


# Schedule of Accreditation

issued by

## United Kingdom Accreditation Service

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

 <b>9880</b> Accredited to ISO 15189:2022	<b>Northern Care Alliance NHS Foundation Trust</b>	
	Issue No: 012      Issue date: 30 April 2026	
	<b>Cellular Pathology and Mortuary Service</b> Royal Oldham Hospital Rochdale Road Oldham Manchester OL1 2JH	<b>Contact: Amanda Ogden</b> Tel: +44 (0) 161 627 8357 Fax: +44 (0) 161 778 1745 E-Mail: amanda.ogden@nca.nhs.uk Website: www.nca.nhs.uk
Testing performed at the above address only		

### Locations covered by the organisation and their relevant activities

#### Site activities performed away from the locations listed above:

Location details	Activity	
<b>Address</b> Royal Oldham Hospital Rochdale Rd Oldham Manchester OL1 2JH	<b>Local contact</b> Amanda Ogden Tel: +44 (0) 161 627 8357	Mortuary Services (body receipt, storage and release)

#### Off Site activities performed away from the locations listed above:

Location details	Activity	
Fairfield General Hospital Rochdale Old Rd Bury BL9 7TD	<b>Local contact:</b> Amanda Ogden Tel: +44 (0) 161 627 8357	Body Store



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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 TISSUES AND FLUIDS</p> <p>Fixed and fresh tissue including biopsies, surgical resection specimens and post mortem tissues</p> <p>Formalin- fixed tissue</p> <p>Formalin- fixed tissue</p> <p>Processed tissue to paraffin wax</p> <p>Formalin-fixed paraffin wax blocks of processed tissue</p>	<p><u>Histological and Cytological examinations to assist in clinical diagnosis</u></p> <p>Examination and preparation of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis</p>	<p>Documented in house methods and manufacturers' instructions for:</p> <p>Tissue Dissection CP-SOP-8 Dissection of formalin fixed specimens by medical staff CP-SOP-11 BMS Cut-up CP-SOP-40 Macropath Digital Imaging System CP-SOP39 Exakt 300 CL/CP Band System CP-SOP-284</p> <p>Decalcification Faxitron Agfa CR-30Digitizer System CP-SOP-283</p> <p>Tissue Processing Menarini Logos Rapid Tissue Processor CP-SOP-41 Sakura VIP6 A1 Tissue Processor CP-SOP-129</p> <p>Tissue Embedding Sakura Tissue Tec6 Embedding Centre CP-SOP-3</p> <p>Tissue Sectioning Sakura accu-cut srm200 CP-SOP-118</p>



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Histological and Cytological examinations to assist in clinical diagnosis</u> (cont'd)	Documented in house methods and manufacturers' instructions for:
FFPE Slides (Formalin- fixed paraffin embedded) tissue on glass slides	Demonstration of General Tissue Architecture	Haematoxylin and Eosin Staining Sakura Tissue Tek Prisma Automated Stainer CP-SOP-4
FFPE Slides	Demonstration of:	Special Stain Manual Techniques:
	Acid Mucins	Alcian Blue CP-SOP 71
	Differentiate between acid and other mucins	Alcian Blue/PAS CP-SOP 72
	Differentiate between acid, other mucins and glycogen	Alcian Blue/PAS/Diastase CP-SOP 74
	Demonstration of Amyloid	Congo Red CP-SOP 75
	Demonstration of Helicobacter	Giemsa CP-SOP 80
	Demonstration of Reticulin	Gordon and Sweets Reticulin CP-SOP 81
	Demonstration of bacteria	Gram Stain CP-SOP 82
	Demonstration of fungi	Grocott Methenamine (Hexamine) CP-SOP 84
	Demonstration of connective tissues: muscle, collagen fibres, fibrin and erythrocytes	Masson Trichrome CP-SOP 86
	Demonstration of elastic fibres	Millers Elastic Stain CP-SOP 87



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Histological and Cytological examinations to assist in clinical diagnosis</u> (cont'd)	Documented in house methods and manufacturers' instructions for:
FFPE Slides (cont'd)	Demonstration of: (cont'd)	Special Stain Manual Techniques:
	Demonstration of neutral mucins and glycogen	Periodic Acid Schiff CP-SOP 90
	Demonstration of neutral mucins and glycogen	Periodic Acid Schiff/ Diastase CP-SOP 91
	Demonstration of hemosiderin and ferric iron	Perl's Prussian Blue CP-SOP 92
	Demonstration of Hepatitis B surface antigen and copper associated protein	Shikata's Orcein CP-SOP 93
	Demonstration of Connective tissue	Van Gieson CP-SOP 95
	Acid- fast bacilli	Ziehl Neelsen CP-SOP 98
FFPE Slides	Demonstration of:	Automated special stains Roche Ventana Benchmark special stainer CP-SOP-418
		AFB (ZN)
		Alcian blue
		Alcian blue for PAS
		Diastase
		EVG
		Giemsa
		GMS II



