


# Schedule of Accreditation

issued by

## United Kingdom Accreditation Service

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

 <b>UKAS</b> MEDICAL <b>10338</b> Accredited to ISO 15189:2012	<b>Aneurin Bevan University Health Board</b>	
	Issue No: 008    Issue date: 25 November 2024	
	<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



10338  
Accredited to  
ISO 15189:2012

**Schedule of Accreditation**  
issued by  
**United Kingdom Accreditation Service**  
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

**Aneurin Bevan University Health Board**

**Issue No: 008 Issue date: 25 November 2024**

Testing performed by the Organisation at the locations specified

DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY TISSUE	<u>Histopathological examination activities for the purposes of clinical diagnosis</u>	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:	
Tissue: biopsy, excision, resection and post-mortem specimens	Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis	Specimen dissection including decalcification	A
		SOPs HI0247 HI0246 HI0165	
As above, including cellblocks		Tissue processing using Excelsior processors	A
		SOP HI376	
As above		Microtomy	A
		SOP HI0170	
Fresh tissue biopsies		Intraoperative frozen sections using Bright OTF 5000 and H&E staining	A
		SOPs HI0421 HI0059 HI0171 (H&E)	



10338  
Accredited to  
ISO 15189:2012

**Schedule of Accreditation**  
issued by  
**United Kingdom Accreditation Service**  
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

**Aneurin Bevan University Health Board**

**Issue No: 008 Issue date: 25 November 2024**

**Testing performed by the Organisation at the locations specified**

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
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



10338  
Accredited to  
ISO 15189:2012

**Schedule of Accreditation**  
issued by  
**United Kingdom Accreditation Service**  
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

**Aneurin Bevan University Health Board**

**Issue No: 008 Issue date: 25 November 2024**

**Testing performed by the Organisation at the locations specified**

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
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



10338  
Accredited to  
ISO 15189:2012

**Schedule of Accreditation**  
issued by  
**United Kingdom Accreditation Service**  
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

**Aneurin Bevan University Health Board**

**Issue No: 008 Issue date: 25 November 2024**

**Testing performed by the Organisation at the locations specified**

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
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	



10338  
Accredited to  
ISO 15189:2012

**Schedule of Accreditation**  
issued by  
**United Kingdom Accreditation Service**  
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

**Aneurin Bevan University Health Board**

**Issue No: 008 Issue date: 25 November 2024**

**Testing performed by the Organisation at the locations specified**

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
<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>



10338  
Accredited to  
ISO 15189:2012

**Schedule of Accreditation**  
issued by  
**United Kingdom Accreditation Service**  
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

**Aneurin Bevan University Health Board**

**Issue No: 008 Issue date: 25 November 2024**

**Testing performed by the Organisation at the locations specified**

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
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	
	Squamous differentiation from adenocarcinoma	CK 5	
	Breast, lung, gynae adenocarcinoma	CK 7	
	Epithelial marker. Urothelial + hepatocellular carcinoma, neuroendocrine tumours, epithelioid malignant mesotheliomas	CK8/18	
	Epithelial marker. Thyroid papillary (+), thyroid follicular (-)	CK19	
	Colon, rectum, prostate adenocarcinoma	CK 20	
	Proliferative zone of epithelium and endothelium. Mantle cell lymphoma	CYCLIN D1	
	Differentiation of ductal (+) carcinoma or breast from lobular (-)	ECAD	
	Smooth muscle and skeletal muscle tumours	DESMIN	



10338  
Accredited to  
ISO 15189:2012

**Schedule of Accreditation**  
issued by  
**United Kingdom Accreditation Service**  
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

**Aneurin Bevan University Health Board**

**Issue No: 008 Issue date: 25 November 2024**

**Testing performed by the Organisation at the locations specified**

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
<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>Epithelial Membrane Antigen. Epithelial marker</p> <p>Endothelial cell marker</p> <p>Fibrohistiocytic marker</p> <p>Melanoma marker</p> <p>Proliferation marker</p> <p>Leukocyte common antigen. General lymphoma marker</p> <p>Melanoma and normal melanocytes</p> <p>Normal lung and lung adenocarcinomas</p> <p>Classification of germ cell tumours and GCNIS</p> <p>HPV related carcinomas</p> <p>Squamous differentiation from adenocarcinoma</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>EMA</p> <p>Factor 8 (vWF)</p> <p>Factor 13a</p> <p>HMB45 Melanoma Marker</p> <p>Ki67</p> <p>LCA</p> <p>MELAN A</p> <p>NAPSIN</p> <p>OCT3/4</p> <p>P16</p> <p>p63</p>	<p>A</p>





10338  
Accredited to  
ISO 15189:2012

**Schedule of Accreditation**  
issued by  
**United Kingdom Accreditation Service**  
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

**Aneurin Bevan University Health Board**

**Issue No: 008 Issue date: 25 November 2024**

**Testing performed by the Organisation at the locations specified**

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
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	
	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	



