Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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



9007

Accredited to ISO 15189:2022

HSL (Analytics) LLP

Issue No: 011 Issue date: 03 June 2025

HSL- Cellular Pathology Department (Histopathology, Diagnostic Cytology & HSL Advanced Diagnostics)

60 Whitfield Street

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E-Mail: ad@hslpathology.com, histology60ws@hslpathology.com

Website: www.hsl-ad.com

Testing performed by the Organisation at the locations specified below

Locations covered by the organisation and their relevant activities

Laboratory locations:

Location details		Activity	Location code
Address	Local contact		
HSL Advanced Diagnostics 60 Whitfield Street London W1T 4EU	Sahar Zargarzadeh	Histopathology Immunohistochemistry Molecular	A
Histopathology & Diagnostic Cytology 60 Whitfield Street London W1T 4EU	Ana Moreira	Histopathology Cytopathology (Non-Gynae)	В
Histopathology & Diagnostic Cytology Royal Free Hospital Pond Street London NW3 2QG	Ana Moreira	Histopathology	С

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Testing performed by the Organisation at the locations specified

Site activities performed away from the locations listed above:

Location details		Activity	Location code
The Clocktower Outpatients Department Chase Farm Hospital The Ridgeway Enfield Middlesex EN2 8JL	Ana Moreira	Mohs Service	D
Dermatology Department Clinic 6, Level 1 Royal Free Hospital Pond Street London NW3 2QG	Ana Moreira	Mohs Service	Е
The Whittington Hospital Histology Department Level 5, K Block Magdala Avenue London, N19 5NF	Ana Moreira	Specimen reception and transport of Cellular Pathology and Diagnostic Cytology samples to Location A for processing	F

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HSL (Analytics) LLP

Issue date: 18 September 2024 Issue No: 011

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	Location Code
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: biopsy, excision, resection and post-mortem specimens	Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis	Specimen Dissection SOPs: HIS-60W4-28 HIS-60W4-34 HIS-60W4-27 HIS-60W4-29	B&C
		Tissue processing	B & C
		SOPs: HIS-60W4-34 HIS-60W4-42 HIS-60W4-41	
		<u>Decalcification</u>	В
		SOPs: HIS-60W4-30 HIS-60W4-32	
		Tissue Embedding	В
		SOPs: HIS-60W4-43 Thermo Histostar embedding centres	
		Tissue Tek 5 embedding centre	С
		Tissue Re-Embedding HIS-60W0-5 HSL-AD —Re-embedding of tissue using the Thermo HistoStar embedding centre and cold plate	А
		of tissue using the Thermo HistoStar embedding centre and	

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
Formalin-fixed paraffin- embedded tissue (cont'd)	Histological examinations for the purpose of clinical diagnosis (cont'd)	Macroscopic and Microscopic examination using in house procedures in conjunction with manufacturer's instructions for the following methods (where relevant):	
Formalin fixed paraffin embedded blocks of processed tissue	Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd):	Tissue Sectioning SOPs: HIS-60W4-45 Leica Histocore & Leica RM2235 microtomes	B & C
		Microtomy HIS-60W0-5 HSL-AD Tissue sectioning using Leica Biocut microtomes	А
Fresh frozen tissue		Cryotomy	
		SOPs: HIS-60W4-37 HIS-60W4-38 Using Thermo Cryostar NX50 cryostats	ВС
FFPE slides (Formalin fixed paraffin embedded) tissue on glass slides		Interpretive/diagnostic microscopy SOP: LP-CPTH-HIST-REPORTING	B & C