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HUMAN TISSUES AND FLUIDS (cont'd)  FFPE Slides	<p><u>Histological and Cytological examinations to assist in clinical diagnosis</u> (cont'd)</p> <p>Demonstration of:</p> <p>Demonstration of various epithelium</p> <p>Non Small Cell Lung Cancer</p> <p>Demonstration of lymphoid malignancies including follicular lymphoma</p> <p>Lymphoma</p> <p>Demonstration of high molecular weight cytokeratins in epithelia</p> <p>Epithelial marker</p> <p>Normal and reactive mesothelium, eccrine glands of skin, Sertoli cells of the testis, ovarian stromal cells and adrenal cortical cells. Primarily used in the diagnosis of mesothelioma.</p> <p>Epithelial marker</p>	<p>Documented in house methods and manufacturers' instructions for:</p> <p>Iron (Perls)</p> <p>PAS</p> <p>Reticulum II</p> <p>Trichrome</p> <p>Immunohistochemistry Automated Detection of Antigens Roche Ventana Benchmark Ultra CP-SOP-55, CP-SOP-64, CP-SOP-263, CP-SOP-309, CP-SOP-314, CP-SOP-330, CP-SOP-332, CP-SOP-338</p> <p>AE1/AE3</p> <p>ALK (D5F3)</p> <p>Bcl-2</p> <p>Bcl-6</p> <p>34βE12</p> <p>Ber EP4</p> <p>Calretinin</p> <p>CAM5.2</p>



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Histological and Cytological examinations to assist in clinical diagnosis</u> (cont'd)	Documented in house methods and manufacturers' instructions for:
FFPE Slides (cont'd)	Demonstration of: (cont'd)	Immunohistochemistry Automated Detection of Antigens Roche Ventana Benchmark Ultra , CP-SOP-55, CP-SOP-64, CP-SOP-263, CP-SOP-309, CP-SOP-314, CP-SOP-330, CP-SOP-332, CP-SOP-338
	Demonstration of T Cell malignancies	CD3
	T and B cells- leukaemia	CD5
	Childhood ALL, follicular lymphoma	CD10
	Reed-Sternberg cells in Hodgkin's lymphoma	CD15
	Pan B-cell marker	CD20
	Follicular dendritic cells, B-cell marker	CD23
	Reed-Sternberg, Hodgkin's lymphoma	CD30
	Endothelial cells - malignancy	CD31
	Vascular epithelium	CD34
	Lymphoid and myelomonolineage	CD43
	Neuroectodermal cells, neurones, astrocytes	CD56
	Macrophages	CD68
	B Cell malignancies	CD79a



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HUMAN TISSUES AND FLUIDS (cont'd)  FFPE Slides (cont'd)	<p><u>Histological and Cytological examinations to assist in clinical diagnosis</u> (cont'd)</p> <p>Demonstration of: (cont'd)</p> <p>Gastrointestinal stromal tumours (GISTs), mast cell diseases, acute myeloid leukaemia (AML), small cell lung carcinoma (SCLC), and Ewing's sarcoma</p> <p>Multiple myeloma sub classification of diffuse large B-cell lymphomas</p> <p>The classification of both primary and metastatic tumours of the gastrointestinal tract</p> <p>The classification of adenocarcinomas,</p> <p>Neuroendocrine-derived tumours</p> <p>Mesothelioma and squamous cell carcinoma of the lung</p> <p>Normal and neoplastic epithelia</p> <p>Cytokeratins - Basal cells of squamous epithelia, some glandular epithelia, myoepithelium, and mesothelial cells.</p> <p>Epithelial subtypes</p> <p>The detection of CMV in infected human embryonic fibroblasts</p> <p>Lymphoid tumours</p>	<p>Documented in house methods and manufacturers' instructions for:</p> <p>Immunohistochemistry Automated Detection of Antigens Roche Ventana Benchmark Ultra CP-SOP-55, CP-SOP-64, CP-SOP-263, CP-SOP-309, CP-SOP-314, CP-SOP-330, CP-SOP-332, CP-SOP-338</p> <p>CD117 (c-kit)</p> <p>CD138</p> <p>CDX2</p> <p>CEA (mono)</p> <p>Chromogranin A</p> <p>CK5/6</p> <p>CK7</p> <p>CK14</p> <p>CK20</p> <p>CMV</p> <p>Cyclin D1</p>



