

Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 8823 Accredited to ISO 15189:2022	University Hospitals of North Midlands NHS Trust	
	Issue No: 007 Issue date: 11 February 2025	
	Royal Stoke University Hospital Main Building –Floor 2 Newcastle Road Stoke-on-Trent ST4 6QG	Contact: Laura Kinghorn-Perry, Pathology Quality Manager Tel: +44 (0)1782 679664 E-Mail: laura.kinghorn-perry@uhnm.nhs.uk Website: www.uhnm.nhs.uk
Testing performed by the Organisation at the locations specified below		

Locations covered by the organisation and their relevant activities

Laboratory locations:

Location details	Activity
Address Pathology Directorate Histopathology University Hospitals of North Midlands NHS Trust Royal Stoke University Hospital (RSUH) Main Building –floor 2 Newcastle Road Stoke-on-Trent ST4 6QG	Local contact As above Histopathology Non-gynae cytology

Additional site activity performed away from the laboratory

Location details	Activities
Royal Stoke University Hospital (RSUH) On-site Mortuary and Body Store incl. Post Mortem	Reception, storage and release of the deceased FNA Clinic



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Site activities performed away from the locations listed above:

Location details	Activity
Body Store County Hospital Weston Road Stafford ST16 3SA	Reception, storage and release of the deceased Reception, storage and release of the deceased
Body Store Macclesfield District General Hospital Victoria Rd Macclesfield SK10 3BL	Reception, storage and release of the deceased
Body Store Leighton Hospital Middlewich Rd Crewe CW1 4QJ	



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DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
<p>HUMAN BODY TISSUE AND FLUIDS</p> <p>Tissue as FFPE; (diagnostic/biopsy, excision and resection specimens from anatomical sites as listed below):</p> <p>Breast Urology Gynaecology Upper GI Lower GI Respiratory Renal Lymphoma Dermatology Head and neck(frozen section) Endocrine Soft tissue and bone</p>	<p><u>Examination in order to identify or exclude morphological and cytological abnormalities for the purposes of diagnosis</u></p> <p><u>Histopathology</u></p>	<p>Macroscopic and Microscopic examination:</p> <p>Documented in house methods incorporating manufacturers' instruction where relevant:</p> <p>Specimen dissection and tissue processing: Micropix Macro Imager system MModal Fluency Direct Speech Recognition SOP HPBG048 AFOS downdraft dissection bench, Mach Air fume cupboard, Shandon tissue processors, Excelsior and VIP Leica 1950 cryostat (frozen sections)</p> <p>HPSOPCU003 – Specimen HPSOPCU011- Decalcification of Calcified specimens HPSOPCU095</p> <p>Tissue embedding Sakura embedding consoles – Tissue Tek TEC 5 EME-2 HPSOPML013 – SMART Automation using Paraform cassettes and A120 automated embedding machine – HPSOPYCU097 HPSOPML073</p> <p>Tissue Sectioning Microtomes HPSOPML043 – Section cutting</p>
	<p>Routine Staining for identification of basophilic and eosinophilic structures</p>	<p>Haematoxylin and Eosin stain Automated: Tissue-Tek Prisma staining machine and cover taper.</p> <p>Vantage specimen tracking system – HPEXTREC-370</p>



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HUMAN BODY TISSUE AND FLUIDS (cont'd)	<u>Examination in order to identify or exclude morphological and cytological abnormalities for the purposes of diagnosis (cont'd)</u>	
FFPE	<u>Histopathology (cont'd)</u> Special staining for identification of: Acid mucins Acid Mucins, Neutral Mucins Acid/Neutral Mucins Amyloid Elastic Fibres, Collagen, Smooth Muscle Cell Nuclei, Cytoplasm, Connective Tissue Differentiation. <i>H. pylori</i> , Haemopoietic Cells Reticulin Fibres Gram positive, Gram negative Bacteria	Roche Ventana automated special stainer Alcian Blue (M) Alcian Blue PAS(ABPAS) (M) Alcian Blue PAS with Amylase (M) Alkaline Congo Red (M) Elastic Van Gieson (EVG) (M) Eosin working solution (M) Giemsa (A) Gordon And Sweet's Reticulin (A) Gram stain (M)