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
Formalin-fixed paraffin- embedded tissue (cont'd)	Histological examinations for the purpose of clinical diagnosis (cont'd)	Macroscopic and Microscopic examination using in house procedures in conjunction with manufacturer's instructions for the following methods (where relevant):	
	Routine morphological staining	,	
FFPE slides (Formalin fixed paraffin embedded), frozen sections and slides prepared from fluids	Basophilic and eosinophilic structures	Haematoxylin and Eosin stain HIS-60W0-9 HSL-AD - Automated H&E staining using the Thermo Gemini AS	A
		Coverslipping of glass slides HIS-60W0-10 HSL-AD - Coverslipping of glass slides using the ClearVue coverslipper	A
	Haematoxylin and Eosin stain	Routine morphological staining using Dako coverstainer, Gemini AS stainer, Mega-Slide staining with Haematoxylin and Eosin stain SOP: HIS-60W4-47 HIS-60W4-46	В
		Routine morphological staining using Leica XL AutoStainer with Haematoxylin and Eosin stain SOP: HIS-60W4-47 HIS-60W4-42	С
	Special staining		
FFPE slides and slides prepared from fluid specimens	Detection of:	Automated staining using Dako Artisan Link Pro Stainer and Manual staining using documented in house methods as follows:	
	Alcian Blue pH 2.5 (AB)	Dako Artisan Link Pro Stainer and Manual methods	В
	Alcian Blue PAS (ABPAS)	Dako Artisan Link Pro Stainer and Manual methods	В

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
Formalin-fixed paraffin- embedded tissue (cont'd)	Histological examinations for the purpose of clinical diagnosis (cont'd)	Macroscopic and Microscopic examination using in house procedures in conjunction with manufacturer's instructions for the following methods (where relevant):	
FFPE slides and slides prepared from fluid specimens (cont'd)	Special staining (cont'd) Detection of: (cont'd)	Automated staining using Dako Artisan Link Pro Stainer and Manual staining using documented in house methods as follows:	
	Fouchet	Dako Artisan Link Pro Stainer and Manual methods	В
	Diastase Periodic Acid Schiff	Dako Artisan Link Pro Stainer and Manual methods	В
	Giemsa	Dako Artisan Link Pro Stainer and Manual methods	В
	Gordon and Sweet (Retic)	Dako Artisan Link Pro Stainer and Manual methods	В
	Periodic Acid Schiff (PAS)	Dako Artisan Link Pro Stainer and Manual methods	В
	Warthin and Starry	Dako Artisan Link Pro Stainer and Manual methods	В
	Perl's Prussian Blue	Dako Artisan Link Pro Stainer and Manual methods	В
	Hexamine Silver	Dako Artisan Link Pro Stainer and Manual methods	В
	Oil Red O	Dako Artisan Link Pro Stainer and Manual methods	В
	Ziehl-Neelsen (ZN)	Dako Artisan Link Pro Stainer and Manual methods	В
	Perls Prussian Blue	Dako Artisan Link Pro Stainer and Manual methods	В

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
Formalin-fixed paraffin- embedded tissue (cont'd)	Histological examinations for the purpose of clinical diagnosis (cont'd) Special staining (cont'd)	Macroscopic and Microscopic examination using in house procedures in conjunction with manufacturer's instructions for the following methods (where relevant):	
FFPE slides and slides prepared from fluid	Detection of: (cont'd)	SOPs: HIS-60W4-49	
specimens (cont'd)		Manual hand staining using Leica CV5030 coverslipper, ClearVue Thermo coverslipper and using the following stains:	
	Elastin H&E	Manual methods	В
	Gram	Manual methods	В
	Haematoxylin Van Gieson (HVG)	Manual methods	В
	Congo Red	Manual methods	В
	Masson Trichrome	Manual methods	В
	Miller's Elastic Van Gieson (EVG)	Manual methods	В
	Victoria Blue	Manual methods	В
	Phosphotungstic Acid Haematoxylin	Manual methods	В
	Rhodanine	Manual methods	В
	Martius Scarlet Blue (MSB).	Manual methods	В
	Haematoxylin and Eosin	Manual methods	B & C
	Orcein	Manual methods	В
	Sirius Red	Manual methods	В
	Southgate's Mucicarmine	Manual methods	В
	Von Kossa	Manual methods	В

