


# Schedule of Accreditation

issued by

## United Kingdom Accreditation Service

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

 <b>UKAS</b> MEDICAL 9577 Accredited to ISO 15189:2012	<b>Gloucestershire Hospitals NHS Foundation Trust</b>	
	Issue No: 008    Issue date: 04 January 2023	
	Department of Histopathology Cheltenham General Hospital Sandford Road Cheltenham GL53 7AN	Contact: Andrew Usher Tel: +44 (0)300 422 4400 E-Mail: andrew.usher1@nhs.net Website: www.gloshospitals.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:	Location code
<b>Address:</b> Department of Histopathology Cheltenham General Hospital Sandford Road Cheltenham GL53 7AN  <b>Local contact:</b> Andrew Usher	Histopathology Rapid frozen section for intra-operative diagnosis Diagnostic Cytopathology	A

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

Location details	Activity	Location code
<b>Address:</b> ENT Clinic Cheltenham General Hospital Sandford Road, Cheltenham GL53 7AN  <b>Local contact:</b> Andrew Usher	FNA Adequacy Clinic	B



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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 TISSUES AND FLUIDS</p> <p>Formalin fixed tissues</p>	<p><u>Histopathology</u></p> <p>Preparation and examination to identify or exclude morphological and cytological abnormalities</p>	<p>Macroscopic and microscopic examination using documented in-house procedures in conjunction with manufacturer's instructions (where relevant)</p> <p><u>Macroanalysis and dissection</u> Manual method using in house methods: HISOP L 002 HISOP L018 and: Steeline Downdraft benches, Micropath camera system Leica IPC Cassette writer Cellpath P1 Cassette Printer</p> <p><u>Tissue processing</u> Automated method using in -house method: HISOP E 002 HIQC 018 and: Thermo Excelsior AS Thermo Excelsior ES</p> <p><u>Decalcification</u> Manual chemical end point detection using in-house method: HISOPL019</p> <p><u>Embedding</u> Manual method using in house method: HISOP L 004 and: Sakura Tissue Tek TEC</p>	<p>A,</p> <p>A</p> <p>A</p>



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Histopathology (cont'd)</u>	Macroscopic and microscopic examination using documented in-house procedures in conjunction with manufacturer's instructions (where relevant)	
Formalin fixed tissues		<u>Microtomy</u> Manual method using in-house method: HISOP L 006 HIQC 012 and: PFM 3003 PFM 3004 Leica RM2235 Leica RM2245 Thermo Shandon Finesse ME Histocore Multicut	A
Fresh frozen tissue	Frozen sections	Automated method using in-house method: HISOP L 015 and CGH: Leica CM1950OTF 5000	A
	Basophilic and eosinophilic structures	Manual method using Haematoxylin and Eosin (Frozen) HISOP SS 014	A
Stained slides prepared using cryotomy	Morphological assessment and interpretation/diagnosis	HISOP Gen 009 (Pathologist reporting)	A



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Histopathology (cont'd)</u>	Macroscopic and microscopic examination using documented in-house procedures in conjunction with manufacturer's instructions (where relevant)	
Formalin fixed; paraffin embedded (FFPE) tissue	Basophilic and eosinophilic structures	<u>Routine Haematoxylin and Eosin Staining:</u> Automated method using in-house methods: HISOP L 006 HISOP E 004 and: Gemini AS Autostainer Leica CV5030 Coverslipper ClearVue Coverslipper	A
FFPE Tissue	Detection of the following:	<u>Special staining</u>  Manual method using in-house methods:  HISOP L 009 and Zeiss Axioplan, Leitz Laborlux microscopes and the following stains:	A
	Weakly sulphated and acidic mucins	Alcian Blue HISOP SS 001	
	Acidic and neutral mucins	Alcian Blue PAS HISOP SS 003	
	Acidic and neutral mucins	Alcian Blue PAS/D HISOP SS 004	
	Amyloid	Congo Red technique HISOP SS 005	
	<u>Copper deposits</u>	Rhodanine Stain HISOP SS 038	



