


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 UKAS MEDICAL 8922 Accredited to ISO 15189:2012	Mid and South Essex NHS Foundation Trust Issue No: 002 Issue date: 23 April 2020	
	Cellular Pathology Laboratory Broomfield Hospital Court Road Chelmsford CM1 7ET United Kingdom	Contact: Sarah Haigh Tel: +44 (0) 1245 515121 E-Mail: sarah.haigh9@nhs.net Website: www.meht.nhs.uk
Testing performed at the above address only		

Site activities performed away from the locations listed above:

Location details	Activity
Broomfield Hospital Court Road Chelmsford CM1 7ET United Kingdom	Mortuary services



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DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
<p>HUMAN BODY TISSUE</p> <p>Urine, bronchial wash, pleural fluids, peritoneal fluids, joint fluids, fine needles, aspirates, sputum</p> <p>Fixed, fresh tissue including excisional and incisional biopsies and surgical resection specimens</p> <p>Fixed, fresh tissue including excisional and incisional biopsies and surgical resection specimens</p> <p>Fresh tissue</p> <p>Formalin- fixed and processed tissue (to paraffin wax) including excisional and incisional biopsies and surgical resection specimens</p>	<p><u>Histological and Cytological examinations to assist in clinical diagnosis</u></p> <p><u>Diagnostic Non Gynae Cytopathology</u></p> <p>Cellular differentiation</p> <p>Squamous cell differentiation</p> <p><u>Histological examinations to assist in clinical diagnosis</u></p> <p>Identification of basophilic and eosinophilic structures</p>	<p>Macroscopic and Microscopic Examination using documented in house methods and manufacturers' instructions for:</p> <p>Sample preparation using: Leec safety cabinet LP-508-010 Thermo-Shandon centrifuge LP-546-023 Shandon Cytospin LP-546-024 T2000 Projector LP-543-011</p> <p>CELL-NG-LP-2 Manual Diff-Quick Giemsa stain</p> <p>CELL-NG-LP-1 - Automated Papanicolaou stain using the Shandon Varistain – CELL-NG-PR-5</p> <p>Tissue Dissection and decalcification Manual Methods SOP - CA-LP 559-019</p> <p><u>Tissue Processing</u></p> <p>Tissue Processors (Thermo-Shandon) CELL-HIST-PR-45, CELL-HIST-PR-46 & CELL-HIST PR-55</p> <p>AFOS Extraction bench CELL-HIST-PR-38</p> <p>Leica cassette printers</p> <p><u>Production of frozen sections: Leica Cryostat CELL-HIST-PR-52</u> <u>Haematoxylin and Eosin Staining Manual - CELL-HIST-LP-13</u></p> <p><u>Embedding</u></p> <p>Embedding machines (Leica) CELL-HIST-PR-58</p>



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HUMAN BODY TISSUE (cont'd)	<u>Histological and Cytological examinations to assist in clinical diagnosis (cont'd)</u>	Macroscopic and Microscopic Examination using documented in house methods and manufacturers' instructions for:
Formalin Fixed Paraffin Embedded Tissue (FFPE)		<u>Microtomy</u> Microm rotary microtomes Leica RM2135 Leica RM2235 Leica RM2245 Jung Autostainer SOP - LP-560-003 CELL-HIST-FR-107
Formalin Fixed Paraffin Embedded Tissue (FFPE) sections	Routine staining for identification of basophilic and eosinophilic structures	Automated H & E staining using Leica Autostainer XL CELL-HIST-NOT-57 CELL-NG-PR-5
Formalin Fixed Paraffin Embedded Tissue (FFPE) sections	Special staining to identify the following:	Manual staining unless stated otherwise LP-546-026 CELL-HIST-NOT-57 CELL-NG-PR-5
	Acid mucins	CELL-HIST-LP-4 Alcian Blue stain
	Acid and neutral mucins	CELL-HIST-LP-3 Alcian blue/Periodic acid Schiff (ABPAS)
	Amyloid	CELL-HIST-LP-2 Congo Red
	glycogen	CELL-HIST-LP-5 Diastase Periodic Acid Schiff (DPAS)
	Elastin fibres	CELL-HIST-LP-18 Miller's Elastin Van Gieson (EVG)



