Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

8990

Accredited to ISO 15189:2022

Swansea Bay University Health Board

Issue No: 016 **Issue date:** 22 October 2026

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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 Singleton Hospital Sketty Lane Swansea SA2 8QA	**Local contact** Clare Rees Quality Manager Tel: +44(0)1792 205666 Ext. 36362 E-mail: clare.rees@wales.nhs.uk	Histopathology Non-gynae cytology Body store	S
Morriston Hospital Heol Maes Eglwys Cwnrhydyceirw Morriston Swansea SA6 6NL	As above	Histopathology dissection and reporting only Mortuary Services	M

Site activities performed away from the locations listed above:

Location details		Activity	Location code
Neath Port-Talbot Hospital Baglan Way Port Talbot SA12 7BX	As above	Body store	NPT

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Testing performed by the Organisation at the locations specified

DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY SAMPLES	Histopathology examination activities for the purpose of clinical diagnosis	Procedures documented in relevant equipment manuals and in-house documented procedures	
Tissue (fresh and fixed) biopsy, excision, resection	Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis	Specimen dissection using AFOS and LEEC downflow benches, Thermoshandon cassette printer,	S, M
		Macropath camera CEL 92 HI-SOP Macro Path Imaging System	S, M
		Macroshot Camera CEL4252 Macroshot Imaging System	M
		Decalcification Kos Microwave CEL 898 Decalcification	S, M
		Numerous dissection SOPs based on the RCPath MDSs	
Formalin-fixed tissue samples including cytology cell blocks/clots		Tissue processing using Thermoshandon Excelsior tissue processors	S
		VIP 6 AI Vacuum Infitration Tissue Processor	S
		CEL796 Shandon Excelsior Block Processing	
Formalin-fixed paraffin-embedded tissue samples		Embedding and Microtomy using:	S
		Shandon Embedding centre Histostar A120 Tissue-Tek AutoTEC Autoembedder Leica RM2255 microtomes	
		CEL 596 Embedding CEL803 Microtomy Main Lab	

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY SAMPLES (cont'd)	Histopathology examination activities for the purpose of clinical diagnosis (cont'd)	Procedures documented in relevant equipment manuals and in-house documented procedures	
Fresh frozen tissue	Intraoperative diagnostic examination processes	Frozen sections using Leica CM1900 Cryostat SOPs: CEL 934 CryotomyCEL 1713 Handstaining H&E Presto Automatic processor/stainer for frozen sections CEL2749 Use of Presto Equipment to Freeze and Stain Tissue for Cryotomy	M
FFPE tissue sections on glass slides	Identification of basophilic and eosinophilic structures. General tissue morphology	Automated H&E staining using Leica Histocore Spectra HI-S-SOP Use and Maintenance of Leica HistoCore Spectra Workstation	S
FFPE tissue sections on glass slides	Special stains to detect the following	Manual Special stains – Ancillary Equipment: KOS Microwave CEL340 HI-A-SOP Preparation of Specials	S
	Glomerular basement membranes and fungi	Methenamine silver CEL1226 HI-A-SOP	
	Acid mucins and neutral mucins	Alcian Blue PAS CEL305 HI-A-SOP ABPAS	
	Acid mucins	Alcian Blue CEL307 HI-A-SOP Alcian Blue	
	Neutral Mucins	Periodic Acid Schiffs CEL309 HI-A-SOP PAS	
	Acid mucins and neutral mucins; glycogen removed by the action of diastase	Alcian Blue Diastase PAS CEL311 HI-S-SOP AB PASD	

