |
| | T-Helper cell, regulatory T-cells | CD4 |
| | T-Cell marker | CD5 |
| | Immature B cells and T cells | CD10 |
| | Reed-Sternberg Cells, Granulocytes | CD15 (Leu M1) |
| | B cell marker | CD20 |
| | Reed Sternberg cells and plasma cells. | CD30 (Ki1) |
| | Stem cells of the haematopoietic system, vascular endothelial cells. | CD31 |



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| FFPE tissue samples and cell blocks (cont'd) | Immunohistochemistry to detect the following: (cont'd) | Immunohistochemical staining - Documented in house methods CPPI 003, CPPI 008, CPPST 0114, CPST 016 and Dako Link 48 Immunostainer and EnVision FLEX (High pH) kit (cont'd) CD34 (QBend) |
| | Haematopoietic progenitor cells and vascular endothelium. | |
| | Used for diff diagnosis of urothelial TCC in situ v non neoplastic changes in the urothelium. | CD44 |
| | Neural cell adhesion molecule. | CD56 |
| | Cells of monocyte/macrophage lineage | CD68 |
| | Ewing's sarcoma | CD99 (MIC2) |
| | GIST and mast cells | CD117 (c-kit) |
| | Plasma cell marker | CD138 |
| | Intestinal epithelium | CDX-2 |
| | Carcinoembryonic antigen (mono) | CEA |
| | As above (poly) | pCEA |
| | Endocrine tumours/Neuroendocrine cells. | Chromogranin A |
| | Squamous and myoepithelial. | CK5/6 |
| | Ductal, glandular, and transitional epithelium. | CK7 |
| | Reacts with wide range of normal and neoplastic epithelia. | CK19 |



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| FFPE tissue samples and cell blocks (cont'd) | Immunohistochemistry to detect the following: (cont'd) | Immunohistochemical staining - Documented in house methods CPPI 003, CPPI 008, CPPST 0114, CPST 016 and Dako Link 48 Immunostainer and EnVision FLEX (High pH) kit (cont'd) CK20 |
| | Gastric and intestinal epithelium, urothelium and Merkel cells. | |
| | Cytomegalovirus | CMV |
| | Normal smooth, skeletal, and cardiac muscle | Desmin |
| | Expressed in cells of epithelial lineage. | E-Cadherin |
| | Normal and neoplastic epithelium | EMA |
| | Breast epithelial cells and some carcinomas. Used as prognostic indicator, hormone receptor status. | Estrogen Receptor |
| | Neutrophils and vascular endothelium. | Galectin-3 |
| | Breast and Urothelial endothelium carcinoma | GATA-3 |
| | Mesothelial cells | HBME-1 |
| | Trophoblasts | Human Chorionic Gonadotropin (hCG) |
| | Benign and malignant liver derived tissues | HEP-PAR1 (Hepatocyte) |
| | Immature melanosomes | HMB45 |
| | Herpes Simplex Virus | Herpes Simplex Virus 1 |



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| FFPE tissue samples and cell blocks (cont'd) | Immunohistochemistry to detect the following: (cont'd) Leydig, sertoli cells Proliferation marker Cells of lymphoid or myeloid origin Mammaglobin protein Melanocytes Pan cytokeratin. Expressed in lung and kidney tissue. +ve adenocarcinoma of lung. Cells of neural and neuroendocrine lineage Embryonic stem cells and germ cells Non-small cell lung cancer tissue P53 suppressor gene product. Alpha-Methyl acyl-CoA enzyme. Nuclei of myoepithelial Prostatic tissue Thyroid gland and kidney. | Immunohistochemical staining - Documented in house methods CPPI 003, CPPI 008, CPPST 0114, CPST 016 and Dako Link 48 Immunostainer and EnVision FLEX (High pH) kit (cont'd) Inhibin Ki67 (MIB1) Leucocyte Common Antigen (LCA) (CD45) Mammaglobin Melan A (MART-1) MNF 116 Napsin A Neuron Specific Enolase (NSE) OCT3/4 PDL-1 p53 P504s P63 Prostatic Acid Phosphatase (PAP) PAX-8 |