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HUMAN BODY TISSUE (cont'd)	<u>Histological and Cytological examinations to assist in clinical diagnosis (cont'd)</u>	Macroscopic and Microscopic Examination using documented in house methods and manufacturers' instructions for:
Formalin Fixed Paraffin Embedded Tissue (FFPE) sections (cont'd)	Special staining to identify the following: (cont'd)	Manual staining unless stated otherwise
	Giemsa stain for protozoans Giemsa stain for parasites Giemsa stain for helicobacter pylori	CELL-HIST-LP-7 (Giemsa stain) CELL-HIST-LP-8 (Giemsa stain for helicobacter pylori)
	Bacteria	CELL-HIST-LP-9 Gram stain
	Fungi Pneumocystis	CELL-HIST-LP-10 Grocott's Methenamine silver stain
	Acid mucopolysaccharides	CELL-HIST-LP-1 Hale's Colloidal Iron
	Basement membranes	CELL-HIST-LP-15 Jones' Methenamine silver
	Melanin Argentaffin reaction	CELL-HIST-LP-16 Masson Fontana
	Collagen	CELL-HIST-LP-17 Masson Trichrome
	Fibrin	CELL-HIST-LP-19 Martius Scarlet Blue (MSB)
	Neutral mucins	CELL-HIST-LP-20 Periodic Acid Schiffs (PAS)
	Haemosiderin	CELL-HIST-LP-21 Perls stain
	Reticulin fibres	CELL-HIST-LP-22 Reticulin Silver stain
	Mast cells	CELL-HIST-LP-23 Toluidine Blue
	Hepatitis	CELL-HIST-LP-24 Victoria Blue



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HUMAN BODY TISSUE (cont'd)	<u>Histological and Cytological examinations to assist in clinical diagnosis (cont'd)</u>	Macroscopic and Microscopic Examination using documented in house methods and manufacturers' instructions for:
Formalin Fixed Paraffin Embedded Tissue (FFPE) sections (cont'd)	Special staining to identify the following: (cont'd)	Manual staining unless stated otherwise
	Leprosy	CELL-HIST-LP-25 Wade Fite
	Spirochaetes	CELL-HIST-LP-26 Warthin –Starry
	Collagen	CELL-HIST-LP-27 Weigert Van Gieson
	Tubercule bacilli	CELL-HIST-LP-28 Ziehl Neelson
Formalin Fixed Paraffin Embedded Tissue (FFPE) sections and cell block sections	Immunochemistry for the identification of:	Immunohisto/cytochemical staining Automated using the Leica Bond III Immunostainer (X3).
	Yolk sac tumours Hepatocellular carcinoma Foetal liver cells	CELL-HIST-PR-31 (introduction IHC) CELL-HIST-PR-68 (Bond user) CELL-HIST-NOT-20 (Antibody list) CELL-HIST-NOT-37 (control list IHC)
	Follicular lymphoma vs. reactive follicles. T cells in germinal centres and mantle zone B cells	Alpha-feto protein (AFP) Bcl-2 oncoprotein



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HUMAN BODY TISSUE (cont'd)	<u>Histological and Cytological examinations to assist in clinical diagnosis (cont'd)</u>	Macroscopic and Microscopic Examination using documented in house methods and manufacturers' instructions for:
Formalin Fixed Paraffin Embedded Tissue (FFPE) sections and cell block sections (cont'd)	Immunohistochemistry for the identification of: (cont'd)	Immunohisto/cytochemical staining Automated using the Leica Bond III Immunostainer (X3).
	Follicular lymphoma Diffuse large B-cell lymphoma Burkitt's lymphoma Hodgkin's disease (nodular)	Bcl-6
	Epithelial glycoprotein (eg.colon) Adenocarcinoma vs. mesothelioma	Ber EP4
	Adenocarcinoma colon; stomach; pancreas ie. gastro intestinal carcinomas & including some ovarian carcinomas (primary/metastatic)	Ca19.9
	Ovarian serous adenocarcinoma Mesothelioma	Ca125
	Medullary carcinoma thyroid C-cells of the thyroid (normal & neoplastic)	Calcitonin
	Mesothelial cells Mesothelioma vs. adenocarcinoma	Calretinin
	Secretory epithelial cells eg. colon Adenocarcinoma vs. mesothelioma Spindle cell carcinomas of skin Paget's disease	Cam 5.2
	T-cells (and NK cells) T-lymphoblastic lymphomas and leukaemias	CD2
	T- cells T-cell lymphoma	CD3
	T-helper cells Macrophages & Monocytes, Dendritic cells (Langerhans cells)	CD4



