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: 001 **Issue date:** 27 March 2018

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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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Testing performed at main address only	

DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY TISSUE	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
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 Gene-SOP-7 Gene-SOP-8
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
Neat urine in manufacturers' preservative	Molecular detection of Infection: Chlamydia trachomatis Neisseria gonorrhoeae	DNA extraction and semi-quantitative PCR utilising the COBAS 4800 CT/NG amplification/detection kit PH-SOP-79

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY TISSUE cont'd	Histopathological examination activities for the purposes of clinical diagnosis cont'd Molecular Techniques cont'd	In-house documented procedures using manual methods or analyses in conjunction with manufacturers' instructions as specified:
Vulvovaginal swab in manufacturers' preservative	Molecular detection of Infection: Chlamydia trachomatis Neisseria gonorrhoeae	DNA extraction and semi-quantitative PCR utilising the COBAS 4800 CT/NG amplification/detection kit PH-SOP-79
Whole Blood	Enumeration of Circulating Tumour Cells (CTCs)	Immunomagnetic Florescence using CellSearch CTC Kit for isolation of CTCs on the CellTracks AutoPrep instrument and semi-quantitative enumeration of CTCs on the CellTracks Analyzer: ONC-SOP-62
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-DOC-101; ONC-SOP-71; ONC-SOP-72; ONC-SOP-73, ONC-SOP-74.
Fixed tissue		Tissue processing using the Thermo Shandon Pathcentres: ONC-SOP-34.
Fixed tissue		Tissue embedding using the Leica EG1140 C & H system: ONC-SOP-34.
FFPE tissue		Microtomy using the Leica, Shandon Finesse and Microm microtomes: ONC-SOP-95.
FFPE tissue		H&E staining using the Leica ST4040 automated stainer: ONC-SOP-75. Coverslipping of slides using the Microm Coverslipper: ONC-SOP-75.

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY TISSUE 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	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	Acid mucins, elastic fibres and connective tissue	MILAB: ONC-SOP-24
FFPE tissue	Amyloid	Congo red: ONC-SOP-15 Sirius Red: ONC-SOP-31
FFPE tissue	Basement membranes	PAS: ONC-SOP-25
FFPE tissue	Connective tissue	Masson Trichrome: ONC-SOP-22
FFPE tissue	Elastic fibres and connective tissue	EVG: ONC-SOP-16
FFPE tissue	Fungi	Grocott: ONC-SOP-19 PAS: ONC-SOP-25 PAS with diastase (DPAS): ONC-SOP-26
FFPE tissue	Glycogen and neutral mucins	PAS: ONC-SOP-25
FFPE tissue	Gram +/- bacteria	Gram: ONC-SOP-18
FFPE tissue	Haematopoietic cells	Giemsa: ONC-SOP-17
FFPE tissue	Haemosiderin (iron)	Perls Prussian Blue: ONC-SOP-27
FFPE tissue	Hepatitis B Antigen	Orcein: ONC-SOP-30
FFPE tissue	H.pylori	AYTB: ONC-SOP-14
Frozen tissue	Lipids	Oil Red O: ONC-SOP-11
FFPE tissue	Melanin	Masson Fontana: ONC-SOP-21

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY TISSUE 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 cont'd	
FFPE tissue	Mycobaterium spp including tuberculosis	ZN: ONC-SOP-32
FFPE tissue	Nuclei and connective tissue	HVG: ONC-SOP-20
FFPE tissue	Reticulin fibres	Reticulin: ONC-SOP-28
	Class 1 Immunohistochemistry for the detection of:	Performed on the Ventana Benchmark XT in accordance with ONC-SOP-97.
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

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY TISSUE cont'd	Histopathological examination activities for the purposes of clinical diagnosis cont'd Class 1 Immunohistochemistry cont'd	In-house documented procedures using manual methods or analyses in conjunction with manufacturers' instructions as specified:
FFPE tissue	Mesenchymal cell types	Vimentin
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

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY TISSUE 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 2 Immunohistochemistry for the detection of:	Performed on the Ventana Benchmark XT or Ultra in accordance with ONC-SOP-97 and ONC-SOP-92
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
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-57, ONC-SOP-56, ONC-SOP-52, ONC-SOP-49, ONC-SOP-34
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