


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 <p>UKAS MEDICAL 9323</p> <p>Accredited to ISO 15189:2012</p>	<h3>Viapath Analytics LLP</h3> <p>Issue No: 012 Issue date: 31 January 2022</p>	
	<p>Cellular Pathology 2nd Floor North Wing St. Thomas' Hospital Westminster Bridge Road London SE1 7EH United Kingdom</p>	<p>Contact: Fiona Denham Tel: +44 (0) 7718195287 Fax: +44 (0) 2071882948 E-Mail: fiona.denham@viapath.co.uk Website: www.viapath.co.uk</p>

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
<p>Address Cellular Pathology 2nd Floor, North Wing St. Thomas' Hospital Westminster Bridge Road London SE1 7EH</p> <p>Local contact Fiona Denham (as above)</p>	<p>Histopathology Rapid frozen section for intra-operative diagnosis Microscopic identification of Glomeruli Diagnostic Cytopathology Andrology</p>	ST
<p>Molecular Oncology Diagnostic Unit (MODU) 4th Floor, Tower Wing Guy's Hospital Great Maze Pond London SE1 9RT</p> <p>Fiona Denham (as above)</p>	Molecular Oncology	GMODU
<p>Head & Neck / Oral Pathology Laboratory 4th Floor, Tower Wing Guy's Hospital Great Maze Pond London SE1 9RT</p> <p>Fiona Denham (as above)</p>	<p>Histopathology Rapid frozen section for intra-operative diagnosis</p>	GHN



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Site activities performed away from the locations listed above:

Location details		Activity	Location code
Gassiot House Andrology Clinic St. Thomas' Hospital	Fiona Denham (as above)	Andrology sample production only	N/A
Fine Needle Aspirate (FNA) Clinics Westminster Bridge Road site	Fiona Denham (as above)	FNA material/slide preparation Cellularity assessment	STFNA
FNA Clinics Great Maze Pond site	Fiona Denham (as above)	FNA material/slide preparation Cellularity assessment	GFNA
Renal Biopsy Theatre/Ward (8 locations) St. Thomas' Hospital	Fiona Denham (as above)	Microscopic identification of Glomeruli	STRB
Renal Biopsy Wards (2 locations) Guy's Hospital	Fiona Denham (as above)	Microscopic identification of Glomeruli	GRB



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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 TISSUES AND FLUIDS Body fluids: Cerebrospinal fluid (CSF) Urine General body fluids Bronchial Brushings, washings and sputum	<u>Diagnostic cytology</u> Preparation and examination of cellular material to identify or exclude morphological & cytological abnormalities	<u>Preparation/centrifugation</u> In-house procedures: CPC-SOP-112 Non-Gynae Preparation in conjunction with manufacturer's instructions using: Thermo Shandon Cytospins 3 & 4 Heraeus Megafuge 1.0 & Megafuge 40 Hologic T2000processor	ST
		<u>Papanicolaou staining</u> Automated using in-house procedures: CPC-SOP-111 Non-Gynae Staining in conjunction with manufacturer's instructions using: Leica Autostainer ST5020 Leica Autostainer XL	ST
	Red & white blood cells	<u>Hemacolor staining</u> Automated using in-house procedures: CPC-SOP-111 Non-Gynae Staining in conjunction with manufacturer's instructions using: Leica Autostainer ST5020 Leica Autostainer XL	ST
	Acid fast bacilli, e.g. <i>Mycobacterium tuberculosis</i>	<u>Special staining</u> Manual Ziehl-Neelsen staining method using in-house procedure: CPH-SOP-23 Special Stains Manual	ST



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HUMAN TISSUES AND FLUIDS (cont'd) Slides prepared in-house from sample types listed above	<u>Diagnostic cytology</u> (cont'd) Morphological assessment and interpretation/diagnosis	<u>Microscopy (qualitative analysis)</u> In-house procedures: CPC-SOP-117 Non-Gynae Screening using microscopes as follows: Olympus BX40F Olympus BX40 Olympus BX41 Olympus BX45 Olympus BX46 Olympus BX53 Nikon	ST
Fine needle aspirations (FNA)	Cellularity assessment (sample adequacy confirmation) followed by subsequent processing and analysis in the Cytopathology Laboratory (ST)	<u>Material/slide preparation followed by microscopy</u> Manual methods using: CPC-SOP-73 FNA and: Olympus BX40, BX41 microscopes Flexible scope protocols: CP-SOP-27 Flexible scope limited to the application of these methods for commissioning & operation of FNA clinics listed in CPC-REC-31 FNA Clinic Log	STFNA GFNA



