


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 <p>Accredited to ISO 15189:2012</p>	East Suffolk and North Essex NHS Foundation Trust (ESNEFT)	
	Issue No: 006 Issue date: 17 May 2023	
	Histopathology Ipswich Hospital Heath Road Ipswich Suffolk IP4 5PD	Contact: Lynn Partridge Tel: +44 (0) 1473 703227 E-Mail: lynn.partridge@esneft.nhs.uk
Testing performed at the above address only		

DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY TISSUE Tissue samples	<u>Histopathological examination activities for the purposes of clinical diagnosis</u>	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified: Specimen dissection: Using SOPs: CELL-IPS-LP-5 - Tissue transfer of category A samples CELL-IPS-CP-2 – dissection of malignant specimens CELL-IPS-CP-5 – dissection of skin specimens CELL-IPS-CP-6 – dissection head and neck specimens CELL-IPS-CP-4 – dissection of gastrointestinal and hepatobiliary specimens CELL-IPS-CP-3 – dissection of gynaecological specimens CELL-IPS-CP-7 – dissection of urological specimens CELL_IPS-CP-8 – dissection osteoarticular and soft tissue specimens CELL-IPS-CP-10 – dissection of malignant gastrointestinal resection specimens CELL-IPS-CP-9 – dissection of endocrine specimens CELL-IPS-CP-11 – dissection of breast specimens Decalcification in formic acid or EDTA using CELL-IPS-LP-46



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<p>HUMAN BODY TISSUE</p> <p>Formalin fixed tissue</p> <p>Formalin Fixed Paraffin Embedded Tissue (FFPE)</p> <p>Formalin Fixed Paraffin Embedded Tissue (FFPE) sections on glass slides</p> <p>Fresh tissue</p>	<p><u>Histopathological examination activities for the purposes of clinical diagnosis (cont'd)</u></p> <p>Basophilic and eosinophilic structures</p>	<p>In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:</p> <p>Tissue processing Sakura VIP 6 and Sakura VIP 6 AI Tissue processors Using SOP CELL-IPS-LP-47-</p> <p>Tissue embedding Sakura Tissue Tec 5 Embedding centres using CELL-IPS-LP-51</p> <p>Microtomy Sections cut using the Leica HistoCore Multicut (Leica RM 2235 and 2245), and PFM Medical 3005 E and SOP CELL-IPS-LP-52-</p> <p>Leica HistoCore SPECTRA ST stainer and integrated HistoCore SPECTRA CV coverslipper Haematoxylin & Eosin (H&E) Staining and coverslipping using SOP CELL-IPS-LP-31</p> <p>Cryotomy Leica CM1860UV Cryostat and using SOP CELL-IPS-LP-1-</p>



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HUMAN BODY TISSUE (cont'd)	<u>Histopathological examination activities for the purposes of clinical diagnosis</u> (cont'd)	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:
Formalin Fixed Paraffin Embedded Tissue (FFPE) sections on glass slides		Documented in-house procedures for manual Tinctorial Histochemical Special Stains
	Elastic fibres	Elastic Van Gieson (Millers) SOP CELL-IPS-LP-40
	Gram +ve and -ve bacteria	Gram SOP CELL-IPS-LP-21
	Connective tissue, fibrin	Mauritius Scarlet Blue (MSB) SOP CELL-IPS-LP-22
	Hepatitis B surface antigen	Victoria Blue SOP CELL-IPS-LP-11
	Mast cells	Toluidine Blue SOP CELL-IPS-LP-28
	Leprosy Bacilli	Wade Fite SOP CELL-IPS-LP-41
	Collagen,muscle,RBCs	Weigerts Haematoxylin van Gieson SOP CELL-IPS-LP-29
		Documented in-house procedures for Automated Tinctorial Histochemical Special Stains using the Ventana Benchmark Special Stain Machine.
	Acid and Neutral Mucopolysaccharides	Alcian Blue/Periodic Acid Schiff SOP CELL-IPS-LP-13
	Amyloid	Congo Red SOP CELL-IPS-LP-14
	Acid Mucins	Alcian Blue (AB) SOP CELL-IPS-LP-12
	Glycogen	Periodic Acid Schiff with Diastase (PAS-D) SOP CELL-IPS-LP-23
	Iron	Perls Prussian Blue SOP CELL-IPS-LP-26



