


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 Accredited to ISO 15189:2022	Mersey and West Lancashire Teaching Hospitals NHS Trust	
	Issue No: 010 Issue date: 12 March 2025	
	Cellular Pathology Whiston Hospital Warrington Road Prescot L35 5DR	Contact: Janine Pennington Tel: +44 (0) 151 430 2372 E-Mail: Janine.Pennington@sthk.nhs.uk Website: www.sthk.nhs.uk

Testing performed by the Organisation at the locations specified below

Locations covered by the organisation and their relevant activities

Location details		Activity	Location code
Address Whiston Hospital Nightingale House Warrington Road Prescot L35 5DR	Local contact Janine Pennington As above	Routine diagnostic service for Histopathology Non-Gynae cytology Out of hours on call service for urgent frozen sections / diagnosis Mortuary services Storage of bodies Viewing facilities Record keeping (body identification and audit trail)	STHK
Address Southport Hospital Town Lane Kew Southport PR8 6PN	Local contact Janine Pennington As above Mortuary +44 (0) 1704 704 014	Histopathology & Cytopathology reporting Mortuary services Storage of bodies Viewing facilities Record keeping (body identification and audit trail)	SOHT



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Additional site activity performed away from the laboratory

Location details	Activity	Location code
Address Whiston Hospital Nightingale House Warrington Road Prescot L35 5DR Local contact As above	FNA Clinic Rapid on site assessment of FNA samples	STHK
Address Ormskirk District General Hospital Wigan Road Ormskirk Lancashire L39 2AZ Local contact As above Mortuary +44 (0) 1704 704 014	FNA clinic Rapid on site assessment of FNA samples Mortuary services Storage of bodies Viewing facilities Record keeping (body identification and audit trail)	ODGH
Address St Helens Hospital Marshalls Cross Road St Helens WA9 3DA Local contact As above	Skin Outpatients Mohs frozen section service	STH



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DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY TISSUE AND FLUIDS	<u>Examination activities in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis</u>	Macroscopic and Microscopic examination: Documented in house methods incorporating manufacturers' instructions where relevant:	
Aspirates Bronchial lavage Cerebrospinal fluid Fluid samples Fine needle aspirates Urine EBUS Bronchial Brushings Bronchoalveolar lavage Ascitic fluid Petitoneal fluid Pleural fluid Cyst Fluid Bile duct brushings	<u>Diagnostic Non Gynae Cytopathology</u> Morphological assessment and interpretation/diagnosis	Documented in house methods incorporating manufacturers' instructions where relevant: Harrier 15/80 Centrifuge Thermo Scientific Cytospin 4 Stuart SA7 Vortex mixer Manual Papanicolaou stain Manual May Grunwald Giemsa (MGG) SOP NGC 10,NGC34 NGC35, NGC22	STHK
Slides prepared in house from above	Morphological assessment and interpretation/diagnosis	Microscopy (qualitative analysis) In-house procedures: SOPs SC2 / SC10 / MED 1.3 Using Nikon Eclipse E400 or Olympus BX45 Microscopes	STHK SOHT



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HUMAN BODY TISSUE AND FLUIDS (cont'd)	<u>Examination activities in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis</u> (cont'd)	Macroscopic and Microscopic examination: Documented in house methods incorporating manufacturers' instructions where relevant:	
Slides prepared from FNA material	Adequacy of sample by rapid on site assessment	Manual Staining and Microscopy using in-house procedures: Papanicolaou stain May Grunwald Giemsa (MGG) SOP NGC 10,NGC34 NGC35, NGC22 SOPs SC2 / SC10 / MED 1.3 Using Nikon Eclipse E400 or Olympus BX45 Microscopes	STHK ODGH
Prepared slides of Synovial fluid specimens (from Microbiology)	Morphological assessment and interpretation/diagnosis	Microscopy (qualitative analysis) In-house procedures: SOPs SC2 / SC10 / MED 1.3 Using Nikon Eclipse E400 or Olympus BX45 Microscopes	STHK
Tissues / organs	<u>Histopathology</u>	<u>Macroanalysis, dissection & decalcification</u> following: SOPs 1.0 / 1.10 / 1.10.2 / 1.1.1	STHK
		<u>Processing</u> following: SOPs 10.2 / 10.1 Thermo Excelsior ES Processor Thermo Excelsior AS Processor Logos Microwave Processor Sakura X120 tissue processor	STHK
As above and cell blocks		<u>Embedding</u> following: SOP 2.2 Thermo Histocentre paraffin embedding centre and Leica embedding station EG1160 Sakura A120 Automated embedder	STHK



