


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>	St Helens & Knowsley Teaching Hospitals NHS Trust	
	Issue No: 005 Issue date: 08 August 2022	
Cellular Pathology Whiston Hospital Warrington Road Prescott L35 5DR	Contact: David Barker Tel: +44 (0) 151 430 1828 Fax: +44 (0) 151 430 1823 E-Mail: david.barker@sthk.nhs.net 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
<p>Address Whiston Hospital Nightingale House Warrington Road Prescott L35 5DR</p> <p>Local contact David Barker As above</p>	<p>Routine diagnostic service for Histopathology Non-Gynae cytology</p> <p>Out of hours on call service for urgent frozen sections / diagnosis</p> <p>Mortuary services Storage of bodies Viewing facilities Record keeping (body identification and audit trail)</p>	STHK
<p>Address Southport Hospital Town Lane Kew Southport PR8 6PN</p> <p>Local contact David Barker As above</p> <p>Mortuary +44 (0) 1704 704 014</p>	<p>Histopathology & Cytopathology reporting</p> <p>Mortuary services Storage of bodies Viewing facilities Record keeping (body identification and audit trail)</p>	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 5DRF	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
<p>HUMAN BODY TISSUE AND FLUIDS</p> <p>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</p> <p>Slides prepared in house from above</p>	<p><u>Examination activities in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis</u></p> <p><u>Diagnostic Non Gynae Cytopathology</u></p> <p>Morphological assessment and interpretation/diagnosis</p> <p>Morphological assessment and interpretation/diagnosis</p>	<p>Macroscopic and Microscopic examination:</p> <p>Documented in house methods incorporating manufacturers' instructions where relevant:</p> <p>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</p> <p>Microscopy (qualitative analysis) In-house procedures: SOPs SC2 / SC10 / MED 1.3 Using Nikon Eclipse E400 or Olympus BX45 Microscopes</p>	<p>STHK</p> <p>STHK SOHT</p>



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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 (cont'd)</u>	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 <u>Processing</u> following: SOPs 10.2 / 10.1 Thermo Excelsior ES Processor Thermo Excelsior AS Processor Logos Microwave Processor	STHK STHK
As above and cell blocks		<u>Embedding</u> following: SOP 2.2 Thermo Histocentre paraffin embedding centre and Leica embedding station EG1160	STHK
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 NX70 Thermo Cryotome SME H&E automated staining using Roche HE600stainer	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 (cont'd)</u>	Macroscopic and Microscopic examination: Documented in house methods incorporating manufacturers' instructions where relevant:	
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 automated staining using Roche HE600 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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FFPE tissue mounted on glass slides prepared in house	<u>Histopathological examination activities for the purposes of clinical diagnosis</u>	Manual Special Staining using documented in house methods SOPs S1-S40	STHK
	Acid and neutral mucins	ABPAS SOP S22	
	Mucins, glycogen, fungus and diastase resistance mucin	PAS+/- Diastase SOP SO7	
	Collagen, muscle	Van Geison SOP S17	
	Fungi	Grocott Hexamine Silver SOP S15	
	Iron (ferric), haemosiderin pigment	Perls Prussian Blue SOP SO8	
	Reticulin fibers	Gordon and Sweets Reticulin SOP S11	
	Amyloid	Congo Red SOP S27	
	Copper Associated Protein/Hepatitis B	Shikata's Orcein SOP S10	
	Connective tissue/elastin fibres, collagen, muscle	Elastic van gieson SOP S17	
	Muscle, Fibrin, Collagen	Massons Trichrome SOP S25	
	Gram positive and negative bacteria	Grams stain SOP S12	
	Tubercle bacilli (AFB)	Ziehl Neelsen SOP S13	
Metachromatic substances, mast cells	Toluidine Blue SOP S34		



