


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 <p>Accredited to ISO 15189:2012</p>	<h3>HSL (Analytics) LLP</h3> <p>Issue No: 002 Issue date: 26 September 2018</p>	
	<p>HSL-Advanced Diagnostics 1st Floor, Rockefeller Building 21 University Street London WC1E 6JJ</p>	<p>Contact: David Allen Tel: +44 (0)20 3912 0280 Fax: +44 (0)20 3912 0288 E-Mail: david.allen@hslpathology.com Website: www.hsl-ad.com</p>
<p>Testing performed at the above address only</p>		

DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
Formalin-fixed paraffin-embedded tissue	<p><u>Histological examinations for the purpose of clinical diagnosis</u></p> <p>Basophilic and eosinophilic structures</p>	<p>Macroscopic and Microscopic examination using in house procedures in conjunction with manufacturer's instructions for the following methods (where relevant):</p> <p>Tissue Re-Embedding IHC LP1 – Re-embedding of tissue using the Leica EG1150H embedding centre and cold plate</p> <p>Microtomy IHC LP1 – Tissue sectioning using Leica RM2235 microtomes</p> <p>Haematoxylin and Eosin stain IHC LP25 – Automated H&E staining using the Leica XL Autostainer</p> <p>Coverslipping of glass slides LP36- Coverslipping of glass slides using the ClearVue coverslipper</p>
Formalin-fixed paraffin-embedded tissue	<p><u>Immunohistochemistry stained tissue with subsequent analysis by an ISO 15189:2012 accredited laboratory for the epitopes listed:</u></p> <p>34BE12</p> <p>ACTH</p>	<p>Automated Immunohistochemistry using Leica Bond III, Ventana/Roche XT & Ultra and Dako Autostainer 48 platforms</p> <p>Immunohistochemistry Automated methods using: IHC LP4, 24, IHC LP30, 31, 29, 32 Leica Bond III, IHC</p> <p>Leica Bond III, IHC</p>



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Formalin-fixed paraffin-embedded tissue (cont'd)	<u>Immunohistochemistry</u> (cont'd):	Automated Immunohistochemistry (cont'd)
	AE1/AE3	Leica Bond III, IHC
	AFP	Leica Bond III, IHC
	ALK (D5F3)	Ventana XT/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
	CD117	Leica Bond III, IHC
	CD11c	Leica Bond III, IHC



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Formalin-fixed paraffin-embedded tissue (cont'd)	<u>Immunohistochemistry</u> (cont'd):	Automated Immunohistochemistry (cont'd)
	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	
CD38	Leica Bond III, IHC	
CD4	Leica Bond III, IHC	



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Formalin-fixed paraffin-embedded tissue (cont'd)	<u>Immunohistochemistry</u> (cont'd):	Automated Immunohistochemistry (cont'd)
	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	
CK5	Leica Bond III, IHC	



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Formalin-fixed paraffin-embedded tissue (cont'd)	<u>Immunohistochemistry</u> (cont'd):	Automated Immunohistochemistry (cont'd)
	CK7	Leica Bond III, IHC
	CK8	Leica Bond III, IHC
	CMV	Leica Bond III, IHC
	c-Myc	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 XT, IHC
	EGFR L858R	Ventana XT, 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	
Factor XIIIa	Leica Bond III, IHC	



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Formalin-fixed paraffin-embedded tissue (cont'd)	<u>Immunohistochemistry</u> (cont'd):	Automated Immunohistochemistry (cont'd)
	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
	HSVI/HSVII cocktail	Leica Bond III, IHC



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Formalin-fixed paraffin-embedded tissue (cont'd)	<u>Immunohistochemistry</u> (cont'd):	Automated Immunohistochemistry (cont'd)
	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	
MUC-1	Leica Bond III, IHC	



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Formalin-fixed paraffin-embedded tissue (cont'd)	<u>Immunohistochemistry</u> (cont'd):	Automated Immunohistochemistry (cont'd)
	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	
PAX-8	Leica Bond III, IHC	



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Formalin-fixed paraffin-embedded tissue (cont'd)	<u>Immunohistochemistry</u> (cont'd):	Automated Immunohistochemistry (cont'd)
	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	
Synaptophysin	Leica Bond III, IHC	



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Formalin-fixed paraffin-embedded tissue (cont'd)	<u>Immunohistochemistry</u> (cont'd):	Automated Immunohistochemistry (cont'd)
	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	<p>In-situ hybridisation stained tissue with subsequent analysis by an ISO 15189:2012 accredited laboratory to detect the presence or absence of targets listed:</p> <p>CMV</p> <p>EBER</p> <p>HPV Family 16</p> <p>HPV Family 6</p> <p>Kappa</p> <p>Lambda</p>	<p>Automated in-situ hybridisation using Leica Bond III and Ventana/Roche Ultra platforms</p> <p>In-situ hybridisation Automated methods using: IHC LP4, 24 IHC LP30, 31, 29, 32</p> <p>Leica Bond III, CISH</p> <p>Leica Bond III, CISH</p> <p>Ventana Ultra, CISH</p> <p>Ventana Ultra, CISH</p> <p>Leica Bond III, CISH</p> <p>Leica Bond III, CISH</p>



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Formalin-fixed paraffin-embedded tissue	In-situ hybridisation stained tissue with subsequent analysis by an ISO 15189:2012 accredited laboratory 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: IHC LP19; IHC LP27, 23, HSL-AD FISH LP1
	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
	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	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 UCLAD MF44 UCLAD QF21, 22, 23, 24, 26
	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
	HPV ISH; high & low risk	Clinical interpretation of CISH 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>Mis</u> Match <u>R</u> epair) IHC	Clinical interpretation of IHC by Consultant Histopathologist	
PD-L1 (22C3) IHC	Clinical interpretation of IHC by Consultant Histopathologist	
END		