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HUMAN BODY TISSUE AND FLUIDS (cont'd)	<u>Examination activities in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis</u> (cont'd)	Macroscopic and Microscopic examination: Documented in house methods incorporating manufacturers' instructions where relevant:	
Fresh tissue	Frozen section examination to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis	<u>Frozen section / Cryotomy</u> following SOPs 8.2 / 8.3 Thermo Cryostar NX50 Thermo Cryotome SME H&E staining using Linistat staining platform	STHK
Formalin Fixed Paraffin Embedded (FFPE) wax blocks of processed tissue.		<u>Microtomy using</u> ID:8938 – 3.3 Epredia and Thermo Scientific microtomes	STHK
Skin	Frozen section examination to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis	<u>Mohs service</u> SOP 8.7 / 8.2.1 Thermo Crytome FSE H&E staining using Linistat staining platform Nikon Eclipse CI L Teaching microscope	STH
Fresh tissue sections mounted on glass slides	Detection of the following antibodies IgG IgA IgM C3	<u>Direct Immunofluorescence (manual) using the following fluorescently labelled antibodies</u> SOPs I 01 / I 02 IgG IgA IgM C3	STHK
FFPE tissue mounted on glass slides prepared in house	Identification of basophilic and eosinophilic structures	Automated Haematoxylin and Eosin Staining using Roche HE600 staining machine SOP 4.2	STHK



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HUMAN BODY TISSUE AND FLUIDS (cont'd)	<u>Histopathological examination activities for the purposes of clinical diagnosis</u>	Manual Special Staining using documented in house methods SOPs S1-S40	STHK
FFPE tissue mounted on glass slides prepared in house	Acid and neutral mucins	ABPAS SOP S22	
	Collagen, muscle	Van Geison SOP S17	
	Fungi	Grocott Hexamine Silver SOP S15	
	Copper Associated Protein/Hepatitis B	Shikata's Orcein SOP S10	
	Connective tissue/elastin fibres, collagen, muscle	Elastic van gieson SOP S17	
	Gram positive and negative bacteria	Grams stain SOP S12	
	Tubercle bacilli (AFB)	Ziehl Neelsen SOP S13	
	Metachromatic substances, mast cells	Toluidine Blue SOP S34	
FFPE tissue mounted on glass slides prepared in house		Automated special staining using Ventana Benchmark Special Stains	STHK
	Mucins, glycogen, fungus and diastase resistance mucin	PAS+/- Diastase	
	Iron (ferric), haemosiderin pigment	Perls Prussian Blue	
	Reticulin fibers Amyloid	Gordon and Sweets Reticulin Congo Red	
	Muscle, Fibrin, Collagen	Massons Trichrome	



