


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 <p>UKAS MEDICAL</p> <p>10011</p> <p>Accredited to ISO 15189:2012</p>	<h3>Dorset County Hospital NHS Foundation Trust</h3>	
	<p>Issue No: 003 Issue date: 07 April 2021</p>	
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<p>Testing performed at the above address only</p>		

DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
<p>HUMAN BODY FLUIDS</p> <p>Fine needle aspirates –Breast, sputum, urine CSF, oesophageal washings and brushings, Conventional Bronchial Brushings, Serous fluids, Bronchial washings and Bronchial Alveolar lavage samples.</p>	<p><u>Cytopathology (Non-Gynae) examination activities for the purposes of clinical diagnosis</u></p> <p>Examination of cellular material in order to identify or exclude morphological and cytological abnormalities</p> <p>Demonstration of: Cells (nuclei and cytoplasm) and micro organisms</p>	<p>In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:</p> <p>Diagnostic cytology (non-gynae) in-house documented manual procedures for preparation Screening and Reporting CYT/NG SOP 0005, CYT/NG SOP 0006, CYT/NG SOP 0008, CYT/NG SOP 0009, CYT/NG SOP 0011, CYT/NG SOP 0013, CYT/NG SOP 0014, CYT/NG SOP 0016, CYT/NG SOP 0017, CYT/NG SOP 0018</p> <p>Papanicolaou stain for Non-Gynae Specimens CYT/NG SOP 0026 Rapid Grocott method for Pneumocystis and Fungi CYT/NG HIST/STAIN SOP0008 Rapid Hema-Gurr staining CYT/NG SOP 0024 H&E Staining HIST/GEN SOP0014 CYT/NG SOP 0010 CYT/NG SOP0012</p>



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<p>HUMAN BODY FLUIDS</p> <p>Slides prepared in-house from sample types listed above</p>	<p><u>Cytopathology (Non-Gynae) examination activities for the purposes of clinical diagnosis Cont.</u></p> <p>Morphological assessment and interpretation/diagnosis</p>	<p>In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:</p> <p>Diagnostic cytology (non-gynae) in-house documented manual procedures for preparation Screening and Reporting CYT/NG SOP 0005, CYT/NG SOP 0006, CYT/NG SOP 0008, CYT/NG SOP 0009, CYT/NG SOP 0011, CYT/NG SOP 0013, CYT/NG SOP 0014, CYT/NG SOP 0015, CYT/NG SOP 0016, CYT/NG SOP 0017, CYT/NG SOP 0018</p>



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<p>HUMAN BODY TISSUE</p> <p>Tissue samples (including breast; gastrointestinal; skin; urological; bronchial/lung/thoracic; endocrine including thyroid, parathyroid, adrenal; lymphoreticular including lymph nodes, spleen, and bone marrow trephines [processing only for bone marrow trephines]; liver; bone and soft tissues; gynaecological; and head and neck)</p>	<p><u>Histopathological examination activities for the purposes of clinical diagnosis</u></p>	<p>In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:</p> <p>Specimen dissection: Cut-up Manual – Routine HIST/CU-SOP 0001 – Appendix HIST/CU-SOP 0002 – Small Cut-up HIST/CU-SOP 0004 – Breast HIST/CU-SOP 0005 – Colectomy tumour HIST/CU-SOP 0006 – Colectomy (non-tumour) HIST/CU-SOP 0007 – Urinary bladder HIST/CU-SOP 0008 – Fallopian tubes HIST/CU-SOP 0009 – Femoral Head HIST/CU-SOP 0011 – Gallbladder HIST/CU-SOP 0013 – Kidney (non-tumour) HIST/CU-SOP 0014 – Kidney (tumour) HIST/CU-SOP 0015 – Lip HIST/CU-SOP 0017 – Lymph Node HIST/CU-SOP 0021 – Ovary HIST/CU-SOP 0024 - Polyps HIST/CU-SOP 0025 – Prostate Gland HIST/CU-SOP 0026 – Salivary Gland HIST/CU-SOP 0027 – Skin HIST/CU-SOP 0028 – Small Bowel HIST/CU-SOP 0029 – Spleen HIST/CU-SOP 0030 – Orchiectomy HIST/CU-SOP 0031 – Thyroid Gland HIST/CU-SOP 0032 – Uterus & Cervix HIST/CU-SOP 0033 – Vas & Fallopian Tube</p>