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HUMAN BODY TISSUE (cont'd)	<u>Histological and Cytological examinations to assist in clinical diagnosis (cont'd)</u>	Macroscopic and Microscopic Examination using documented in house methods and manufacturers' instructions for:
Formalin Fixed Paraffin Embedded Tissue (FFPE) sections and cell block sections (cont'd)	<p>Immunohistochemistry for the identification of: (cont'd)</p> <p>T-cells, Mantle zone cells Small lymphocytic B-cell Chronic Lymphocytic leukaemia (CLL) Mantle cell lymphoma</p> <p>T-cells (and NK cells) Precursor T-lymphoblastic lymphoma & leukaemia</p> <p>T-cell suppressor subset (NK cells) T-cell lymphoma Kikuchi histiocytic necrotising lymphadenopathy</p> <p>Germinal centre B-cells Burkitt's lymphoma Follicular lymphoma Myoepithelial cells (breast) B-cell lymphoblastic leukaemia</p> <p>Mature neutrophils Reed-Sternberg cells (classical Hodgkin's lymphoma) Acute myeloid leukaemia (AML) Some epithelial tumours, including some adenocarcinomas</p> <p>B-cells B-cell lymphoma Follicular/mantle cell lymphoma Hairy cell leukaemia</p> <p>Small cell lymphocytic lymphoma (B-cell type) CLL vs. mantle cell lymphoma</p>	<p>Immunohisto/cytochemical staining Automated using the Leica Bond III Immunostainer (X3).</p> <p>CD5</p> <p>CD7</p> <p>CD8</p> <p>CD10</p> <p>CD15</p> <p>CD20</p> <p>CD23</p>



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<p>HUMAN BODY TISSUE (cont'd)</p> <p>Formalin Fixed Paraffin Embedded Tissue (FFPE) sections and cell block sections (cont'd)</p>	<p><u>Histological and Cytological examinations to assist in clinical diagnosis (cont'd)</u></p> <p>Immunochemistry for the identification of: (cont'd)</p> <p>Reed-Sternberg cells - Hodgkin's lymphoma Anaplastic large cell lymphoma ALCL Embryonal carcinoma</p> <p>Endothelial cells Vascular neoplasms Epithelioid and spindle tumours of skin and soft tissue.</p> <p>Endothelial cells GIST Other Mesenchymal neoplasms</p> <p>Prognostic marker in various tumours, such as ovarian cancer. Cancer stem cells, such as prostate & breast. Present on T-lymphs; granulocytes; RBCs & epithelial cells.</p> <p>Haematolymphoid cells Leukaemias & lymphomas</p> <p>NK cells Neural tumours Neuroendocrine tumours e.g. small cell carcinoma; carcinoid tumours; Merkel cell carcinoma.</p> <p>Macrophages AML</p> <p>B-cells Precursor B lymphoblastic leukaemia</p>	<p>Macroscopic and Microscopic Examination using documented in house methods and manufacturers' instructions for:</p> <p>Immunohisto/cytochemical staining Automated using the Leica Bond III Immunostainer (X3).</p> <p>CD30</p> <p>CD31</p> <p>CD34</p> <p>CD44</p> <p>CD45 (LCA)</p> <p>CD56</p> <p>CD68 (PGM1)</p> <p>CD79a</p>



