# **Schedule of Accreditation**

issued by

# **United Kingdom Accreditation Service**

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



9571

Accredited to ISO 15189: 2022

### **Source Bioscience Limited (trading as Source LDPath)**

Issue No: 015 Issue date: 27 October 2025

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Nottingham E-Mail: Nick.Bills@sourcebioscience.com

NG8 6PX Website: www.sourcebioscience.com

United Kingdom

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
Source Bioscience Ltd 1 Orchard Place Business Park Nottingham NG8 6PX	Local contact Nick Bills Tel: +44 (0) 115 973 9034 EMail: Nick.Bills@sourcebioscience.com Website: www.sourcebioscience.com	Histopathology	A
Source Bioscience Ltd (trading as Source LDPath) The Courtyard Laboratory Units 3, 4 & 5 Vinnetrow Business Park Vinnetrow Road Chichester PO20 1QH	Local contact Nick Bills Tel: +44 (0) 115 973 9034 EMail: Nick.Bills@sourcebioscience.com Website: www.sourcebioscience.com	Histopathology	В

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

Location details	Activity	Location code
External laboratories and other approved locations listed in Document; ONC-DOC-12	Morphological assessment, interpretation/diagnosis and reporting on pre-prepared slides	С

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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 TISSUES	Histopathological examination activities for the purposes of clinical diagnosis  Molecular Techniques	In-house documented procedures using manual methods or analyses in conjunction with manufacturers' instructions as specified:	
Tissue (FFPE)	Nucleic Acid Isolation and Purification	Manual in-house methods Gene-SOP-25 Gene-SOP-81	А
DNA extracted from FFPE tissue	Targeted gene mutation analysis: BRAF	Targeted amplification (PCR) and pyrosequencing analysis on the Qiagen pyromark Q24 and Q96 platforms and Nanodrop Gene-SOP-6	A
DNA extracted from FFPE tissue	Targeted gene mutation analysis: EGFR	Targeted amplification (PCR) and pyrosequencing analysis on the Qiagen pyromark Q24 platform and Nanodrop Gene-SOP-28 Gene-SOP-29	A
DNA extracted from FFPE tissue	Targeted gene mutation analysis: KRAS	Targeted amplification (PCR) and pyrosequencing analysis on the Qiagen pyromark Q24 and Q96 platforms and Nanodrop Gene-SOP-58 Gene-SOP-59 Gene-SOP-60	A
DNA extracted from FFPE tissue	Targeted gene mutation analysis: NRAS	Targeted amplification (PCR) and pyrosequencing analysis on the Qiagen pyromark Q24 and Q96 platforms and Nanodrop Gene-SOP-89	A

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY TISSUES (cont'd)	Histopathological examination activities for the purposes of clinical diagnosis (cont'd)	In-house documented procedures using manual methods or analyses in conjunction with manufacturers' instructions as specified:	A
	Routine histopathology activities for the purpose of clinical diagnosis		
Fixed tissue, FFPE tissue blocks	Sample Reception	Booking in of clinical cases: ONC-SOP-34	А
Fixed tissue	Histological Dissection	Specimen dissection: ONC-SOP-101; ONC-SOP-71; ONC-SOP-72; ONC-SOP-73, ONC-SOP-74.	A
Fixed tissue	Formalin Fixed Tissue Processing	Tissue processing using the Sakura VIP6 A1: ONC-SOP-34.	А
Fixed tissue blocks	Processed Tissue Embedding	Tissue embedding using the Thermo Scientific HistoStar: ONC-SOP-34.	А
FFPE tissue blocks	Microtomy	Microtomy using the Sakura accucut, Solmedia 4062, Thermo Shandon Finesse E, Epredia HM325 and Lieca RM2135 microtomes: ONC-SOP-95.	A
FFPE tissue slides	Haematoxylin and Eosin (H&E) Staining	H&E staining using the Sakura Prisma Plus H&E stainer and coverslipper: ONC-SOP-109	А
Digital images from slides prepared in house as above, or prepared at customer sites	Morphological assessment and interpretation/diagnosis	Slide scanning using 3DHISTECH Panoramic 1000 slide DIG-SOP-1 - Digital Pathology	А
	Special Stains to detect the following:	Special staining using the following stains & procedures:	А
FFPE tissue	Acid mucins	Alcian blue (AB): ONC-SOP-12	А
FFPE tissue	Acid, neutral and mixed mucins	Alcian blue/Periodic acid Schiffs (ABPAS): ONC-SOP-105	A
FFPE tissue	Basement membranes Fungi Glycogen and neutral mucins	Periodic Acid Schiff (PAS): ONC- SOP-25	A

