Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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



9007

Accredited to ISO 15189:2012

HSL (Analytics) LLP

Issue No: 008 Issue date: 15 April 2024

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Testing performed at the above address only

DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
Formalin-fixed paraffin-embedded tissue	Histological examinations for the purpose of clinical diagnosis	Macroscopic and Microscopic examination using in house procedures in conjunction with manufacturer's instructions for the following methods (where relevant):
		Tissue Re-Embedding HIS-60W0-5 HSL-AD –Re-embedding of tissue using the Thermo HistoStar embedding centre and cold plate
		Microtomy HIS-60W0-5 HSL-AD — Tissue sectioning using Leica Biocut microtomes
	Basophilic and eosinophilic structures	Haematoxylin and Eosin stain HIS- 60W0-9 HSL-AD - Automated H&E staining using the Thermo Gemini AS
		Coverslipping of glass slides HIS- 60W0-10 HSL-AD - Coverslipping of glass slides using the ClearVue coverslipper
Formalin-fixed paraffin-embedded tissue	Immunohistochemistry staining for the purpose of subsequent analysis by a referring laboratory for the epitopes listed:	Automated Immunohistochemistry using Leica Bond III, Ventana/Roche Ultra and Dako Autostainer 48 platforms
		Immunohistochemistry Automated methods using: HIS-60W0-11 HSL-AD, HIS-60W0-12 HSL-AD, HIS-60W0-13 HSL-AD, HIS-60W0-14 HSL-AD
	34BE12	Leica Bond III, IHC

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
Formalin-fixed paraffin-embedded tissue (cont'd)	Immunohistochemistry (cont'd):	Automated Immunohistochemistry (cont'd)
	ACTH	Leica Bond III, IHC
	AE1/AE3	Leica Bond III, IHC
	AFP	Leica Bond III, IHC
	ALK (D5F3)	Ventana Ultra, IHC
	ALK (5A4)	Leica Bond III, IHC
	AMACR (Racemase)	Leica Bond III, IHC
	AMACR/p63 cocktail	Leica Bond III, IHC
	Androgen Receptor	Leica Bond III, IHC
	Bcl-2	Leica Bond III, IHC
	Bcl-6	Leica Bond III, IHC
	BerEP4	Leica Bond III, IHC
	Beta-catenin	Leica Bond III, IHC
	BOB-1	Leica Bond III, IHC
	CA125	Leica Bond III, IHC
	CA19.9	Leica Bond III, IHC
	CA-IX	Leica Bond III, IHC
	Calcitonin	Leica Bond III, IHC
	Calponin	Leica Bond III, IHC
	Calretinin	Leica Bond III, IHC
	CAM 5.2	Leica Bond III, IHC
	CD10	Leica Bond III, IHC
	CD103	Leica Bond III, IHC

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
Formalin-fixed paraffin-embedded tissue (cont'd)	Immunohistochemistry (cont'd):	Automated Immunohistochemistry (cont'd)
	CD117	Leica Bond III, IHC
	CD11c	Leica Bond III, IHC
	CD123	Leica Bond III, IHC
	CD138	Leica Bond III, IHC
	CD14	Leica Bond III, IHC
	CD15	Leica Bond III, IHC
	CD16	Leica Bond III, IHC
	CD163	Leica Bond III, IHC
	CD19	Leica Bond III, IHC
	CD1a	Leica Bond III, IHC
	CD2	Leica Bond III, IHC
	CD20	Leica Bond III, IHC
	CD21	Leica Bond III, IHC
	CD22	Leica Bond III, IHC
	CD23	Leica Bond III, IHC
	CD235a	Leica Bond III, IHC
	CD25	Leica Bond III, IHC
	CD3	Leica Bond III, IHC
	CD30	Leica Bond III, IHC
	CD31	Leica Bond III, IHC
	CD33	Leica Bond III, IHC
	CD34	Leica Bond III, IHC

