


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: 013 Issue date: 11 December 2024	
	1 Orchard Place Business Park Nottingham NG8 6PX United Kingdom	Contact: Nick Bills Tel: +44 (0) 115 973 9034 E-Mail: Nick.Bills@sourcebioscience.com Website: www.sourcebioscience.com
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	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	B

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	C



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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	<u>Histopathological examination activities for the purposes of clinical diagnosis</u>	In-house documented procedures using manual methods or analyses in conjunction with manufacturers' instructions as specified:	
Tissue (FFPE)	<u>Molecular Techniques</u> Nucleic Acid Isolation and Purification	Manual in-house methods Gene-SOP-25 Gene-SOP-81	A
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)	<u>Histopathological examination activities for the purposes of clinical diagnosis (cont'd)</u>	In-house documented procedures using manual methods or analyses in conjunction with manufacturers' instructions as specified:	A
Fixed tissue, FFPE tissue blocks	Routine histopathology activities for the purpose of clinical diagnosis Sample Reception	Booking in of clinical cases: ONC-SOP-34	A
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.	A
Fixed tissue blocks	Processed Tissue Embedding	Tissue embedding using the Thermo Scientific HistoStar: ONC-SOP-34.	A
FFPE tissue blocks	Microtomy	Microtomy using the Sakura accu cut, 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	A
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	A
	<u>Special Stains to detect the following:</u>	Special staining using the following stains & procedures:	A
FFPE tissue	Acid mucins	Alcian blue (AB): ONC-SOP-12	A
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)	<u>Histopathological examination activities for the purposes of clinical diagnosis (cont'd)</u>	In-house documented procedures using manual methods or analyses in conjunction with manufacturers' instructions as specified:	
	<u>Special Stains to detect the following (cont'd):</u>	Manual special staining using the following stains & procedures:	A
FFPE tissue	Elastic fibres and connective tissue	Elastic Van-Gieson (EVG): ONC-SOP-16	A
FFPE tissue	Fungi	Periodic Acid Schiff with Diastase (DPAS): ONC-SOP-26	A
	<u>Class 1 Immunohistochemistry for the detection of:</u>	Performed on the Ventana Ultra in accordance with ONC-SOP-92	A
FFPE tissue	Basal cells of squamous epithelia	P63	A
FFPE tissue	Cytokeratin (pan)	AE1/AE3	A
FFPE tissue	Endothelia	CD34	A
FFPE tissue	Follicular epithelial cells of the thyroid, type II pneumocytes	TTF-1	A
FFPE tissue	Glandular, transitional epithelia	CK7	A



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HUMAN BODY TISSUES (cont'd)	<u>Histopathological examination activities for the purposes of clinical diagnosis (cont'd)</u>	In-house documented procedures using manual methods or analyses in conjunction with manufacturers' instructions as specified:	
	<u>Class 1 Immunohistochemistry (cont'd)</u>	Performed on the Ventana Ultra in accordance with ONC-SOP-92	A
FFPE tissue	Mature B-cells, follicular dendritic cells	CD10	A
FFPE tissue	Melanoma	Melan-A	A
FFPE tissue	Melanoma, melanosomes	HMB45	A
FFPE tissue	Melanoma, S100+ neoplasms, neuroendocrine cells	S100	A
FFPE tissue	Proliferating cells	Ki67 (MIB-1)	A
FFPE tissue	Smooth muscle cells	SMA SMM	A
FFPE tissue	Squamous and basal epithelia	CK14	A
FFPE tissue	Squamous and myoepithelia	CK5/6	A
FFPE tissue	T-cells	CD3	A



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HUMAN BODY TISSUES (cont'd)	<u>Histopathological examination activities for the purposes of clinical diagnosis (cont'd)</u>	In-house documented procedures using manual methods or analyses in conjunction with manufacturers' instructions as specified:	
	<u>Class 2 Immunohistochemistry for the detection of:</u>	Performed on the Ventana Ultra in accordance with ONC-SOP-92	A
FFPE tissue	Oestrogen receptor	ER (SP1)	A
FFPE tissue	Progesterone receptor	PR (1E2)	A
FFPE tissue	HER2	HER2 (4B5)	A
FFPE tissue	HER2 gene amplification status	Fluorescent in situ hybridisation (FISH) testing. ONC-SOP-90, ONC-SOP-93	A
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	B
Fixed tissue	Formalin Fixed Tissue Processing	Tissue processing using the Leica HistoCore PELORIS 3: TCL-SOP-16	B
Fixed tissue	Processed Tissue Embedding	Tissue embedding using the Leica HistoCore Arcadia centre: TCL-SOP-18	B
FFPE tissue	Microtomy	Microtomy using the Leica HistoCore Multicut microtomes: TCL-SOP-19	B
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	B



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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:	
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	B
	<u>Special Stains to detect the following:</u>	Manual special staining using the following stains & procedures:	
FFPE tissue	Mucins – Acid, Neutral & Mixed	Alcian Blue/Periodic Acid Schiff (ABPAS): TCL-SOP-42	B
FFPE tissue	Neutral Mucins Fungi	Periodic Acid Schiff with Diastase (DPAS): TCL-SOP-40	B
FFPE tissue	Basement Membranes Glycogen Neutral Mucins Fungi	Periodic Acid Schiff (PAS): TCL-SOP-40	B
FFPE tissue	Acid Mucins	Alcian Blue: TCL-SOP-17	B
FFPE tissue	Mucins Glycogen	Alcian Blue Periodic Acid Schiff with Diastase (ABDPAS): TCL-SOP-7	B
FFPE tissue	Elastin fibres Connective Tissue	Elastic Van-Gieson (EVG): TCL-SOP-34	B
FFPE tissue	Ferric Iron	Pearls Prussian Blue; TCL-SOP-33	B
FFPE tissue	Reticulin fibres	Reticulin; TCL-SOP-45	B



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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:	
	<u>Class 1 Immunohistochemistry for the detection of:</u>	Performed on the Lecia Bond Max; TCL-SOP-39	B
FFPE tissue	Melanocytes, Melanoma & Adrenocortical Carcinomas	Melan-A	B
FFPE tissue	Cytokeratin (Pan)	AE1/AE3	B
FFPE tissue	T-Cells	CD3	B
FFPE tissue	Mature B-cells, follicular dendritic cells	CD10	B
FFPE tissue	B-cells	CD20	B
FFPE tissue	Activated T & B cells	CD31	B
FFPE tissue	Endothelia	CD34	B
FFPE tissue	Detection of activated platelets, neutrophils and basophils	CD68	B
FFPE tissue	Gastrointestinal epithelia	CK20	B
FFPE tissue	Squamous Epithelia	CK5	B
FFPE tissue	Glandular, transitional epithelia	CK7	B
FFPE tissue	Striated muscle cells and smooth muscle cells	Desmin	B
FFPE tissue	Epithelial membrane antigen	EMA	B
FFPE tissue	Melanoma, melanosomes	HMB45	B
FFPE tissue	Proliferating cells	Ki67	B
FFPE tissue	Melanoma	PRAME	B
FFPE tissue	P40	P40	B



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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: (cont'd)	Performed on the Lecia Bond Max; TCL-SOP-39	B
FFPE tissue	Basal Cells of Squamous Epithelia	P63	B
FFPE tissue	Melanoma, S100+ neoplasms, neuroendocrine cells	S100	B
FFPE tissue	Smooth Muscle	SMA	B
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	C

END