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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
Unstained sections from FFPE tissue and cell blocks prepared in-house	<u>Immunohistochemical examination activities for the purposes of clinical diagnosis</u>	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
	Epithelial marker, Cytokeratin 40 to 70 kD	AE1/3	
	Primary liver tumours/yolk sac tumours, Glycoprotein 70 kD	AFP	
	Transmembrane receptor tyrosine kinase 200 kD Anaplastic lymphomas and inflammatory myofibroblastic tumours	ALK1	
	Oncoprotein 26 kD B-cell in germinal centres and mantle cells	BOB 1	
	Proto-oncogene 92-98 kD Marker for apoptosis	BCL-2	
	Germinal centres in follicular lymphoma, diffuse large B cell lymphoma and Reed-Sternberg cells	BCL-6	
	Polypeptides 34 & 39 kD Epithelial marker	BER-EP4	
	Marker of smooth muscle	CALDESMON	
	Calcium binding protein 32 kD Marker for mesothelioma	CALRETININ Carbonic anhydrase	
Common acute lymphoblastic leukemia antigen 85kD Lymphoid/endometrial malignancies	CD10		



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Unstained sections from FFPE tissue and cell blocks prepared in-house (cont'd)	<u>Immunohistochemical examination activities for the purposes of clinical diagnosis (cont'd)</u>	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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Unstained sections from FFPE tissue and cell blocks prepared in-house (cont'd)	<u>Immunohistochemical examination activities for the purposes of clinical diagnosis (cont'd)</u>	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
	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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Unstained sections from FFPE tissue and cell blocks prepared in-house (cont'd)	<p><u>Immunohistochemical examination activities for the purposes of clinical diagnosis (cont'd)</u></p> <p>Transmembrane siaglycoprotein Podoplanin 38 kD Lymphatic vessels</p> <p>Class III intermediate filament 53 kD Pan muscle marker</p> <p>Transmembrane cell adhesion molecule 120 kD Cell adhesion molecule</p> <p>Epithelial membrane antigen 150 kD Epithelial marker</p> <p>Estrogen receptor alpha protein 66 kD Estrogen receptor/ prognostic breast marker</p> <p>Factor 8 protein of Von Willibrand Factor 293 kD VW factor in endothelial cells</p> <p>Secretory glycoprotein 15 kD Breast carcinoma and mestastic tumours</p> <p>Zinc finger transcription factor 48 kD Breast and urothelial carcinoma</p> <p>2 subunit glycoprotein (α & β) 40 kD hCG containing cells and cells with trophoblastic elements</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>D2-40</p> <p>DESMIN</p> <p>E-CAD</p> <p>EMA</p> <p>ER</p> <p>Factor VIII</p> <p>Factor 13</p> <p>GCDFP-15</p> <p>GATA-3</p> <p>HCG</p>	STHK



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Unstained sections from FFPE tissue and cell blocks prepared in-house (cont'd)	<u>Immunohistochemical examination activities for the purposes of clinical diagnosis (cont'd)</u>	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
	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	
Transcription factor - Mantle cell, diffuse large cell, marginal zone and classic Hodgkin's lymphoma marker	OCT 2		



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Unstained sections from FFPE tissue and cell blocks prepared in-house (cont'd)	<p><u>Immunohistochemical examination activities for the purposes of clinical diagnosis (cont'd)</u></p> <p>OCT 3 protein 52 kD OCT 4 protein 45 kD Pluripotent germ cell tumours</p> <p>B cell specific activator protein 150 kD Pre-B cells</p> <p>Cyclin-dependent kinase inhibitor 150 kD Marker of CIN</p> <p>Tumour suppressor protein 53 kD Carcinomas: many neoplasms and normal cells</p> <p>Transcription factor 44-77 kD Marker in breast/prostate tumours</p> <p>Progesterone receptor A & B 60-110 kD Prognostic breast marker</p> <p>Prostate specific antigen 33 kD Marker of normal/malignant prostate</p> <p>Prostatic acid phosphatase 58 kD Marker of normal/malignant prostate</p> <p>Alpha-methylacyl-CoA racemase 54 kD HGPIN, prostate adenocarcinoma</p> <p>Ca binding protein 11 kD Nerve sheath, neural marker</p> <p>MHC-1 205 kD & MHC-2 200 kD Smooth muscle marker</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>OCT 3-4</p> <p>PAX-5</p> <p>P16</p> <p>P53</p> <p>p63</p> <p>PR</p> <p>PSA</p> <p>PSAP</p> <p>RACEMASE (AMACR)</p> <p>S100</p> <p>SMM</p>	STHK



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Unstained sections from FFPE tissue and cell blocks prepared in-house (cont'd)	<u>Immunohistochemical examination activities for the purposes of clinical diagnosis (cont'd)</u>	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
	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	
	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		



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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
END			