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
Formalin-fixed paraffin-embedded tissue (cont'd)	Immunohistochemistry (cont'd):	Automated Immunohistochemistry (cont'd)
	CD38	Leica Bond III, IHC
	CD4	Leica Bond III, IHC
	CD43	Leica Bond III, IHC
	CD45	Leica Bond III, IHC
	CD45RO	Leica Bond III, IHC
	CD5	Leica Bond III, IHC
	CD56	Leica Bond III, IHC
	CD57	Leica Bond III, IHC
	CD61	Leica Bond III, IHC
	CD68(KP1)	Leica Bond III, IHC
	CD68(PGM1)	Leica Bond III, IHC
	CD7	Leica Bond III, IHC
	CD79a	Leica Bond III, IHC
	CD8	Leica Bond III, IHC
	CD99	Leica Bond III, IHC
	CDX-2	Leica Bond III, IHC
	CEA polyclonal	Leica Bond III, IHC
	CEA	Leica Bond III, IHC
	Chromogranin A	Leica Bond III, IHC
	CK14	Leica Bond III, IHC
	CK17	Leica Bond III, IHC
	CK19	Leica Bond III, IHC
	CK20	Leica Bond III, IHC

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Formalin-fixed paraffin-embedded tissue (cont'd)	Immunohistochemistry (cont'd):	Automated Immunohistochemistry (cont'd)
	CK5	Leica Bond III, IHC
	CK7	Leica Bond III, IHC
	CK8	Leica Bond III, IHC
	CMV	Leica Bond III, IHC
	с-Мус	Leica Bond III, IHC
	Collagen IV	Leica Bond III, IHC
	COX-2	Leica Bond III, IHC
	Cyclin D1	Leica Bond III, IHC
	D240	Leica Bond III, IHC
	DBA44	Leica Bond III, IHC
	Desmin	Leica Bond III, IHC
	DOG-1	Leica Bond III, IHC
	E cadherin	Leica Bond III, IHC
	EBV	Leica Bond III, IHC
	EGFR (C36)	Ventana Ultra, IHC
	EGFR E746-A750	Ventana Ultra, IHC
	EGFR L858R	Ventana Ultra, IHC
	EMA	Leica Bond III, IHC
	ER (6F11)	Leica Bond III, IHC
	ER (EP1)	Leica Bond III, IHC
	ERG	Ventana Ultra, IHC
	Factor VIII	Leica Bond III, IHC

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Formalin-fixed paraffin-embedded tissue (cont'd)	Immunohistochemistry (cont'd):	Automated Immunohistochemistry (cont'd)
	Factor XIIIa	Leica Bond III, IHC
	Fascin	Leica Bond III, IHC
	FSH	Leica Bond III, IHC
	Galectin 3	Leica Bond III, IHC
	Gastrin	Leica Bond III, IHC
	GATA3	Leica Bond III, IHC
	GCDFP-15	Leica Bond III, IHC
	GFAP	Leica Bond III, IHC
	GH	Leica Bond III, IHC
	Glucagon	Leica Bond III, IHC
	Glycophorin C	Leica Bond III, IHC
	Glypican 3	Leica Bond III, IHC
	Granzyme B	Leica Bond III, IHC
	H pylori	Leica Bond III, IHC
	Haemoglobin	Leica Bond III, IHC
	HBME-1	Leica Bond III, IHC
	h-caldesmon	Leica Bond III, IHC
	HCG	Leica Bond III, IHC
	Her-2	Ventana Ultra, IHC
	HMA (MSA)	Leica Bond III, IHC
	HMB45	Leica Bond III, IHC
	HSA (HepPar1)	Leica Bond III, IHC

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
Formalin-fixed paraffin-embedded tissue (cont'd)	Immunohistochemistry (cont'd):	Automated Immunohistochemistry (cont'd)
	HSVI/HSVII cocktail	Leica Bond III, IHC
	IDH-1	Leica Bond III, IHC
	IgA	Leica Bond III, IHC
	IgD	Leica Bond III, IHC
	IgG	Leica Bond III, IHC
	IgM	Leica Bond III, IHC
	Inhibin	Leica Bond III, IHC
	Insulin	Leica Bond III, IHC
	Kappa (various dilutions)	Leica Bond III, IHC
	KSHV (HHV-8)	Leica Bond III, IHC
	Lambda (various dilutions)	Leica Bond III, IHC
	Lysozyme	Leica Bond III, IHC
	Mast cell tryptase	Leica Bond III, IHC
	Melan A	Leica Bond III, IHC
	Mesothelin	Leica Bond III, IHC
	MIB-1	Leica Bond III, IHC
	mLH1	Leica Bond III, IHC
	MNF116	Leica Bond III, IHC
	MOC31	Leica Bond III, IHC
	MSH2	Leica Bond III, IHC
	MSH6	Leica Bond III, IHC
	MUC-5AC	Leica Bond III, IHC