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HUMAN BODY TISSUE Cont.	<u>Histopathological examination activities for the purposes of clinical diagnosis Cont.</u>	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:
Fresh tissue		Cryotomy: Leica CM1950 Cryostat using HIST/GEN-SOP 0011
Fresh tissue on glass slides	Basophilic and eosinophilic structures	H&E staining HIST/GEN SOP 0011
	Special stains for the detection of:	Documented in-house procedures for automated special stains using Sakura Tissue-Tek
Formalin Fixed Paraffin Embedded Tissue (FFPE) sections on glass slides	Acid and Neutral Mucopolysaccharides	Alcian Blue/Periodic Acid Schiff HIST/STAIN SOP 0002
	Neutral Mucopolysaccharides, glycogen and fungus	Periodic Acid Schiff (PAS) HIST/STAIN SOP 0017
	Acid Mucopolysaccharides	Alcian Blue HIST/STAIN SOP 0001
	Amyloid	Congo Red HIST/STAIN SOP 0003
	Elastic fibres and connective tissue	Elastic Van Gieson (EVG) Millers HIST SOP 0013
	Helicobacter/Microorganisms	Giemsa HIST/STAIN SOP 0005
	Gram positive and negative micro-organisms	Gram HIST/STAIN SOP 0006
	Connective tissue and fibrin	Martius Yellow, Brilliant Crystal Scarlet, Soluble Blue (MSB) HIST/STAIN SOP 0009
	Melanin, Argentaffin cells and Lipofuscin pigment	Melanin Bleach HIST/STAIN SOP 0011
	Connective tissue	Masson's Trichrome HIST/STAIN SOP 0010



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<p>HUMAN BODY TISSUE Cont'd</p> <p>Formalin Fixed Paraffin Embedded Tissue (FFPE) sections on glass slides prepared in house</p>	<p><u>Histopathological examination activities for the purposes of clinical diagnosis Cont.</u></p> <p>Special stains for the detection of:</p> <p>Haemosiderin and ferric iron</p> <p>Reticulin fibres</p> <p>Copper-associated protein and Hepatitis B-affected cells</p> <p>Tubercle bacilli</p> <p>Calcium</p> <p>Fungi (Aspergillus) and Pneumocystis</p> <p>Elastic fibres and connective tissue</p> <p>Leprosy</p> <p>Melanin, Argentaffin cells and Lipofuscin pigment</p>	<p>In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:</p> <p>Documented in-house procedures for manual special stains</p> <p>Perl's Prussian Blue HIST/STAIN SOP 0018</p> <p>Reticulin (James) HIST/STAIN SOP 0020</p> <p>Orcein HIST/STAIN SOP 0016</p> <p>Ziehl Neelsen (ZN) HIST/STAIN SOP 0030</p> <p>Modified Von Kossa HIST/STAIN SOP 0027</p> <p>Grocott HIST/STAIN SOP 0008</p> <p>Van Gieson HIST/STAIN SOP 0026</p> <p>Wade Fite HIST/STAIN SOP 0028</p> <p>Masson Fontana HIST/STAIN SOP 0032</p>



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<p>HUMAN BODY TISSUE Cont'd</p> <p>FFPE slides prepared in house</p>	<p><u>Immunohistochemical examination activities for the purposes of clinical diagnosis cont'd.</u></p> <p>Demonstration of :</p> <p>Acid and basic cytokeratin's</p> <p>Embryonic cell in normal tissues and germ tumours</p> <p>Nuclear expression of B-Catenin in cancer tumorigenesis</p> <p>Diffuse lymph-proliferative disease and neoplastic cells of follicular lymphomas.</p> <p>Germinal centre cells</p> <p>Epithelial cell types</p> <p>Ovarian cancer</p> <p>Reacts with human calretinin and intracellular calcium binding protein. Marker for mesotheliomas</p> <p>Adenocarcinoma and carcinoid (intestinal epithelium)</p> <p>T cells</p>	<p>In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:</p> <p>Ventana Benchmark ULTRA immunostainers HIST/ICC-SOP-0001, 0002, 0006, 0010, 0017, 0018 and 0019</p> <p>AE1/AE3</p> <p>Alpha Fetoprotein</p> <p>B-Catenin</p> <p>Bcl2 oncoprotein</p> <p>Bcl6</p> <p>Ber Ep4</p> <p>CA 125</p> <p>Calretinin</p> <p>CDX2</p> <p>CD3</p>