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Histopathology</u> (cont'd) Preparation and examination to identify or exclude morphological & cytological abnormalities (cont'd)	Macroscopic and Microscopic examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant)	
Formalin fixed tissues		<u>Embedding</u> Manual method using: CPH-SOP-109 Main Laboratory – Embedding and: Sakura Tissue Tek 5 & TEC 6 embedding centres	ST
		<u>Microtomy</u> Manual method using: CPH-SOP-110 Main Laboratory - Microtomy and: Leica RM2235 microtomes Microm HM 325 microtomes	ST
		<u>PCR sectioning</u> Manual method using: CPH-SOP-82 Preparation of Molecular Requests and: Leica RM2235 microtomes Microm HM 325 microtomes	ST
Fresh tissue Frozen tissue	Intra-operative diagnosis	<u>Rapid frozen section</u> Cryotomy and manual Haematoxylin & Eosin (H&E) staining method using: CPH-SOP-29 Frozen Section Room and: Leica CM1950 Cryostat Bright Cryostat	ST
		CPH-SOP-30 Frozen Section Room (GH) and: Thermo Scientific FSE Cryostat	GHN



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Fresh lymph node tissue Frozen lymph node tissue	Granulomas (TB) Lymphoma General tissue architecture	<u>Imprints</u> Manual methods using Hemacolor and Papanicolaou staining and: CPH-INST-40 Fresh Lymph Nodes	ST
Formalin fixed, paraffin embedded (FFPE) tissue	Basophilic and eosinophilic tissue structures	<u>Routine Haematoxylin & Eosin (H&E) staining and coverslipping</u> Automated method using: CPH-SOP-111 Main Laboratory – Staining, Correlation & Verification and: Leica XL ST5010 stainer Leica CV5030 coverslipper	ST
FFPE tissue	Detection of the following:	<u>Special staining</u> Manual methods using: CPH-SOP-23 Special Stains Manual and the following stains:	ST
	Acid and sulphated mucins	Alcian Blue	
	Foetal cells in amniotic fluid	Attwood's	
	Elastic fibres & collagen	Miller's Elastic Van Gieson (EVG)	
	Differentiating between haemopoetic cells	Giemsa	
	Gram positive and gram negative organisms	Gram's	
	Amyloid	Highman's Congo Red	
	Collagen and fibrosis	Haematoxylin Van Gieson (HVG)	



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Histopathology</u> (cont'd) Preparation and examination to identify or exclude morphological & cytological abnormalities (cont'd)	Macroscopic and Microscopic examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant)	ST
FFPE & Cytological fluids	Detection of the following: (cont'd)	<u>Special staining</u> (manual, cont'd)	
	Fungi	Grocott Gomori Methanamine Silver	
	Myelin sheath	Luxol Fast Blue	
	Connective tissue and fibrin	Lendrum's Martius, Scarlet, Blue (MSB)	
	5HT in melanin and lipofuscins	onMasson Fontana	
	Collagen and smooth muscle	Masson Trichrome	
	<i>Helicobacter pylori</i>	Modified Giemsa	
	Hepatitis B surface antigen	Shikata's Orcein	
	Basement membranes	PAMS: Jones Methenamine Silver	
	Liberated aldehydes	Periodic Acid Schiff's (+/- diastase)	
	Haemosiderin	Perls' Prussian Blue	
	Weakly acidic mucins	Southgate's Mucicarmine	
	Mast cell granules	Toluidine Blue Metachromatic	
	Calcium salts	Von Kossa	
	Acid fast bacilli, e.g. <i>M. leprae</i>	Wade-Fite	
	Acid fast bacilli, e.g. <i>M. tuberculosis</i>	Ziehl-Neelsen	



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FFPE tissue	Detection of the following:	<u>Special staining</u> Automated methods using: CPH-SOP-95 Dako Artisan Link Pro and: Dako Artisan Link Pro with the following stains:	ST
	Fungi	Grocott Methenamine Silver	
	Haemosiderin	Perls' Prussian Blue	
	Reticulin fibres	Reticulin method	
	Reticulin fibres	Untoned Reticulin Method	
	Spirochetes	Warthin-Starry	
Fresh frozen tissue	Detection of the following:	<u>Special staining</u> Manual methods using: CPH-SOP-23 and the following stains:	ST
	ACE expression in nerves	Acetyl cholinesterase	
	Hydrophobic (neutral) lipids	Oil Red O	



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HUMAN TISSUES AND FLUIDS (cont'd) FFPE tissue	<p><u>Histopathology</u> (cont'd)</p> <p>Preparation and examination to identify or exclude morphological & cytological abnormalities (cont'd)</p> <p>Detection of the following:</p> <p>Pan-keratin (Simple & complex epithelia)</p> <p>Expression of Alphaphetoprotein</p> <p>Anaplastic lymphoma kinase (Human p80 protein)</p> <p>Acinar, myoepithelial, stromal and neoplastic epithelial cells</p> <p>B-catenin protein, binds to cytoplasmic tail of E-cadherin</p> <p><i>M. tuberculosis</i></p> <p>Mantle zone B lymphocytes & interfollicular T lymphocytes and other rare tumour types</p> <p>Germinal centre B lymphocytes</p> <p>Cell membrane glycoproteins expressed on healthy epithelia and in various carcinomas</p> <p>Cancer antigen 125</p>	<p>Macroscopic and Microscopic examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant)</p> <p><u>Immunohistochemistry</u> Automated methods using: CPH-SOP-85 Programming and management of Bond III Immunostainer and: Leica Bond III and the following antibodies</p> <p>AE1/AE3</p> <p>Alphaphetoprotein</p> <p>ALK</p> <p>Androgen receptor</p> <p>B-catenin</p> <p>BCG</p> <p>Bcl2</p> <p>Bcl6</p> <p>BerEp4</p> <p>CA125</p>	ST