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
Formalin-fixed paraffin-embedded tissue (cont'd)	Immunohistochemistry (cont'd):	Automated Immunohistochemistry (cont'd)
	MUC-1	Leica Bond III, IHC
	MUC-2	Leica Bond III, IHC
	MUC-4	Leica Bond III, IHC
	MUC-6	Leica Bond III, IHC
	MUM-1	Leica Bond III, IHC
	Myeloperoxidase	Leica Bond III, IHC
	MYO D1	Leica Bond III, IHC
	Myogenin	Leica Bond III, IHC
	Myoglobin	Leica Bond III, IHC
	Napsin A	Leica Bond III, IHC
	Neurofilament	Leica Bond III, IHC
	Neutrophil elastase	Leica Bond III, IHC
	NSE	Leica Bond III, IHC
	OCT-2	Leica Bond III, IHC
	OCT-3/4	Leica Bond III, IHC
	p16 INK4a	Ventana Ultra, IHC
	p40	Leica Bond III, IHC
	p53	Leica Bond III, IHC
	p57	Leica Bond III, IHC
	p63	Leica Bond III, IHC
	Parvovirus B19	Leica Bond III, IHC
	PAX-2	Leica Bond III, IHC

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Formalin-fixed paraffin-embedded tissue (cont'd)	Immunohistochemistry (cont'd):	Automated Immunohistochemistry (cont'd)
	PAX-8	Leica Bond III, IHC
	PD-L1 (22C3)	Dako Autostainer Link 48, IHC
	Perforin	Leica Bond III, IHC
	PGP 9.5	Leica Bond III, IHC
	PLAP	Leica Bond III, IHC
	PMS2	Leica Bond III, IHC
	PR	Leica Bond III, IHC
	Prolactin	Leica Bond III, IHC
	Prostein (P501s)	Leica Bond III, IHC
	PSA	Leica Bond III, IHC
	PSAP	Leica Bond III, IHC
	PTEN	Leica Bond III, IHC
	RCC	Leica Bond III, IHC
	S100	Leica Bond III, IHC
	SALL4	Leica Bond III, IHC
	Serotonin	Leica Bond III, IHC
	SMA	Leica Bond III, IHC
	SMM	Leica Bond III, IHC
	Somatostatin	Leica Bond III, IHC
	SOX-10	Leica Bond III, IHC
	SOX-11	Leica Bond III, IHC
	STAT6	Leica Bond III, IHC

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
Formalin-fixed paraffin-embedded tissue (cont'd)	Immunohistochemistry (cont'd):	Automated Immunohistochemistry (cont'd)
	Synaptophysin	Leica Bond III, IHC
	TAL1B5 (HLA-DR)	Leica Bond III, IHC
	Tdt	Leica Bond III, IHC
	Thyroglobulin	Leica Bond III, IHC
	TRAP	Leica Bond III, IHC
	TSH	Leica Bond III, IHC
	TTF-1	Leica Bond III, IHC
	Uroplakin III	Leica Bond III, IHC
	Villin	Leica Bond III, IHC
	Vimentin	Leica Bond III, IHC
	VS38c	Leica Bond III, IHC
	VZV	Leica Bond III, IHC
	WT1	Leica Bond III, IHC
	ZAP 70	Leica Bond III, IHC

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
Formalin-fixed paraffin-embedded tissue (cont'd)	Immunohistochemistry (cont'd):	Automated Immunohistochemistry (cont'd)
	In-situ hybridisation staining for the purpose of subsequent analysis by a referring laboratory for the	Automated in-situ hybridisation using Leica Bond III and Ventana/Roche Ultra platforms
	epitopes listed:	In-situ hybridisation Automated methods using: HIS-60W0-11 HSL-AD, HIS-60W0- 12 HSL-AD, HIS-60W0-13 HSL-AD, HIS-60W0-14 HSL-AD
	CMV	Leica Bond III, CISH
	EBER	Leica Bond III, CISH
	Карра	Leica Bond III, CISH
	Lambda	Leica Bond III, CISH
Formalin-fixed paraffin-embedded tissue (cont'd)	In-situ hybridisation stained tissue to detect the presence or absence of targets listed:	Semi-automated fluorescent in-situ hybridisation using Abbott Molecular VP2000 platform Interpretation by manual fluorescent microscopy and semi-automated BioView system
		Fluorescent in-situ hybridisation Semi-automated methods using: HIS-60W0-17 HSL-AD, HIS-60W0- 19 HSL-AD, HIS-60W0-23 HSL-AD
	ALK breakapart	VP2000, Manual/BioView Reporting
	BCL2 breakapart	VP2000, Manual/BioView Reporting
	BCL2:IGH fusion	VP2000, Manual/BioView Reporting
	BCL6 breakapart	VP2000, Manual/BioView Reporting
	CCND1 breakapart	VP2000, Manual/BioView Reporting
	FGFR1 amplification	VP2000, Manual/BioView Reporting
	FGFR2 amplification	VP2000, Manual/BioView Reporting

