


# Schedule of Accreditation

issued by

## United Kingdom Accreditation Service

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

	<b>Aneurin Bevan University Health Board</b>	
	Issue No: 0010 Issue date: 05 August 2025	
	<b>Cellular Pathology Department</b> Royal Gwent Hospital Cardiff Road Newport NP20 2UB	<b>Contact: Gwenan Jones</b> Tel: +44 (0)1633 234513 E-Mail: Gwenan.Jones2@wales.nhs.uk Website: www.wales.nhs.uk/sitesplus/866/home

**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
Cellular Pathology Department Royal Gwent Hospital Cardiff Road Newport NP20 2UB	<b>Local contact</b> Gwenan Jones +44 (0)1633 234513	Cellular Pathology: <ul style="list-style-type: none"><li>• Histopathology</li><li>• Cytopathology</li><li>• Reporting</li></ul> A
Nevill Hall Hospital Brecon Road Abergavenny NP7 7EG	<b>Local contact</b> Gwenan Jones +44 (0)1633 234513	Cellular Pathology: <ul style="list-style-type: none"><li>• Reporting</li></ul> 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
HUMAN BODY TISSUE  Tissue: biopsy, excision, resection and post-mortem specimens	<u>Histopathological examination activities for the purposes of clinical diagnosis</u>  Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:  Specimen dissection including decalcification  SOPs HI0247 HI0246 HI0165	A
FFPE Tissue and Cell Blocks		Tissue processing using Thermo Scientific Excelsior AS processors  SOP HI376	A
FFPE Tissue and Cell Blocks		Tissue embedding using Leica Arcadia HistoCore  SOP CEP0106	A
FFPE Tissue and Cell Blocks		Microtomy using Leica HistoCore Biocut Microtome (SN 3371, 3386, 5726, 5729, 1567, 1568 and 2241) Leica RM2235 Microtome (SN 2792, 2793 and 10380)SOP HI0170	
Fresh Tissue		Intraoperative frozen sections using Bright OTF 5000 and H&E staining  SOPs HI0421 HI0059 HI0171 (H&E)	A



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HUMAN BODY TISSUE (cont'd)	<u>Histopathological examination activities for the purposes of clinical diagnosis</u> (cont'd)	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:	
FFPE slides (Formalin fixed paraffin embedded)	Demonstration of:	Macroscopic and Microscopic examination	
	Basophilic and eosinophilic structures	Automated Haematoxylin and Eosin (H & E) staining using Sakura Prisma Stainer SOP HI0171	A
	Glycogen, mucins, BMs and Fungi	Manual Special Stains as follows:  Periodic acid Schiff's SOP HI0035 PAS	A
	Acid and neutral Mucopolysaccharides	Alcian Blue/Periodic acid Schiff's SOP HI0036 ABPAS	A
	Acid and neutral Mucopolysaccharides	Alcian Blue SOP HI0411 Alcian Blue	A
	Glycogen	Periodic acid Schiff's with diastase SOP HI0037 DPAS	A
	Elastin	Elastic van Gieson SOP HI0048 EVG	A
	Collagen, muscle	Haematoxylin, Van Gieson SOP HI0054 CBHVG	A
	Fungi	Grocott SOP HI0072 Grocott	A
	Reticulin fibres	James' Reticulin stain SOP HI0052 Retic	A
	Melanin	Masson Fontana SOP HI0136 Fontana	A



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HUMAN BODY TISSUE (cont'd)	<u>Histopathological examination activities for the purposes of clinical diagnosis</u> (cont'd)	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:	
FFPE slides (Formalin fixed paraffin embedded) (cont'd)	Demonstration of: (cont'd)	Macroscopic and Microscopic examination	
		Manual Special Stains as follows:	
	Amyloid	Congo Red SOP HI0026 Congo Red	A
	Ferric iron, haemosiderin	Perls' Prussian Blue SOP HI0126 PPB	A
	Helicobacter pylori	Giemsa SOP HI0074 Giemsa	A
	Bacteria	Gram SOP HI0067 Gram	A
	TB	Ziehl Neelsen SOP HI0073 ZN	A
	Fibrin	Martius Yellow-Brilliant Crystal Scarlet-Methyl Blue SOP HI0027 MSB	A
	Elastin, Copper associated protein.	Orcein SOP HI0049 Orcein	A



