


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 Accredited to ISO 15189:2022	Swansea Bay University Health Board	
	Issue No: 013 Issue date: 27 January 2025	
	One Talbot Gateway Baglan Energy Park Baglan Port-Talbot SA12 7BR	Contact: Chris Bowden Tel: +44 (0)656 752752 E-Mail: chris.bowden@wales.nhs.uk Website: www.wales.nhs.uk/sitesplus/863/page/41169

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
Morrison Hospital Heol Maes Eglwys Cwnrhydyceirw Morrison 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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DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY SAMPLES	<u>Histopathology examination activities for the purpose of clinical diagnosis</u>	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, Macropath camera CEL 92 HI-SOP Macro Path Imaging System Decalcification Kos Microwave CEL 898 Decalcification Numerous dissection SOPs based on the RCPATH MDSs	S, M
Formalin-fixed tissue samples including cytology cell blocks/clots		Tissue processing using Thermoshandon Excelsior tissue processors CEL796 Shandon Excelsior Block Processing	S
Formalin-fixed paraffin-embedded tissue samples		Embedding and Microtomy using: Shandon Embedding centre Histostar Leica RM2255 microtomes CEL 596 Embedding CEL803 Microtomy Main Lab	S
Fresh frozen tissue	Intraoperative diagnostic examination processes	Frozen sections using Leica CM1900 Cryostat SOPs: CEL 934 Cryotomy CEL 1713 Handstaining H&E Presto Automatic processor/stainer for frozen sections CEL2749 Use of Presto Equipment to Freeze and Stain Tissue for Cryotomy	M



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HUMAN BODY SAMPLES (cont'd)	<u>Histopathology examination activities for the purpose of clinical diagnosis (cont'd)</u>	Procedures documented in relevant equipment manuals and in-house documented procedures	
FFPE tissue sections on glass slides	Identification of basophilic and eosinophilic structures. General tissue morphology	Automated H&E staining using Dako Coverstainer Leica coverslipper Leica CV5030	S
	Special stains to detect the following	HI-S-SOP Routine H&E staining on Dako Coverstainer	
		Manual Special stains	S
	Glomerular basement membranes and fungi	CEL340 HI-A-SOP Preparation of Specials	
		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 Schiff's		
	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		
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		



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HUMAN BODY SAMPLES (cont'd)	<u>Histopathology examination activities for the purpose of clinical diagnosis</u> (cont'd)	Procedures documented in relevant equipment manuals and in-house documented procedures	S
FFPE tissue sections on glass slides (cont'd)	Special stains to detect the following (cont'd)	Manual Special stains	
	Calcium	CEL340 HI-A-SOP Preparation of Specials 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 Bleach	
	Acid mucin	Hales Collodial Iron CEL331 HI-S-SOP Hales Colloidal Iron	
	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)	<u>Histopathology examination activities for the purpose of clinical diagnosis</u> (cont'd)	Procedures documented in relevant equipment manuals and in-house documented procedures	S
FFPE tissue sections on glass slides (cont'd)	Special stains to detect the following (cont'd)	Manual Special stains	
	Collagen and muscle	CEL340 HI-A-SOP Preparation of Specials Masson Trichrome CEL 489 HI-A-SOP Masson Trichrome	
	Hep B surface antigen	Orcein CEL726 HI-A-SOP Orcein	
	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)	<u>Histopathology examination activities for the purpose of clinical diagnosis</u> (cont'd)	Procedures documented in relevant equipment manuals and in-house documented procedures	S
FFPE tissue sections on glass slides	Immunohistochemistry to detect the following	Automated method using Ventana Ultra platform and the following antibodies (supplier in brackets)	
	Rhabdoid cellular elements. Smooth and skeletal muscle differentiation	IHC-S-SOP Staining Actin (HHF35) (Agilent)	
	Anaplastic large cell lymphomas, Inflammatory myofibroblastic tumour	Alk1 Protein (Agilent)	
	Atypical fibroxanthoma, deficiency in liver biopsies	Alpha 1 Antitrypsin (Agilent)	
	Testicular, ovarian germ cell tumours and hepatocellular carcinomas	Alpha Fetoprotein (Agilent)	
	Identification of the mutant protein BRAF V600	Anti-BRAF V600E (VE1)	
	Anti-LEF1 antibody	Anti Lef-1 antibody (abcam)	
	Fibromatosis and colon cancer	β- Catenin (Leica)	
	T cells / B cell mantle zone Follicular centre B cells	BCL 6 (Leica)	
	MALT lymphomas	BCL 10 (Agilent)	
	Gastrointestinal and pancreaticobiliary carcinomas	CA19.9 (A.Menarini)	
	Ovarian carcinoma and colon carcinoma.	CA125(Leica)	
	Medullary carcinoma of the thyroid (neuroendocrine tumour)	Calcitonin (AMenarini)	