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
Formalin-fixed paraffin- embedded tissue (cont'd)	Histological examinations for the purpose of clinical diagnosis (cont'd) Special staining (cont'd)	Macroscopic and Microscopic examination using in house procedures in conjunction with manufacturer's instructions for the following methods (where relevant):	
FFPE slides and slides prepared from fluid	Detection of: (cont'd)	SOPs: HIS-60W4-49	
specimens (cont'd)		Manual hand staining using Leica CV5030 coverslipper, ClearVue Thermo coverslipper and using the following stains:	
	Wade Fite	Manual methods	В
	Melanin Bleach	Manual methods	В
	Toluidine Blue	Manual methods	В
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	A
		Immunohistochemistry Automated methods using: HIS-60W0-11 HSL-AD, HIS- 60W0-12 HSL-AD, HIS-60W0-13 HSL-AD, HIS-60W0-14 HSL-AD	A
	34BE12	Leica Bond III, IHC	А
	ACTH	Leica Bond III, IHC	A
	AE1/AE3	Leica Bond III, IHC	A
	AFP	Leica Bond III, IHC	А
	ALK (D5F3)	Ventana Ultra, IHC	А
	ALK (5A4)	Leica Bond III, IHC	А

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
Formalin-fixed paraffin- embedded tissue (cont'd)	Immunohistochemistry (cont'd):	Automated Immunohistochemistry (cont'd)	
	AMACR (Racemase)	Leica Bond III, IHC	А
	AMACR/p63 cocktail	Leica Bond III, IHC	А
	Androgen Receptor	Leica Bond III, IHC	А
	Bcl-2	Leica Bond III, IHC	А
	Bcl-6	Leica Bond III, IHC	А
	BerEP4	Leica Bond III, IHC	А
	Beta-catenin	Leica Bond III, IHC	А
	BOB-1	Leica Bond III, IHC	А
	BCL-10	Leica Bond III, IHC	А
	BRAF (V600E)	Ventana Ultra, IHC	А
	CA125	Leica Bond III, IHC	А
	CA19.9	Leica Bond III, IHC	А
	CA-IX	Leica Bond III, IHC	А
	Calcitonin	Leica Bond III, IHC	А
	Calponin	Leica Bond III, IHC	А
	Calretinin	Leica Bond III, IHC	А
	CAM 5.2	Leica Bond III, IHC	А
	CD10	Leica Bond III, IHC	А
	CD103	Leica Bond III, IHC	Α
	CD117	Leica Bond III, IHC	А
	CD11c	Leica Bond III, IHC	А
	CD123	Leica Bond III, IHC	А

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
Formalin-fixed paraffin- embedded tissue (cont'd)	Immunohistochemistry (cont'd):	Automated Immunohistochemistry (cont'd)	
	CD138	Leica Bond III, IHC	А
	CD14	Leica Bond III, IHC	А
	CD15	Leica Bond III, IHC	А
	CD16	Leica Bond III, IHC	А
	CD163	Leica Bond III, IHC	А
	CD19	Leica Bond III, IHC	А
	CD1a	Leica Bond III, IHC	А
	CD2	Leica Bond III, IHC	А
	CD20	Leica Bond III, IHC	А
	CD21	Leica Bond III, IHC	А
	CD22	Leica Bond III, IHC	А
	CD23	Leica Bond III, IHC	А
	CD235a	Leica Bond III, IHC	А
	CD25	Leica Bond III, IHC	А
	CD3	Leica Bond III, IHC	А
	CD30	Leica Bond III, IHC	А
	CD31	Leica Bond III, IHC	А
	CD33	Leica Bond III, IHC	А
	CD34	Leica Bond III, IHC	А
	CD38	Leica Bond III, IHC	А
	CD4	Leica Bond III, IHC	А
	CD43	Leica Bond III, IHC	А