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Histopathology</u> (cont'd) Preparation and examination to identify or exclude morphological & cytological abnormalities (cont'd)	Macroscopic and Microscopic examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant)	ST
FFPE tissue (cont'd)	Detection of the following: (cont'd) Sialyl-Lewis A, marker for the detection of pancreatic cancer Calcitonin molecules in the parafollicular C cells Calcium binding protein structurally related to S100 and inhibin Simple glandular & transitional and columnar epithelia, Normal, early progenitor lymphoid cells; B lymphocytes in germinal centres Stem cell factor receptor, proto-oncogene activated in GIST tumors Human c-kit oncoprotein – mast cell disease/neoplasms Interleukin 3 receptor a-chain in Monocytes; neutrophils; basophils Myeloid antigen Heparan sulfate proteoglycan, syndecan-1 in the late stage of B cell differentiation	<u>Immunohistochemistry</u> (Automated Leica Bond III, cont'd) Ca19.9 Calcitonin Calretinin Cytokeratin 8 & 18 CD10 CD117 CD117 (monoclonal) CD123 CD13 CD138	



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FFPE tissue (cont'd)	Detection of the following: (cont'd) Monocyte differentiation antigen	<u>Immunohistochemistry</u> (Automated Leica Bond III, cont'd) CD14	
	Hodgkin's & Reed-Sternberg cells	CD15	
	Common B cell marker, expressed by B cells and follicular dendritic cells	CD19	
	MHC class 1 related cell surface glycoprotein in cortical thymocytes; Langerhan's cells; interdigitating reticulum cells	CD1a	
	Circulating T lymphocytes	CD2	
	B lymphocytes	CD20	
	Follicular dendritic cells	CD21	
	Key molecule for B cell activation and growth	CD23	
	Activated T lymphocytes; NK cells	CD25	
	T lymphocytes; helper/inducer T lymphocytes	CD3	
	Hodgkin's & Reed-Sternberg cells	CD30	
	Endothelial cells; plasma cells; activated B & T lymphocytes	CD31	
	Classic myeloid antigen	CD33	



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Histopathology</u> (cont'd) Preparation and examination to identify or exclude morphological & cytological abnormalities (cont'd)	Macroscopic and Microscopic examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant)	ST
FFPE tissue (cont'd)	Detection of the following: (cont'd) Haemopoietic precursor cells; endothelial cells; fibroblasts; other cell types in various solid tumours	<u>Immunohistochemistry</u> (Automated Leica Bond III, cont'd) CD34	
	Multifunctional enzyme, identify plasma cells and plasmablastic differentiation	CD38	
	Helper/inducer T lymphocytes	CD4	
	T lymphocytes; myeloid lineage cells	CD43	
	T & B lymphocytes	CD45	
	Germinal centre T lymphocytes; B lymphocyte subset	CD5	
	B and T cells and B cell precursors, monocytes, osteoclasts, endothelial cells and epithelial cells	CD54	
	Peripheral nerves; NK cells; neuroendocrine differentiation	CD56	
	Glycoprotein with cell adhesion functions. Marker of NK cells and neuroendocrine tumours	CD57	
	Identify platelets, megakaryocytes and platelet thrombi	CD61	



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FFPE tissue (cont'd)	Detection of the following: (cont'd)	<u>Immunohistochemistry</u> (Automated Leica Bond III, cont'd)	
	Macrophages; monocytes; granulocytes	CD68	
	Peripheral blood T lymphocytes; NK cells; thymocytes	CD7	
	Follicular center cell lymphoma; identify Reed-Sternberg cells	CD75	
	Normal & neoplastic B lymphocytes	CD79a	
	Suppressor/cytotoxic T lymphocytes	CD8	
	Fairly specific marker of GI origin for adenocarcinomas	CDX2	
	Carcino-embryonic antigen (Adenocarcinomas, epithelial cells of the glandular lumen)	CEA (polyclonal)	
	Carcino-embryonic antigen (Adenocarcinomas, epithelial cells of the glandular lumen)	CEA (monoclonal)	
	Chromogranin A (neuroendocrine cells and tumours)	Chromogranin	



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Histopathology</u> (cont'd) Preparation and examination to identify or exclude morphological & cytological abnormalities (cont'd)	Macroscopic and Microscopic examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant)	ST
FFPE tissue (cont'd)	Detection of the following: (cont'd) Hair follicles, basal keratinocytes in stratified epithelium (various tissue/organs), myoepithelial cells (breast and salivary gland), thyroid oncocytes	<u>Immunohistochemistry</u> (Automated Leica Bond III, cont'd) Cytokeratin 14	
	Simple (i.e. non stratified) epithelial cells, eccrine glands, endothelium of veins, venules and lymphatics, trophoblast	Cytokeratin 18	
	Epithelia	Cytokeratin 19	
	GI epithelia	Cytokeratin 20	
	High molecular weight keratin relatively specific for prostate basal cells	Cytokeratin 34Be12	
	Squamous epithelium	Cytokeratins 5	
	Simple, glandular & transitional epithelia	Cytokeratin 7	
	Cytomegalovirus viral inclusions	CMV	
	Mantle cell lymphoma	Cyclin D1	
	Smooth & striated muscle cells	Desmin	
	Interstitial cells of Cajal in GI tract, GIST	DOG-1	
	B cell centroblastic cell line	DBA44	