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HUMAN BODY SAMPLES (cont'd)	<u>Histopathology examination activities for the purpose of clinical diagnosis</u> (cont'd)	Procedures documented in relevant equipment manuals and in-house documented procedures	S
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)	
	Smooth muscle, leiomyosarcoma.	IHC-S-SOP Staining Caldesmon (Agilent)	
	Smooth muscle tumours	Calponin (Agilent)	
	Mesothelial cells	Calretinin (Roche)	
	Low Molecular Weight Cytokeratin	Cam 5.2 (CK8) (BDBiosciences)	
	Juvenile xanthogranuloma. stains langerhans cells	CD1a (Leica)	
	T-cell marker	CD2 (Leica)	
	General T-cell marker	CD3 (Agilent)	
	CD4 Helper T cells	CD4 (Leica)	
	AT-cell lymphomas also B-chronic lymphocytic leukaemia	CD5 (Leica)	
	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)	
	Granulocytic sarcomas	CD13 (Leica)	
	CD 15 expression Hodgkin's lymphoma	CD15 (Roche)	



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HUMAN BODY SAMPLES (cont'd)	<u>Histopathology examination activities for the purpose of clinical diagnosis</u> (cont'd)	Procedures documented in relevant equipment manuals and in-house documented procedures	S
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	
	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)	
	Follicular dendritic cell tumours/sarcomas	CD35 (Leica)	
	Detection of CD38 molecules	CD38 (Leica)	
	Platelet/platelet activation plugging endothelial cell surfaces	CD41 (ABCam)	
	T cell marker. Mycosis fungoides, a cutaneous T-cell lymphoma, mantle cell lymphomas	CD43 (Roche)	
	Leucocyte common antigen, General lymphoma marker	CD45 (LCA) (Ahilent)	
	NK cells/ neuroendocrine cells	CD56 (Leica)	



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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	
	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)	
	Small round cell tumours Ewing's sarcoma, synovial sarcoma	CD99 (Thermofisher)	
	T-Cell lymphoma marker	CD103 (Leica)	
	Gastro Intestinal Stromal Tumour, melanocytic myeloid and mast cells.	CD117 (C Kit)(Leica)	
	Plasma cell differentiation	CD138 (Bio-Rad)	
	Colorectal carcinoma	CDX2 (Roche)	
	Epithelial cell marker	CEA (Agilent)	
	Neuroendocrine marker	Chromogranin (Agilent)	
	Epithelial marker Merkel cell carcinoma and focal and synovial sarcoma	CK AE1/AE3 (Agilent)	
	Epithelial marker epithelioid sarcomas	CK PAN (Agilent)	



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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)	
	Epithelial/ basal marker	IHC-S-SOP Staining 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)	
	Cytomegalovirus	CMV (Leica)	
	Burkitts lymphoma and DLBCL	C-Myc (Roche)	
	Normal epithelium, endothelium and macrophages	Cyclin D1 (Thermofisher)	
	Smooth muscle and skeletal tumours	Desmin (Agilent)	
	Gastro Intestinal Stromal tumour	DOG1 (Leica)	
	Epstein barr virus	EBV (LMP1) (Agilent)	
	Ductal carcinoma of the breast and negative in lobular	E Cadherin (Agilent)	