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
Formalin-fixed paraffin- embedded tissue (cont'd)	Immunohistochemistry (cont'd):	Automated Immunohistochemistry (cont'd)	
	CD45	Leica Bond III, IHC	А
	CD45RO	Leica Bond III, IHC	А
	CD5	Leica Bond III, IHC	А
	CD56	Leica Bond III, IHC	А
	CD57	Leica Bond III, IHC	А
	CD61	Leica Bond III, IHC	А
	CD68(KP1)	Leica Bond III, IHC	А
	CD68(PGM1)	Leica Bond III, IHC	А
	CD7	Leica Bond III, IHC	А
	CD79a	Leica Bond III, IHC	А
	CD8	Leica Bond III, IHC	А
	CD99	Leica Bond III, IHC	А
	CDX-2	Leica Bond III, IHC	А
	CEA polyclonal	Leica Bond III, IHC	А
	CEA	Leica Bond III, IHC	А
	Chromogranin A	Leica Bond III, IHC	А
	CK8/18	Leica Bond III, IHC	А
	CK14	Leica Bond III, IHC	А
	CK17	Leica Bond III, IHC	A
	CK19	Leica Bond III, IHC	A
	CK20	Leica Bond III, IHC	A
	CK5	Leica Bond III, IHC	А

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
Formalin-fixed paraffin- embedded tissue (cont'd)	Immunohistochemistry (cont'd):	Automated Immunohistochemistry (cont'd)	
	CK7	Leica Bond III, IHC	А
	CK8	Leica Bond III, IHC	А
	CMV	Leica Bond III, IHC	А
	с-Мус	Leica Bond III, IHC	А
	Collagen IV	Leica Bond III, IHC	А
	COX-2	Leica Bond III, IHC	А
	Cyclin D1	Leica Bond III, IHC	А
	D240	Leica Bond III, IHC	А
	DBA44	Leica Bond III, IHC	А
	Desmin	Leica Bond III, IHC	А
	DOG-1	Leica Bond III, IHC	А
	E cadherin	Leica Bond III, IHC	А
	EBV	Leica Bond III, IHC	А
	EGFR (C36)	Ventana Ultra, IHC	А
	EGFR E746-A750	Ventana Ultra, IHC	А
	EGFR L858R	Ventana Ultra, IHC	А
	EMA	Leica Bond III, IHC	А
	ER (6F11)	Leica Bond III, IHC	А
	ER (EP1)	Leica Bond III, IHC	А
	ER (Clone SP1)	Ventana Ultra, IHC	A
	ERG	Ventana Ultra, IHC	А
	Factor VIII	Leica Bond III, IHC	А

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

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Formalin-fixed paraffin- embedded tissue (cont'd)	Immunohistochemistry (cont'd):	Automated Immunohistochemistry (cont'd)	
	HSVI/HSVII cocktail	Leica Bond III, IHC	А
	IDH-1	Leica Bond III, IHC	А
	IgA	Leica Bond III, IHC	А
	IgD	Leica Bond III, IHC	Α
	IgG	Leica Bond III, IHC	А
	IgM	Leica Bond III, IHC	А
	Inhibin	Leica Bond III, IHC	А
	Insulin	Leica Bond III, IHC	А
	Kappa (various dilutions)	Leica Bond III, IHC	А
	KSHV (HHV-8)	Leica Bond III, IHC	А
	Lambda (various dilutions)	Leica Bond III, IHC	А
	Lysozyme	Leica Bond III, IHC	А
	Mammaglobin	Leica Bond III, IHC	А
	Mast cell tryptase	Leica Bond III, IHC	А
	Melan A	Leica Bond III, IHC	А
	Mesothelin	Leica Bond III, IHC	А
	MIB-1	Leica Bond III, IHC	А
	mLH1	Leica Bond III, IHC	А
	MNF116	Leica Bond III, IHC	А
	MOC31	Leica Bond III, IHC	А
	MSH2	Leica Bond III, IHC	А
	MSH6	Leica Bond III, IHC	А