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HUMAN BODY TISSUES (cont'd)	Histopathological examination activities for the purposes of clinical diagnosis (cont'd)	In-house documented procedures using manual methods or analyses in conjunction with manufacturers' instructions as specified:	
	Special Stains to detect the following (cont'd):	Manual special staining using the following stains & procedures:	A
FFPE tissue	Elastic fibres and connective tissue	Elastic Van-Gieson (EVG): ONC- SOP-16	А
FFPE tissue	Fungi	Periodic Acid Schiff with Diastase (DPAS): ONC-SOP-26	А
	Class 1 Immunohistochemistry for the detection of:	Performed on the Ventana Ultra in accordance with ONC-SOP-92	А
FFPE tissue	Basal cells of squamous epithelia	P63	А
FFPE tissue	Cytokeratin (pan)	AE1/AE3	А
FFPE tissue	Endothelia	CD34	A
FFPE tissue	Follicular epithelial cells of the thyroid, type II pneumocytes	TTF-1	А
FFPE tissue	Glandular, transitional epithelia	CK7	А

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HUMAN BODY TISSUES (cont'd)	Histopathological examination activities for the purposes of clinical diagnosis (cont'd)	In-house documented procedures using manual methods or analyses in conjunction with manufacturers' instructions as specified:	
	Class 1 Immunohistochemistry (cont'd)	Performed on the Ventana Ultra in accordance with ONC-SOP-92	А
FFPE tissue	Mature B-cells, follicular dendritic cells	CD10	А
FFPE tissue	Melanoma	Melan-A	Α
FFPE tissue	Melanoma, melanosomes	HMB45	А
FFPE tissue	Melanoma, S100+ neoplasms, neuroendocrine cells	S100	А
FFPE tissue	Proliferating cells	Ki67 (MIB-1)	Α
FFPE tissue	Smooth muscle cells	SMA SMM	А
FFPE tissue	Squamous and basal epithelia	CK14	А
FFPE tissue	Squamous and myoepithelia	CK5/6	А
FFPE tissue	T-cells	CD3	А
	Class 2 Immunohistochemistry for the detection of:	Performed on the Ventana Ultra in accordance with ONC-SOP-92	
FFPE tissue	Oestrogen receptor	ER (SP1)	Α
FFPE tissue	Progesterone receptor	PR (1E2)	Α
FFPE tissue	HER2	HER2 (4B5)	А
FFPE tissue	HER2 gene amplification status	Fluorescent in situ hybridisation (FISH) testing. ONC-SOP-90, ONC-SOP-93	А

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY TISSUES (cont'd)	Histopathological examination activities for the purposes of clinical diagnosis (cont'd)	In-house documented procedures using manual methods or analyses in conjunction with manufacturers' instructions as specified:	
FFPE Tissue	Class 1 Immunohistochemistry for the detection of:	Performed on the Sakura Tissue- Tek Genie Advanced Staining System in accordance with ONC- SOP-137	A
	Endothelia	CD34	
	Detection of activated platelets, neutrophils and basophils	CD68	
	Smooth muscle actin	αSMA	
	Ovarian cancer/HPV	p16	
	Calponin (calcium binding) protein (Vascular & peripheral smooth muscle; other contractile cells)	Calponin	
	Cytoplasm of ductal or lobular epithelium.	CK8/18	
	Distinguish lobular from ductal carcinoma	ECAD	
	Oestrogen receptors	ER	
	Breast carcinoma	GCDFP-15	
	Proliferating cells	Ki67	
	Smooth muscle myosin	SMM	
	P40 protein. P40 is selectively expressed in lung SCC	p40	
	Progesterone receptor	PR	
	Demonstration of cytokeratins	CK5/6	
	H.pylori	H pylori	

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HUMAN BODY TISSUES (cont'd)	Histopathological examination activities for the purposes of clinical diagnosis (cont'd)	In-house documented procedures using manual methods or analyses in conjunction with manufacturers' instructions as specified:	
FFPE Tissue	Class 1 Immunohistochemistry for the detection of (cont'd):	Performed on the Sakura Tissue- Tek Genie Advanced Staining System in accordance with ONC- SOP-137	A
	Malignant melonomas	CD63	
	Melanoma	Melan A	
	Melanoma, melanosomes	HMB45	
	Melanocytic tumours	SOX10	
	Neuroanatomical marker	Calretinin	
	GI carcinoma	CEA	
	Epithelial tumors	EpCAM	
	Lymphatic endothelium	D2-40 (Podoplanin)	
	Gastrointestinal epithelia	CK20	
	Glandular, transitional epithelia	CK7	
	Cytokeratin (pan)	Pan-CK (AE1/AE3)	
	Melanoma, S100+ neoplasms, neuroendocrine cells	S100	
	Filaments in mesenchymal cells	Vimentin	
	Endothelial marker	CD31	
	Smooth and striated muscle cells	Desmin	
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HUMAN BODY TISSUES (cont'd)	Histopathological examination activities for the purposes of clinical diagnosis (cont'd)	In-house documented procedures using manual methods or analyses in conjunction with manufacturers' instructions as specified:	
FFPE Tissue	Class 1 Immunohistochemistry for the detection of (cont'd):	Performed on the Sakura Tissue- Tek Genie Advanced Staining System in accordance with ONC- SOP-137	A
	Differentiates between dermatofibromas (DF) and a host of other fibrohistiocytic entities, most notably dermatofibrosarcoma protuberans (DFSP)	Factor XIII	
	Protein in epithelial cells	EMA	
	MLH1 mismatch repair protein	MLH1	
	MSH2 mismatch repair protein	MSH2	
	MSH6 mismatch repair protein	MSH6	
	PMS2 mismatch repair protein	PMS2	