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY SAMPLES (cont'd)	Histopathology examination activities for the purpose of clinical diagnosis (cont'd)	Procedures documented in relevant equipment manuals and in-house documented procedures	
FFPE tissue sections on glass slides (cont'd)	Special stains to detect the following (cont'd)	Manual Special stains – Ancillary Equipment: KOS Microwave	S
		CEL340 HI-A-SOP Preparation of Specials	
	Haemosiderin	Perls method	
		CEL313 HI-A-SOP Perls	
	Neutral mucin; glycogen removed by action of diastase	Alcian Blue Diastase PAS	
		CEL315 HI-A-SOP PASD	
	Calcium	Von Kossa method	
		CEL319 HI-S-SOP Von Kossa	
	Collagen	Sirius Red	
		CEL323 HI-S-SOP Sirius Red	
	Melanin bleach	Mallory Bleach	
		CEL329 HI-S-SOP Mallory Bleah	
	Acid mucins other than Hyaluronic acid	Alcian Blue	
		CEL333 HI-S-SOP AB Hyaluronidase	
	Mycobacterium bacillus	Ziehl Neelsen	
		CEL335 HI-A-SOP Ziehl Neelsen	
	Elastin	Millers EVG	
		CEL361 HI-A-SOP MillersEVG	
	Collagen	Van Gieson	
		CEL363 HI-A-SOP Van Gieson	

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HUMAN BODY SAMPLES (cont'd)	Histopathology examination activities for the purpose of clinical diagnosis (cont'd)	Procedures documented in relevant equipment manuals and in-house documented procedures	
FFPE tissue sections on glass slides (cont'd)	Special stains to detect the following (cont'd)	Manual Special stains – Ancillary Equipment: KOS Microwave	S
		CEL340 HI-A-SOP Preparation of Specials	
	Collagen and muscle	Masson Trichrome	
		CEL 489 HI-A-SOP Masson Trichrome	
	Fungi	Grocott Methenamine silver	
		CEL728 HI-A-SOP Grocott Methenamine Silver	
	Gram positive and negative bacteria	Gram	
		CEL733 HI-A-SOP Gram	
	Reticulin fibres	Gordon and Sweet's reticulin	
		CEL734 HI-A-SOP Retic	
	Fibrin/ connective tissue	Martius Scarlet Blue	
		CEL737 HI-A-SOP Martius Scarlet Blue	
	Reticulin fibres	Gomori	
		CEL738 HI-A-SOP Gomori	
	Helicobacter pylori	Modified Giemsa	
		CEL741HI-A-SOP Giemsa	
	Amyloid	Congo Red	
		CEL777 HI-A-SOP Congo Red	

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HUMAN BODY SAMPLES (cont'd)	Histopathology examination activities for the purpose of clinical diagnosis (cont'd)	Procedures documented in relevant equipment manuals and in-house documented procedures	
FFPE tissue sections on glass slides	Immunohistochemistry to detect the following	Automated method using Ventana Ultra platform and the following antibodies (supplier in brackets)	S
		IHC-S-SOP Staining	
	Anaplastic large cell lymphomas, Inflammatory myofibroblastic tumour	Alk1 Protein (Agilent)	
	Identification of the mutant protein BRAF V600	Anti-BRAF V600E (VE1)	
	Fibromatosis and colon cancer	β- Catenin (Leica)	
	T cells / B cell mantle zone Follicular centre B cells	BCL 6 (Leica)	
	Gastrointestinal and pancreaticobiliary carcinomas	CA19.9 (A.Menarini)	
	Ovarian carcinoma and colon carcinoma.	CA125(Leica)	
	Smooth muscle, leiomyosarcoma.	Caldesmon (Agilent)	
	Smooth muscle tumours	Calponin (Roche)	
	Mesothelial cells	Calretinin (Roche)	
	Low Molecular Weight Cytokeratin	Cam 5.2 (CK8) (Leica)	
	Juvenile xanthogranuloma. stains langerhans cells	CD1a (Leica)	
	T-cell marker	CD2 (Leica)	
	General T-cell marker	CD3 (Agilent)	
	CD4 Helper T cells	CD4 (Leica)	

