


# Schedule of Accreditation

issued by

## United Kingdom Accreditation Service

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

 <p>Accredited to ISO 15189:2012</p>	<h3>Bedfordshire Hospitals NHS Foundation Trust</h3> <p>Issue No: 006    Issue date: 15 July 2020</p>	
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<p><b>Testing provided at the above address only</b></p>		

### DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN TISSUES AND FLUIDS	<p><u>Histopathology examination activities for the purpose of clinical diagnosis</u></p> <p>Preparation and examination to identify or exclude morphological &amp; cytological abnormalities</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>Macroanalysis and dissection</u> Manual method using: BED-SOP-347 Dissection for Histopathologists BED-SOP-361 Dissection room BED-SOP-626 Dissection for Biomedical Scientists</p> <p><u>Decalcification</u> Manual method using: BED-SOP-361 Dissection room</p> <p><u>Tissue Processing</u> Automated method using: BED-SOP-356 Tissue Processing and tissue processors: Sakura VIP 6 Leica ASP300S</p>
Formalin fixed tissues		
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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Histopathology examination activities for the purpose of clinical diagnosis (cont'd)</u>	
Formalin fixed tissues	Preparation and examination to identify or exclude morphological & cytological abnormalities	<u>Embedding</u> Manual method using: BED-SOP-349 Embedding Centre Operation and Maintenance and embedding centres: Sakura Tissue Tek Leica EG1150
Formalin fixed, paraffin embedded (FFPE) tissue		<u>Microtomy</u> Manual method using: BED-SOP-351 Microtomy and microtomes: Leica RM2235 Leica RM2035
FFPE tissue	Basophilic & eosinophilic tissue structures	<u>Routine Haematoxylin &amp; Eosin (H&amp;E) staining and coverslipping</u> Automated method using: BED-SOP-355 Staining Machine BED-SOP-715 Mounting Stained Slides in Cellular Pathology and: Leica XL ST5010 stainer Leica CV5030 coverslipper
FFPE tissue (unless stated) and Cytological preparations	Detection of the following:  Acid and sulphated mucins  Polysaccharides Mucosubstances  Amyloid	<u>Special staining</u> Manual methods using: BED-SOP-355 Special Stains BED-SOP-715 Mounting Stained Slides in Cellular Pathology and the following stains:  Alcian Blue  Alcian Blue Periodic Acid Schiff's (ABPAS)  Congo Red (Puchtler's modification)



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Histopathology examination activities for the purpose of clinical diagnosis (cont'd)</u>	
	Detection of the following:	<u>Special staining, manual (cont'd)</u>
FFPE tissue (unless stated)	Glycogen concentration	Alcian Blue Diastase Periodic Acid Schiff's (ABDPAS)
	Amyloid	Highman's Crystal Violet
	Elastic fibres & collagen	Miller's Elastic Van Gieson (EVG)
and Cytological preparations	Gram positive & gram negative organisms	Gram's
and Cytological preparations	Fungal organisms (inc. <i>Pneumocystis jiroveci</i> )	Grocott's methanamine silver
	Basophilic & eosinophilic tissue structures	H&E (manual)
	Collagen and fibrosis	Haematoxylin Van Gieson (HVG)
	Myelin sheath	Luxol Fast Blue
	5HT in melanin and lipofuscins	Masson Fontana
	Collagen and smooth muscle	Masson Trichrome
and Cytological preparations	<i>Helicobacter pylori</i>	May Grunwald Giemsa
	DNA, RNA	Methyl Green Pyronin
Cytological preparations only	Hydrophobic (neutral) lipids	Oil Red O
and Cytological preparations	Liberated aldehydes	Periodic Acid Schiff's (+/- diastase)
and Cytological preparations	Haemosiderin	Perls' Prussian Blue



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<p>HUMAN TISSUES AND FLUIDS (cont'd)</p> <p>and Cytological preparations</p> <p>FFPE tissue</p>	<p><u>Histopathology examination activities for the purpose of clinical diagnosis (cont'd)</u></p> <p>Detection of the following:</p> <p>Mast cell granules</p> <p>Calcium salts</p> <p>Acid fast bacilli, e.g. <i>M. tuberculosis</i></p> <p>Detection of the following:</p> <p>Cytokeratins 1, 5, 10, 14</p> <p>Muscle</p> <p>Cytokeratins 65-67, 64, 59, 58, 56.5, 54, 52, 50, 48</p> <p>Granular cell tumour versus histolytic reaction</p> <p>Mantle zone B lymphocytes &amp; interfollicular T lymphocytes and other rare tumour types</p> <p>Cell membrane glycoproteins expressed on healthy epithelia and in various carcinomas</p>	<p><u>Special staining, manual (cont'd)</u></p> <p>Toluidine Blue Metachromatic</p> <p>Von Kossa</p> <p>Ziehl-Neelsen</p> <p><u>Immunohistochemistry</u> Automated methods using: BED-SOP-624 Immunocytochemistry BED-SOP-715 Mounting Stained Slides in Cellular Pathology and: Roche Ventana Benchmark Autostainer and the following antibodies:</p> <p>34-Beta anti-cytokeratin</p> <p>Actin</p> <p>AE1/3</p> <p>Alphafetoprotein</p> <p>Bcl 2-oncoprotein</p> <p>BerEp4</p>