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HUMAN BODY TISSUE AND FLUIDS (cont'd)	<u>Examination in order to identify or exclude morphological and cytological abnormalities for the purposes of diagnosis (cont'd)</u>	
FFPE (cont'd)	<u>Histopathology (cont'd)</u> Special staining for identification of (cont'd): Fungi Collagen, Smooth muscle Glomerular basement membranes Fibrin Melanin Connective tissue, smooth muscle Melanin Lipids Neutral Mucins	Roche Ventana automated special stainer Grocott (A) Haematoxylin Van Gieson (HVG) (M) Jones Silver Methenamine (PA silver) (A) Martius Scarlet Blue (MSB) (M) Masson Fontana (M) Masson Trichrome (A) Melanin Bleach (M) Oil Red O (M) PAS With Amylase (HPSOPSS028) (A)



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HUMAN BODY TISSUE AND FLUIDS (cont'd)	<u>Examination in order to identify or exclude morphological and cytological abnormalities for the purposes of diagnosis (cont'd)</u>	
FFPE (cont'd)	<u>Histopathology (cont'd)</u> Special staining for identification of (cont'd): Mineralised bone <i>Mycobacterium.leprae</i> Spirochetes Mycobacterium bacilli <u>Immunohistochemistry for the identification of:</u> Smooth muscle cells, myoepithelial cells Macrophages, neutrophils, A1AT accumulation Embryonic cell in normal tissues and germ tumours Used in prostate biopsies to determine invasive components	Von Kossa (M) Wade Fite (M) Warthin and Starry (A) Ziehl Neelson (ZN) (M) Roche Ventana automated special stainer and 1plus Ventana Benchmark Ultra and Ventana Benchmark XT Documented in house methods incorporating manufacturers' instruction where relevant: HPSOPICC – Programming of the Benchmark Ultra Actin Alpha-1-Antitrypsin Alpha Fetoprotein 34βE12



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HUMAN BODY TISSUE AND FLUIDS (cont'd)	<u>Examination in order to identify or exclude morphological and cytological abnormalities for the purposes of diagnosis</u>	
FFPE (cont'd)	<u>Immunohistochemistry for the identification of (cont'd):</u>	
	Differentiates adrenal cortical tumours and renal cell carcinoma. Sex cord stromal tumours of the ovary and trophoblastic tumours.	A inhibin
	p80 protein	Anaplastic lymphoma kinase (ALK)
	HGPIN, prostate adenocarcinoma	Alpha methyl acyl coenzyme A racemase (AMACR)
	Diffuse lymph-proliferative disease and neoplastic cells of follicular lymphomas.	BCL-2
	Follicular lymphomas, diffuse large B cell lymphomas, Burkitt's lymphomas, lymphocyte predominant Hodgkin's disease.	BCL-6
	Epithelial cell types	Ber-EP4
	BK Virus (SV40) infected cells in renal transplant	BK virus
	Detectable in B cell populations in reactive lymphoid tissues,	BOB-1
	C4d complement in renal tubules, peritubular& glomerular capillaries.	C4d
	Adenocarcinomas of the pancreas, stomach, colon and gall bladder, primary and metastatic ovarian carcinomas.	CA19.9
	Marker for ovarian epithelial malignancies, also found in adenocarcinoma of colon, breast carcinoma, thyroid follicular adenoma and transitional cell carcinoma	CA125



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<p>HUMAN BODY TISSUE AND FLUIDS (cont'd)</p> <p>FFPE (cont'd)</p>	<p><u>Examination in order to identify or exclude morphological and cytological abnormalities for the purposes of diagnosis (cont'd)</u></p> <p><u>Immunohistochemistry for the identification of (cont'd):</u></p> <p>Parafollicular cells in thyroid and medullary thyroid carcinomas</p> <p>Marker for mesotheliomas</p> <p>T cells, subset of natural killer cells</p> <p>Langerhan's cells, interdigitating dendritic cells, associated disease states</p> <p>T cells in thymus, bone marrow, peripheral lymphoid tissue and blood.</p> <p>T cells (helper and mature)</p> <p>Mature T cells, T cell lymphomas</p> <p>CD7 is used to aid in the identification of T cell lymphomas</p> <p>T cells</p> <p>Mature B cells, follicular dendritic cells, CALLA</p>	<p>Calcitonin</p> <p>Calretinin</p> <p>CD2</p> <p>CD1A</p> <p>CD3</p> <p>CD4</p> <p>CD5</p> <p>CD7</p> <p>CD8</p> <p>CD10</p>