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HUMAN BODY TISSUE Cont'd	<u>Immunohistochemical examination activities for the purposes of clinical diagnosis cont'd.</u>	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:
FFPE slides prepared in house	Immunohistochemistry to detect the following:	Ventana Benchmark ULTRA immunostainers HIST/ICC SOP 0018, HIST/ICC SOP 0019,
	T cells (helper+mature)	CD4
	Mature T cells, T cell lymphomas	CD5
	Cytotoxic and suppressor T cells	CD8
	Precursor B&T cells, germinal centre B-cells, granulocytes, liver canaliculi, myoepithelial cells, endometrial stroma	CD10
	Reed-sternberg and lymphomas	CD15
	Mature B cells, Follicular dendritic cells	CD20
	B cells, some T cells	CD21
	B cells, follicular dendritic cells, monocytes	CD23
	Reed-Sternberg cells and ALCL	CD30
	Haematopoietic cells, vascular endothelium	CD31
	Neuroendocrine cells	CD56
	Macrophages	CD68
	B lymphocytes	CD79alpha
	GIST	CD117
	Plasma cells	CD138



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<p>HUMAN BODY TISSUE Cont'd.</p> <p>FFPE slides prepared in house</p>	<p><u>Immunohistochemical examination activities for the purposes of clinical diagnosis cont'd.</u></p> <p>Demonstration of :</p> <p>CEA glycoproteins in adenocarcinoma</p> <p>Tissues of neuroendocrine origin</p> <p>Cyto Megalo Virus</p> <p>Expressed in variety tumours e.g. Mantle cell lymphoma</p> <p>Stratified squamous epithelium, basal cells, mesotheliomas</p> <p>Stratified squamous epithelium, basal cells, mesotheliomas and Squamous epithelium cocktail</p> <p>Normal and neoplastic epithelia</p> <p>Low-molecular weight keratins present in simple (non-squamous) epithelia</p> <p>Low-molecular weight keratin used as a part of an antibody panel for the characterization of normal and malignant cells of epithelial origin</p> <p>Adenocarcinomas, columnar epithelial cells</p>	<p>In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:</p> <p>Ventana Benchmark ULTRA immunostainers HIST/ICC SOP 0018, HIST/ICC SOP 0019,</p> <p>CEA</p> <p>Chromogranin</p> <p>CMV</p> <p>Cyclin D1</p> <p>CK5</p> <p>CK5 + P63 cocktail</p> <p>CK7</p> <p>CK8/18</p> <p>CK19</p> <p>CK20</p>



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HUMAN BODY TISSUE Cont. FFPE slides prepared in house	<p><u>Immunohistochemical examination activities for the purposes of clinical diagnosis cont'd.</u></p> <p>Demonstration of :</p> <p>Striated and smooth muscle cells</p> <p>Normal duct epithelial cells, ductal carcinoma</p> <p>Normal and neoplastic epithelium</p> <p>T cells and some soft tissue</p> <p>Nuclei of cells containing a high level of oestrogen</p> <p>Her2 gene amplification or</p> <p>HER2 Expression testing for Breast and Gastric Carcinoma</p> <p>Mesothelial Cells</p> <p>Melanoma, melanocyte differentiation</p> <p>B cells and plasma cells</p> <p>Proliferating Cells</p> <p>B cells and plasma cells</p> <p>B cells, T cells, monocytes, macrophages</p> <p>Melanoma marker</p> <p>Epithelial tissue from glandular to stratified squamous</p> <p>Neutrophil granulocytes, monocytes</p>	<p>In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:</p> <p>Ventana Benchmark ULTRA immunostainers HIST/ICC SOP 0018, HIST/ICC SOP 0019,</p> <p>Desmin</p> <p>E-Cadherin</p> <p>EMA</p> <p>END/CD34</p> <p>ER</p> <p>HER2 using Ventana 4B5 assay (Roche)</p> <p>HMBE1</p> <p>HMB45</p> <p>Kappa ISH</p> <p>Ki67</p> <p>Lambda ISH</p> <p>LCA/CD45</p> <p>Mel A</p> <p>MNF 116</p> <p>MPO (Myeloperoxidase)</p>