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
Formalin-fixed paraffin- embedded tissue (cont'd)	Immunohistochemistry (cont'd):	Automated Immunohistochemistry (cont'd)	
	MUC-5AC	Leica Bond III, IHC	А
	MUC-1	Leica Bond III, IHC	А
	MUC-2	Leica Bond III, IHC	А
	MUC-4	Leica Bond III, IHC	А
	MUC-6	Leica Bond III, IHC	A
	MUM-1	Leica Bond III, IHC	A
	Myeloperoxidase	Leica Bond III, IHC	A
	MYO D1	Leica Bond III, IHC	A
	Myogenin	Leica Bond III, IHC	A
	Myoglobin	Leica Bond III, IHC	А
	Napsin A	Leica Bond III, IHC	А
	Neurofilament	Leica Bond III, IHC	А
	Neutrophil elastase	Leica Bond III, IHC	А
	NSE	Leica Bond III, IHC	А
	OCT-2	Leica Bond III, IHC	A
	OCT-3/4	Leica Bond III, IHC	А
	p16 INK4a	Ventana Ultra, IHC	А
	p40	Leica Bond III, IHC	А
	p53	Leica Bond III, IHC	А
	p57	Leica Bond III, IHC	А
	p63	Leica Bond III, IHC	А
	Parvovirus B19	Leica Bond III, IHC	А

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Formalin-fixed paraffin- embedded tissue (cont'd)	Immunohistochemistry (cont'd):	Automated Immunohistochemistry (cont'd)	
	PAX-2	Leica Bond III, IHC	А
	PAX-8	Leica Bond III, IHC	А
	PD-L1 (22C3)	Dako Autostainer Link 48, IHC	А
	PD-L1 (Clone28-8)	Dako Autostainer Link 48, IHC	А
	PD-L1 (Clone SP142)	Ventana Ultra, IHC	А
	Perforin	Leica Bond III, IHC	А
	PGP 9.5	Leica Bond III, IHC	А
	PLAP	Leica Bond III, IHC	А
	PMS2	Leica Bond III, IHC	А
	PR	Leica Bond III, IHC	А
	Prolactin	Leica Bond III, IHC	А
	Prostein (P501s)	Leica Bond III, IHC	А
	PSA	Leica Bond III, IHC	А
	PSAP	Leica Bond III, IHC	А
	PTEN	Leica Bond III, IHC	А
	RCC	Leica Bond III, IHC	А
	ROS-1	Ventana Ultra, IHC	А
	S100	Leica Bond III, IHC	А
	SALL4	Leica Bond III, IHC	А
	SATB2	Leica Bond III, IHC	А
	Serotonin	Leica Bond III, IHC	А
	SMA	Leica Bond III, IHC	А

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
Formalin-fixed paraffin- embedded tissue (cont'd)	Immunohistochemistry (cont'd):	Automated Immunohistochemistry (cont'd)	
	SMM	Leica Bond III, IHC	А
	Somatostatin	Leica Bond III, IHC	А
	SOX-10	Leica Bond III, IHC	А
	SOX-11	Leica Bond III, IHC	Α
	STAT6	Leica Bond III, IHC	А
	Synaptophysin	Leica Bond III, IHC	А
	TAL1B5 (HLA-DR)	Leica Bond III, IHC	А
	Tdt	Leica Bond III, IHC	А
	Thyroglobulin	Leica Bond III, IHC	А
	TRAP	Leica Bond III, IHC	А
	Trypsin	Leica Bond III, IHC	А
	TSH	Leica Bond III, IHC	А
	TTF-1	Leica Bond III, IHC	А
	Uroplakin II	Leica Bond III, IHC	А
	Uroplakin III	Leica Bond III, IHC	А
	Villin	Leica Bond III, IHC	Α
	Vimentin	Leica Bond III, IHC	Α
	VS38c	Leica Bond III, IHC	Α
	VZV	Leica Bond III, IHC	А
	WT1	Leica Bond III, IHC	А
	ZAP 70	Leica Bond III, IHC	А

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
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	А
	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	A
	CMV	Leica Bond III, CISH	A
	EBER	Leica Bond III, CISH	А
	Карра	Leica Bond III, CISH	A
	Lambda	Leica Bond III, CISH	A
	RNAscopelSH (Low and High-Risk HPV Genotype)	Leica Bond III, CISH	А
	In-situ hybridisation stained tissue to detect the presence or absence of targets listed:	Semi-automated fluorescent insitu hybridisation using Abbott Molecular VP2000 platform Interpretation by manual fluorescent microscopy and semi-automated BioView system	A
		Fluorescent in-situ hybridisation Semi-automated methods using: HIS-60W0-17 HSL-AD, HIS- 60W0-19 HSL-AD, HIS-60W0-23 HSL-AD	А
	ALK breakapart	VP2000, Manual/BioView Reporting	А
	BCL2 breakapart	VP2000, Manual/BioView Reporting	A
	BCL2:IGH fusion	VP2000, Manual/BioView Reporting	A