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
Formalin-fixed paraffin-embedded tissue (cont'd)	Immunohistochemistry (cont'd):	Automated Immunohistochemistry (cont'd)
	In-situ hybridisation stained tissue to detect the presence or absence of targets listed (cont'd):	Semi-automated fluorescent in-situ hybridisation using Abbott Molecular VP2000 platform Interpretation by manual fluorescent microscopy and semi-automated BioView system
		Fluorescent in-situ hybridisation Semi-automated methods using: HIS-60W0-17 HSL-AD, HIS-60W0- 19 HSL-AD, HIS-60W0-23 HSL-AD
	FGFR2 breakapart	VP2000, Manual Reporting
	HER2 amplification	VP2000, Manual/BioView Reporting
	IGH breakapart	VP2000, Manual/BioView Reporting
	MALT breakapart	VP2000, Manual/BioView Reporting
	Melanoma FISH	VP2000, Manual/BioView Reporting
	MET amplification	VP2000, Manual/BioView Reporting
	MYC breakapart	VP2000, Manual/BioView Reporting
	MYC:IGH fusion	VP2000, Manual/BioView Reporting
	ROS1 breakapart	VP2000, Manual/BioView Reporting

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Formalin-fixed paraffin-embedded tissue (cont'd)	Morphological assessment and interpretation/diagnosis limited to the following antigenic targets:	Microscopy (qualitative analysis) and reporting
		Morphological and immunohistochemistry.in-situ hybridisation assessment of tissue
	ALK IHC	Clinical interpretation of IHC by Consultant Histopathologist
	Her-2 IHC	Clinical interpretation of IHC by Consultant Histopathologist
	ER IHC	Clinical interpretation of IHC by Consultant Histopathologist
	PR IHC	Clinical interpretation of IHC by Consultant Histopathologist
	p16 IHC	Clinical interpretation of IHC by Consultant Histopathologist
	EGFR IHC	Clinical interpretation of IHC by Consultant Histopathologist
	EGFR Mutation specific IHC	Clinical interpretation of IHC by Consultant Histopathologist
	MMR (<u>M</u> is <u>M</u> atch <u>R</u> epair) IHC	Clinical interpretation of IHC by Consultant Histopathologist
	PD-L1 (22C3) IHC	Clinical interpretation of IHC by Consultant Histopathologist

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	
Formalin-fixed paraffin-embedded tissue Formalin-fixed paraffin-embedded tissue	Molecular Testing Detection of Human Papilloma Virus genotypes: 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59 26, 34, 53, 66, 67, 68a, 68b, 69, 70, 73, 82IS39, 82MM4 6, 11, 40, 42, 43, 44, 54, 55, 57, 61, 62, 72, 81CP8304, 83MM7, 84MM8, 90, 91 Detection and measurement of breast tumour gene expression	Tissue sectioning and macro- dissection using Leica Biocut microtomes SOP HIS-60W0-5 HSL-AD DNA extraction from FFPE using dry baths, Maxwell SC and Promega FFPE DNA extraction kit DNA quantification using Nanodrop One C Genotyping of HPV and risk rating using DNA extracted from FFPE and Proflex thermal cycler, VisionArray HPV Chip 1.0, Plustek Hydridiser, ZytoVision HPV PreCise Master Mix, Zytovision Vision Optic Array, Reader (Plustek Optic Film 8100) and Vision Array Analyzer software. Prosigna Breast Cancer Prognostic Gene Signature Assay using RNA	
	profile	isolated from FFPE using the Roche FFPET RNA Isolation Kits with measurement by Nanodrop One C. PCR using Veriti Thermal Cycler, nanostring nCounter PrepStation and analysis using nCounter Analyser	
END			

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