


Schedule of Accreditation

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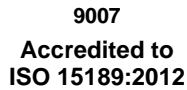
United Kingdom Accreditation Service

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

 Accredited to ISO 15189:2012	HSL (Analytics) LLP	
	Issue No: 008 Issue date: 15 April 2024	
	HSL-Advanced Diagnostics 60 Whitfield Street London W1T 4EU	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
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	<u>Histological examinations for the purpose of clinical diagnosis</u>	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 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	Basophilic and eosinophilic structures <u>Immunohistochemistry staining for the purpose of subsequent analysis by a referring laboratory for the epitopes listed:</u> 34BE12	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 Leica Bond III, IHC



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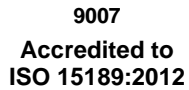
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Formalin-fixed paraffin-embedded tissue (cont'd)	<u>Immunohistochemistry</u> (cont'd): CK5 CK7 CK8 CMV c-Myc Collagen IV COX-2 Cyclin D1 D240 DBA44 Desmin DOG-1 E cadherin EBV EGFR (C36) EGFR E746-A750 EGFR L858R EMA ER (6F11) ER (EP1) ERG Factor VIII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



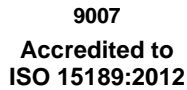
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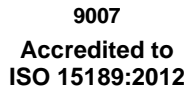
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Assessment Manager: KW1



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



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Formalin-fixed paraffin-embedded tissue (cont'd)	<u>Immunohistochemistry</u> (cont'd): Synaptophysin TAL1B5 (HLA-DR) Tdt Thyroglobulin TRAP TSH TTF-1 Uroplakin III Villin Vimentin VS38c VZV WT1 ZAP 70	Automated Immunohistochemistry (cont'd) Leica Bond III, IHC Leica Bond III, IHC Leica Bond III, IHC Leica Bond III, IHC Leica Bond III, IHC Leica Bond III, IHC Leica Bond III, IHC Leica Bond III, IHC Leica Bond III, IHC Leica Bond III, IHC Leica Bond III, IHC Leica Bond III, IHC Leica Bond III, IHC Leica Bond III, IHC Leica Bond III, IHC



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Formalin-fixed paraffin-embedded tissue (cont'd)	<u>Immunohistochemistry</u> (cont'd): <u>In-situ hybridisation staining for the purpose of subsequent analysis by a referring laboratory for the epitopes listed:</u> CMV EBER Kappa Lambda	Automated Immunohistochemistry (cont'd) Automated in-situ hybridisation using Leica Bond III and Ventana/Roche Ultra platforms 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 Leica Bond III, CISH Leica Bond III, CISH Leica Bond III, CISH 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: ALK breakapart BCL2 breakapart BCL2:IGH fusion BCL6 breakapart CCND1 breakapart FGFR1 amplification FGFR2 amplification	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 VP2000, Manual/BioView Reporting VP2000, Manual/BioView Reporting VP2000, Manual/BioView Reporting VP2000, Manual/BioView Reporting VP2000, Manual/BioView Reporting VP2000, Manual/BioView Reporting VP2000, Manual/BioView Reporting



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Formalin-fixed paraffin-embedded tissue (cont'd)	<u>Immunohistochemistry</u> (cont'd): In-situ hybridisation stained tissue to detect the presence or absence of targets listed (cont'd): FGFR2 breakapart HER2 amplification IGH breakapart MALT breakapart Melanoma FISH MET amplification MYC breakapart MYC:IGH fusion ROS1 breakapart	Automated Immunohistochemistry (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 VP2000, Manual Reporting VP2000, Manual/BioView Reporting VP2000, Manual/BioView Reporting VP2000, Manual/BioView Reporting VP2000, Manual/BioView Reporting VP2000, Manual/BioView Reporting VP2000, Manual/BioView Reporting 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: ALK IHC Her-2 IHC ER IHC PR IHC p16 IHC EGFR IHC EGFR Mutation specific IHC MMR (<u>Mis</u> <u>Match</u> <u>Repair</u>) IHC PD-L1 (22C3) IHC	Microscopy (qualitative analysis) and reporting Morphological and immunohistochemistry.in-situ hybridisation assessment of tissue Clinical interpretation of IHC by Consultant Histopathologist Clinical interpretation of IHC by Consultant Histopathologist Clinical interpretation of IHC by Consultant Histopathologist Clinical interpretation of IHC by Consultant Histopathologist Clinical interpretation of IHC by Consultant Histopathologist Clinical interpretation of IHC by Consultant Histopathologist Clinical interpretation of IHC by Consultant Histopathologist Clinical interpretation of IHC by Consultant Histopathologist



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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 FFPET RNA Isolation Kits with measurement by Nanodrop One C. PCR using Veriti Thermal Cycler, nanostring nCounter PrepStation and analysis using nCounter Analyser
END		