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United Kingdom Accreditation Service 2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

HSL (Analytics) LLP

Issue date: 18 September 2024 **Issue No:** 011

Testing performed at main address only

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
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 insitu hybridisation using Abbott Molecular VP2000 platform Interpretation by manual fluorescent microscopy and semi-automated BioView system	A
		Fluorescent in-situ hybridisation Semi-automated methods using: HIS-60W0-17 HSL-AD, HIS- 60W0-19 HSL-AD, HIS-60W0-23 HSL-AD	A
	BCL6 breakapart	VP2000, Manual/BioView Reporting	А
	CCND1 breakapart	VP2000, Manual/BioView Reporting	А
	CDK4/CEN12	VP2000, Manual/BioView Reporting	А
	DUSP22	VP2000, Manual/BioView Reporting	А
	DDIT3	VP2000, Manual/BioView Reporting	А
	ETV6	VP2000, Manual/BioView Reporting	
	FGFR1 amplification	VP2000, Manual/BioView Reporting	А
	FGFR2 amplification	VP2000, Manual/BioView Reporting	А
	FGFR2 breakapart	VP2000, Manual Reporting	А
	HER2 amplification	VP2000, Manual/BioView Reporting	А
	IGH breakapart	VP2000, Manual/BioView Reporting	А

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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 insitu hybridisation using Abbott Molecular VP2000 platform Interpretation by manual fluorescent microscopy and semi-automated BioView system	A
		Fluorescent in-situ hybridisation Semi-automated methods using: HIS-60W0-17 HSL-AD, HIS- 60W0-19 HSL-AD, HIS-60W0-23 HSL-AD	A
	IGH/BCL2	VP2000, Manual/BioView Reporting	А
	IGL	VP2000, Manual/BioView Reporting	А
	IGK	VP2000, Manual/BioView Reporting	А
	IRF4	VP2000, Manual/BioView Reporting	А
	MAML2	VP2000, Manual/BioView Reporting	А
	MALT breakapart	VP2000, Manual/BioView Reporting	А
	MDM2/CEP12	VP2000, Manual/BioView Reporting	А
	Melanoma FISH	VP2000, Manual/BioView Reporting	А
	МҮВ	VP2000, Manual/BioView Reporting	А
	MET amplification	VP2000, Manual/BioView Reporting	А

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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 insitu hybridisation using Abbott Molecular VP2000 platform Interpretation by manual fluorescent microscopy and semi-automated BioView system	А
		Fluorescent in-situ hybridisation Semi-automated methods using: HIS-60W0-17 HSL-AD, HIS- 60W0-19 HSL-AD, HIS-60W0-23 HSL-AD	A
	MYC breakapart	VP2000, Manual/BioView Reporting	А
	MYC:IGH fusion	VP2000, Manual/BioView Reporting	А
	NTRK1	VP2000, Manual/BioView Reporting	
	NTRK2	VP2000, Manual/BioView Reporting	
	NTRK3	VP2000, Manual/BioView Reporting	
	ROS1 breakapart	VP2000, Manual/BioView Reporting	А

