


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 8062 Accredited to ISO 15189:2012	Maidstone and Tunbridge Wells NHS Trust	
	Issue No: 006 Issue date: 11 July 2023	
	Cellular Pathology Department Maidstone Hospital Hermitage Lane Maidstone ME16 9QQ	Contact: Mrs Theresa Welfare Tel: +44 (0)1622 227238 E-Mail: theresa.welfare@nhs.net
Testing performed at the above address only		

Activities performed away from the location listed above:

Location details		Activity
Address Maidstone Hospital Hermitage Lane Maidstone ME16 9QQ	Local Contact Theresa Welfare	Body Store: body storage, and release
Address Tunbridge Wells Hospital Tonbridge Road Tunbridge Wells TN2 4QJ	Local Contact Theresa Welfare	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
HUMAN BODY TISSUE	<u>Histopathological examination activities for the purposes of clinical diagnosis</u> Preparation and examination to identify or exclude morphological & cytological abnormalities	Macroscopic and Microscopic examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant)
Fresh tissue	Rapid intra-operative for rapid examination of tissues to identify or exclude morphological abnormalities for the purpose of clinical diagnosis	<u>Rapid frozen section</u> Cryotomy using Cryostat CM1850 UV. RWF-CP-HIS- SOP9 RWF-CP-HIS-LI104
Formalin fixed tissue unless specified	Examination of tissues to identify or exclude morphological abnormalities for the purpose of clinical diagnosis	<u>Macroanalysis and dissection</u> Manual method using: SOP's: RWF-CP-HIS-SOP2 RWF-CP-HIS-SOP3 RWF-CP-HIS-SOP4 RWF-CP-HIS-SOP5
Formalin fixed tissue		<u>Decalcification</u> Manual method using: RWF-CP-HIS-SOP6
Formalin fixed tissue		<u>Tissue Processing</u> Automated method using: Sakura VIP6AI tissue processor (RWF-CP-HIS-SOP72)



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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:</p> <p>Leica HistoCore Arcadia H Embedding Centre and HistoCore Arcadia C Coldplate RWF-CP-HIS-SOP36</p> <p><u>Microtomy</u></p> <p>Manual method using:</p> <p>Leica RM2135, Leica RM2235 and Ergostar microtomes RWF-CP-HIS-SOP37</p> <p><u>Routine Haematoxylin & Eosin (H&E) staining and coverslipping</u></p> <p>Automated method using:</p> <p>Sakura Tissue-Tek Prisma Stainer, Sakura Tissue-Tek Film Coverslipper. RWF-CP-HIS-SOP41</p> <p><u>Special stains</u></p> <p>PAS, PASD, ABPAS and ABPASD stains and automated method using:</p> <p>Sakura Tissue-Tek Prisma Stainer, Sakura Tissue-Tek Film Coverslipper RWF-CP-HIS-SOP41</p>



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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 Haematopoietic cells Helicobacter Bacteria Nuclei and connective tissue Mucins and glycogen Fungi and pneumocystis Melanin Connective tissue 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) Formalin fixed, paraffin embedded (FFPE) tissue (cont'd)	<u>Histopathology</u> (cont'd) Detection of: (cont'd) Reticulin fibres Mast cells Mycobacterium leprae Spirochetes Mycobacterium spp inc.tuberculosis Detection of: Broad spectrum cytokeratins Foetal liver cells Anaplastic large-cell lymphomas Lymphocytes from mantle zone Follicular centre cells Epithelial cells Epithelial cell membrane Luminal cells of fallopian tubes Mesothelial cell lining Parafollicular (c-cells)	Documented in-house procedures <u>Special staining</u> Reticulin (RWF-CP-HIS-LI131) Toluidine Blue (RWF-CP-HIS-LI138) Wade Fite (RWF-CP_HISLI140) Warthin Starry (RWF-CP-HIS-LI141) ZN (RWF-CP-LI142) <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: AE1/AE3 AFP ALK-1 Bcl-2 Bcl-6 Ber EP4 β-Catenin Ca125 Calretinin Calcitonin