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HUMAN BODY TISSUE AND FLUIDS (cont'd)	<u>Examination in order to identify or exclude morphological and cytological abnormalities for the purposes of diagnosis (cont'd)</u>	
FFPE (cont'd)	<u>Immunohistochemistry for the identification of: (cont'd)</u>	
	Granulocytes, Reed-Sternberg cells	CD15
	B cells and B-cell neoplasms	CD20
	Mature B cells, Follicular dendritic cells	CD21
	B cells, some T cells	CD23
	ALCL, Reed Sternberg cells, Hodgkin's disease	CD30
	Endothelial cells	CD31
	Haematopoietic cells, vascular endothelium	CD34
	T cells and myeloid lineage cells	CD43
	Natural killer cells, neuroendocrine tissues	CD56
	NK cells found in follicular centre cell lymphomas, neuroendocrine cells derived tumours, carcinoid tumour, medulloblastoma and astrocytoma.	CD57
	Glycoprotein	CD61
	Macrophages, monocytes, granulocytes	CD68
	Mast cells	CD79 alpha
	Ewing's sarcoma and T cell lymphoma.	CD99



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<p>HUMAN BODY TISSUE AND FLUIDS (cont'd)</p> <p>FFPE (cont'd)</p>	<p><u>Examination in order to identify or exclude morphological and cytological abnormalities for the purposes of diagnosis (cont'd)</u></p> <p><u>Immunohistochemistry for the identification of: (cont'd)</u></p> <p>Stem cells. Melanocytes, Mast cells, germ cells, Skin basal cells</p> <p>Plasma cells, Multiple myeloma</p> <p>CEA glycoproteins</p> <p>Tissues of neuroendocrine origin</p> <p>ID squamous cell carcinoma; distinguishing malignant mesothelioma from lung adenocarcinomas.</p> <p>Distinguish between ovarian carcinomas from colon carcinomas.</p> <p>Determine if a tumour is invasive or in situ in breast specimens. Distinguish between stratified and simple epithelia.</p> <p>Normal & neoplastic epithelia (colon)</p> <p>Overexpressed in a range of neoplasms</p> <p>HCMV infected cells</p> <p>Striated and smooth muscle cells</p> <p>Identification and diagnosis of gastrointestinal stromal tumours</p> <p>Epstein Barr Virus infected cells.</p> <p>Epithelial cells</p> <p>Normal and neoplastic epithelium</p> <p>Determine tumour origin</p>	<p>CD117</p> <p>C138</p> <p>Carcinoembryonic antigen (CEA) (P&M)</p> <p>Chromogranin (CHROM)</p> <p>CK5/6</p> <p>CK7</p> <p>CK14</p> <p>CK20</p> <p>Cyclin D1 (CYC D1)</p> <p>CMV</p> <p>Desmin</p> <p>DOG-1</p> <p>EBV(LMP)</p> <p>E-Cadherin</p> <p>EMA</p> <p>ER</p>



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<p>HUMAN BODY TISSUE AND FLUIDS (cont'd)</p> <p>FFPE (cont'd)</p>	<p><u>Examination in order to identify or exclude morphological and cytological abnormalities for the purposes of diagnosis (cont'd)</u></p> <p><u>Immunohistochemistry for the identification of: (cont'd)</u></p> <p>Distinguishing neoplasms of astrocytic origin from other neoplasms in the central nervous system.</p> <p>Diagnosis of myeloproliferative disorders</p> <p>Cytotoxic T lymphocytes and in natural killer cells.</p> <p>Gross cystic disease fluid protein (apocrine cells)</p> <p>Distinguishing mesothelioma from adenocarcinomas of various origins. Distinguishing thyroid carcinomas from benign lesions.</p> <p>Differential diagnosis hepatoblastoma versus other small round cell tumours.</p> <p>Aid in assessment of breast cancer when Herceptin treatment is considered.</p> <p>Diagnosis of hairy cell leukaemia and lymphoma in the spleen.</p> <p>Placental trophoblasts</p> <p>Hep B infected cells (core Ag)</p> <p>Melanoma, melanocyte differentiation</p> <p>Follicle cells – ID leukaemia's, plasmacytomas, and certain non-Hodgkin's lymphomas.</p> <p>B cell follicles</p>	<p>GFAP</p> <p>Glycophorin C</p> <p>Granzyme B</p> <p>GCDFP 15</p> <p>HBME1</p> <p>HEPPAR 1</p> <p>HER2</p> <p>Hairy Cell Leukaemia (HCL)</p> <p>HCG</p> <p>HEPB C</p> <p>HMB45</p> <p>Kappa</p> <p>LAMDA</p>