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| FFPE tissue samples and cell blocks (cont'd) | Immunohistochemistry to detect the following: (cont'd) | Immunohistochemical staining - Documented in house methods CPPI 003, CPPI 008, CPPST 0114, CPST 016 and Dako Link 48 Immunostainer and EnVision FLEX (High pH) kit (cont'd) |
| | Germ cell tumours | Placental Alkaline Phosphatase (PLAP) |
| | Expressed in lymphatic endothelium. | Podoplanin (D2-40) |
| | Breast, ovarian, endometrial epithelia, and myometrial nuclei. Used in conjunction with ER. | Progesterone Receptor |
| | Normal prostate and prostate carcinoma. | Prostate Specific Antigen (PSA) |
| | Renal Cell Carcinoma | Renal Cell Carcinoma (RCC) |
| | Melanoma and neuroendocrine | S100 |
| | Myofibroblasts, myoepithelial cells. Does not stain cardiac or skeletal muscle. | Smooth Muscle Actin (SMA) |
| | Smooth muscle cells | Smooth Muscle Myosin (SMM) |
| | Neuroendocrine cells | Synaptophysin |
| | Endothelial and mesothelial cells. | Thrombomodulin (CD141) |
| | Thyroglobulin. Precursor for T4 and T3 thyroid hormones. | Thyroglobulin |
| | Thyroid Transcription Factor -1 (Lung and Thyroid) | TTF-1 |



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| FFPE tissue samples and cell blocks (cont'd) | Immunohistochemistry to detect the following: (cont'd) | Immunohistochemical staining - Documented in house methods CPPI 003, CPPI 008, CPPST 0114, CPST 016 and Dako Link 48 Immunostainer and EnVision FLEX (High pH) kit (cont'd) |
| | Variety of mesenchymal cells | Vimentin |
| | Wilms' tumour protein | WT1 |
| FFPE tissue samples and cell blocks | Immunohistochemistry (using antibodies) to detect the following for the purposes of clinical diagnosis | Immunohistochemical staining - Documented in house methods CPPST 012 and Ventana Benchmark platform |
| | Non-small lung cancer tissue | ALK fusion protein ROS-1 fusion protein |
| FFPE tissue samples and cell blocks | Detection of EGFR mutations for the purposes of clinical diagnosis | Qualitative PCR using Biocartis Idylla EGFR kit CPPST 002 |
| | Non-small lung cancer tissue (Exon 18-21) mutation | EGFR mutation test kit |
| Slides prepared in house from samples listed above | Morphological assessment and interpretation/diagnosis | <u>Microscopy (qualitative analysis)</u> using: Leica/Nikon microscopes Consultant Reporting CPPP 003 CPPP 008 CPPM 003 |



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| <p>HUMAN BODY TISSUE AND FLUIDS (cont'd)</p> <p>Variety of cytology samples including washings, brushings, EBUS, CSF, Fine needle aspirations, urines and fluids.</p> <p>Synovial fluids</p> <p>Slides prepared in house from samples listed above</p> | <p><u>Cytopathological examination of tissues and fluids for the purpose of diagnosis</u></p> <p>Examination of fluids in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis</p> <p>Crystal identification - calcium pyrophosphate, urate and cholesterol</p> <p>Staining for nuclear detail in cells present</p> <p>Morphological assessment and interpretation/diagnosis</p> | <p>Macroscopic and Microscopic examination using in house procedures in conjunction with manufacturer's instructions for the following methods (where relevant):</p> <p><u>Sample preparation</u> using:</p> <p>CPFM005 CPF020 and Thermo Scientific "Cytospin 4" cytology centrifuge</p> <p>CPFM006 CPF014, 015,016 and Shandon "Varistain 24-4" cytology stainer</p> <p>CPF 006 Non-gynae preparation for all fixed and non-fixed fluids</p> <p>CPF 034 Preparation of cell block for Cytology specimens</p> <p>CPF007 Joint Fluid Preparation</p> <p><u>Staining</u> using:</p> <p>CPF015 Automated Papanicolaou Staining method</p> <p>CPFM006 Manual staining</p> <p><u>Microscopy (quantitative analysis):</u></p> <p>Leica/Nikon microscopes</p> <p>CPF011, CPF012 Screening and Reporting Non-Gynae Cytology Specimens</p> <p>CPMS 006 Consultant Reporting</p> |

