


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 9009 Accredited to ISO 15189:2012	Blackpool Teaching Hospitals NHS Foundation Trust	
	Issue No: 009 Issue date: 03 January 2024	
	Department of Cellular Pathology Blackpool Teaching Hospitals NHS Foundation Trust Victoria Hospital Whinney Heys Road Blackpool FY3 8NR	Contact: Dr Darek Golka Tel: +44 (0) 1253 953 151 Tel: +44 (0) 1253 956 949 E-Mail: dr.golka@nhs.net Website: http://www.bfwh.nhs.uk
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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</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	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>Toluidine blue</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) Reticulin Copper associated protein / HepBsAg Differentiation of collagen from other connective tissues Acid fast Bacilli	Special staining manual techniques (cont'd): Reticulin - silver impregnation technique Shikata's Orcein Van Gieson Stain Ziehl Neelsen (ZN)
FFPE tissue sample and cell blocks	Immunohistochemistry (using antibodies) to detect the following for the purposes of clinical diagnosis Non-small cell lung cancer tissue Normal smooth, skeletal and cardiac muscle	Automated Immunohistochemical staining – Documented in house methods CPPI 003, CPPI 008 CPPST 0114, CPPST 016 and Dako Link 48 Immunostainer and En Vision FLEX (High pH) kit PDL-1 Desmin



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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>Immunohistochemistry (using antibodies) to detect the following for the purposes of clinical diagnosis</p> <p>Epithelial marker</p> <p>Epitheliod Mesothelioma</p> <p>Cytokeratins 1,5,10, and 14.</p> <p>B cells in mantle zone and interfollicular T cells.</p> <p>Epithelial marker</p> <p>Associated with E-Cadherin. Fibromatous lesions of the breast and abdomen.</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>Automated</u> Immunohistochemical staining - Documented in house methods CPPST 025 Dako OMNIS and EnVision Flex Kit</p> <p>AE1/AE3</p> <p>BAP-1</p> <p>High Molecular weight CK34BE12</p> <p>BCL-2</p> <p>BerEP4</p> <p>Beta-Catenin</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)	Immunohistochemistry to detect the following: (cont'd)	Immunohistochemical staining - Documented in house methods CPPST 025 Dako OMNIS and EnVision Flex Kit
	High weight glycoprotein. Luminal cells of fallopian tube	CA125
	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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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) Haematopoietic progenitor cells and vascular endothelium. Used for diff diagnosis of urothelial TCC in situ v non neoplastic changes in the urothelium. Neural cell adhesion molecule. Cells of monocyte/macrophage lineage Ewing's sarcoma GIST and mast cells Plasma cell marker Intestinal epithelium Carcinoembryonic antigen (mono) As above (poly) Endocrine tumours/Neuroendocrine cells. Squamous and myoepithelial. Ductal, glandular, and transitional epithelium. Reacts with wide range of normal and neoplastic epithelia.	Immunohistochemical staining - Documented in house methods CPPST 025 Dako OMNIS and EnVision Flex Kit CD34 (QBend) CD44 CD56 CD68 CD99 (MIC2) CD117 (c-kit) CD138 CDX-2 CEA pCEA Chromogranin A CK5/6 CK7 CK19



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<p>HUMAN BODY TISSUE AND FLUIDS (cont'd)</p> <p>FFPE tissue samples and cell blocks (cont'd)</p>	<p><u>Histopathological examination of tissues for the purpose of diagnosis</u> (cont'd)</p> <p>Immunohistochemistry to detect the following: (cont'd)</p> <p>Gastric and intestinal epithelium, urothelium and Merkel cells.</p> <p>Cytomegalovirus</p> <p>GIST</p> <p>Expressed in cells of epithelial lineage.</p> <p>Normal and neoplastic epithelium</p> <p>Breast epithelial cells and some carcinomas. Used as prognostic indicator, hormone receptor status.</p> <p>Neutrophils and vascular endothelium.</p> <p>Breast and Urothelial endothelium carcinoma</p> <p>Trophoblasts</p> <p>Immature melanosomes</p> <p>Herpes Simplex Virus</p> <p><i>Helicobacter pylori</i></p>	<p>Macroscopic and Microscopic examination using in house procedures in conjunction with manufacturer's instructions for the following methods (where relevant):</p> <p>Immunohistochemical staining - Documented in house methods CPPST 025 Dako OMNIS and EnVision Flex Kit CK20</p> <p>CMV</p> <p>Dog-1</p> <p>E-Cadherin</p> <p>EMA</p> <p>Estrogen Receptor</p> <p>Galectin-3</p> <p>GATA-3</p> <p>Human Chorionic Gonadotropin (hCG)</p> <p>HMB45</p> <p>Herpes Simplex Virus 1</p> <p>H-Pylori</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)	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 Normal Human Hepatocytes Embryonic stem cells and germ cells P53 suppressor gene product. Alpha-Methyl acyl-CoA enzyme. Nuclei of myoepithelial Prostatic tissue Thyroid gland and kidney.	Immunohistochemical staining - Documented in house methods CPPST 025 Dako OMNIS and EnVision Flex Kit Inhibin Ki67 (MIB1) Leucocyte Common Antigen (LCA) (CD45) Mammaglobin Melan A (MART-1) MNF 116 Napsin A Neuron Specific Enolase (NSE) OCH OCT3/4 p53 P504s P63 Prostatic Acid Phosphatase (PAP) PAX-8