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FFPE (cont'd)	<u>Immunohistochemistry for the identification of: (cont'd)</u>	
	T & B Cells (Pan-lymphocyte marker)	LCA
	Melanoma marker	Melan-A
	Nuclear protein	MIB 1
	Diagnosis various epithelial tumours	MNF 116
	Negative marker for mesothelioma. Differentiating tumours of unknown origin in liver cancers and distinguishing cholangiocarcinoma (+) from hepatocellular carcinomas (-). Demonstration of epithelial cell neoplasms	MOC 31
	Multiple myeloma oncogene-1	MUM1
	Differentiating between myeloid and lymphoid leukaemia.	MYELO
	Rhabdomyoblastic differentiation	MYOG
	Demonstration of Hirschsprung's disease, gangliomas, Merkel Cell tumours.	NFP2
	Peripheral nerves, neuroendocrine tumours	NSE
	Germinal centre derived lymphomas, some B cell lymphomas.	OCT2
	Detected in Germ cell tumours, seminomas and embryonal carcinomas	OCT3/4
	Pro-, pre- and mature B-cells	PAX-5
	HPV Marker	P16



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HUMAN BODY TISSUE AND FLUIDS (cont'd)	<u>Examination in order to identify or exclude morphological and cytological abnormalities for the purposes of diagnosis (cont'd)</u>	
FFPE (cont'd)	<u>Immunohistochemistry for the identification of (cont'd)</u>	
	Tumour suppressor protein (carcinomas, many neoplasms and normal cells)	p53
	Prostate basal cells, proliferative cells	p63
	Nuclei of cells expressing progesterone	Progesterone receptors
	Neurones, melanocytes, neuroendocrine cells	Protein Gene product (PGP9.5) PGM1
	Germ cell tumours	PLAP
	Prostate secretory and ductal epithelium	PSA
	Antigenic markers of prostatic carcinoma.	PSAP
	Diagnosis of renal cell carcinoma	RCC
	Schwann cells, nerve processes, S100+ neoplasms	S100
	Neuroendocrine cells	Synaptophysin (SYNAP)
	Marker for diagnosis & classification of acute lymphoblastic lymphoma/leukaemia.	TDT
	Thyroid follicular cells	TTF
	Thyroglobulin containing cells	Thyroglobulin
	Lymphocytes with cytolytic potential.	TIA-1
	Cells of mesenchymal origin	Vimentin



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HUMAN BODY TISSUE AND FLUIDS (cont'd)	<u>Examination in order to identify or exclude morphological and cytological abnormalities for the purposes of diagnosis (cont'd)</u>	WT-1
FFPE (cont'd)	<u>Immunohistochemistry for the identification of (cont'd)</u>	
HUMAN BODY TISSUE AND FLUIDS (cont'd)	<u>Examination in order to identify or exclude morphological and cytological abnormalities for the purposes of diagnosis (cont'd)</u>	HPSOPO047 – Voice dictation of report using Dragon dictation
Stained Slides prepared as above	<u>Histopathology</u> Morphological assessment and interpretation/diagnosis	