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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	A
	ALK IHC	Clinical interpretation of IHC by Consultant Histopathologist	А
	BRAF (V600E)	Clinical interpretation of IHC by Consultant Histopathologist	А
	Her-2 IHC	Clinical interpretation of IHC by Consultant Histopathologist	A
	ER IHC	Clinical interpretation of IHC by Consultant Histopathologist	A
	PD-L1 (Clone 28-8)	Clinical interpretation of IHC by Consultant Histopathologist	A
	PD-L1 (Clone SP142)	Clinical interpretation of IHC by Consultant Histopathologist	А
	PR IHC	Clinical interpretation of IHC by Consultant Histopathologist	A
	p16 IHC	Clinical interpretation of IHC by Consultant Histopathologist	A
	EGFR IHC	Clinical interpretation of IHC by Consultant Histopathologist	A
	EGFR Mutation specific IHC	Clinical interpretation of IHC by Consultant Histopathologist	A
	MMR (MisMatch Repair) IHC	Clinical interpretation of IHC by Consultant Histopathologist	А
	PD-L1 (22C3) IHC	Clinical interpretation of IHC by Consultant Histopathologist	А
	ROS-1	Clinical interpretation of IHC by Consultant Histopathologist	A

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY TISSUE AND FLUIDS	Non-Gynae Cytopathological examination activities for the purposes of clinical diagnosis	Macroscopic and Microscopic examination: Documented in house procedures in conjunction with manufacturers' instructions where relevant:	
Ascitic fluid, bile, biliary brushings, bladder washing, bronchial brushings and washings, broncho-alveolar lavage, common bile duct brushings, cell block, cerebrospinal fluid, cystic fluid, endobronchial ultrasound guided sample (EBUS) fine needle aspirations, hydrocele fluid, joint/synovial fluid, kidney washings, mediastinal fluid, needle washings, nipple discharge, oesophageal brushings, ovarian cyst fluid, pancreatic brushings, pericardial, peritoneal and pleural fluid, sputum, urine, ureteric washings/brushings		SOPs: CYT-60W2-38 Cytocentrifugation and direct preparations of samples Liquid based Cytology technique using Hologic Genesis	В

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HUMAN BODY TISSUE AND FLUIDS (cont'd)	Non-Gynae Cytopathological examination activities for the purposes of clinical diagnosis (cont'd)	Macroscopic and Microscopic examination: Documented in house procedures in conjunction with manufacturers' instructions where relevant:	
Stained Slides prepared inhouse	Examination of cellular material in order to identify or exclude morphological and cytological abnormalities	Routine morphological staining using Leica Autostainer XL with the following stains: SOP: CYT-60W2-40	В
	Papanicoloau	Leica Autostainer XL	В
	May-Grunwald Giemsa	Gemini AS	В
	RAL 555	Manual methods	В
		Interpretive/diagnostic microscopy (qualitative analysis)	В
		SOPs: CYT-60W2-37 CYT-60W2-42 CYT-60W2-43	
Skin from Mohs micrographic surgery	Histopathological examination to provide assessment of circumpheral, peripheral and depe margins of potential skin malignancies	Preparation of Mohs frozen blocks and slides using Leica cryostat and Leica Slide Stainer with Haematoxylin and Eosin stain followed by microscopy using Leica Microscope SOP: HIS-60W4-39	D
Skin from Mohs micrographic surgery	Histopathological examination to provide assessment of circumpheral, peripheral and depe margins of potential skin malignancies	Preparation of Mohs frozen blocks and slides using Leica cryostat and Leica Slide Stainer with Haematoxylin and Eosin stain and manual Toluidine Blue stain followed by microscopy using Leica Microscope SOP: HIS-60W4-39	E

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HUMAN BODY TISSUE AND FLUIDS (cont'd)	Non-Gynae Cytopathological examination activities for the purposes of clinical diagnosis (cont'd) Molecular Testing	Macroscopic and Microscopic examination: Documented in house procedures in conjunction with manufacturers' instructions where relevant:	
		Tissue sectioning and macro- dissection using Leica Biocut microtomes SOP HIS-60W0-5 HSL-AD	A
Formalin-fixed paraffin- embedded tissue	Detection of Human Papilloma Virus genotypes: 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59	DNA extraction from FFPE using dry baths, Maxwell SC and Promega FFPE DNA extraction kit	A
	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	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	
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 FFPET RNA Isolation Kits with measurement by Nanodrop One C. PCR using Veriti Thermal Cycler, nanostring nCounter PrepStation and analysis using nCounter Analyser	A
	END		

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