


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 9571 Accredited to ISO 15189:2012	Source Bioscience UK Ltd	
	Issue No: 008 Issue date: 27 May 2022	
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Testing performed at the above address only		

Site activities performed away from the location listed above:

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



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DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY TISSUE	<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
DNA extracted from FFPE tissue	Targeted gene mutation analysis: BRAF (colorectal cancer, melanoma)	Targeted amplification (PCR) and pyrosequencing analysis on the Qiagen pyromark Q24 and Q96 platforms and Nanodrop Gene-SOP-6
DNA extracted from FFPE tissue	Targeted gene mutation analysis: EGFR (NSCLC)	Targeted amplification (PCR) and pyrosequencing analysis on the Qiagen pyromark Q24 platform and Nanodrop Gene-SOP-28 Gene-SOP-29
DNA extracted from FFPE tissue	Targeted gene mutation analysis: KRAS (colorectal cancer)	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
DNA extracted from FFPE tissue	Targeted gene mutation analysis: NRAS (colorectal cancer)	Targeted amplification (PCR) and pyrosequencing analysis on the Qiagen pyromark Q24 and Q96 platforms and Nanodrop Gene-SOP-89



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HUMAN BODY TISSUE (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:
Fixed, FFPE and frozen tissue	Routine histopathology activities for the purpose of clinical diagnosis	Booking in of clinical cases: ONC-SOP-34
Fixed tissue		Specimen dissection: ONC-SOP-101; ONC-SOP-71; ONC-SOP-72; ONC-SOP-73, ONC-SOP-74.
Fixed tissue		Tissue processing using the Sakura VIP6 A1: ONC-SOP-34.
Fixed tissue		Tissue embedding using the Thermo Scientific HistoStar: ONC-SOP-34.
FFPE tissue		Microtomy using the Sakura accu cut microtomes: ONC-SOP-95.
FFPE tissue		H&E staining using the Sakura Prisma Plus H&E stainer and coverslipper: ONC-SOP-109
Digital images from slides prepared in house as above	Morphological assessment and interpretation/diagnosis	The Philips IntelliSite Pathology Solution (PIPS), Ultra-Fast Scanner (UFS) and Image Management System (IMS) DIG-SOP-1 - Digital Pathology
	<u>Special Stains to detect the following:</u>	Manual special staining using the following stains & procedures:
FFPE tissue	Acid mucins	Alcian blue (AB): ONC-SOP-12
FFPE tissue	Acid, neutral and mixed mucins	Alcian blue/Periodic acid Schiffs (ABPAS): ONC-SOP-105
FFPE tissue	Basement membranes	PAS: ONC-SOP-25
FFPE tissue	Elastic fibres and connective tissue	EVG: ONC-SOP-16
FFPE tissue	Fungi	PAS: ONC-SOP-25 PAS with diastase (DPAS): ONC-SOP-26



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HUMAN BODY TISSUE (cont'd)	<u>Special Stains to detect the following (cont'd):</u>	In-house documented procedures using manual methods or analyses in conjunction with manufacturers' instructions as specified:
FFPE tissue	Glycogen and neutral mucins	PAS: ONC-SOP-25
FFPE tissue	<u>Class 1 Immunohistochemistry for the detection of:</u>	Performed on the Ventana Benchmark XT or Ultra in accordance with ONC-SOP-97 and ONC-SOP-92
FFPE tissue	Adhesion protein	E-cadherin
FFPE tissue	Basal cells, squamous epithelium, prostate adenocarcinoma	HMWCK
FFPE tissue	Basal cells of squamous epithelia	P63
FFPE tissue	Cytokeratin (pan)	AE1/AE3 MNF116
FFPE tissue	Endothelia	CD34
FFPE tissue	Epithelial membrane antigen	EMA
FFPE tissue	Follicular epithelial cells of the thyroid, type II pneumocytes	TTF-1
FFPE tissue	Gastrointestinal epithelia	CK20
FFPE tissue	Glandular, transitional epithelia	CK7
FFPE tissue	Mature B-cells, follicular dendritic cells	CD10
FFPE tissue	Melanoma	Melan-A
FFPE tissue	Melanoma, melanosomes	HMB45
FFPE tissue	Melanoma, S100+ neoplasms, neuroendocrine cells	S100
FFPE tissue	Mesenchymal cell types	Vimentin



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HUMAN BODY TISSUE (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>	
FFPE tissue	Neoplastic prostate glands	AMACR
FFPE tissue	Proliferating cells	Ki67 (MIB-1)
FFPE tissue	Prostate malignancy	Antibody cocktail; AMACR/p63, AMACR/HMWCK.
FFPE tissue	Hodgkins Lymphoma	CD30
FFPE tissue	Prostate specific antigen	PSA
FFPE tissue	Prostatic acid phosphatase	PAP
FFPE tissue	Smooth muscle cells	SMA SMM
FFPE tissue	Squamous and basal epithelia	CK14
FFPE tissue	Squamous and myoepithelia	CK5/6
FFPE tissue	Striated muscle cells and smooth muscle cells	Desmin
FFPE tissue	T-cells	CD3
	<u>Class 2 Immunohistochemistry for the detection of:</u>	Performed on the Ventana Benchmark XT in accordance with ONC-SOP-97
FFPE tissue	Oestrogen receptor	ER (SP1)
FFPE tissue	Progesterone receptor	PR (1E2)
FFPE tissue	HER2	HER2 (4B5)
FFPE tissue	HER2 gene amplification status	Fluorescent in situ hybridisation (FISH) testing. ONC-SOP-90, ONC-SOP-93



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HUMAN BODY TISSUE (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:
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
HUMAN BODY TISSUE AND FLUIDS	<u>Virology/ Microbiology</u>	In house documented procedures based on equipment manuals and standard methods as specified:
	Molecular examination activities for the purpose of clinical diagnosis	Documented in house methods including UKHSA (United Kingdom Health Safety Agency) requirements for private providers of COVID-19 testing, for General Population Testing
Nasopharyngeal and combined nose / throat swabs in viral transport media (VTM)	Detection of SARS CoV-2 virus RNA (COVID-19) specific gene sequences; N gene and ORF1ab gene	PerkinElmer SARS-CoV-2 RT-PCR assay using the PerkinElmer chemagic Viral DNA/RNA 300 H96 kit using the PerkinElmer MSM1 and 360 Chemagic extraction robots and the Thermo QuantStudio™ 5 Dx real time thermocycler SOP ONC-SOP-111
Nasopharyngeal and combined nose / throat swabs in transport media (VTM, UTM or MTM)	Detection of SARS-CoV-2 RNA targets: S-gene, N-gene and <i>orf1ab</i>	TaqPath™ COVID-19 CE-IVD RT-PCR Kit using the MSM1 or Chemagic 360 instrument with the Chemagic Viral DNA/RNA kit, followed by amplification using the Thermo QuantStudio 5 DX thermal cycler



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HUMAN BODY TISSUE AND FLUIDS (cont'd) Extracted RNA from the samples listed above (self collection)	<u>Virology/ Microbiology (cont'd)</u> Molecular examination activities for the purpose of clinical diagnosis (cont'd) Variant detection of SARS-CoV 2	In house documented procedures based on equipment manuals and standard methods as specified: Documented in house methods for detection of SARS-CoV-2 virus RNA and sequencing Thermo Fisher Ion AmpliSeq SARS CoV-2 panel together with the Ion Chef and Ion Gene Studio S5 and the Kingfisher Flex extraction robot system for nucleic acid extraction. SOP ONC-SOP-115 ONC-SOP-123
END		