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FFPE tissue (cont'd)	Detection of the following: (cont'd) Epithelial membrane antigen (Glandular & ductal epithelia, perineurium; other cell types in various tumours) Cellular estrogen receptor expression Glial fibrillary acidic protein (Neural cells) Gross cystic disease fluid protein (Apocrine cells) Erythroid cells Human Chorionic Gonadotropin (Trophoblastic elements, e.g. in germ cell tumours) Major histocompatibility complex class II cell surface receptor on antigen-presenting cells B cells, activated T cells and on thymic epithelial cells Human melanoma black 45 antigen (Activated melanocytes; melanocytic tumours) Herpes virus simplex type 1 Herpes virus simplex type 2	<u>Immunohistochemistry</u> (Automated Leica Bond III, cont'd) EMA Estrogen receptor (ER) GFAP GCDFP-15 Glycophorin A bHCG HLA-DR HMB45 HSV1 HSV2	



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FFPE tissue (cont'd)	Detection of the following: (cont'd)	<u>Immunohistochemistry</u> (Automated Leica Bond III, cont'd)	
	Plasma cells and related lymphoid cells containing IgA	IgA	
	Plasma cells and related lymphoid cells containing IgD	IgD	
	Plasma cells and related lymphoid cells containing IgG	IgG	
	Plasma cells and related lymphoid cells containing IgG4	IgG4	
	Plasma cells and related lymphoid cells containing IgM	IgM	
	Sertoli cells (diffuse and strong), granulosa cells, prostate, brain, adrenal	Inhibin A	
	Plasma cells and related lymphoid cells containing Kappa light chains	Kappa light chains	
	Plasma cells and related lymphoid cells containing Lambda light chains	Lambda light chains	
	Basement membranes	Laminin	
	L1 (Calprotectin) molecule (Histiocytes; macrophages)	MAC387	



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FFPE tissue (cont'd)	Detection of the following: (cont'd) Very atypical or immature mast cells (MC) in mast cell leukaemia, cutaneous mastocytosis	<u>Immunohistochemistry</u> (Automated Leica Bond III, cont'd) Mast Cell	
	Melan A (MART-1) differentiation antigen (Normal, activated & neoplastic melanocytes)	Melan A	
	MSH6 mismatch repair protein in colorectal carcinomas	MSH6	
	Ki-67 nuclear antigen (Proliferating cells; cells in cycle)	MIB1	
	MLH-1 mismatch repair protein	MLH1	
	Myeloperoxidase in Neutrophils, eosinophils, monocytes	MPO	
	MSH-2 mismatch repair protein	MSH2	
	Multiple myeloma oncogene-1	MUM-1	
	Striated muscle (cardiac, skeletal)	Myoglobin	
	Napsin A, expressed in type II pneumocytes, kidney and foetal lung	Napsin A	



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FFPE tissue (cont'd)	Preparation and examination to identify or exclude morphological & cytological abnormalities (cont'd)		
	Detection of the following: (cont'd)	<u>Immunohistochemistry</u> (Automated Leica Bond III, cont'd)	
	Pluripotent germ cell tumours	Oct3/4	
	p16INK4a oncoprotein (Normal, activated and neoplastic melanocytes)	p16	
	Expression of p21WAF1/Cip1	p21	
	p24 capsid protein of HIV virus	HIV-1 p24	
	Expression of Alpha Methyl Acyl Coenzyme A Racemase	p504s	
	Carcinomas; many neoplasms and normal cells	p53 tumour suppressor protein	
	Normal proliferating cells; poorly differentiated squamous cell carcinoma, basal cells; abluminal cells	p63	
	Cytokeratins 5, 6, 8, 17, 19 (All epithelia)	PANK (MNF116)	
	Pre-B cells	Pax 5	
	Systemic lupus erythematosus, T-cells in germinal centres, mantle zones and interfollicular zones	PD 1	
	Perforin in cytotoxic T-lymphocytes	Perforin	



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FFPE tissue (cont'd)	Detection of the following: (cont'd) Placental Alkaline Phosphatase in germ cell tumours, particularly seminomas; also breast, lung, ovarian carcinomas PMS2 mismatch repair protein in colorectal carcinomas Cellular progesterone receptor expression Prostate specific antigen Normal and neoplastic melanocytes; macrophages; adipocytes; nerve fibres; many tumour types Succinate dehydrogenase iron-sulfur subunit Smooth muscle, myoepithelial and other contractile cells Smooth muscle myosin heavy chain <i>Treponema pallidum</i> / Spirochete Synaptic vesicle protein (neurons; neuroendocrine cells)	<u>Immunohistochemistry</u> (Automated Leica Bond III, cont'd) PLAP PMS2 Progesterone receptor (PR) PSA S100 protein SDHB Smooth muscle actin SMMHC Spirochete Synaptophysin	