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<p>HUMAN BODY TISSUE AND FLUIDS (cont'd)</p> <p>Unstained sections from FFPE tissue and cell blocks prepared in-house</p>	<p><u>Immunohistochemical examination activities for the purposes of clinical diagnosis</u></p> <p>Epithelial marker, Cytokertain 40 to 70 kD</p> <p>Primary liver tumours/yolk sac tumours, Glycoprotein 70 kD</p> <p>Transmembrane receptor tyrosine kinase 200 kD Anaplastic lymphomas and inflammatory myofibroblastic tumours</p> <p>Oncoprotein 26 kD B-cell in germinal centres and mantle cells</p> <p>Proto-oncogene 92-98 kD Marker for apoptosis</p> <p>Germinal centres in follicular lymphoma, diffuse large B cell lymphoma and Reed-Sternberg cells</p> <p>Polypeptides 34 & 39 kD Epithelial marker</p> <p>Marker of smooth muscle</p> <p>Calcium binding protein 32 kD Marker for mesothelioma</p> <p>Common acute lymphoblastic leukemia antigen 85kD Lymphoid/endometrial malignancies</p>	<p>Automated Immunohistochemical staining (IHC and ISH) following: SOPs I03 / I04 / Appx 4a Roche Ventana Benchmark Ultra immuno platform, polymer refine detection kit,using the following monoclonal, polyclonal and cocktail antibodies:</p> <p>AE1/3</p> <p>AFP</p> <p>ALK1</p> <p>BOB 1</p> <p>BCL-2</p> <p>BCL-6</p> <p>BER-EP4</p> <p>CALDESMON</p> <p>CALRETININ</p> <p>Carbonic anhydrase</p> <p>CD10</p>	STHK



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<p>HUMAN BODY TISSUE AND FLUIDS (cont'd)</p> <p>Unstained sections from FFPE tissue and cell blocks prepared in-house (cont'd)</p>	<u>Immunohistochemical examination activities for the purposes of clinical diagnosis</u> (cont'd)	Automated Immunohistochemical staining (IHC and ISH) following: SOPs I03 / I04 / Appx 4a Roche Ventana Benchmark Ultra immuno platform, polymer refine detection kit, using the following monoclonal, polyclonal and cocktail antibodies:	STHK
	Glycolipids & glycoproteins 220kD Hogkins lymphoma	CD15	
	Transmembrane non-glycosylated protein 33 kD B lymphocytes	CD20	
	Transmembrane glycoprotein 47kD B lymphocytes, some T-cells	CD23	
	Transmembrane cytokine receptor 120 kD Hogkins lymphoma	CD30	
	Transmembrane protein 135 kD Endothelial marker	CD31	
	Transmembrane protein 116 kD Vascular and lymphatic tumours	CD34	
	Transmembrane glycoprotein 59 kD T cells	CD4	
	Transmembrane glycoprotein 59 kD T cells and myeloid lineage cells	CD43	
	Transmembrane glycoprotein 67 kD Mature T-cells and T-cell lymphomas	CD5	
	Homophilic binding glycoprotein 140 kD Marker of nerve/neuroendocrine tumours	CD56	



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	Lysosomal glycoprotein 110 kD Histiocytes/macrophages	CD68	
	Glycoprotein 40-45 kD B lymphocytes	CD79a	
	Transmembrane tyrosine kinase 145 kD Gastrointestinal stromal tumour marker	CD117	
	Transmembrane proteoglycan 30.5 kD Plasma cells, multiple myeloma	CD138	
	Transcription factor 34 kD GI tract tumours	CDX2	
	Carcinoembryonic Antigen glycoprotein 18 kD Epithelial marker	CEA	
	Protein prohormone 48 kD Neuroendocrine cells	CHROMOGRANIN	
	Cytokeratin 5 – 58 kD & cytokeratin 6 – 56 kD Epithelial marker	CK5/6	
	Cytokeratin 7 - 54 kD Epithelial marker	CK7	
	Cytokeratin 20 - 46 kD Epithelial marker	CK20	
	Proto-oncogene 36 kD Mantle cell lymphomas	CYCLIN D1	



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	Transmembrane siaglycoprotein Podoplanin 38 kD Lymphatic vessels	D2-40	
	Class III intermediate filament 53 kD Pan muscle marker	DESMIN	
	Transmembrane cell adhesion molecule 120 kD Cell adhesion molecule	E-CAD	
	Epithelial membrane antigen 150 kD Epithelial marker	EMA	
	Estrogen receptor alpha protein 66 kD Estrogen receptor/ prognostic breast marker	ER	
	Factor 8 protein of Von Willibrand Factor 293 kD VW factor in endothelial cells	Factor VIII	
		Factor 13	
	Secretory glycoprotein 15 kD Breast carcinoma and mestastic tumours	GCDFP-15	
	Zinc finger transcription factor 48 kD Breast and urothelial carcinoma	GATA-3	
	2 subunit glycoprotein (α & β) 40 kD hCG containing cells and cells with trophoblastic elements	HCG	