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HUMAN BODY SAMPLES (cont'd)	Histopathology examination activities for the purpose of clinical diagnosis (cont'd)	Procedures documented in relevant equipment manuals and in-house documented procedures	
FFPE tissue sections on glass slides (cont'd)	Immunohistochemistry to detect the following (cont'd)	Automated method using Ventana Ultra platform and the following antibodies (supplier in brackets)	S
		IHC-S-SOP Staining	
	AT-cell lymphomas also B-chronic lymphocytic leukaemia	CD5 (Roche)	
	T-cell marker	CD7 (Leica)	
	CD8 T Cell subsets (Cytotoxic/Suppressor)	CD8 (Leica)	
	CD10 expression	CD10 (Leica)	
	Hairy cell leukaemia. Also for histiocytes/macrophages	CD11c (Leica)	
	CD 15 expression Hodgkin's lymphoma	CD15 (Roche)	
	General B-cell marker	CD20 (Agilent)	
	Follicular dendritic cell marker	CD21 (Leica)	
	Hairy cell leukaemia	CD22 (Leica)	
	Follicular dendritic cells/ sub population of mantle zone b cells mediastinal large B-cell lymphoma and CLL/SLL	CD23 (Leica)	
	Reed Sternberg cells, cutaneous T-cell lymphoma	CD30 (Agilent)	
	Endothelial cell marker	CD31 (Leica)	
	Endothelial cell marker	CD34 (Dako)	
	Detection of CD38 molecules	CD38 (Leica)	

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY SAMPLES (cont'd)	Histopathology examination activities for the purpose of clinical diagnosis (cont'd)	Procedures documented in relevant equipment manuals and in-house documented procedures	
FFPE tissue sections on glass slides (cont'd)	Immunohistochemistry to detect the following (cont'd)	Automated method using Ventana Ultra platform and the following antibodies (supplier in brackets)	S
		IHC-S-SOP Staining	
	T cell marker. Mycosis fungoides, a cutaneous T-cell lymphoma, mantle cell lymphomas	CD43 (Roche)	
	Leucocyte common antigen, General lymphoma marker	CD45 (LCA) (Agilent)	
	NK cells/ neuroendocrine cells	CD56 (Leica)	
	T cell subset, nerve sheath and neuroendocrine tumours	CD57 (Agilent)	
	Megakaryocytes plasma cells and megakaryoblastic leukaemia	CD61 (Agilent)	
	Monocytes/macrophages	CD68 (Agilent)	
	B cell lymphomas	CD79a (Agilent	
	T-Cell lymphoma marker	CD103 (Leica)	
	Gastro Intestinal Stromal Tumour, melanocytic myeloid and mast cells.	CD117 (C Kit)(Leica)	
	Plasma cell differentiation	CD138 (Leica)	
	Colorectal carcinoma	CDX2 (Roche)	
	Epithelial cell marker	CEA (Agilent)	
	Neuroendocrine marker	Chromogranin (Agilent)	

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY SAMPLES (cont'd)	Histopathology examination activities for the purpose of clinical diagnosis (cont'd)	Procedures documented in relevant equipment manuals and in-house documented procedures	
FFPE tissue sections on glass slides (cont'd)	Immunohistochemistry to detect the following (cont'd)	Automated method using Ventana Ultra platform and the following antibodies (supplier in brackets)	S
		IHC-S-SOP Staining	
	Epithelial marker Merkel cell carcinoma and focal and synovial sarcoma	CK AE1/AE3 (Agilent)	
	Epithelial marker epithelioid sarcomas	CK PAN (Agilent)	
	Epithelial/ basal marker	CK 34BE12 (Agilent)	
	Squamous differentiation from adenocarcinoma	CK5/6 (Agilent)	
	Cytokeratin 7 expression Breast, lung, gynae adenocarcinoma	CK7 (Leica)	
	Epithelial marker thyroid papillary but negative in follicular carcinoma	CK19 (Leica)	
	Colon and rectum and prostate	CK20 (Agilent)	
	Burkitts lymphoma and DLBCL	C-Myc (Roche)	
	Normal epithelium, endothelium and macrophages	Cyclin D1 (Agilent)	
	Smooth muscle and skeletal tumours	Desmin (Agilent)	
	Gastro Intestinal Stromal tumour	DOG1 (Leica)	
	Epstein barr virus	EBV (LMP1) (Agilent)	