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Histopathology</u> (cont'd) Preparation and examination to identify or exclude morphological & cytological abnormalities (cont'd)	Macroscopic and Microscopic examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant)	ST
FFPE tissue (cont'd)	Detection of the following: (cont'd) a/b TCR bearing T lymphocytes) Terminal deoxynucleotidyl transferase in thymic and small number of bone marrow cortical lymphocytes Thyroglobulin in thyroid follicles and thyrocytes Cytolytic lymphocytes, cytotoxic T- cells Tartrate resistant acid phosphatase in Hairy cell leukemia Thyroid transcription factor-1 (Thyroid follicular & C cells) Vimentin intermediate filament Von Willebrand Factor (endothelial cells) WT1 expression T cells and natural killer (NK) cells	<u>Immunohistochemistry</u> (Automated Leica Bond III, cont'd) TCR BF1 TdT Thyroglobulin TIA-1 protein TRAP TTF-1 Vimentin vWF (FVIII) WT1 ZAP70	



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Histopathology</u> (cont'd) Preparation and examination to identify or exclude morphological & cytological abnormalities (cont'd)	Macroscopic and Microscopic examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant)	
FFPE tissue	Detection of the following:	<u>In-situ hybridisation (ISH)</u> Automated methods using: CPH-SOP-85 Programming and management of Bond III Immunostainer and: Leica Bond III and the following probes	ST
	Epstein Barr Virus RNA	EBER	
	Kappa RNA in B cells	Kappa	
	Lambda RNA in B cells	Lambda	
HUMAN TISSUES AND FLUIDS (cont'd)	<u>Histopathology</u> (cont'd) Preparation and examination to identify or exclude morphological & cytological abnormalities (cont'd)	Macroscopic and Microscopic examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant)	
FFPE tissue	Detection of the following:	<u>Immunohistochemistry</u> Automated methods using: CPH-SOP-86 Programming and management of Ventana Ultra Immunostainer and: Roche Ventana Benchmark Ultra and the following antibodies:	ST
	HER-2 positive cells in breast and gastric neoplastic tissues	4B5	
	Anaplastic lymphoma kinase in NSCLC	ALK LU	



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Histopathology</u> (cont'd) Preparation and examination to identify or exclude morphological & cytological abnormalities (cont'd)	Macroscopic and Microscopic examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant)	ST
FFPE tissue	Detection of the following:	<u>Immunohistochemistry</u> Automated methods using: CPH-SOP-86 Programming and management of Ventana Ultra Immunostainer and: Roche Ventana Benchmark Ultra and the following antibodies:	
	Amyloid A in tissues, and aids in the identification and classification of AA-amyloidosis	Amyloid A	
	Carbonic Anhydrase IX – Clear renal cell carcinoma and clear cell papillary renal cell carcinoma	CA-IX	
	Special tissue marker for humoral immunity	C4D	
	Vascular & peripheral smooth muscle; other contractile cells	H-caldesmon	
	T lymphocytes; islet cells; endothelial cells, Ewing's sarcoma; other rare spindle cell tumours	CD99	
	Acute phase regulated transmembrane protein (monocytes and macrophages)	CD163	



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Histopathology</u> (cont'd)	Macroscopic and Microscopic examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant)	ST
FFPE tissue	Preparation and examination to identify or exclude morphological & cytological abnormalities (cont'd)		
	Detection of the following:	<u>Immunohistochemistry</u> Automated methods using: CPH-SOP-86 Programming and management of Ventana Ultra Immunostainer and: Roche Ventana Benchmark Ultra and the following antibodies:	
	Basement membrane	Collagen IV	
	Mantle cell lymphoma	Cyclin-D1	
	GATA binding protein, transcription factor in cell preparation	GATA-3	
	NKX3.1 gene expression in prostatic adenocarcinoma	NKX3.1	
	ROS1 fusion proteins (NSCLC)	ROS-1	
	Transcription factor - marker for mantle cell lymphoma	SOX-11	
	Kaposi's sarcoma	HHV-8 (Human Herpes virus 8)	
	Benign and malignant liver cells	HSA (anti-Hepatocyte Specific Antigen)	
	Neuronal intermediate filament	Neurofilament (2F11)	



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Histopathology</u> (cont'd) Preparation and examination to identify or exclude morphological & cytological abnormalities (cont'd)	Macroscopic and Microscopic examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant)	ST
FFPE tissue (cont'd)	Detection of the following: (cont'd)	<u>Immunohistochemistry</u> (Automated Ventana Ultra, cont'd)	
	P16INK4a oncoprotein (normal, activated and neoplastic melanocytes)	p16	
	P40 protein in squamous cell carcinomas (lung, urothelial, head and neck)	P40	
	Cytotrophoblast, Syncytio trophoblasts, Stromal cells	P57	
	PD-L1 Protein in non-small cell lung cancers	PD-L1	
	Transmembrane mucoprotein	Podoplanin	
	Prolactin receptor associated protein	PRAP	
	Smooth muscle myosin heavy chain	SMMHC	
	<i>Toxoplasma gondii</i>	Toxoplasma	
	BK virus	BKV	
	Parvovirus	Parvovirus	
	Adenovirus	Adenovirus	
	Paired box (PAX) family of transcription factor 8	Pax 8	
	Inducible T cell costimulator (CD278)	ICOS	