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Histological and Cytological examinations to assist in clinical diagnosis</u> (cont'd)	Documented in house methods and manufacturers' instructions for:
FFPE Slides (cont'd)	Demonstration of: (cont'd)	Immunohistochemistry Automated Detection of Antigens Roche Ventana Benchmark Ultra CP-SOP-55, CP-SOP-64, CP-SOP-263, CP-SOP-309, CP-SOP-314, CP-SOP-330, CP-SOP-332, CP-SOP-338
	Lymphatic invasion of primary tumours	D2-40
	Smooth and striated muscle	Desmin
	EBV infection	EBV
	Ductal breast carcinomas	E-Cadherin
	Epithelial subtypes	EMA
	Identify treatment with antihormonal therapies as well as aid in prognosis and management of breast cancer	Oestrogen (ER)
	The classification of breast tumours	GATA-3
	The classification of breast tumours	GCDFP-15
	Identification of H pylori	<i>H. pylori</i>
	Breast carcinoma	Her2
	Determination of Her2 gene status.	DDISH (chromogenic in-situ Hybridisation) Automated with Roche Ventana Ultra
	Kaposi's sarcoma	HHV8
	melanomas	HMB45
	proliferating cells	Ki-67
	lymphoid neoplasms	LCA
	melanocytes	Mart-1 (Melan A)



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HUMAN TISSUES AND FLUIDS (cont'd)  FFPE Slides (cont'd)	<p><u>Histological and Cytological examinations to assist in clinical diagnosis</u> (cont'd)</p> <p>Demonstration of: (cont'd)</p> <p>Mismatch repair panel for endometrial carcinoma - Detection of proteins in the diagnosis of proficient/deficient Endometrial tissue.</p> <p>Epithelial cells</p> <p>B-cell lymphomas</p> <p>lung adenocarcinoma</p> <p>Prostate and prostate adenocarcinoma.</p> <p>germ cell tumours</p> <p>ovarian epithelial cancer cells</p> <p>Cervical biopsies</p> <p>Lung adenocarcinomas, squamous cell carcinoma of head and neck</p> <p>Breast carcinomas</p> <p>Squamous/adeno/Small cell differentiation</p> <p>Prostate and bladder</p> <p>Triple negative breast cancer - tumour cells and tumour-infiltrating immune cells in TNBC.</p>	<p>Documented in house methods and manufacturers' instructions for:</p> <p>Immunohistochemistry Automated Detection of Antigens Roche Ventana Benchmark Ultra CP-SOP-55, CP-SOP-64, CP-SOP-263, CP-SOP-309, CP-SOP-314, CP-SOP-330, CP-SOP-332, CP-SOP-338</p> <p>MMR (MLH-1, MSH-2, MSH-6 and PMS-2)</p> <p>MNF116</p> <p>MUM1</p> <p>Napsin-A</p> <p>NKX 3.1</p> <p>OCT3/4</p> <p>PAX8</p> <p>p16</p> <p>p40</p> <p>p53</p> <p>p63</p> <p>PAP (PSAP)</p> <p>PDL-1 CLONE SP142</p>



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HUMAN TISSUES AND FLUIDS (cont'd)  FFPE Slides (cont'd)	<p><u>Histological and Cytological examinations to assist in clinical diagnosis</u> (cont'd)</p> <p>Demonstration of: (cont'd)</p> <p>Programmed death-ligand 1 (PD-L1) expression in tumour cell (TC) membrane in NSCLC</p> <p>Identify treatment with antihormonal therapies as well as aid in prognosis and management of breast cancer</p> <p>human prostate-specific antigen.</p> <p>Hepatocellular carcinoma</p> <p>ROS-1 protein, a receptor tyrosine kinase of the insulin receptor family.</p> <p>The classification of malignant melanocytic tumours of skin and metastases of human malignant melanomas</p> <p>Smooth muscle</p> <p>Neuroendocrine cells</p> <p>Thyroid carcinomas.</p> <p>Thyroid, lung, thyroid and lung tumours</p> <p>Tumours of mesenchymal origin</p> <p>Mesothelioma, ovarian carcinoma and Wilm's tumor</p>	<p>Documented in house methods and manufacturers' instructions for:</p> <p>Immunohistochemistry Automated Detection of Antigens Roche Ventana Benchmark Ultra CP-SOP-55, CP-SOP-64, CP-SOP-263, CP-SOP-309, CP-SOP-314, CP-SOP-330, CP-SOP-332, CP-SOP-338</p> <p>PDL-1 CLONE SP263</p> <p>PR</p> <p>PSA</p> <p>Racemase P504S</p> <p>ROS-1 SP384</p> <p>S100</p> <p>SMA</p> <p>Synaptophysin</p> <p>Thyroglobulin</p> <p>TTF-1</p> <p>Vimentin</p> <p>WT-1</p>