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<p>HUMAN BODY TISSUE (cont'd)</p> <p>Formalin Fixed Paraffin Embedded Tissue (FFPE) sections and cell block sections (cont'd)</p>	<p><u>Histological and Cytological examinations to assist in clinical diagnosis (cont'd)</u></p> <p>Immunochemistry for the identification of: (cont'd)</p> <p>Gastro-intestinal tumours (GIST) Mast cells Seminomas Small cell carcinoma of lung</p> <p>Plasma cells Myeloma Some carcinomas and melanomas</p> <p>Proliferation and differentiation of intestinal epithelial cells. GI tract; ovary; bladder; pancreas Ca.</p> <p>Adenocarcinoma vs. mesothelioma</p> <p>Neuroendocrine differentiation Pancreatic islet cells</p> <p>Tumour cells of epithelial origin. SCC Basal cell marker (prostate glands) Papillary Ca. thyroid</p> <p>Squamous epithelium Squamous cell carcinoma Mesothelioma</p> <p>Cytokeratin found in glandular and transitional epithelium. Ovarian/breast & lung adenoca.</p> <p>Squamous epithelium Basal and myoepithelial differentiation SCC & breast cancer positive – poor prognosis</p>	<p>Macroscopic and Microscopic Examination using documented in house methods and manufacturers' instructions for:</p> <p>Immunohisto/cytochemical staining Automated using the Leica Bond III Immunostainer (X3).</p> <p>CD117 (c-kit)</p> <p>CD138</p> <p>CDX2</p> <p>CEA (Carcinoembryonic antigen)</p> <p>Chromogranin A</p> <p>CK34βE12 (CK1/10)</p> <p>CK5/6 cytokeratin</p> <p>CK7</p> <p>CK14</p>



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HUMAN BODY TISSUE (cont'd)	<u>Histological and Cytological examinations to assist in clinical diagnosis (cont'd)</u>	Macroscopic and Microscopic Examination using documented in house methods and manufacturers' instructions for:
Formalin Fixed Paraffin Embedded Tissue (FFPE) sections and cell block sections (cont'd)	<p>Immunohistochemistry for the identification of: (cont'd)</p> <p>Basal cells and myoepithelial cells of complex epithelia. BCC & SCC</p> <p>Epithelial cells of appendix and large pancreatic ducts. Papillary thyroid carcinoma Some oral cancers</p> <p>Gastrointestinal epithelium Urothelium & Merkel cells Colorectal Ca.; some gastric tumours TCC bladder</p> <p>Mantle cell lymphoma vs. small B-cell lymphoma</p> <p>Cytomegalovirus inclusions</p> <p>Intermediate filament protein found in both striated and smooth muscle cells. Leiomyosarcomas Rhabdomyosarcomas</p> <p>Gastrointestinal tumours (GIST)</p> <p>Epithelial cell membranes (cell adhesion molecule) Ductal vs. lobular breast cancer</p> <p>Normal epithelial cells (except squamous cells or hepatocytes). Some carcinomas and plasma cell tumours.</p>	<p>Immunohisto/cytochemical staining Automated using the Leica Bond III Immunostainer (X3).</p> <p>CK17</p> <p>CK19</p> <p>CK20</p> <p>Cyclin D1</p> <p>Cytomegalovirus (CMV)</p> <p>Desmin</p> <p>DOG-1</p> <p>E-Cadherin</p> <p>Epithelial Membrane Antigen (EMA)</p>



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HUMAN BODY TISSUE (cont'd)	<u>Histological and Cytological examinations to assist in clinical diagnosis (cont'd)</u>	Macroscopic and Microscopic Examination using documented in house methods and manufacturers' instructions for:
Formalin Fixed Paraffin Embedded Tissue (FFPE) sections and cell block sections (cont'd)	<p>Immunohistochemistry for the identification of: (cont'd)</p> <p>Endothelial cells Megakaryocytes Benign blood vessels Angiogenesis in neoplasms</p> <p>Dermal dendrocytes Dermatofibroma vs.DFSP Atypical fibroxanthoma</p> <p>Epithelial cells of sweat glands Apocrine differentiation marker Breast tumours (primary & metastatic)</p> <p>Glial cells- astrocytes/ependymal cells Schwann cells. Gliomas.</p> <p>Membrane glycoprotein found on RBCs. Some leukaemias (erythroid lineage)</p> <p>Placental trophoblasts secreting HCG. Tumours of trophoblast origin e.g. choriocarcinomas and teratomas. Germ cell tumour classification. Adenocarcinoma lung and prostate.</p> <p>Mesothelial cells. Lung; colon & breast adenocarcinoma Follicular/papillary thyroid tumours- Benign vs. malignant.</p>	<p>Immunohisto/cytochemical staining Automated using the Leica Bond III Immunostainer (X3).</p> <p>Factor VIII (von Willebrand Factor)</p> <p>Factor XIIIa</p> <p>GCDFP15 (Gross Cystic Disease Fluid Protein)</p> <p>GFAP (Glial Fibrillary Acidic Protein)</p> <p>Glycophorin C</p> <p>Human Chorionic Gonadotrophin (HCG)</p> <p>HBME-1</p>