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Histopathology</u> (cont'd) Preparation and examination to identify or exclude morphological & cytological abnormalities (cont'd)	Macroscopic and Microscopic examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant)	
FFPE tissue (cont'd)	Detection of the following: (cont'd) Renal Cell Carcinoma Glycoprotein	<u>Immunohistochemistry</u> (Automated Ventana Ultra, cont'd) RCC	ST
FFPE renal biopsies	Detection of the following: Fibrin in tissue sections Plasma cells and related lymphoid cells containing Kappa light chains Plasma cells and related lymphoid cells containing Lambda light chains Plasma cells and related lymphoid cells containing IgG Plasma cells and related lymphoid cells containing IgA Plasma cells and related lymphoid cells containing IgM Complement 3 Complement 1q	<u>Immunohistochemistry</u> Manual methods using: CPH-SOP-24 Renal IHC Staining Manual and the following antibodies: Fibrinogen Kappa light chains Lambda light chains IgG IgA IgM C3 C1q	ST



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Histopathology</u> (cont'd) Preparation and examination to identify or exclude morphological & cytological abnormalities (cont'd)	Macroscopic and Microscopic examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant)	
Slides prepared in-house from sample types listed above	Morphological assessment and interpretation/diagnosis	<u>Microscopy (qualitative analysis)</u> In-house procedures: CPH-SOP-64 Consultant Reporting using: Olympus BX40 Olympus BX50 Olympus BX51 Nikon 80i Nikon E400 Nikon 50i Leica DM2500	ST
Fresh renal biopsies	Identification of Glomeruli	CPH-SOP-64 Consultant Reporting using: Nikon E400 Olympus BH2	GHN
Tissue samples from head and neck	Preparation and examination to identify or exclude morphological & cytological abnormalities (cont'd)	<u>Microscopy (qualitative analysis)</u> In-house procedure: CPH-SOP-13 Renal Histopathology and: Vickers Dissecting Microscope	ST STRB GRB
		<u>Macroanalysis and dissection</u> Manual method using: HN-SOP-45 HN-SOP-20 HN-SOP-84	GHN
		<u>Decalcification</u> Manual method using: HN-SOP-46	GHN
		<u>Tissue processing</u> Automated method using: HN-SOP-47 and: Sakura Tissue Tek VIP6	GHN



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Histopathology</u> (cont'd)	Macroscopic and Microscopic examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant)	
Tissue samples from head and neck	Preparation and examination to identify or exclude morphological & cytological abnormalities (cont'd)	<u>Embedding</u> Manual method using: HN-SOP-48 and: Leica EG1150 Embedding Centre	GHN
	Preparation and examination to identify or exclude morphological & cytological abnormalities (cont'd)	<u>Microtomy</u> Manual method using: HN-SOP-48 and: Reichert Jung 2030 & Leica RM2235 rotary microtomes	GHN
FFPE tissue	Basophilic and eosinophilic tissue structures	<u>Routine Haematoxylin & Eosin (H&E) staining</u> Automated method using: HN-SOP-80 and: Leica Autostainer XL	GHN
FFPE tissue	Carbohydrates	<u>Special staining</u> Partially automated method using: HN-SOP-49 and: PAS +/-diastase stain with counterstaining using: Leica Autostainer XL	GHN
FFPE tissue	Detection of the following:	<u>Special staining</u> Manual methods using: HN-SOP-49 and the following stains:	GHN
	Acid mucins (sulphomucins & sialomucins); neutral mucins; mixed mucins	Alcian Blue/PAS +/-diastase	



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Histopathology</u> (cont'd)	Macroscopic and Microscopic examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant)	GHN
FFPE tissue	Preparation and examination to identify or exclude morphological & cytological abnormalities (cont'd)		
	Detection of the following:	<u>Special staining</u> Manual methods using: HN-SOP-49 and the following stains:	
	Acid mucins (sulphomucins & sialomucins); neutral mucins; mixed mucins	Long ABPAS	
	Amyloid	Highman's Congo Red	
	Gram positive/negative bacteria	Gram's stain	
	Fungi	Grocott	
	All tissue structures	Haematoxylin & Eosin (manual)	
	Connective tissue; muscle	Haematoxylin Van Gieson	
	Fibrin	Martius, Scarlet & Blue (MSB)	
	Melanin	Masson Fontana	
	Melanin	Melanin Bleach	
	Elastic fibres	Miller's Elastic Van Gieson	
	Haemosiderin	Perls' Prussian Blue	
	<i>Mycobacterium tuberculosis</i>	Ziehl Neelsen	