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HUMAN BODY TISSUE (cont'd)	<u>Histopathological examination activities for the purposes of clinical diagnosis</u> (cont'd)	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:	A
FFPE slides from tissue (Formalin fixed paraffin embedded) and cytology cell block	Immunohistochemistry examination activities for detection of:	Leica Bond III fully automated immunohistochemistry platform CEP0200 Immunohistochemistry CEP0210 Use of pipettes CEP0211 Making up enzyme from the kit for the Leica BOND CEP0212 Stock control and acceptance testing in IHC	
	Epithelial/basal marker. Squamous differentiation from adenocarcinoma.	34BE12 HMW cytokeratin	
	Epithelial marker	AE1/AE3 Cytokeratin	
	T-Cells, mantle zone B-Cells	BCL-2	
	Smooth muscle	CALPONIN	
	Mesothelial cells Classification of lymphomas and carcinomas	CALRETININ CD10	
	Gastrointestinal stromal tumour and mast cells	CD117	
	Plasma cell differentiation	CD138	
	CD15 expression in Hodgkin's lymphoma	CD15	
	General B-cell marker	CD20	
	Follicular dendritic cell marker	CD21	
	Follicular dendritic cell marker	CD23	



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<p>HUMAN BODY TISSUE (cont'd)</p> <p>FFPE slides from tissue (Formalin fixed paraffin embedded) and cytology cell block (cont'd)</p>	<p><u>Histopathological examination activities for the purposes of clinical diagnosis</u> (cont'd)</p> <p>Immunohistochemistry examination activities for detection of: (cont'd)</p> <p>General T-cell marker</p> <p>Reed-Sternberg cells</p> <p>Endothelial cell marker</p> <p>Endothelial cell marker</p> <p>Helper/inducer T cells</p> <p>T-cells, sub-set of B cells, classification of lymphomas</p> <p>NK-cells, neuroendocrine cells</p> <p>Macrophages</p> <p>B-cell lymphomas</p> <p>Suppressor/cytotoxic T cells</p> <p>Colorectal carcinoma</p> <p>Epithelial cell marker</p> <p>Neuroendocrine marker</p>	<p>In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:</p> <p>Leica Bond III fully automated immunohistochemistry platform CEP0200 Immunohistochemistry CEP0210 Use of pipettes CEP0211 Making up enzyme from the kit for the Leica BOND CEP0212 Stock control and acceptance testing in IHC</p> <p>CD3</p> <p>CD30</p> <p>CD31</p> <p>CD34</p> <p>CD4</p> <p>CD5</p> <p>CD56</p> <p>CD68</p> <p>CD79A</p> <p>CD8</p> <p>CDX2</p> <p>CEA</p> <p>CHRO</p>	<p>A</p>



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<p>HUMAN BODY TISSUE (cont'd)</p> <p>FFPE slides from tissue (Formalin fixed paraffin embedded) and cytology cell block (cont'd)</p>	<p><u>Histopathological examination activities for the purposes of clinical diagnosis</u> (cont'd)</p> <p>Immunohistochemistry examination activities for detection of: (cont'd)</p> <p>Squamous differentiation from adenocarcinoma</p> <p>Breast, lung, gynae adenocarcinoma</p> <p>Epithelial marker. Urothelial + hepatocellular carcinoma, neuroendocrine tumours, epithelioid malignant mesotheliomas</p> <p>Epithelial marker. Thyroid papillary (+), thyroid follicular (-)</p> <p>Colon, rectum, prostate adenocarcinoma</p> <p>Proliferative zone of epithelium and endothelium. Mantle cell lymphoma</p> <p>Differentiation of ductal (+) carcinoma or breast from lobular (-)</p> <p>Smooth muscle and skeletal muscle tumours</p>	<p>In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:</p> <p>Leica Bond III fully automated immunohistochemistry platform CEP0200 Immunohistochemistry CEP0210 Use of pipettes CEP0211 Making up enzyme from the kit for the Leica BOND CEP0212 Stock control and acceptance testing in IHC</p> <p>CK 5</p> <p>CK 7</p> <p>CK8/18</p> <p>CK19</p> <p>CK 20</p> <p>CYCLIN D1</p> <p>ECAD</p> <p>DESMIN</p>	<p>A</p>