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Histopathology (cont'd)</u>	Macroscopic and microscopic examination using documented in-house procedures in conjunction with manufacturer's instructions (where relevant)	A
FFPE Tissue (cont'd)	Detection of the following: (cont'd)	<u>Special staining</u>	
	Elastic connective tissue fibres	Manual method using in-house methods: HISOP L 009 and Zeiss Axioplan, Leitz Laborlux microscopes  Elastic van-Gieson (EVG) (Verhoeffs) technique HISOP SS 026	
	Elastic connective tissue fibres	Elastic van-Gieson (EVG) (Miller's) technique HISOP SS 019	
	Microorganisms	Giemsa HISOP SS 006	
	Gram positive and Gram-negative organisms	Gram technique HISOP SS 007	
	Basement membrane and fungal hyphae	Grocott Hexamine Silver technique HISOP SS 009	
	Collagen connective tissue fibres	Haematoxylin Van Gieson HISOP SS 011	
	Reticulin fibres	Reticulin HISOP SS 013	
	Fibrin and connective tissue	Martius Yellow Scarlet Blue (MSB) technique HISOP SS 015	
	Melanin and argetaffin granules	Masson Fontana silver technique HISOP SS 016	
	Muscle fibrin and connective tissue	Masson Trichrome technique HISOP SS 017	



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Histopathology (cont'd)</u>	Macroscopic and microscopic examination using documented in-house procedures in conjunction with manufacturer's instructions (where relevant)	A
FFPE Tissue (cont'd)	Detection of the following: (cont'd)	<u>Special staining</u>	
	Removal of melanin pigment	Manual method using in-house methods: HISOP L 009 and Zeiss Axioplan, Leitz Laborlux microscopes and the following stains:  Melanin Bleach HISOP SS 018	
	Copper associated protein in Hepatitis B surface antigen	Orcein (Shikata) technique HISOP SS 020	
	Polysaccharides including glycogen and basement membrane	Periodic Acid-Schiff Silver /Jones (PAS) technique HISOP SS 021	
	Polysaccharides including glycogen	Periodic Acid-Schiff (PAS) technique HISOP SS 022	
	Glycogen	Diastase Periodic Acid-Schiff (D PAS) technique HISOP SS 023	
	Haemosiderin	Perls Prussian Blue HISOP SS 024	
	Collagen	Picric Sirius red HISOP SS 037	
	Amyloid	Sirius Red HISOP SS 025	



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Histopathology (cont'd)</u>	Macroscopic and microscopic examination using documented in-house procedures in conjunction with manufacturer's instructions (where relevant)	A
FFPE Tissue (cont'd)	Detection of the following: (cont'd)	<u>Special staining</u>	
	Mast cells	Manual method using in-house methods: HISOP L 009 and Zeiss Axioplan, Leitz Laborlux microscopes and the following stains:  Toluidine Blue HISOP SS 027	
	<i>Helicobacter pylori</i>	Toluidine Blue HISOP SS 012	
	Calcium salts	Von Kossa technique HISOP SS 028	A
	Acid and alcohol-fast bacilli	Ziehl-Neelsen (ZN) technique HISOP SS 030	
FFPE tissue	Detection of the following:	<u>Immunohistochemistry</u> Automated method using in-house method: HISOP L 021 and: Roche Ventana Ultra ICC incorporating the following antibodies:	
	Pan cytokeratin CK1-8, 10, 14-16 and 19	AE1/AE3	
	Germ Cell tumours	Alpha Fetoprotein	
	Huma p80 protein	ALK -1	A
	T-cells, B-cells in the mantle zone	BCL2	
	Follicular centre B-cells	BCL-6	



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FFPE tissue (cont'd)	Detection of the following: (cont'd)	<u>Immunohistochemistry</u> Automated method using in-house method: HISOP L 021 and: Roche Ventana Ultra ICC incorporating the following antibodies:	
	Differentiation of basal cell carcinoma	BEREP4	
	Ovarian epithelial malignancies, seminal vesicle carcinoma, anaplastic lymphoma	CA125	
	Pancreatic carcinoma	CA 19.9	
	Mesothelial cell lining	Calretinin	
	T cell marker	CD3	
	T helper cells	CD4	
	T cells and B cells in the mantle zone	CD5	
	Mature B cells, follicular dendritic cells, CALLA	CD10	
	Immature B lymphocytes	CD15	
	B-cell marker	CD20	
	Mature B cells and FDC	CD21	