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Histopathology</u> (cont'd)	Macroscopic and Microscopic examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant)	GHN
FFPE tissue	Preparation and examination to identify or exclude morphological & cytological abnormalities (cont'd)		
	Detection of the following:	<u>Immunohistochemistry</u> Automated methods using: HN-SOP-50 and: Roche Ventana Benchmark Ultra and the following antibodies:	
	Pan-keratin (simple & complex epithelia)	AE1/3	
	Bcl-oncoprotein (mantle zone B lymphocytes & interfollicular T lymphocytes; other rare tumour types)	BCI2	
	Epithelial antigen (basal cell carcinoma)	BerEp4	
	T-Brachyury transcription factor (chordoma)	Brachyury	
	Calcitonin (Thyroid C cells)	Calcitonin	
	H-caldesmon (vascular & peripheral smooth muscle; other contractile cells)	Caldesmon (H)	
	Calponin (calcium binding) protein (Vascular & peripheral smooth muscle; other contractile cells)	Calponin	
	MHC class 1 related cell surface glycoprotein (cortical thymocytes; Langerhan's cells; interdigitating reticulum cells)	CD1a	
	CD3 (T lymphocytes; helper/inducer T lymphocytes)	CD3	



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Histopathology</u> (cont'd)	Macroscopic and Microscopic examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant)	GHN
FFPE tissue	Preparation and examination to identify or exclude morphological & cytological abnormalities (cont'd)		
	Detection of the following (cont'd):	<u>Immunohistochemistry</u> (Automated Ventana Ultra, cont'd)	
	CD20 (B lymphocytes)	CD20	
	CD31 (Endothelial cells; plasma cells; activated B & T lymphocytes)	CD31	
	CD34 (Haemopoietic precursor cells; endothelial cells; fibroblasts; other cell types in various solid tumours)	CD34	
	CD45 (T & B lymphocytes)	CD45 (LCA)	
	CD56 (Peripheral nerves; NK cells; neuroendocrine differentiation)	CD56 (NCAM)	
	CD68 (Macrophages; monocytes; granulocytes)	CD68	
	CD79a (Normal & neoplastic B lymphocytes)	CD79a	
	CD99 (T lymphocytes; islet cells; endothelial cells; Ewing's sarcoma; other rare spindle cell tumours)	CD99	
	Carcino-embryonic antigen (Adenocarcinomas)	CEA	
	Chromogranin A (neuroendocrine cells and tumours)	Chromogranin	
	Cytokeratins 5 & 6 (squamous epithelium)	CK5/6	



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Histopathology</u> (cont'd)	Macroscopic and Microscopic examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant)	GHN
FFPE tissue	Preparation and examination to identify or exclude morphological & cytological abnormalities (cont'd)		
	Detection of the following (cont'd):	<u>Immunohistochemistry</u> (Automated Ventana Ultra, cont'd)	
	Cytokeratin 7 (simple, glandular & transitional epithelia)	CK7	
	Cytokeratin 8 & 18 (simple & glandular epithelia)	CK8/18/Cam5.2	
	Cytokeratin 18	CK18	
	Cytokeratin 19 (epithelia)	CK19	
	Cytokeratin 20 (GI epithelia)	CK20	
	Cytomegalovirus viral inclusions	CMV	
	Podoplanin transmembrane mucoprotein (Lymphatic endothelial cells; FDCs; dysplastic keratinocytes)	D2-40 (Podoplanin)	
	Desmin (Smooth & striated muscle cells)	Desmin	
	Latent membrane protein 1 (Epstein Barr virus infected cells)	EBV	
	Epithelial membrane antigen (Glandular & ductal epithelia; perineurium; other cell types in various tumours)	EMA	
	Glial fibrillary acidic protein (neural cells)	GFAP	



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Histopathology</u> (cont'd)	Macroscopic and Microscopic examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant)	GHN
FFPE tissue	Preparation and examination to identify or exclude morphological & cytological abnormalities (cont'd)		
	Detection of the following (cont'd):	<u>Immunohistochemistry</u> (Automated Ventana Ultra, cont'd)	
	Human melanoma black 45 antigen (Activated melanocytes; melanocytic tumours)	HMB45	
	Type 1 Human papilloma virus capsid protein	HPV	
	Type 1 Herpes simplex virus	HSV	
	Melan A differentiation antigen (Normal, activated & neoplastic melanocytes)	Melan-A	
	Ki-67 nuclear antigen (proliferating cells; cells in cycle)	MIB-1	
	Cytokeratins 5, 6, 8, 17, 19 (all epithelia)	MNF116	
	Neuronal intermediate filament	Neurofilament	
	Enolase gamma subunit (neuronal & neuroendocrine cells)	NSE	
	p16INK4a oncoprotein	p16	
	p24 capsid protein of HIV virus	p24	