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<p>HUMAN BODY TISSUE Cont.</p> <p>FFPE slides prepared in house</p>	<p><u>Immunohistochemical examination activities for the purposes of clinical diagnosis cont'd.</u></p> <p>Demonstration of :</p> <p>Detection of human multiple myeloma oncogen 1 in normal and neoplastic tissues</p> <p>Alveolar macrophages, plasma cells, lung adenocarcinoma</p> <p>HPV driven tumour eg Squamous cell carcinoma</p> <p>Neoplastic cells in epithelium</p> <p>Squamous epithelium</p> <p>Germ cell tumours</p> <p>Nuclei of cells showing expression of Progesterone</p> <p>Prostate specific antigen</p> <p>Prostatic carcinoma</p> <p>prostatic carcinoma + proliferating cells</p> <p>Schwann cells, nerve processes, S100 +ve neoplasms e.g. Melanoma</p> <p>Smooth muscle cells, myoepithelial cells</p> <p>Smooth muscle cells, myoepithelial cells</p>	<p>In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:</p> <p>Ventana Benchmark ULTRA immunostainers HIST/ICC SOP 0018, HIST/ICC SOP 0019,</p> <p>MUM1</p> <p>Napsin A</p> <p>P16</p> <p>P53</p> <p>P63</p> <p>PLAP</p> <p>Progesterone Receptors</p> <p>PSA</p> <p>Racemase</p> <p>Racemase + Ki67 cocktail</p> <p>S100</p> <p>SMA</p> <p>Smooth Muscle Myosin (SMM)</p>



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<p>HUMAN BODY TISSUE Cont.</p> <p>FFPE slides prepared in house</p>	<p><u>Immunohistochemical examination activities for the purposes of clinical diagnosis cont'd.</u></p> <p>Demonstration of :</p> <p>Neuroendocrine cells</p> <p>TTF-1 found in lung and thyroid (thyroid follicular cells)</p> <p>Cells of mesenchymal origin</p> <p>Epithelial cells and smooth muscle in fallopian tube. Wilms tumour</p>	<p>In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:</p> <p>Immunohistochemistry: Ventana Benchmark ULTRA immunostainers HIST/ICC SOP 0018, HIST/ICC SOP 0019,</p> <p>Synaptophysin</p> <p>TTF-1</p> <p>Vimentin</p> <p>WT-1/Wilms'</p>



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<p>HUMAN BODY TISSUE Cont.</p> <p>Stained slides prepared in-house from sample types listed above</p> <p>Ejaculate - Seminal fluid</p> <p>Ejaculate - Seminal fluid</p>	<p><u>Histopathological examination activities for the purposes of clinical diagnosis Cont.</u></p> <p>Morphological assessment and interpretation/diagnosis</p> <p><u>Andrological examination activities for the purpose of clinical diagnosis</u></p> <p><u>Fertility screening</u> Semen volume Semen pH Sperm motility Sperm concentration Sperm morphology</p> <p><u>Post Vasectomy (PVSA)</u> Detection of presence/absence of sperm</p>	<p>In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:</p> <p>Interpretive Microscopy Using SOP HIST/GEN-SOP 0036 – Using the microscope</p> <p><u>Semen Analysis</u> Macroscopic and Microscopic examination using in house procedures in conjunction with manufacturer's instructions for the following methods (where relevant):</p> <p>Preparation and reporting of post vasectomy and fertility samples using documented in-house procedures based on WHO guidelines 5th Edition (2010):</p> <p>Centrifugation and slide assessment by manual light microscopy using SOP CYT NG 0010</p> <p>Centrifugation followed by manual light microscopy using in-house procedure using SOP CYT NG 0012</p>
END		