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HUMAN BODY SAMPLES (cont'd)	Histopathology examination activities for the purpose of clinical diagnosis (cont'd)	Procedures documented in relevant equipment manuals and in-house documented procedures	
FFPE tissue sections on glass slides (cont'd)	Immunohistochemistry to detect the following (cont'd)	Automated method using Ventana Ultra platform and the following antibodies (supplier in brackets)	S
		IHC-S-SOP Staining	
	Ductal carcinoma of the breast and negative in lobular	E Cadherin (Agilent)	
	Epithelial marker	EMA (Agilent)	
	BCC and adenocarcinomas,	Epithelial Antigen (Agilent)	
	Prognostic breast marker.	ER (Roche)	
	Vascular tumours, angiosarcoma and prostatic adenocarcinoma	ERG (Roche)	
	Endothelial cells	Factor 8 (Agilent)	
	Fibrohistiocytic marker Positive in benign fibrous histiocytomas and dermatofibroma, dermatofibrosarcoma protuberans cases are negative	Factor 13A (Leica)	
	Breast marker	GATA3 (Roche)	
	Breast marker. Identification of metastatic from breast carcinoma.	GCDFP (Agilent)	
	Erythroid leukemias	Glycophorin A (Agilent)	
	Granzyme B granules	Granzyme B (Leica)	
	Mesotheliomas and papillary thyroid carcinomas	HBME 1 (Agilent)	

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HUMAN BODY SAMPLES (cont'd)	Histopathology examination activities for the purpose of clinical diagnosis (cont'd)	Procedures documented in relevant equipment manuals and in-house documented procedures	
FFPE tissue sections on glass slides (cont'd)	Immunohistochemistry to detect the following (cont'd)	Automated method using Ventana Ultra platform and the following antibodies (supplier in brackets)	S
		IHC-S-SOP Staining	
	Large Cell Carcinoma and Adenocarcinoma of Lung positive in 90% and 60% of cases respectively. 20% of Squamous Cell Lung Carcinomas are positive. Expression by non-trophoblastic tumours may indicate aggressive Leukaemia	HCG (Leica)	
	Positivity shows patient will have a response to Herceptin chemotherapy	Her-2 (Roche)	
	Melanoma marker. Positive in clear cell sarcoma	HMB45 (Agilent)	
	Autoimmune marker	IgG4 (Roche)	
	Alpha inhibin expression ovarian sex cord stromal tumours	Inhibin alpha (Agilent)	
	Kappa light chain restriction in normal and neoplastic cells	Kappa (Agilent)	
	Distinction between polyclona proliferations associated with benign reactive plasma cell and B-cell lymphoid proliferations and monoclonal proliferations associated with neoplastic plasma cell and B-cell lymphoid proliferations	Kappa ISH	

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HUMAN BODY SAMPLES (cont'd)	Histopathology examination activities for the purpose of clinical diagnosis (cont'd)	Procedures documented in relevant equipment manuals and in-house documented procedures	
FFPE tissue sections on glass slides (cont'd)	Immunohistochemistry to detect the following (cont'd)	Automated method using Ventana Ultra platform and the following antibodies (supplier in brackets)	S
		IHC-S-SOP Staining	
	Proliferation marker.	Ki67 (2B Scientific)	
	Lambda light chain restriction in normal and neoplastic cells	Lambda (Agilent)	
	Distinction between polyclonal proliferations associated with benign reactive plasma cell and Bcell lymphoid proliferations; and monoclonal proliferations associated with neoplastic plasma cell and B-cell lymphoid proliferations	Lambda ISH	
	Melanoma marker and positive in normal melanocytes	Melan A (Agilent)	
	Moc31 detection of epithelial cell adhesion molecule expression	Moc31	
	Pancreatic carcinoma	MUC1 (Roche)	
	Plasma cell myeloma Reed Sternberg cells in Hodgkin lymphoma and malignant melanoma	Mum 1 (Agilent)	
	Neoplastic tissue. It detects granulocytes and myeloid series in the bone marrow	Myeloperoxidase (Roche)	
	Rhabdomyoscarcoma Identifies skeletal muscle differentiation	MyoD1 (Roche)	

