Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

9316

Accredited to ISO 15189:2022

East Suffolk and North Essex NHS Foundation Trust (ESNEFT)

Issue No: 007 **Issue date:** 16 June 2025

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	Histopathological examination activities for the purposes of clinical diagnosis	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 – dissectionof 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 hepatobilary 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

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

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY TISSUE (cont'd)	Histopathological examination activities for the purposes of clinical diagnosis (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 Scarlett 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

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY TISSUE (cont'd)	Histopathological examination activities for the purposes of clinical diagnosis (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	Immunohistochemistry	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

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY TISSUE (cont'd)	Histopathological examination activities for the purposes of clinical diagnosis (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

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY TISSUE	Histopathological examination activities for the purposes of clinical diagnosis (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
	Used to aid classification of lymphomas and renal carcinomas.	CD10
	Mature B cells, Follicular dentritic cells	CD34
	Used to aid classification of lymphocytes and lymphomas	CD20 (L26)
	Classification of lymphomas.	CD30
	Identification of endothelial cells.	CD31
	Used to identify lymphocytes.	CD45 (LCA)
	Identification of the presence of human CD56 molecules, used to aid with the classification of tumours	CD56
	Used to identify macrophages.	CD68
	Identification of cells expressing CD99.	CD99
	Identification of cells expressing the transmembrane tyrosine kinase receptor CD117/c-kit	CD117
	Detection of the CD138 protein in human tissue	CD138
	Identification of cells expressing CEA glycoproteins	CEA

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY TISSUE (cont'd)	Histopathological examination activities for the purposes of clinical diagnosis (cont'd)	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:
	Identification of secretory granules of endocrine cells.	Chromogranin A
Formalin Fixed Paraffin Embedded Tissue (FFPE) sections on glass slides	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 epitheloid and mesothelioma and lung adenocarcinoma	D2-40 (Podoplanin)

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY TISSUE (cont'd)	Histopathological examination activities for the purposes of clinical diagnosis (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

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY TISSUE (cont'd)	Histopathological examination activities for the purposes of clinical diagnosis (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 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

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY TISSUE (cont'd)	Histopathological examination activities for the purposes of clinical diagnosis	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 human prostate specific antigen.	PSA
	Used to identify and evaluate progesterone receptors.	PR
	Used to assist in distinguishing morphologically difficult tissue as benign, atypical or cancerous.	Racemase (p504s)
	Identification of normal and neoplastic cells expressing S100 protein.	S100
	Identification of cells containing Synaptophysin molecules.	Synaptophysin
	Thyroglobulin containing cells	Thyroglobulin
	TTF-1 found in lung and thyroid (thyroid follicular cells)	TTF-1
	Identification of cells containing Vimentin 55 kDa intermediate filament (IF) protein	Vimentin
	Epithelial cells and smooth muscle in fallopian tube. Wilms tumour	WT-1

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY TISSUE (cont'd)	Histopathological examination activities for the purposes of clinical diagnosis (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		In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:
Slides prepared in-house from sample types listed above	Morphological assessment and interpretation/diagnosis	Interpretive Microscopy Using CELL-IPS-CP-12Histopathology Reporting, including BCS and BSS cases.
HUMAN BODY TISSUE	Cytopathological examination activities for the purposes of clinical diagnosis	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:
Non gynaecological cytology samples including: Serous fluids - Ascitic, pleural and pericardial. Respiratory samples, including Bronchial washings, brushings and sputum. EBUS samples. Cereprospinal 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.	Examination of cellular material in order to identify or exclude morphological and cytological abnormalities	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 Papanicolaou Stain using SOP CELL-IPS-LP-36 Vision Biosystems Autostainer Rst. MGG staining, SOP CELL-IPS-LP-44

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY TISSUE	Cytopathological examination activities for the purposes of clinical diagnosis (cont'd)	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:
Synovial Fluid	Identification of crystals in synovial fluid using polarising microscopy for: Urate (monosodium urate monohydrate) CPPD (calcium pyrophosphate dihydrate)	Microscopy using polarised filters using SOP: CELL-IPS-LP-49
Slides prepared in-house from sample types listed above	Morphological assessment and interpretation/diagnosis	Interpretive Microscopy Screening and Reporting using: CELL-IPS-CP-13
END		