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<p>HUMAN BODY TISSUE AND FLUIDS (cont'd)</p> <p>FFPE tissue samples and cell blocks (cont'd)</p>	<p><u>Histopathological examination of tissues for the purpose of diagnosis</u> (cont'd)</p> <p>Immunohistochemistry to detect the following: (cont'd)</p> <p>Germ cell tumours</p> <p>Expressed in lymphatic endothelium.</p> <p>Breast, ovarian, endometrial epithelia, and myometrial nuclei. Used in conjunction with ER.</p> <p>Normal prostate and prostate carcinoma.</p> <p>Renal Cell Carcinoma</p> <p>Melanoma and neuroendocrine</p> <p>Myofibroblasts, myoepithelial cells. Does not stain cardiac or skeletal muscle.</p> <p>Smooth muscle cells</p> <p>Neuroendocrine cells</p> <p>Endothelial and mesothelial cells.</p> <p>Thyroglobulin. Precursor for T4 and T3 thyroid hormones.</p> <p>Thyroid Transcription Factor -1 (Lung and Thyroid)</p>	<p>Macroscopic and Microscopic examination using in house procedures in conjunction with manufacturer's instructions for the following methods (where relevant):</p> <p>Immunohistochemical staining - Documented in house methods CPPST 025 Dako OMNIS and EnVision Flex Kit</p> <p>Placental Alkaline Phosphatase (PLAP)</p> <p>Podoplanin (D2-40)</p> <p>Progesterone Receptor</p> <p>Prostate Specific Antigen (PSA)</p> <p>Renal Cell Carcinoma (RCC)</p> <p>S100</p> <p>Smooth Muscle Actin (SMA)</p> <p>Smooth Muscle Myosin (SMM)</p> <p>Synaptophysin</p> <p>Thrombomodulin (CD141)</p> <p>Thyroglobulin</p> <p>TTF-1</p>



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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 CPPST 025 Dako OMNIS and EnVision Flex Kit
	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
	HPV infection	P16
	Melanoma	SOX-10
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
	Detection of BRAF mutations for the purposes of clinical diagnosis	Qualitative PCR using Biocartis Idylla BRAF kit BRAF 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>



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HUMAN BODY FLUIDS	<u>Andrological examination activities for the purposes of clinical diagnosis</u>	
Semen	<u>Post vasectomy:</u> Detection of sperm	Based on 2016 Laboratory guidelines for post vasectomy semen analysis: Association of Biomedical Andrologists, the British Andrology Society and the British Association of Urological Surgeons) Manual method using large volume chambers/ manual microscopy and documented in-house procedure: CPF 037 Examination of Post Vasectomy Samples
Semen	<u>Fertility testing:</u> Volume Sperm morphology including TZI scoring Sperm concentration Sperm motility Sperm vitality	Based on WHO laboratory manual for the examination and processing of human semen (Sixth edition 2021) and manual method/ documented in-house procedures: CPF 003 Analysis Seminal Fluids CPF 037 Examination of Post Vasectomy Samples CPF015 Rapid Papanicolaou method CPF054 Special clearance Volume/weight Stained slides (Papanicolaou) microscopy (Bright field) Improved Neubauer counting chambers and Microscopy (Phase contrast) Microscopy (Phase contrast) Stained slide (Eosin/Nigrosin dye exclusion test) microscopy (Bright field)

END