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HUMAN BODY SAMPLES (cont'd)	<u>Histopathology examination activities for the purpose of clinical diagnosis</u> (cont'd)	Procedures documented in relevant equipment manuals and in-house documented procedures	S
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)	
	Predicts response to ERBITUX chemotherapy in advanced colorectal cancer	IHC-S-SOP Staining EGFR (Roche)	
	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)	
	Follicular adenoma (negative), follicular carcinoma (positive) and papillary carcinoma (positive) of the thyroid.	Galectin (ABCam)	
	Breast marker	GATA3 (Roche)	
	Breast marker. Identification of metastatic from breast carcinoma.	GCDFP (Agilent)	
	Glial cells	GFAP (Agilent)	



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<p>HUMAN BODY SAMPLES (cont'd)</p> <p>FFPE tissue sections on glass slides (cont'd)</p>	<p><u>Histopathology examination activities for the purpose of clinical diagnosis</u> (cont'd)</p> <p>Immunohistochemistry to detect the following (cont'd)</p> <p>Erythroid leukemias</p> <p>GPC3 expression in malignant and non-malignant liver tissue samples</p> <p>Granzyme B granules</p> <p>Mesotheliomas and papillary thyroid carcinomas</p> <p>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</p> <p>Hairy cell leukaemia.</p> <p>Positivity shows patient will have a response to Herceptin chemotherapy</p> <p>Melanoma marker. Positive in clear cell sarcoma</p> <p>Autoimmune marker</p> <p>Alpha inhibin expression ovarian sex cord stromal tumours</p>	<p>Procedures documented in relevant equipment manuals and in-house documented procedures</p> <p>Automated method using Ventana Ultra platform and the following antibodies (supplier in brackets)</p> <p>IHC-S-SOP Staining</p> <p>Glycophorin A (Agilent)</p> <p>Glypican 3 (Zeta)</p> <p>Granzyme B (Leica)</p> <p>HBME 1 (Agilent)</p> <p>HCG (Leica)</p> <p>HCL (DBA44) (Agilent)</p> <p>Her-2 (Roche)</p> <p>HMB45 (Agilent)</p> <p>IgG4 (Roche)</p> <p>Inhibin alpha (Bio-Rad)</p>	<p>S</p>



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<p>HUMAN BODY SAMPLES (cont'd)</p> <p>FFPE tissue sections on glass slides (cont'd)</p>	<p><u>Histopathology examination activities for the purpose of clinical diagnosis</u> (cont'd)</p> <p>Immunohistochemistry to detect the following (cont'd)</p> <p>Kappa light chain restriction in normal and neoplastic cells</p> <p>Distinction between polyclonal 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</p> <p>Proliferation marker.</p> <p>Lambda light chain restriction in normal and neoplastic cells</p> <p>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</p> <p>Liposarcoma but not in benign lipoma</p> <p>Melanoma marker and positive in normal melanocytes</p> <p>Microphthalmia transcription factor Metastatic melanoma marker but is not specific</p>	<p>Procedures documented in relevant equipment manuals and in-house documented procedures</p> <p>Automated method using Ventana Ultra platform and the following antibodies (supplier in brackets)</p> <p>IHC-S-SOP Staining</p> <p>Kappa (Agilent)</p> <p>Kappa ISH</p> <p>Ki67 (Leica)</p> <p>Lambda (Agilent)</p> <p>Lambda ISH</p> <p>MDM-2 (Leica)</p> <p>Melan A (Agilent)</p> <p>MITF (Agilent)</p>	<p>S</p>