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<p>HUMAN BODY TISSUE AND FLUIDS (cont'd)</p> <p>Diagnostic/biopsy, excision and resection specimens from anatomical sites as listed below):</p> <p>Breast Urology Gynaecology Upper GI Lower GI Respiratory Renal Lymphoma Dermatology Head and neck(frozen section) Endocrine Soft tissue and bone</p> <p>Frozen Section on glass slide prepared as above</p>	<p><u>Examination in order to identify or exclude morphological and cytological abnormalities for the purposes of diagnosis (cont'd)</u></p> <p><u>Histopathology (cont'd)</u></p> <p>Staining to identify or exclude morphological and cytological abnormalities in:</p> <p>Cell Nuclei, Cytoplasm, Connective tissue differentiation</p> <p>IgA</p> <p>IgM</p> <p>Fibrinogen</p> <p>The first component of complement (C1)</p> <p>C3 complement</p> <p>Follicle cells -Identification of leukaemia's, plasmacytomas, and certain non-Hodgkin's lymphomas.</p>	<p>Manufacturer's instructions and documented in-house procedures with reference to:</p> <p>HOSOPCU017 –Performing a frozen section</p> <p>Immunofluorescence: Leica 1950 cryostat. Ventana Benchmark Ultra. EUROstar UV microscope</p> <p>FITC labelled IgA</p> <p>FITC labelled IgM</p> <p>FITC labelled Fibrinogen</p> <p>FITC C1q</p> <p>FITC labelledC3c</p> <p>Kappa</p>



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<p>HUMAN BODY TISSUE AND FLUIDS (cont'd)</p> <p>Bronchoalveolar lavage (BAL) Bronchial brushings Bronchial washings Biliary brushings</p> <p>FNA samples including EUS, EBUS, Lymph Node, Pancreatic, salivary gland and Thyroid.</p> <p>FNA samples including Head & Neck obtained at FNA clinic</p> <p>Fluids including pericardial, peritoneal, lung squeeze washings and brushings, Sputum Urine CSF Cyst Fluid</p> <p>Slides, clots and cell blocks prepared in house as above</p>	<p><u>Examination in order to identify or exclude morphological and cytological abnormalities for the purposes of diagnosis (cont'd)</u></p> <p>Preparation and screening to identify or exclude cytological abnormalities for the purpose of diagnosis</p> <p>Diagnostic cytology examinations to assist in clinical investigations</p> <p>Immunocytochemical stains</p> <p>Epithelial cell types</p> <p>Marker for mesotheliomas</p> <p>Glandular cells</p> <p>T cells in thymus, bone marrow, peripheral lymphoid tissue and blood</p> <p>B cells and B-cell neoplasms</p> <p>CEA glycoproteins</p> <p>Squamous cell carcinoma</p>	<p>Manufacturer's instructions and documented in-house procedures with reference to:</p> <p>Thermo Scientific centrifuge Thermo Shandon Cytospin 3 Leica Auto stainer XL</p> <p>HPSOPNG001, HPSOPNG002 HPSOPNG003, HPSOPNG004, HPSOPNG005, HPSOPNG006,</p> <p>In house documented procedure in conjunction with manufacturer's instructions for: Ventana Benchmark Ultra</p> <p>Ber-EP4</p> <p>Calretinin</p> <p><u>CAM5.2</u></p> <p><u>CD3</u></p> <p><u>CD20</u></p> <p><u>CEA</u></p> <p><u>CK5/6</u></p>



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Slides, clots and cell blocks prepared in house as above	<p>Diagnostic cytology examinations to assist in clinical investigations</p> <p>Immunocytochemical stains</p> <p>Distinguish between ovarian carcinomas and colon carcinomas</p> <p>Identification and distinguishing adenocarcinoma and glandular tumours</p> <p>Normal and neoplastic epithelium</p> <p>Leucocyte differentiation</p> <p>Schwann cells</p>	<p>In house documented procedure in conjunction with manufacturer's instructions for:</p> <p>Ventana Benchmark Ultra</p> <p>CK7</p> <p>CK20</p> <p>EMA</p> <p>LCA</p> <p>S100</p>
Slides, clots and cell blocks prepared in house as above	<p>Diagnostic cytology examinations to assist in clinical investigations</p>	<p>In house documented procedure in conjunction with manufacturer's instructions for:</p> <p>Routine Stains (Manual)</p> <p>Rapi-Diff II stain Atom Scientific</p>
Slides, clots and cell blocks prepared in house as above	<p>Diagnostic cytology examinations to assist in clinical investigations</p> <p>Cellular deposits of Iron and Sideroblasts</p> <p>Lipids</p>	<p>In house documented procedure in conjunction with manufacturer's instructions for:</p> <p>Perls</p> <p>Oil red O</p>
END		