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<p>HUMAN TISSUES AND FLUIDS (cont'd)</p> <p>FFPE Slides (cont'd)</p> <p>Stained FFPE Slides prepared in-house from sample types listed above</p>	<p><u>Histological and Cytological examinations to assist in clinical diagnosis</u> (cont'd)</p> <p>Demonstration of: (cont'd)</p> <p>Morphological assessment and interpretation/diagnosis</p>	<p>Documented in house methods and manufacturers' instructions for:</p> <p>Immunohistochemistry Automated Detection of Antigens Roche Ventana Benchmark Ultra CP-SOP-55, CP-SOP-64, CP-SOP-263, CP-SOP-309, CP-SOP-314, CP-SOP-330, CP-SOP-332, CP-SOP-338</p> <p>Interpretative/ diagnostic microscopy to reach a diagnosis CP-SOP-49 Cellular Pathology Reporting CP-SOP-53 Setting Up and Use of Microscopes CP-SOP-52 Microscope QC</p>



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<p>HUMAN TISSUES AND FLUIDS (cont'd)</p> <p>Fluids/ FNAs fresh and fixed samples</p> <p>Urines Sputum Breast FNA Thyroid FNA Node FNA Bronchial lavage and washes Ovarian Fluid</p> <p>CSF's Head and Neck FNA Ascetic and plural fluids</p> <p>Bronchial wash/trap/lavage FNA's, serous fluids, urines</p> <p>Stained Cytological Preparations on Slides</p>	<p><u>Histological and Cytological examinations to assist in clinical diagnosis</u> (cont'd)</p> <p><u>Diagnostic Cytology</u></p> <p>Demonstration of</p> <p>Demonstration of cellular content of body cavity fluids and tissues aspirates</p> <p>Examination to identify or exclude non-gynae cytological abnormalities for the purpose of diagnosis</p> <p>Cytological assessment and interpretation/diagnosis</p>	<p>Documented in house methods and manufacturers' instructions for:</p> <p>Preparation of diagnostic cytology specimens to cell block or stained slides CP-SOP-18 CP-SOP-24 CP-SOP-25 CP-SOP-26 CP-SOP-28 CP-SOP-30 CP-SOP-360 CP-SOP-361 Using: Sakura Cytospin Centrifuge CP-SOP-23 CL31R Centrifuge CP-SOP-27 Leica XL Staining Machine CP-SOP32 (PAP and MGG Stains) CP-SOP-22 May Grunwald Giemsa Stain</p> <p>Hologic Thin prep T2000 CP-SOP-28 CP-SOP-416 CP-SOP-417</p> <p>CP-SOP-143 Primary Screening CP-SOP- 298 Use of The G2 Dictation System in Diagnostic Cytology</p>



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HUMAN BODY FLUIDS	<u>Andrological examination activities for the purposes of clinical diagnosis</u>	
Semen	<u>Post vasectomy:</u> Detection of sperm	Based on 2016 Laboratory guidelines for post vasectomy semen analysis: Association of Biomedical Andrologists, the British Andrology Society and the British Association of Urological Surgeons) Manual method using large volume chambers/ manual microscopy OR wet prep and centrifugation and documented in-house procedure SOP CP-SOP-396, CP-SOP-181
Semen	<u>Fertility testing:</u>  Volume pH Sperm morphology excluding TZI scoring Sperm concentration Sperm motility	Based on WHO laboratory manual for the examination and processing of human semen (Sixth edition 2021) and manual method and documented in-house procedure SOP CP-SOP-223  Volume/weight Colorimetric strips Stained slides (Papanicolau) microscopy (Bright field) Improved Neubauer counting chambers and Microscopy (Phase contrast) Microscopy (Phase contrast)
END		