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	Marker for H pylori Gram negative rod bacteria	Helicobacter	
	c-erbB-2 oncoprotein 185 kD Marker of Her2 amplification in breast tumours	HER 2	
	Glycoprotein 150 kD Melanoma marker	HMB45	
		Inhibin	
	Nuclear protein 345-395 kD Proliferation marker	KI67	
	Transmembrane glycoprotein 180 000 -220 000 Leucocytes	LCA	
	Transmembrane protein 20-22 kD Melanoma marker	MELAN-A	
	Cytokeratin 40-58 kD Epithelial marker	MNF 116	
	Myeloma associated oncogene 50 kD Multiple myeloma oncogene-1	MUM1	
	Heme peroxidase 150 kD Neutrophil granulocytes, monocytes	Myeloperoxidase	
	Mismatch repair (MMR panel)	MLH-1	
	Mismatch repair (MMR panel)	MSH2	
	Mismatch repair (MMR panel)	MSH6	



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	Transcription factor - Mantle cell, diffuse large cell, marginal zone and classic Hodgkin's lymphoma marker	OCT 2	
	OCT 3 protein 52 kD OCT 4 protein 45 kD Pluripotent germ cell tumours	OCT 3-4	
	B cell specific activator protein 150 kD Pre-B cells	PAX-5	
	Cyclin-dependent kinase inhibitor 150 kD Marker of CIN	P16	
	Squamous cell carcinoma	P40	
	Tumour suppressor protein 53 kD Carcinomas: many neoplasms and normal cells	P53	
	Transcription factor 44-77 kD Marker in breast/prostate tumours	p63	
	Mismatch repair (MMR panel)	PMS2	
	Progesterone receptor A & B 60-110 kD Prognostic breast marker	PR	
	Prostate specific antigen 33 kD Marker of normal/malignant prostate	PSA	
	Prostatic acid phosphatase 58 kD Marker of normal/malignant prostate	PSAP	



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	Alpha-methylacyl-CoA racemase 54 kD HGPIN, prostate adenocarcinoma	RACEMASE (AMACR)	
	Ca binding protein 11 kD Nerve sheath, neural marker	S100	
	MHC-1 205 kD & MHC-2 200 kD Smooth muscle marker	SMM	
	Nuclear transcription factor 56 kD Marker for malignant melanoma and schwannoma	SOX10	
	Membrane glycoprotein 34 kD Marker of neural cells/neuroendocrine tumors	Synaptophysin	
	Transcription factor 40 kD Marker of normal throid/lung tumours	TTF-1	
	Intermediate filament protein 57 kD Mesenchymal tumours	Vimentin	
	Zinc finger transcription factor 46-49 kD Wilms tumour/mesothelioma	WT-1	
	Identification of HER-2 gene & chromosome 17 Determination of Her2 gene status	DDISH	
	Type Cytokeratin 50 kDa	CK1	
	High Molecular weight glycoprotein of the mucin family 1519 kDa	CA125	



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	Epithelial marker, cytokeratin 50-67 kDa	34BE12	
	Transcription factor 48 kDa	PAX 8	
	Glycoprotein B 112 kDa	CMV	
	CD3 complex of T cell lineage 20-28 kDa	CD3	
	Heterodimeric, transmembrane glycoprotein of T cell lineage 34 kDa	CD8	
	Kappa	Kappa	
	Lambda	Lambda	
Slides prepared in house as above	Morphological assessment and interpretation / diagnosis	Interpretive / diagnostic microscopy (qualitative analysis) In-house procedures: SOPs SC2 / SC10 / MED 1.3 Using Nikon Eclipse E400 or Olympus BX45 Microscopes	STHK SOHT
Digital images from slides prepared in house as above	Morphological assessment and interpretation / diagnosis	Using Philips Digital Pathology solution Slide Scanning Slide Reporting	STHK
END			