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<p>HUMAN BODY TISSUE (cont'd)</p> <p>Formalin Fixed Paraffin Embedded Tissue (FFPE) sections and cell block sections (cont'd)</p>	<p><u>Histological and Cytological examinations to assist in clinical diagnosis (cont'd)</u></p> <p>Immunohistochemistry for the identification of: (cont'd)</p> <p>Hairy cell leukaemia High & low grade B-cell lymphomas</p> <p>Hepatocyte marker Hepatocellular carcinoma (HCC) HCC vs. cholangiocarcinoma</p> <p>Invasive breast carcinoma</p> <p>Melanoma (except desmoplastic type)</p> <p>Immunoglobulin producing cells, mainly used in renal biopsy diagnosis.</p> <p>Granulosa cell tumours Adrenal cortical tumours Leydig cell tumours of the testis Sertoli cell tumours Sex cord stromal tumours</p> <p>Myeloma Plasma cells B-lymphocytes</p> <p>Proliferating germinal centre cells Cell proliferation marker Lymphomas</p> <p>Melanocytes Melanoma</p> <p>Ewing's sarcoma Neuroectodermal tumours (PNET)</p>	<p>Macroscopic and Microscopic Examination using documented in house methods and manufacturers' instructions for:</p> <p>Immunohisto/cytochemical staining Automated using the Leica Bond III Immunostainer (X3).</p> <p>Hairy Cell Leukaemia (HCL) DBA.44</p> <p>Hep Par-1</p> <p>Her2 gene protein</p> <p>HMB45</p> <p>Immunoglobulins – IgA; IgG; IgM C3c & C1q complement</p> <p>Inhibin (peptide hormone)</p> <p>Kappa & Lambda light chains</p> <p>Ki-67 (MIB-1)</p> <p>Melan-A (MART-1)</p> <p>MIC 2 (CD99)</p>



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HUMAN BODY TISSUE (cont'd)	<u>Histological and Cytological examinations to assist in clinical diagnosis (cont'd)</u>	Macroscopic and Microscopic Examination using documented in house methods and manufacturers' instructions for:
Formalin Fixed Paraffin Embedded Tissue (FFPE) sections and cell block sections (cont'd)	<p>Immunohistochemistry for the identification of: (cont'd)</p> <p>Cytokeratins (broad spectrum) Epithelial cells Squamous cell carcinoma; small cell carcinoma; adenocarcinoma; mesotheliomas.</p> <p>Lymphoid malignancy Myeloma Lymphoplasmacytic lymphoma Diffuse large B-cell lymphoma</p> <p>Granulocytes & histiocytes Acute myeloid leukaemia (AML)</p> <p>Embryonic stem cells and germ cells of ovary /testis. Testicular seminoma Embryonal carcinoma</p> <p>Breast tumour & normal glands Prognostic indicators</p> <p><i>Tumour suppressor protein High grade squamous epithelial lesions (cervix & oral lesions)</i></p> <p>Tumour suppressor gene (poor prognosis/ high grade lesions). Ca. breast; prostate & bladder. Papillary serous carcinoma (ovary/uterus)</p> <p>Tumour suppressor gene. Basal squamous cells; urothelium & myoepithelial breast cells. Poorly differentiated lung SCC vs. small cell.</p>	<p>Immunohisto/cytochemical staining Automated using the Leica Bond III Immunostainer (X3).</p> <p>MNF116</p> <p>MUM -1 protein (Multiple Myeloma Oncogene 1)</p> <p>Myeloperoxidase</p> <p>OCT 3/4</p> <p>Oestrogen Receptor (ER) & Progesterone (PR) hormones</p> <p><i>p16 gene – exported to Source bioscience</i></p> <p>p53 gene</p> <p>p63 gene</p>