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY SAMPLES (cont'd)	Histopathology examination activities for the purpose of clinical diagnosis (cont'd)	Procedures documented in relevant equipment manuals and in-house documented procedures	
FFPE tissue sections on glass slides (cont'd)	Immunohistochemistry to detect the following (cont'd)	Automated method using Ventana Ultra platform and the following antibodies (supplier in brackets)	S
		IHC-S-SOP Staining	
	Normal lung and lung adenocarcinoma	Napsin A (Roche)	
	Neurospecific enolase Neural marker but also positive in a wide range of non-neuroendocrine cells	NSE (Agilent)	
	Mature B-cell lines B cell lymphomas and negative in classic Hodgkin lymphoma	OCT2 (Roche)	
	Germ cell marker	OCT ¾ (Leica)	
	Surrogate marker for HPV	P16 (Roche)	
	Differentiate benign and malignant glands	P40 (Roche)	
	p 53 expression, Tumour suppressor gene	P53 (Agilent)	
	P63 tumour suppressor protein determine squamous differentiation from adenocarcinoma	P63 (Roche)	
	Mullarian derived tumours, renal and thyroid	PAX 8 (Roche)	
	Programmed death-1 ligand 1 expression	PDL1-SP263 (Ventana)	
	Placental Alkaline phosphatase Germ cell marker	PLAP (Agilent)	

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HUMAN BODY SAMPLES (cont'd)	Histopathology examination activities for the purpose of clinical diagnosis (cont'd)	Procedures documented in relevant equipment manuals and in-house documented procedures	
FFPE tissue sections on glass slides (cont'd)	Immunohistochemistry to detect the following (cont'd)	Automated method using Ventana Ultra platform and the following antibodies (supplier in brackets)	S
		IHC-S-SOP Staining	
	Transmembrane Mucoprotien	Podoplanin (D2-40)	
	Progesterone marker in breast cancer cases	PR (Leica)	
	Marker for prostate adenocarcinoma	PSA (poly) (Agilent)	
	Prostate adenocarcinoma. May help to differentiate intravascular large B-cell lymphoma from other lymphomas.	PSAP (Roche)	
	Immune complex glomerulonephritis by presence of Immunoglobulin A	Renal IgA (Agilent)	
	Immune complex glomerulonephritis by presence of Immunoglobulin G	Renal IgG (Agilent)	
	Immune complex glomerulonephritis by presence of Immunoglobulin M	Renal IgM (Agilent)	
	Any immune complex disease	Renal C3 (Roche)	
	Melanoma marker	S100 (Leica)	
	Smooth muscle marker	SMA (Roche)	
	Neuroendocrine marker	Synaptophysin (Leica)	