10338  
Accredited to  
ISO 15189:2012

**Schedule of Accreditation**  
issued by  
**United Kingdom Accreditation Service**  
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

**Aneurin Bevan University Health Board**

**Issue No: 008 Issue date: 25 November 2024**

**Testing performed by the Organisation at the locations specified**

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY TISSUE (cont'd)  FFPE slides from tissue (Formalin fixed paraffin embedded) and cytology cell block (cont'd)	<u>Histopathological examination activities for the purposes of clinical diagnosis</u> (cont'd)  Immunohistochemistry examination activities for detection of: (cont'd)  Oestrogen Receptor. Prognostic breast cancer marker  Lymphatic endothelial cells  Endothelial cells, mesothelioma  Low molecular weight cytokeratin marker  Malignant mesothelioma, BAP1-deficient melanocytic lesions  Epithelial cell marker  Breast and urothelial carcinoma  Gynae related tumours, renal and thyroid  Prostate adenocarcinoma  Melanoma/metastatic melanoma	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:  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  ER  D240  Thrombomodulin  CAM 5.2 (anti-cyto)  BAP-1  EPCAM  GATA3  Pax 8  NKX3.1  SOX-10	A



10338  
Accredited to  
ISO 15189:2012

**Schedule of Accreditation**  
issued by  
**United Kingdom Accreditation Service**  
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

**Aneurin Bevan University Health Board**

**Issue No: 008 Issue date: 25 November 2024**

**Testing performed by the Organisation at the locations specified**

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
<p>HUMAN BODY TISSUE (cont'd)</p> <p>FFPE slides from (Formalin fixed paraffin embedded) tissue and cytology cell block (cont'd)</p> <p>Slides stained in-house as above</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>Smooth muscle differentiation</p> <p>Retention or loss of MLH1 protein expression in colorectal and endometrial cancers</p> <p>Retention or loss of MSH2 protein expression in colorectal and endometrial cancers</p> <p>Retention or loss of MSH6 protein expression in colorectal and endometrial cancers</p> <p>Retention or loss of PMS2 protein expression in colorectal and endometrial cancers</p> <p>Squamous cell carcinoma</p> <p>Malignant melanoma</p> <p>Smooth muscle differentiation</p> <p>Morphological assessment and interpretation/diagnosis</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>Caldesmon</p> <p>MMR MLH1</p> <p>MMR MSH2</p> <p>MMR MSH6</p> <p>MMR PMS2</p> <p>P40</p> <p>Prame</p> <p>SMA</p> <p>Using various microscopes</p> <p>SOP HI0389 SOP HI0390</p>	<p>A</p> <p>A, B</p>



10338  
Accredited to  
ISO 15189:2012

**Schedule of Accreditation**  
issued by  
**United Kingdom Accreditation Service**  
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

**Aneurin Bevan University Health Board**

**Issue No: 008 Issue date: 25 November 2024**

**Testing performed by the Organisation at the locations specified**

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
<p>HUMAN BODY FLUIDS</p> <p>Joint fluids</p> <p>Human body fluids, bronchial washings/brushings, fine needle aspiration samples, endoscopy brushings</p>	<p><u>Cytopathological activities for the purposes of clinical diagnosis</u></p> <p>Identification of sodium urate crystals and calcium pyrophosphate crystals</p> <p>Examination of cellular material in order to identify or exclude morphological and cytological abnormalities</p> <p>Preparation of cell blocks followed by subsequent processing, staining and analysis as above</p>	<p>In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:</p> <p>Using wet prep and light microscopy</p> <p>SOP HI0094</p> <p>Specimen preparation using Hologic Genesis, centrifuge and cytocentrifuge</p> <p>SOPs: Bronchial brushings CY007 Bronchial washings CY008 CSF CY013 Endoscopy brushings CY019 Fine needle aspirations CY024 Serous fluids CY058 Sputum CY063 Thyroid collection CY115 Urine CY071 Ebus CY138</p> <p>Automated staining using Leica autostainer XL and Stainmate autostainer</p> <p>Leica autostainer – PAP Stainmate – MGG and diff quik</p> <p>SOPs: Staining machine Leica autostainer XL CY065</p> <p>Stainmate autostainer CY098</p> <p>Using in- house cell block preparation</p> <ul style="list-style-type: none"> <li>CEP0015 Preparation of Clot and Agar Blocks)- sample types: bronchial washings/brushings, FNAs and endoscopy brushings.</li> </ul>	<p>A</p> <p>A</p> <p>A</p> <p>A</p>



10338  
Accredited to  
ISO 15189:2012

**Schedule of Accreditation**  
issued by  
**United Kingdom Accreditation Service**  
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

**Aneurin Bevan University Health Board**

**Issue No: 008 Issue date: 25 November 2024**

**Testing performed by the Organisation at the locations specified**

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd)  Slides prepared in-house as above	<u>Cytopathological activities for the purposes of clinical diagnosis (cont'd)</u>  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			