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HUMAN BODY TISSUE (cont'd)	<u>Histopathological examination activities for the purposes of clinical diagnosis</u> (cont'd)	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:	A
FFPE slides from tissue (Formalin fixed paraffin embedded) and cytology cell block (cont'd)	Immunohistochemistry examination activities for detection of: (cont'd)	Leica Bond III fully automated immunohistochemistry platform CEP0200 Immunohistochemistry CEP0210 Use of pipettes CEP0211 Making up enzyme from the kit for the Leica BOND CEP0212 Stock control and acceptance testing in IHC	
	Epithelial Membrane Antigen. Epithelial marker	EMA	
	Endothelial cell marker	Factor 8 (vWF)	
	Fibrohistiocytic marker	Factor 13a	
	Melanoma marker	HMB45 Melanoma Marker	
	Proliferation marker	Ki67	
	Leukocyte common antigen. General lymphoma marker	LCA	
	Melanoma and normal melanocytes	MELAN A	
	Normal lung and lung adenocarcinomas	NAPSIN	
	Classification of germ cell tumours and GCNIS	OCT3/4	
	HPV related carcinomas	P16	
	Squamous differentiation from adenocarcinoma	p63	



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FFPE slides from tissue (Formalin fixed paraffin embedded) and cytology cell block (cont'd)	Immunohistochemistry examination activities for detection of: (cont'd)	Leica Bond III fully automated immunohistochemistry platform CEP0200 Immunohistochemistry CEP0210 Use of pipettes CEP0211 Making up enzyme from the kit for the Leica BOND CEP0212 Stock control and acceptance testing in IHC	
	Placental Alkaline Phosphatase. Classification of germ cell tumours	PLAP	
	Prognostic breast cancer marker	PR	
	Prostate Specific Antigen. Prostate adenocarcinoma	PSA	
	Melanoma and neuroendocrine differentiation	S100	
	Thyroid Transcription Factor 1. Lung and thyroid marker	TTF1	
	General soft tissue marker	VIMENTIN	
	Ovarian serous carcinoma, malignant mesothelioma	WT1	
	P53 expression	p53	
	Neuroendocrine cell marker	SYNAPTOPHYSIN	
	Epithelial cell marker	BER EP4	



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<p>HUMAN BODY TISSUE (cont'd)</p> <p>FFPE slides from tissue (Formalin fixed paraffin embedded) and cytology cell block (cont'd)</p>	<p><u>Histopathological examination activities for the purposes of clinical diagnosis</u> (cont'd)</p> <p>Immunohistochemistry examination activities for detection of: (cont'd)</p> <p>Oestrogen Receptor. Prognostic breast cancer marker</p> <p>Lymphatic endothelial cells</p> <p>Endothelial cells, mesothelioma</p> <p>Low molecular weight cytokeratin marker</p> <p>Malignant mesothelioma, BAP1-deficient melanocytic lesions</p> <p>Epithelial cell marker</p> <p>Breast and urothelial carcinoma</p> <p>Gynae related tumours, renal and thyroid</p> <p>Prostate adenocarcinoma</p> <p>Melanoma/metastatic melanoma</p>	<p>In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:</p> <p>Leica Bond III fully automated immunohistochemistry platform CEP0200 Immunohistochemistry CEP0210 Use of pipettes CEP0211 Making up enzyme from the kit for the Leica BOND CEP0212 Stock control and acceptance testing in IHC</p> <p>ER</p> <p>D240</p> <p>Thrombomodulin</p> <p>CAM 5.2 (anti-cyto)</p> <p>BAP-1</p> <p>EPCAM</p> <p>GATA3</p> <p>Pax 8</p> <p>NKX3.1</p> <p>SOX-10</p>	<p>A</p>



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FFPE slides from (Formalin fixed paraffin embedded) tissue and cytology cell block (cont'd)	Immunohistochemistry examination activities for detection of: (cont'd)	Leica Bond III fully automated immunohistochemistry platform CEP0200 Immunohistochemistry CEP0210 Use of pipettes CEP0211 Making up enzyme from the kit for the Leica BOND CEP0212 Stock control and acceptance testing in IHC	
	Smooth muscle differentiation	Caldesmon	
	Retention or loss of MLH1 protein expression in colorectal and endometrial cancers	MMR MLH1	
	Retention or loss of MSH2 protein expression in colorectal and endometrial cancers	MMR MSH2	
	Retention or loss of MSH6 protein expression in colorectal and endometrial cancers	MMR MSH6	
	Retention or loss of PMS2 protein expression in colorectal and endometrial cancers	MMR PMS2	
	Squamous cell carcinoma	P40	
	Malignant melanoma	Prame	
	Smooth muscle differentiation	SMA	
Slides stained in-house as above	Morphological assessment and interpretation/diagnosis	Using various microscopes SOP HI0389 SOP HI0390	A, B





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HUMAN BODY FLUIDS (cont'd)  Slides prepared in-house as above	<u>Cytopathological activities for the purposes of clinical diagnosis</u> (cont'd)  Morphological assessment and interpretation/diagnosis	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:  Light microscopy using a variety of microscopes SOP Non-gynae reporting CY093	A, B
END			