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HUMAN BODY SAMPLES (cont'd)	Histopathology examination activities for the purpose of clinical diagnosis (cont'd)	Procedures documented in relevant equipment manuals and in-house documented procedures	
FFPE tissue sections on glass slides (cont'd)	Immunohistochemistry to detect the following (cont'd)	Automated method using Ventana Ultra platform and the following antibodies (supplier in brackets)	S
		IHC-S-SOP Staining	
	Terminal deoxynucleotidyl transferase pre-B and pre-T lymphocytes	TdT (Leica)	
	Endothelial cells mesothelioma	Thrombomodulin (2b Scientific)	
	Follicular and papillary carcinomas of the thyroid	Thyroglobulin (Agilent)	
	Thyroid Transcription factor Lung and thyroid marker	TTF-1 (Leica)	
	Vimentin expression general soft tissue marker	Vimentin (Agilent)	
	Wilms tumour protein expression.	WT1 (Agilent)	
	Qualitatively identify human DNA mismatch repair (MMR) protein MLH1	MLH1 (Roche)	
	Identification of microsatellite instability	MSH2 (Roche)	
	Qualitatively identify human DNA mismatch repair (MMR) protein MSH6	MSH6 (Roche)	
	Aid in diagnostic determination of MSI-H tumours	PMS2 (Roche)	
	Mucin expression pattern of gastric carcinoma	MUC5AC (Roche)	

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HUMAN BODY SAMPLES (cont'd)	Histopathology examination activities for the purpose of clinical diagnosis (cont'd)	Procedures documented in relevant equipment manuals and in-house documented procedures	
FFPE tissue sections on glass slides (cont'd)	Immunohistochemistry to detect the following (cont'd)	Automated method using Ventana Ultra platform and the following antibodies (supplier in brackets) IHC-S-SOP Staining	S
	Mucin expression pattern of gastric carcinoma	MUC6 (Roche)	
	Haematopoietic marker	CD123 (Leica)	
	Positive in B-cell in mantle and marginal zone. Positive in DLBCL, SLL/CLL and follicular lymphomas.	BCL2 (Agilent)	
	Distinguishes between neoplastic mast cell aggregates from reactive proliferations in the diagnosis of Systemic Mastocytosis	CD25 (Roche)	
	Metastatic melanoma	SOX-10 (Roche)	
	Mantle cell lymphomas	SOX-11 (Roche)	
FFPE tissue sections on glass slides	In situ hybridsation to detect the following	Automated method using Ventana Ultra platform and the following antibody (supplier in brackets) IHC-S-SOP Staining	S
	RNA transcripts of EBV infection that accumulate in the nucleus of EBV infected cells	EBER (Roche)	

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY SAMPLES (cont'd)	Histopathology examination activities for the purpose of clinical diagnosis (cont'd)	Procedures documented in relevant equipment manuals and in-house documented procedures	
Slides prepared as above	Morphological assessment and interpretation/diagnosis	Using light microscopy CEL 63 CEL-A-SOP Setting Up a Microscope Numerous SOPs based on the RCPath MDSs for reporting	S, M
	Cytopathological activities for the purposes of clinical diagnosis	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:	
Body fluids / Fine needle aspirations from a range of body sites, urines, bronchial washings/brushings and sputum samples	Examination of cellular material in order to identify or exclude morphological or cytological abnormalities	Sample preparation using Thermo Shandon Centrifuge and ThermoShandon Cytospin Including Preparation of clots/cell blocks (processed by histology) CEL3152 GENESIS Non Gynae Thin Prep CEL 615 Cell Block Preparation	S
Non-gynae cytology preparations on glass slides		Hologic Genesis Cell Monolayer Preparation Platform Papanicolaou and Haematoxylin and eosin staining using Leica Autoasainer with CV 5030 CEL 1176 Stains for Non-Gynae Samples	S
Slides prepared as above	Morphological assessments and interpretation/diagnosis	Using light microscopy CEL 63 CEL-A-SOP Setting Up a Microscope Numerous SOPs based on the RCPath MDSs for reporting	S, M

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY SAMPLES (cont'd)	Molecular examination activities for the purpose of clinical diagnosis	Procedures documented in relevant equipment manuals and in-house documented procedures	
FFPE tissue sections on glass slides	Detection of genetic HER2 amplification in invasive breast cancers	Using Dual Hapten Dual Colour In Situ Hybridisation (DDISH) on the Ventana Benchmark Ultra SOP IHC-S-SOP Staining	S
END			