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HUMAN BODY TISSUE (cont'd)	<u>Histological and Cytological examinations to assist in clinical diagnosis (cont'd)</u>	Macroscopic and Microscopic Examination using documented in house methods and manufacturers' instructions for:
Formalin Fixed Paraffin Embedded Tissue (FFPE) sections and cell block sections (cont'd)	<p>Immunohistochemistry for the identification of: (cont'd)</p> <p>Anaplastic large cell lymphoma Transmembrane tyrosine kinase receptor. Glial cells, neurons & endothelial cells.</p> <p>Germ cell tumours, including seminomas. Placental trophoblasts.</p> <p>Secretory and ductal epithelium of the prostate (benign & malignant). Prostatic adenocarcinoma</p> <p>Schwann cells; adipocytes; cartilage. Melanocytes Myoepithelial cells Follicular dendritic cells; Langerhan's Melanoma</p> <p>Smooth muscle; myofibroblasts; myoepithelium; pericytes. Leiomyosarcoma</p> <p>Contractile apparatus in smooth muscle cells. Smooth muscle cell tumours and myoepithelial tumours In-situ vs. invasive breast cancer.</p> <p>Neruroendocrine differentiation Neuroblastomas Ganglioneuromas Phaeochromocytomas Pancreatic islet cells</p>	<p>Immunohisto/cytochemical staining Automated using the Leica Bond III Immunostainer (X3).</p> <p>p80 (ALK-1, Anaplastic Lymphoma Kinase 1)</p> <p>PLAP (Placental Alkaline Phosphatase)</p> <p>PSA (Prostate Specific Antigen)</p> <p>S100 protein</p> <p>Smooth Muscle Actin (SMA)</p> <p>Smooth Muscle Myosin Heavy Chain (SM-MHC)</p> <p>Synaptophysin</p>



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HUMAN BODY TISSUE (cont'd)	<u>Histological and Cytological examinations to assist in clinical diagnosis (cont'd)</u>	Macroscopic and Microscopic Examination using documented in house methods and manufacturers' instructions for:
Formalin Fixed Paraffin Embedded Tissue (FFPE) sections and cell block sections (cont'd)	<p>Immunochemistry for the identification of: (cont'd)</p> <p>B & T cell lymphocytes Acute lymphoblastic leukaemias (ALL) Acute lymphocytic leukaemias Some myeloid leukaemias Lymphoblastic lymphoma Thymoma</p> <p>Endothelium & mesothelial cells Lymphatic & vascular tumours Mesothelioma Urothelial bladder tumours</p> <p>Thyroid follicular epithelial cells Papillary & follicular thyroid carcinoma</p> <p>Follicular thyroid epithelial cells (& C cells). Type II pneumocytes. Thyroid and lung carcinomas</p> <p>Intermediate filament protein present in mesenchymal cells, such as fibroblasts and endothelial cells. Sarcomas Lymphomas Some carcinomas</p> <p>Mesothelial cells Myoepithelial cells of breast Desmoplastic small round cell tumours Mesothelioma vs. adenocarcinoma Renal Wilm's tumour Endometrial carcinoma Ovarian serous carcinoma Acute leukaemia</p>	<p>Immunohisto/cytochemical staining Automated using the Leica Bond III Immunostainer (X3).</p> <p>TdT (Terminal Deoxynucleotidyl Transferase)</p> <p>Thrombomodulin</p> <p>Thyroglobulin</p> <p>TTF-1 (Thyroid Transcription Factor)</p> <p>Vimentin</p> <p>Wilms' Tumour -1 Gene Protein (WT1)</p>



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HUMAN BODY TISSUE (cont'd) Stained tissue slides	<u>Histological and Cytological examinations to assist in clinical diagnosis (cont'd)</u> Morphological assessment and interpretation / diagnosis	Macroscopic and Microscopic Examination using documented in house methods and manufacturers' instructions for: Medical Reporting of Histology and Non-Gynaecological specimen Cases - HIST-ALL-PR-47
END		