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<p>HUMAN BODY SAMPLES (cont'd)</p> <p>FFPE tissue sections on glass slides (cont'd)</p>	<p><u>Histopathology examination activities for the purpose of clinical diagnosis</u> (cont'd)</p> <p>Immunohistochemistry to detect the following (cont'd)</p> <p>Moc31 detection of epithelial cell adhesion molecule expression</p> <p>Pancreatic carcinoma</p> <p>Normal intestinal epithelium. MUC2 expression: specifically expressed in goblet cells of the small intestine & colon</p> <p>Plasma cell myeloma Reed Sternberg cells in Hodgkin lymphoma and malignant melanoma</p> <p>Neoplastic tissue. It detects granulocytes and myeloid series in the bone marrow</p> <p>Rhabdomyosarcoma Identifies skeletal muscle differentiation</p> <p>Distinguishes between benign sclerosing breast lesions and infiltrating carcinomas in difficult cases</p> <p>Normal lung and lung adenocarcinoma</p>	<p>Procedures documented in relevant equipment manuals and in-house documented procedures</p> <p>Automated method using Ventana Ultra platform and the following antibodies (supplier in brackets)</p> <p>IHC-S-SOP Staining</p> <p>Moc31</p> <p>MUC1 (Roche)</p> <p>MUC2 (Roche)</p> <p>Mum 1 (Agilent)</p> <p>Myeloperoxidase (Leica)</p> <p>MyoD1 (Agilent)</p> <p>Myosin (Leica)</p> <p>Napsin A (Roche)</p>	<p>S</p>



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HUMAN BODY SAMPLES (cont'd)	<u>Histopathology examination activities for the purpose of clinical diagnosis</u> (cont'd)	Procedures documented in relevant equipment manuals and in-house documented procedures	S
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)	
	Neurospecific enolase Neural marker but also positive in a wide range of non-neuroendocrine cells	IHC-S-SOP Staining NSE (Agilent)	
	Mature B-cell lines B cell lymphomas and negative in classic Hodgkin lymphoma	OCT2 (Leica)	
	Germ cell marker	OCT ¾ (Santa Cruz)	
	Surrogate marker for HPV	P16 (Roche)	
	Loss of staining relates to poor outcome in carcinomas of the breast, prostate, GI tract and lung	P27 (Leica)	
	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)	
	Functionally active cytotoxic T-lymphocytes (CTLs) and natural killer (NK) cells	Perforin (Leica)	



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<p>HUMAN BODY SAMPLES (cont'd)</p> <p>FFPE tissue sections on glass slides (cont'd)</p>	<p><u>Histopathology examination activities for the purpose of clinical diagnosis</u> (cont'd)</p> <p>Immunohistochemistry to detect the following (cont'd)</p> <p>Positive in many mesenchymal neoplasms. Positive in neuroendocrine differentiation, but its specificity is low, Neuroendocrine identification of atrial myxomas</p> <p>Programmed death-1 ligand 1 expression</p> <p>Placental Alkaline phosphatase Germ cell marker</p> <p>Transmembrane Mucoprotien</p> <p>Progesterone marker in breast cancer cases</p> <p>Marker for prostate adenocarcinoma</p> <p>Prostate adenocarcinoma. May help to differentiate intravascular large B-cell lymphoma from other lymphomas.</p> <p>Immune complex glomerulonephritis by presence of Immunoglobulin A</p> <p>Immune complex glomerulonephritis by presence of Immunoglobulin G</p>	<p>Procedures documented in relevant equipment manuals and in-house documented procedures</p> <p>Automated method using Ventana Ultra platform and the following antibodies (supplier in brackets)</p> <p>IHC-S-SOP Staining</p> <p>PGP 9.5 (Leica)</p> <p>PDL1-SP263 (Ventana)</p> <p>PLAP (Agilent)</p> <p>Podoplanin (D2-40)</p> <p>PR (Leica)</p> <p>PSA (poly) (Agilent)</p> <p>PSAP (Agilent)</p> <p>Renal IgA (Agilent)</p> <p>Renal IgG (Agilent)</p>	<p>S</p>