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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) Smooth muscle 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 Cytotoxic/suppressor T cells Haematopoietic cells RS cells B cells Follicular dendritic cells/mature B cells FDC and EBV transformed blasts RS cells Endothelial cells Endothelial cells T cell activation Leukocytes Neurons, Schwann cells, NK cells and subset of activated T cells	Documented in-house procedures <u>Immunocytochemistry</u> Caldesmon Cam5.2 CD1a CD2 CD3 CD4 CD5 CD8 CD10 CD15 CD20 CD21 CD23 CD30 CD31 CD34 CD43 CD45 CD56



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



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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) 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	Documented in-house procedures <u>Immunocytochemistry</u> 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



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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) Tumour suppressor gene p57 protein (Kip 2) Basal cell marker Placental alkaline phosphatase Progesterone receptor Prostate specific antigen Prostatic acid phosphatase Melanoma and neuroendocrine Mesenchymal marker Neuroendocrine marker Bone marrow Lymphocytes & 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 renal cell carcinoma, thyroid carcinoma and ovarian carcinoma	Documented in-house procedures <u>Immunocytochemistry</u> P53 P57 P63 PLAP PR PSA PSAP S100 SMA Synaptophysin Tdt Thyroglobulin TTF-1 Vimentin WT1 MOC-31 Naspin-A PAX-5 PAX-8



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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>metastatic urothelial and breast carcinomas</p> <p>squamous cell carcinomas, urothelial carcinomas and rare cases of lung adenocarcinomas.</p> <p>prostate adenocarcinoma.</p> <p>Morphological assessment and interpretation/ diagnosis</p>	<p>Documented in-house procedures</p> <p><u>Immunocytochemistry</u></p> <p>GATA3</p> <p>P40</p> <p>NKX3.1</p> <p><u>Microscopy/ qualitative analysis</u></p> <p>In house procedures for Setting Up a Microscope: RWF-CP-SOP22 Procedure for Skin Immunofluorescence RWF-CP-HIS-SOP32 Pathologist Reporting Process 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>



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<p>HUMAN BODY TISSUE (cont'd)</p> <p>Fresh and frozen tissue</p> <p>Slides prepared in-house from sample types specified above</p>	<p><u>Histopathology</u> (cont'd)</p> <p>Detection of:</p> <p>Fibrinogen</p> <p>Anti-human C3CFITC</p> <p>Anti-human IgG FITC</p> <p>Anti-human IgM FITC</p> <p>Anti-human IgA FITC</p> <p>Morphological assessment and interpretation/ diagnosis</p>	<p>Documented in-house procedures</p> <p><u>Immunofluorescence</u></p> <p>Manual methods using documented in-house procedures RWF-CP-HIS-SOP32 and conjugated antibodies as follows:</p> <p>Anti-human Fibrinogen FITC</p> <p>C3C</p> <p>IgG</p> <p>IgM</p> <p>IgA</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 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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HUMAN BODY FLUIDS (cont'd)	<u>Cytopathology (Non-Gynae) examination activities for the purposes of clinical diagnosis</u> (cont'd)	Documented in-house procedures
Slides prepared in-house from sample types specified above	Morphological assessment and interpretation/ diagnosis	<u>Microscopy/ qualitative analysis</u> 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
Formalin fixed, paraffin embedded tissue	Detection of:	<u>Immunohistochemistry</u> Documented in house procedures (RWF-CP-MOL-SOP23) in conjunction with manufacturer's instructions for Ventana Benchmark XT
	Her-2 overexpression	4B5
	MMR (Mis-Match Repair Protein)	Mismatch repair protein
	ALK-1	Anaplastic Lymphoma Kinase protein in NSCLC.
	PD-L1	Programmed Death Ligand 1 protein expression in the NSCLC tumours.



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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>
	HER-2 amplification	Using documented in-house procedures in conjunction with manufacturer's instructions for VP2000
		HER-2 / CEP17 dual target probe (RWF-CP-MOL-SOP6)
		Using Fluorescence microscope Olympus BX41
Formalin fixed, paraffin embedded tissue	Real-time PCR mutation testing for the presence of:	<u>Real time PCR</u>
		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		