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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Histopathology (cont'd)</u>	Macroscopic and microscopic examination using documented in-house procedures in conjunction with manufacturer's instructions (where relevant)	A
FFPE Tissue (cont'd)	Detection of the following: (cont'd)	<u>Immunohistochemistry</u> Automated method using in-house method: HISOP L 021 and: Roche Ventana Ultra ICC incorporating the following antibodies:	
	FDC and EBV transformed blasts	CD23	
	Reed-Sternberg cells in Hodgkin lymphoma.	CD30	
	Endothelial cell marker	CD31	
	Endothelial cell marker	CD34 CD43	
	Leucocyte common antigen	CD45	
	Neutral cell adhesion molecule	CD56	
	Platelet glycoprotein IIIa	CD61	
	Macrophages.	CD68	
	B Cell marker	CD79a	
	Mast cells and GIST	CD117	
	Plasma cells	CD138	
	Glycophorin	CD235a	



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FFPE Tissue (cont'd)	Detection of the following: (cont'd)	<u>Immunohistochemistry</u> Automated method using in-house method: HISOP L 021 and: Roche Ventana Ultra ICC incorporating the following antibodies:	
	Intestinal epithelial cells, colorectal + other adenocarcinomas	CDX2	
	Carcinoembryonic antigen	CEA	
	Neuroendocrine cells in epithelial surface of colon show cytoplasmic staining. Nerve/ganglion cells stain weak/moderate.	CHROMO	
	Stains epithelial tissues from simple glandular to stratified squamous. For Id of tumours of epithelial origin.	MNF 116	
	Squamous and myoepithelial cells	CK5/6	
	Normal and neoplastic epithelia	CK7	
	Epithelial cells	CK8	
	Gastrointestinal epithelia	CK20	



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FFPE Tissue (cont'd)	Detection of the following: (cont'd)	<u>Immunohistochemistry</u> Automated method using in-house method: HISOP L 021 and: Roche Ventana Ultra ICC incorporating the following antibodies:	
	High MW Cytokeratin	34 BE12	
	Mantle cell lymphoma	CYCLIN D1	
	Striated and smooth muscle cells	DESMIN	
	Stains most GISTs.	DOG-1	
	Differential diagnosis of ductal and lobular breast cancer	ECAD	
	Normal and neoplastic epithelium	EMA	
	Estrogen receptor status in breast cancer	ER	
	Identification of metastases from breast Ca.	GCDFP	
	Cytotoxic T cells granules	Granzyme B	
	Identification of melanocytes (immature)	HMB45	
	Hepatocytes	Hepatocyte Specific Antigen (HAS)	



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FFPE Tissue (cont'd)	Detection of the following: (cont'd)	<u>Immunohistochemistry</u> Automated method using in-house method: HISOP L 021 and: Roche Ventana Ultra ICC incorporating the following antibodies:	
	Sex chord stromal tumours	INHIBIN	
	Mantle zone B cells Kappa	KAPPA	
	Cell proliferation marker	KI67	
	Mantle zone B cells	LAMBDA	
	Breast cancer	MAMMAGLOBIN	
	Melanocytes	MELAN A (Mart-1)	
	Mismatch repair protein	MLH-1	
	Mismatch repair protein	MSH-1	
	B-cells	MUM-1	
	Myeloid cells	Myeloperoxidase (MPO)	
	Muscle	Myosin	
	Classification of tumours with neuronal differentiation	NFP	



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Histopathology (cont'd)</u>	Macroscopic and microscopic examination using documented in-house procedures in conjunction with manufacturer's instructions (where relevant)	A
FFPE Tissue (cont'd)	Detection of the following: (cont'd)	<u>Immunohistochemistry</u> Automated method using in-house method: HISOP L 021 and: Roche Ventana Ultra ICC incorporating the following antibodies:	
	Neuroendocrine marker	NSE	
	Seminoma	Oct-2	
	Tumour suppressor gene	P53	
	Basal cell marker	P63	
	ALL	PAX-5	
	Mismatch repair protein	PMS-2	
	Progesterone receptor	PR	
	Placental alkaline phosphatase	PLAP	
	Prostatic specific antigen	PSA	
	Melanoma, neuroendocrine cells	S100	
	Smooth muscle cells	SMA	



