

# Schedule of Accreditation

issued by

## United Kingdom Accreditation Service

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

 <p><b>UKAS</b> MEDICAL 9007</p> <p>Accredited to ISO 15189:2022</p>	<h3>HSL (Analytics) LLP</h3> <p><b>Issue No: 009    Issue date: 18 September 2024</b></p>	
	<p><b>HSL-Advanced Diagnostics</b> 60 Whitfield Street London W1T 4EU</p>	<p><b>Contact: David Allen</b> <b>Tel: +44 (0)20 3912 0280</b> <b>Fax: +44 (0)20 3912 0288</b> <b>E-Mail: david.allen@hslpathology.com</b> <b>Website: www.hsl-ad.com</b></p>
<p><b>Testing performed at the above address only</b></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 HIS-60W0-5 HSL-AD –Re-embedding of tissue using the Thermo HistoStar embedding centre and cold plate</p> <p>Microtomy HIS-60W0-5 HSL-AD – Tissue sectioning using Leica Biocut microtomes</p> <p>Haematoxylin and Eosin stain HIS-60W0-9 HSL-AD - Automated H&amp;E staining using the Thermo Gemini AS</p> <p>Coverslipping of glass slides HIS-60W0-10 HSL-AD - Coverslipping of glass slides using the ClearVue coverslipper</p>



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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)	<u>Immunohistochemistry staining for the purpose of subsequent analysis by a referring laboratory for the epitopes listed:</u>	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
	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	



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Formalin-fixed paraffin-embedded tissue (cont'd)	<u>Immunohistochemistry</u> (cont'd):	Automated Immunohistochemistry (cont'd)
	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
	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	



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Formalin-fixed paraffin-embedded tissue (cont'd)	<u>Immunohistochemistry</u> (cont'd):  CD3 CD30 CD31 CD33 CD34 CD38 CD4 CD43 CD45 CD45RO CD5 CD56 CD57 CD61 CD68(KP1) CD68(PGM1) CD7 CD79a CD8 CD99 CDX-2 CEA polyclonal	Automated Immunohistochemistry (cont'd)  Leica Bond III, IHC



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



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Formalin-fixed paraffin-embedded tissue (cont'd)	<u>Immunohistochemistry</u> (cont'd):	Automated Immunohistochemistry (cont'd)
	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
	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



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Formalin-fixed paraffin-embedded tissue (cont'd)	<u>Immunohistochemistry</u> (cont'd):	Automated Immunohistochemistry (cont'd)
	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
	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	



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Formalin-fixed paraffin-embedded tissue (cont'd)	<u>Immunohistochemistry</u> (cont'd):	Automated Immunohistochemistry (cont'd)
	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
	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





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Formalin-fixed paraffin-embedded tissue (cont'd)	<u>Immunohistochemistry</u> (cont'd):	Automated Immunohistochemistry (cont'd)
	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
	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	



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Formalin-fixed paraffin-embedded tissue (cont'd)	<u>Immunohistochemistry</u> (cont'd):	Automated Immunohistochemistry (cont'd)
	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
	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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Formalin-fixed paraffin-embedded tissue (cont'd)	<p><u>Immunohistochemistry</u> (cont'd):</p> <p>In-situ hybridisation staining for the purpose of subsequent analysis by a referring laboratory for the epitopes listed:</p> <p>CMV</p> <p>EBER</p> <p>Kappa</p> <p>Lambda</p> <p>In-situ hybridisation stained tissue to detect the presence or absence of targets listed:</p> <p>ALK breakapart</p> <p>BCL2 breakapart</p> <p>BCL2:IGH fusion</p> <p>BCL6 breakapart</p> <p>CCND1 breakapart</p> <p>FGFR1 amplification</p> <p>FGFR2 amplification</p>	<p>Automated Immunohistochemistry (cont'd)</p> <p>Automated in-situ hybridisation using Leica Bond III and Ventana/Roche Ultra platforms</p> <p>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</p> <p>Leica Bond III, CISH</p> <p>Leica Bond III, CISH</p> <p>Leica Bond III, CISH</p> <p>Leica Bond III, CISH</p> <p>Semi-automated fluorescent in-situ hybridisation using Abbott Molecular VP2000 platform Interpretation by manual fluorescent microscopy and semi-automated BioView system</p> <p>Fluorescent in-situ hybridisation Semi-automated methods using: HIS-60W0-17 HSL-AD, HIS-60W0-19 HSL-AD, HIS-60W0-23 HSL-AD</p> <p>VP2000, Manual/BioView Reporting</p> <p>VP2000, Manual/BioView Reporting</p> <p>VP2000, Manual/BioView Reporting</p> <p>VP2000, Manual/BioView Reporting</p> <p>VP2000, Manual/BioView Reporting</p> <p>VP2000, Manual/BioView Reporting</p> <p>VP2000, Manual/BioView Reporting</p> <p>VP2000, Manual/BioView Reporting</p>



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Formalin-fixed paraffin-embedded tissue (cont'd)	<p><u>Immunohistochemistry</u> (cont'd):</p> <p>In-situ hybridisation stained tissue to detect the presence or absence of targets listed (cont'd):</p> <p>FGFR2 breakapart</p> <p>HER2 amplification</p> <p>IGH breakapart</p> <p>MALT breakapart</p> <p>Melanoma FISH</p> <p>MET amplification</p> <p>MYC breakapart</p> <p>MYC:IGH fusion</p> <p>ROS1 breakapart</p>	<p>Automated Immunohistochemistry (cont'd)</p> <p>Semi-automated fluorescent in-situ hybridisation using Abbott Molecular VP2000 platform Interpretation by manual fluorescent microscopy and semi-automated BioView system</p> <p>Fluorescent in-situ hybridisation Semi-automated methods using: HIS-60W0-17 HSL-AD, HIS-60W0-19 HSL-AD, HIS-60W0-23 HSL-AD</p> <p>VP2000, Manual Reporting</p> <p>VP2000, Manual/BioView Reporting</p> <p>VP2000, Manual/BioView Reporting</p> <p>VP2000, Manual/BioView Reporting</p> <p>VP2000, Manual/BioView Reporting</p> <p>VP2000, Manual/BioView Reporting</p> <p>VP2000, Manual/BioView Reporting</p> <p>VP2000, Manual/BioView Reporting</p> <p>VP2000, Manual/BioView Reporting</p>



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



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Formalin-fixed paraffin-embedded tissue	<u>Molecular Testing</u>  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	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.
Formalin-fixed paraffin-embedded tissue	Detection and measurement of breast tumour gene expression profile	Prosigna Breast Cancer Prognostic Gene Signature Assay using RNA isolated from FFPE using the Roche FFPE RNA Isolation Kits with measurement by Nanodrop One C. PCR using Veriti Thermal Cycler, nanostring nCounter PrepStation and analysis using nCounter Analyser

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