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
Fixed tissue, FFPE tissue blocks	Routine histopathology activities for the purpose of clinical diagnosis		
Fixed tissue	Sample Reception	Booking in of clinical cases: TCL- SOP-11	В
Tissue – Formalin Fixed, Slides (FFPE)	Specimen Dissection	TCL-SOP-12 Specimen Cut- Up Procedure TCL-SOP-6 Decalcifying and Tissue Softening Procedures	В
Fixed tissue	Formalin Fixed Tissue Processing	Tissue processing using the Leica HistoCore PELORIS 3: TCL-SOP- 16	В
Fixed tissue	Processed Tissue Embedding	Tissue embedding using the Leica HistoCore Arcadia centre: TCL- SOP-18	В
FFPE tissue	Microtomy	Microtomy using the Leica HistoCore Multicut microtomes: TCL-SOP-19	В
FFPE tissue slides	Haematoxylin and Eosin (H&E) Staining	H&E staining using the Leica ST5020 Multistainer and CV5030 coverslipper: TCL-SOP-23 H&E staining using the Leica Spectra ST Stainer and Spectra CV coverslipper: TCL-SOP-21	В
Digital images from slides prepared in house as above, or prepared at customer sites	Morphological assessment and interpretation/diagnosis	Slide scanning using 3DHISTECH Panoramic 1000 slide DIG-SOP-1 - Digital Pathology	В

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HUMAN BODY TISSUES (cont'd)	Histopathological examination activities for the purposes of clinical diagnosis (cont'd)	In-house documented procedures using manual methods or analyses in conjunction with manufacturers' instructions as specified:	
	Special Stains to detect the following:	Manual special staining using the following stains & procedures:	
FFPE tissue	Mucins – Acid, Neutral & Mixed	Alcian Blue/Periodic Acid Schiff (ABPAS): TCL-SOP-42	В
FFPE tissue	Neutral Mucins Fungi	Periodic Acid Schiff with Diastase (DPAS): TCL-SOP-40	В
FFPE tissue	Basement Membranes Glycogen Neutral Mucins Fungi	Periodic Acid Schiff (PAS): TCL- SOP-40	В
FFPE tissue	Acid Mucins	Alcian Blue: TCL-SOP-17	В
FFPE tissue	Mucins Glycogen	Alcian Blue Periodic Acid Schiff with Diastase (ABDPAS): TCL- SOP-7	В
FFPE tissue	Elastin fibres Connective Tissue	Elastic Van-Gieson (EVG): TCL- SOP-34	В
FFPE tissue	Ferric Iron	Pearls Prussian Blue; TCL-SOP-33	В
FFPE tissue	Reticulin fibres	Reticulin; TCL-SOP-45	В

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HUMAN BODY TISSUES (cont'd)	Histopathological examination activities for the purposes of clinical diagnosis (cont'd)	In-house documented procedures using manual methods or analyses in conjunction with manufacturers' instructions as specified:	
	Class 1 Immunohistochemistry for the detection of:	Performed on the Lecia Bond Max; TCL-SOP-39	В
FFPE tissue	Melanocytes, Melanoma & Adrenocortical Carcinomas	Melan-A	В
FFPE tissue	Cytokeratin (Pan)	AE1/AE3	В
FFPE tissue	T-Cells	CD3	В
FFPE tissue	Mature B-cells, follicular dendritic cells	CD10	В
FFPE tissue	B-cells	CD20	В
FFPE tissue	Activated T & B cells	CD31	В
FFPE tissue	Endothelia	CD34	В
FFPE tissue	Detection of activated platelets, neutrophils and basophils	CD68	В
FFPE tissue	Gastrointestinal epithelia	CK20	В
FFPE tissue	Squamous Epithelia	CK5	В
FFPE tissue	Glandular, transitional epithelia	CK7	В
FFPE tissue	Striated muscle cells and smooth muscle cells	Desmin	В
FFPE tissue	Epithelial membrane antigen	EMA	В
FFPE tissue	Melanoma, melanosomes	HMB45	В
FFPE tissue	Proliferating cells	Ki67	В
FFPE tissue	Melanoma	PRAME	В
FFPE tissue	P40	P40	В

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	Class 1 Immunohistochemistry for the detection of: (cont'd)	Performed on the Lecia Bond Max; TCL-SOP-39	В
FFPE tissue	Basal Cells of Squamous Epithelia	P63	В
FFPE tissue	Melanoma, S100+ neoplasms, neuroendocrine cells	S100	В
FFPE tissue	Smooth Muscle	SMA	В
FFPE tissue	Morphological assessment and interpretation/diagnosis	Receipt and reporting of clinical cases. ONC-SOP-82, ONC-SOP-85, ONC-SOP-84, ONC-SOP-83, ONC-SOP-55, ONC-SOP-54, ONC-SOP-51, ONC-SOP-56, ONC-SOP-52, ONC-SOP-49, ONC-SOP-34	С
END			

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