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Histopathology</u> (cont'd)	Macroscopic and Microscopic examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant)	GHN
FFPE tissue	Preparation and examination to identify or exclude morphological & cytological abnormalities (cont'd)		
	Detection of the following (cont'd):	<u>Immunohistochemistry</u> (Automated Ventana Ultra, cont'd)	
	p53 tumour suppressor protein (carcinomas; many neoplasms and normal cells)	p53	
	p63 (normal proliferating cells; poorly differentiated squamous cell carcinoma; basal cells; abluminal cells)	p63	
	Parathyroid hormone	Parathyroid hormone	
	S100 protein (Normal and neoplastic melanocytes; macrophages; adipocytes; nerve fibres; many tumour types)	S100	
	Smooth muscle actin (smooth muscle, myoepithelial and other contractile cells)	SMA	
	Synaptic vesicle protein (neurones; neuroendocrine cells)	Synaptophysin	
	Thyroglobulin protein (thyroid follicles)	Thyroglobulin	
	Thyroid transcription factor-1 (thyroid follicular & C cells)	TTF-1	
	Vimentin intermediate filament	Vimentin	



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Histopathology</u> (cont'd) Preparation and examination to identify or exclude morphological & cytological abnormalities (cont'd)	Macroscopic and Microscopic examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant)	
FFPE tissue	Detection of the following:	<u>In-situ hybridisation</u> Automated methods using: HN-SOP-50 and: Roche Ventana Benchmark Ultra and the following probes:	GHN
	EBV	EBV - ISH	
	HPV (High risk)	HPV (High Risk) - ISH	
	HPV (Low risk)	HPV (Low Risk) - ISH	
Intra-operative frozen sections from head and neck	Frozen section examination to identify or exclude morphological & cytological abnormalities	<u>Cryotomy</u> using: HN-SOP-18 and: Leica CM1850 Cryostat	GHN
	Basophilic and eosinophilic tissue structures	<u>Routine H&E staining</u> Manual method using: HN-SOP-48 Automated method using: HN-SOP-18 HN-EXT-84 and Thermo Shandon Linistat	GHN
Slides prepared in house from samples listed above	Morphological assessment and interpretation/diagnosis	<u>Microscopy (qualitative analysis)</u> using: HN-SOP-26 and microscopes : Olympus BX50 Olympus BX51 Olympus BX53 Olympus BH2 Nikon Eclipse E400	GHN



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Histopathology</u> (cont'd) Preparation and examination to identify or exclude morphological & cytological abnormalities (cont'd)	Macroscopic and Microscopic examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant)	
Tissue samples from oral mucosa	Ploidy examination to identify or exclude chromosomal instability indicative of malignant transformation for the purpose of diagnosis	<u>Preparation of monolayers</u> Manual methods using: HN-SOP-59 and: Aquatron Shaking Water Bath, Dade Microfuge Immunofuge II, and Thermo Shandon Cytospin IV	GHN
Slides prepared in house from samples listed above	Chromosomal material	<u>Feulgen staining</u> Manual method using: HN-SOP-59	GHN
	Assessment and interpretation/diagnosis	<u>Scanning monolayers, qualitative and histogram analysis</u> using: HN-SOP-59 and: Zeiss Axioplan microscope DNA Image Ploidy System Prior Scientific robotic stage & controller Zeiss Axiocam Rev3 computer	GHN
HUMAN TISSUES AND FLUIDS (cont'd)	<u>Andrology</u>	<u>Semen Analysis</u> In house procedures following the guidelines below:	
Ejaculate	Fertility screening: Semen pH Semen volume	WHO Laboratory Manual for the Examination of Human Semen and Sperm-Cervical Mucus Interaction 5th Edition. Manual methods using in-house procedure: CPC-SOP-118 Semen Analysis	ST



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HUMAN TISSUES AND FLUIDS (cont'd) Ejaculate	<u>Andrology</u>	<u>Semen Analysis</u> In house procedures following the guidelines below:	
	Sperm concentration Sperm vitality Sperm morphology	Manual microscopy method using in-house procedure: CPC-SOP-118 Semen Analysis using: Olympus BX53	ST
	Sperm concentration Sperm motility	Automated using in-house procedure: CPC-SOP-118 Semen Analysis in conjunction with manufacturer's instructions using: SAMI CASA system	ST
	Post-vasectomy semen analysis (PVSA):	2016 Laboratory guidelines for postvasectomy semen analysis: Association of Biomedical Andrologists, the British Andrology Society and the British Association of Urological Surgeons. P Hancock, B J Woodward, A Muneer, J C Kirkman-Brown. <i>J Clin Pathol</i> doi:10.1136/jclinpath-2016-203731	
	Detection of sperm	Large volume chamber microscopy using in-house procedure: CPC-SOP-118 Semen Analysis using: Olympus BX40	ST



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Molecular genetics</u> Detection of the nucleic acid sequence variants listed		
FFPE tissue		<u>DNA extraction</u> Manual method using in-house procedure: CPH-SOP-77 DNA extraction from FFPE sections	GMODU
DNA extracted in-house	B Cell Clonality (detection of B Cell rearrangements)	Automated capillary electrophoresis Sanger sequencing using: ABI 3730 gene analyser and: CPH-SOP-119 B Cell - IgH Clonality procedure	GMODU
DNA extracted in-house	T Cell Clonality (detection of T Cell rearrangements)	Automated capillary electrophoresis Sanger sequencing using: ABI 3730 gene analyser and: CPH-SOP-120 T Cell - TCR Clonality procedure	GMODU
END			