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FFPE Tissue (cont'd)	Detection of the following: (cont'd)	<u>Immunohistochemistry</u> Automated method using in-house method: HISOP L 021 and: Roche Ventana Ultra ICC incorporating the following antibodies:	
	Neuroendocrine marker	Synaptophysin	
	Early B-Cell, thymocyte marker	TdT	
	Lumen of thyroid follicles	Thyroglobulin	
	Thyroid transcription factor-1	TTF1	
	Mesenchymal marker	Vimentin	
	Wilms Tumour gene product	WT-1	



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<p>HUMAN TISSUES AND FLUIDS (cont'd)</p> <p>Slides prepared in-house from sample types above</p>	<p><u>Histopathology (cont'd)</u></p> <p>Morphological assessment and interpretation/diagnosis</p>	<p>Macroscopic and microscopic examination using documented in-house procedures in conjunction with manufacturer's instructions (where relevant)</p> <p>Microscopy (qualitative analysis) In-house method: SOP HISOP Gen 009 using: Microscopes: Olympus BX50 Leica DMR Olympus BX51 Nikon Eclipse 50i Leica DM4000 B Nikon Eclipse 80i Leica DM400 Olympus BX53 F2 Olympus BX45 Olympus BX50 Nikon Eclipse Olympus CX41 Zeis Axioplan</p>	A



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<p>Body Fluids: Urines, sputum, bronchial washings, bronchial brushings, serous fluids, CSF</p>	<p><u>Cytopathological examination of fluids for the purpose of diagnosis</u></p> <p>Examination of fluids in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis</p>	<p>Documented in house methods incorporating manufacturers' instructions where relevant:</p> <p>Samples centrifuged and processed using Hologic ThinPrep technique - Hologic T2000 CYNS17</p> <p>Shandon Cytocentrifuge CYNS12 Preparation of Urines CYNS13 Preparation of Sputum CYNS15 Preparation of Bronchial Washings CYNS16 Preparation of Bronchial Brushings CYNS18</p>	<p>A</p>





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<p>HUMAN TISSUES AND FLUIDS (cont'd)</p> <p>Body Fluids: Urines, sputum, bronchial washings, bronchial washings, serous fluids, CSF</p> <p>Slides prepared in house from sample types listed above</p>	<p><u>Cytopathological examination of fluids for the purpose of diagnosis (cont'd)</u></p> <p>Examination of fluids in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis</p> <p>Morphological assessment and interpretation/diagnosis</p>	<p>Preparation of Serous Fluids CYNS14 Preparation of CSF CYNS23 Processing FNA samples CYNS19</p> <p>Documented in house methods incorporating manufacturers' instructions where relevant:</p> <p>Non gynae sample receipt CYNS21</p> <p><u>May Grunwald Giemsa staining Manual using in house procedures:</u></p> <p>May Grunwald Giemsa CYNS34 <u>Papanicolaou staining</u> Automated using in house procedures:</p> <p>Papanicolaou staining CYGPS25</p> <p>In conjunction with manufacturer's instructions for:</p> <p>Leica XL Autostainer CYGPS25</p> <p>Leica CV5030 Coverslipper CYGPS30</p> <p><u>Microscopy (qualitative analysis)</u></p> <p>Non-Gynae cytology Screening and Reporting CYCOS01</p>	A



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<p>HUMAN TISSUES AND FLUIDS (cont'd)</p> <p>Fine needle aspiration (FNA): Head and neck FNA samples</p>	<p><u>Cytopathological examination of fluids for the purpose of diagnosis (cont'd)</u></p> <p>Examination of samples in order to assess cellularity and adequacy for diagnosis</p>	<p>In House documented manual procedures for:</p> <p>Rapid on-site evaluation (ROSE) of Fine Needle Aspiration Cytology Samples in Head &amp; Neck Adequacy Clinic using a Nikon E400 Eclipse Microscope CYNS29 Processing of FNA samples CYNS19</p> <p>Rapid Staining with Hemacolor CYNS30</p>	B
END			