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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)	
	Immune complex glomerulonephritis by presence of Immunoglobulin M	IHC-S-SOP Staining Renal IgM (Agilent)	
	Any immune complex disease	Renal C3 (Agilent)	
	Melanoma marker	S100 (Agilent)	
	Smooth muscle marker	SMA (Agilent)	
	DNA tumour viruses	SV40 (Calbiochem)	
	Neuroendocrine marker	Synaptophysin (Leica)	
	Terminal deoxynucleotidyl transferase pre-B and pre-T lymphocytes	TdT (Leica)	
	Endothelial cells mesothelioma	Thrombomodulin (Agilent)	
	Follicular and papillary carcinomas of the thyroid	Thyroglobulin (Agilent)	
	Ubiquitous protozoan parasite	Toxoplasma (Biogenex)	
	Thyroid Transcription factor Lung and thyroid marker	TTF-1 (Leica)	
	Vimentin expression general soft tissue marker	Vimentin (Agilent)	
	Wilms tumour protein expression.	WT1 (Agilent)	
	Peripheral T-Cell lymphoma marker	Zap-70 (Leica)	



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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
<p>HUMAN BODY SAMPLES (cont'd)</p> <p>FFPE tissue sections on glass slides (cont'd)</p>	<p><u>Histopathology examination activities for the purpose of clinical diagnosis</u> (cont'd)</p> <p>Immunohistochemistry to detect the following (cont'd)</p> <p>Qualitatively identify human DNA mismatch repair (MMR) protein MLH1</p> <p>Identification of microsatellite instability</p> <p>Qualitatively identify human DNA mismatch repair (MMR) protein MSH6</p> <p>Aid in diagnostic determination of MSI-H tumours</p> <p>Mucin expression pattern of gastric carcinoma</p> <p>Mucin expression pattern of gastric carcinoma</p> <p>Detection of Human herpes virus type 8</p> <p>Haematopoietic marker</p> <p>Hairy cell leukemia but not in other B-cell lymphomas</p> <p>Positive in B-cell in mantle and marginal zone. Positive in DLBCL, SLL/CLL and follicular lymphomas.</p>	<p>Procedures documented in relevant equipment manuals and in-house documented procedures</p> <p>Automated method using Ventana Ultra platform and the following antibodies (supplier in brackets)</p> <p>IHC-S-SOP Staining</p> <p>MLH1 (Roche)</p> <p>MSH2 (Roche)</p> <p>MSH6 (Roche)</p> <p>PMS2 (Roche)</p> <p>MUC5AC (Roche)</p> <p>MUC6 (Roche)</p> <p>HHV8 (Roche)</p> <p>CD123 (Leica)</p> <p>Annexin A (Roche)</p> <p>BCL2 (Leica)</p>	<p>S</p>



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HUMAN BODY SAMPLES (cont'd)	<u>Histopathology examination activities for the purpose of clinical diagnosis</u> (cont'd)	Procedures documented in relevant equipment manuals and in-house documented procedures	S
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)	
	Distinguishes between neoplastic mast cell aggregates from reactive proliferations in the diagnosis of Systemic Mastocytosis	IHC-S-SOP Staining CD25 (Roche)	
	Metastatic melanoma Mantle cell lymphomas	SOX-10 (Roche) SOX-11 (Roche)	
FFPE tissue sections on glass slides	In situ hybridisation to detect the following	Automated method using Ventana Ultra platform and the following antibody (supplier in brackets)	S
	RNA transcripts of EBV infection that accumulate in the nucleus of EBV infected cells	IHC-S-SOP Staining EBER (Roche)	
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



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HUMAN BODY FLUIDS	<u>Cytopathological activities for the purposes of clinical diagnosis</u>	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:	S
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	
Non-gynae cytology preparations on glass slides		Hologic Genesis Cell Monolayer Preparation Platform Papanicolaou and Haematoxylin and eosin staining 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



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HUMAN BODY FLUIDS (cont'd) FFPE tissue sections on glass slides	<u>Molecular examination activities for the purpose of clinical diagnosis</u> Detection of genetic HER2 amplification in invasive breast cancers	Procedures documented in relevant equipment manuals and in-house documented procedures Using Dual Hapten Dual Colour In Situ Hybridisation (DDISH) on the Ventana Benchmark Ultra SOP IHC-S-SOP Staining	S
END			