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HUMAN BODY TISSUE (cont'd)	<u>Histopathological examination activities for the purposes of clinical diagnosis</u> (cont'd)	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified: Documented in-house procedures for Automated Tinctorial Histochemical Special Stains using the Ventana Benchmark Special Stain Machine
Formalin Fixed Paraffin Embedded Tissue (FFPE) sections on glass slides	Reticulin fibres	Reticulin stain. SOP CELL-IPS-LP-15
	Fungi and Pneumocystis jiroveci	Grocott Hexamine silver SOP CELL-IPS-LP-27
	Fungi/mucopolysaccharides	Periodic acid Schiff reaction (PAS) SOP CELL-IPS-LP-30
	Tubercle bacilli	Ziehl Neelsen SOP CELL-IPS-LP-42
Formalin Fixed Paraffin Embedded Tissue (FFPE) sections on glass slides	<u>Immunohistochemistry</u>	Documented in house procedures and Ventana Immunostainer. Using SOP CELL-IPS-LP-35
	Identification of Smooth muscle cells, myofibroblasts and myoepithelial cells	Actin (Smooth muscle)
	Identification of normal and abnormal epithelial cells	AE1/3
	Determination of human alpha-1-fetoprotein	AFP
	Determination of the presence of p80 protein found in human tissues.	ALK
	Used as an aid in the identification of Androgen Receptor positivity	Androgen receptor
	Identification of HCG containing cells.	b.HCG



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HUMAN BODY TISSUE (cont'd)	<u>Histopathological examination activities for the purposes of clinical diagnosis</u> (cont'd)	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:
Formalin Fixed Paraffin Embedded Tissue (FFPE) sections on glass slides	Immunohistochemistry	Documented in house procedures and Ventana Immunostainer. Using SOP CELL-IPS-LP-35
	Identification of cells expressing bcl-2	BCL2
	Used for the detection of the bcl6 protein	BCL6
	Identification of most epithelial cells, used as a discriminant in the differential diagnosis of adenocarcinoma versus malignant mesothelioma	BerEp4
	Human thyroid C-cells, and other calcitonin-containing cells.	Calcitonin
	Characterisation of neoplasms, especially those of lung, endometrial and ovarian	CA125
	Reacts with human calretinin and intracellular calcium binding protein. Marker for mesotheliomas	Calretinin
	Identification of the CD3 protein expressed by T-cell lymphocytes.	CD3



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<p>HUMAN BODY TISSUE</p> <p>Formalin Fixed Paraffin Embedded Tissue (FFPE) sections on glass slides</p>	<p><u>Histopathological examination activities for the purposes of clinical diagnosis</u> (cont'd)</p> <p>Immunohistochemistry</p> <p>Used to aid classification of lymphomas and renal carcinomas.</p> <p>Mature B cells, Follicular dendritic cells</p> <p>Used to aid classification of lymphocytes and lymphomas</p> <p>Classification of lymphomas.</p> <p>Identification of endothelial cells.</p> <p>Used to identify lymphocytes.</p> <p>Identification of the presence of human CD56 molecules, used to aid with the classification of tumours</p> <p>Used to identify macrophages.</p> <p>Identification of cells expressing CD99.</p> <p>Identification of cells expressing the transmembrane tyrosine kinase receptor CD117/c-kit</p> <p>Detection of the CD138 protein in human tissue</p> <p>Identification of cells expressing CEA glycoproteins</p>	<p>In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:</p> <p>Documented in house procedures and Ventana Immunostainer. Using SOP CELL-IPS-LP-35</p> <p>CD10</p> <p>CD34</p> <p>CD20 (L26)</p> <p>CD30</p> <p>CD31</p> <p>CD45 (LCA)</p> <p>CD56</p> <p>CD68</p> <p>CD99</p> <p>CD117</p> <p>CD138</p> <p>CEA</p>



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HUMAN BODY TISSUE (cont'd)	<u>Histopathological examination activities for the purposes of clinical diagnosis</u> (cont'd)	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:
Formalin Fixed Paraffin Embedded Tissue (FFPE) sections on glass slides	Identification of secretory granules of endocrine cells.	Chromogranin A
	Immunohistochemistry	Documented in house procedures and Ventana Immunostainer. Using SOP CELL-IPS-LP-35
	Used to aid the diagnosis of low differentiated squamous cell carcinoma and adenocarcinoma and between epithelioid mesothelioma and lung carcinoma	CK5/6
	Identification of glandular and transitional cells, normal and neoplastic.	CK7
	Used in the classification of tumours, particularly useful for identification of basal like carcinomas of breast.	CK14
	Identification of epithelial cells and classification of epithelial cell tumours.	CK8/18
	Identification of normal and abnormal gastric and intestinal epithelium, urothelium and Merkel cells	CK20
	Used to identify Cytomegalovirus	CMV
Use of this antibody is indicated,, as an aid in the identification of lymphatic invasion of a variety of tumors and between epithelioid and mesothelioma and lung adenocarcinoma	D2-40 (Podoplanin)	



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HUMAN BODY TISSUE (cont'd)	<u>Histopathological examination activities for the purposes of clinical diagnosis</u> (cont'd)	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:
Formalin Fixed Paraffin Embedded Tissue (FFPE) sections on glass slides	Immunohistochemistry	Documented in house procedures and Ventana Immunostainer. Using SOP CELL-IPS-LP-35
	Identification of myocytic cells	Desmin
	Used to identify DOG-1 presence, to aid with the classification of tumours.	DOG-1
	To identify cells positive for E-cadherin.	E Cadherin
	Normal and abnormal epithelial and mesothelial cells.	EMA
	Used to identify and evaluate oestrogen receptors.	ER
	Study of Angiogenesis in neoplasms and for the identification of epithelioid hemangioendothelioma	Factor VIII
	Used for differentiating skin lesions particularly dermal lesions.	Factor XIIIa
	Detection of HER2 antigen in sections	HER 2
	Identification of hepatocytes and hepatocellular tumours	Hepatocyte



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HUMAN BODY TISSUE (cont'd)	<u>Histopathological 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:
Formalin Fixed Paraffin Embedded Tissue (FFPE) sections on glass slides	Immunohistochemistry	Documented in house procedures and Ventana Immunostainer. Using SOP CELL-IPS-LP-35
	Identification of melanocytes and classification of melanomas and melanocytic lesions	HMB45
	Subclassification of neoplastic tissue as carcinoma or epithelial in origin	HMC (high molecular weight cytokeratin)
	Proliferating cells	KI67
	Used for the identification of Melanoma.	Melan A
	Identification of normal and neoplastic cells of neuronal and neuroendocrine origin	NSE
	Detection of the p16INK4a protein	P16
	Used in the detection of p40 protein in human tissue, particularly useful for classification of lung carcinomas.	P40
	Identification of wild type and mutant p53	P53
Identification of the p63 protein. Used to aid differentiation of benign and malignant prostatic or breast lesions, and in the differentiation of lung squamous cell carcinoma and lung adenocarcinoma.	P63	
Identification of cells expressing placental alkaline phosphatase (PLAP) and PLAP-like alkaline phosphatase, also named germ cell AP (GCAP)	PLAP	



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<p>HUMAN BODY TISSUE (cont'd)</p> <p>Formalin Fixed Paraffin Embedded Tissue (FFPE) sections on glass slides</p>	<p><u>Histopathological examination activities for the purposes of clinical diagnosis</u></p> <p>Immunohistochemistry</p> <p>Identification of human prostate specific antigen.</p> <p>Used to identify and evaluate progesterone receptors.</p> <p>Used to assist in distinguishing morphologically difficult tissue as benign, atypical or cancerous.</p> <p>Identification of normal and neoplastic cells expressing S100 protein.</p> <p>Identification of cells containing Synaptophysin molecules.</p> <p>Thyroglobulin containing cells</p> <p>TTF-1 found in lung and thyroid (thyroid follicular cells)</p> <p>Identification of cells containing Vimentin 55 kDa intermediate filament (IF) protein</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>Documented in house procedures and Ventana Immunostainer. Using SOP CELL-IPS-LP-35</p> <p>PSA</p> <p>PR</p> <p>Racemase (p504s)</p> <p>S100</p> <p>Synaptophysin</p> <p>Thyroglobulin</p> <p>TTF-1</p> <p>Vimentin</p> <p>WT-1</p>



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<p>HUMAN BODY TISSUE (cont'd)</p> <p>Formalin Fixed Paraffin Embedded Tissue (FFPE) sections on glass slides</p> <p>Slides prepared in-house from sample types listed above</p>	<p><u>Histopathological examination activities for the purposes of clinical diagnosis (cont'd)</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>In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:</p> <p>Interpretive Microscopy Using CELL-IPS-CP-12 Histopathology Reporting, including BCS and BSS cases.</p>
<p>HUMAN BODY TISSUE</p> <p>Non gynaecological cytology samples including: Serous fluids - Ascitic, pleural and pericardial. Respiratory samples, including Bronchial washings, brushings and sputum. EBUS samples. Cerebrospinal fluid samples. Cyst fluids, - ovarian cyst fluids, breast cyst Synovial fluid Urine samples Semen for cell morphology. Fine needle aspirates, - soft tissue, thyroid, lymph node, salivary gland, breast and head and neck samples.</p>	<p><u>Cytopathological 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>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 using SOPs: CELL-IPS-LP-50 CELL-IPS-LP-32 CELL-IPS-LP-17 CELL-IPS-LP-53, CELL-IPS-LP-8 CELL-IPS-LP-2, CELL-IPS-LP-9</p> <p>Papanicolaou Stain using SOP CELL-IPS-LP-36 Vision Biosystems Autostainer Rst. MGG staining, SOP CELL-IPS-LP-44</p>



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<p>HUMAN BODY TISSUE</p> <p>Synovial Fluid</p> <p>Slides prepared in-house from sample types listed above</p>	<p><u>Cytopathological examination activities for the purposes of clinical diagnosis (cont'd)</u></p> <p>Identification of crystals in synovial fluid using polarising microscopy for:</p> <p>Urate (monosodium urate monohydrate) CPPD (calcium pyrophosphate dihydrate)</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>Microscopy using polarised filters using SOP: CELL-IPS-LP-49</p> <p>Interpretive Microscopy Screening and Reporting using: CELL-IPS-CP-13</p>
END		