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<p>HUMAN TISSUES AND FLUIDS (cont'd)</p> <p>FFPE tissue</p>	<p><u>Histopathology examination activities for the purpose of clinical diagnosis (cont'd)</u></p> <p>Detection of the following:</p> <p>Calcium binding protein structurally related to S100 and inhibin</p> <p>Cancer antigen 125</p> <p>Cytokeratins 7, 8</p> <p>Normal, early progenitor lymphoid cells; B lymphocytes in germinal centres</p> <p>Stem cell factor receptor, proto-oncogene activated in GIST tumors</p> <p>Hodgkin's &amp; Reed-Sternberg cells</p> <p>B lymphocytes</p> <p>T lymphocytes; helper/inducer T lymphocytes</p> <p>Hodgkin's &amp; Reed-Sternberg cells</p> <p>Endothelial cells; plasma cells; activated B &amp; T lymphocytes</p> <p>Haemopoietic precursor cells; endothelial cells; fibroblasts; other cell types in various solid tumours</p> <p>T &amp; B lymphocytes</p> <p>Peripheral nerves; NK cells; neuroendocrine differentiation</p> <p>Macrophages; monocytes; granulocytes</p> <p>Fairly specific marker of GI origin for adenocarcinomas</p>	<p><u>Immunohistochemistry</u> Automated using Roche Ventana Benchmark Autostainer (cont'd)</p> <p>Calretinin</p> <p>CA125</p> <p>CAM 5.2</p> <p>CD10</p> <p>CD117</p> <p>CD15</p> <p>CD20</p> <p>CD3</p> <p>CD30</p> <p>CD31</p> <p>CD34</p> <p>CD45 / LCA</p> <p>CD56</p> <p>CD68</p> <p>CDX2</p>



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<p>HUMAN TISSUES AND FLUIDS (cont'd)</p> <p>FFPE tissue</p>	<p><u>Histopathology examination activities for the purpose of clinical diagnosis (cont'd)</u></p> <p>Detection of the following:</p> <p>Adenocarcinomas, epithelial cells of the glandular lumen</p> <p>Neuroendocrine cells and tumours</p> <p>Epithelia</p> <p>GI epithelia</p> <p>Squamous epithelium</p> <p>Simple, glandular &amp; transitional epithelia</p> <p>Identification of cells of epithelial origin</p> <p>Cytomegalovirus viral inclusions</p> <p>Smooth &amp; striated muscle cells</p> <p>Interstitial cells of Cajal in GI tract, GIST</p> <p>E-cadherin positive cells in normal and neoplastic tissues</p> <p>Glandular &amp; ductal epithelia, perineurium; other cell types in various tumours</p> <p>Cellular estrogen receptor expression</p> <p>Positivity seen in dermatofibroma, haemangioblastoma, hepatocellular carcinoma</p> <p>Trophoblastic elements, e.g. in germ cell tumours</p> <p>Activated melanocytes; melanocytic tumours</p>	<p><u>Immunohistochemistry</u> Automated using Roche Ventana Benchmark Autostainer (cont'd)</p> <p>Carcino-embryonic antigen</p> <p>Chromogranin A</p> <p>Cytokeratin 19</p> <p>Cytokeratin 20</p> <p>Cytokeratins 5 &amp; 6</p> <p>Cytokeratin 7</p> <p>Cytokeratin MNF 116</p> <p>CMV</p> <p>Desmin</p> <p>DOG-1</p> <p>E-cadherin</p> <p>Epithelial membrane antigen (EMA)</p> <p>Oestrogen receptor</p> <p>Factor 13A</p> <p>Human Chorionic Gonadotropin</p> <p>Human melanoma black 45 antigen</p>



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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Histopathology examination activities for the purpose of clinical diagnosis (cont'd)</u>	<u>Immunohistochemistry</u> Automated using Roche Ventana Benchmark Autostainer (cont'd)
FFPE tissue	Detection of the following:  Proliferating cells; cells in cycle  Normal, activated & neoplastic melanocytes  p16INK4a oncoprotein (Normal, activated and neoplastic melanocytes)  Carcinomas; many neoplasms and normal cells  Normal proliferating cells; poorly differentiated squamous cell carcinoma, basal cells; abluminal cells  Placental Alkaline Phosphatase in germ cell tumours, particularly seminomas; also breast, lung, ovarian carcinomas  Cellular progesterone receptor expression  Prostate specific antigen  Prostate carcinoma  Smooth muscle myosin heavy chain  Synaptic vesicle protein (neurones; neuroendocrine cells)  Thyroid follicles  Thyroid follicular & C cells, lung cancer  Vimentin intermediate filament  WT1 expression	Ki-67 nuclear antigen  Melan A (MART-1) differentiation antigen  p16  p53 tumour suppressor protein  p63  PLAP  Progesterone receptor  PSA  Racemase / AMACR  SMMHC  Synaptophysin  Thyroglobulin protein  Thyroid transcription factor-1  Vimentin  WT1







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<p>HUMAN TISSUES AND FLUIDS (cont'd)</p> <p>Cerebrospinal fluid (CSF) Urine General body fluids Bronchial Brushings Bronchial Washings Sputum</p> <p>Slides prepared in-house from sample types listed above</p> <p>Ejaculate</p>	<p><u>Diagnostic cytology examination activities for the purpose of clinical diagnosis</u> (cont'd)</p> <p>Preparation and examination of cellular material to identify or exclude morphological &amp; cytological abnormalities</p> <p>Morphological assessment and interpretation/diagnosis</p> <p><u>Andrology examination activities for the purpose of clinical diagnosis</u></p>	<p><u>Papanicolaou staining</u> Automated using in-house procedures: BED-SOP-297 Cytology Staining Machine &amp; Coverslipper in conjunction with manufacturer's instructions using: Leica Autostainer ST5020 Leica 5030 coverslipper</p> <p><u>Microscopy (qualitative analysis)</u> In-house procedures: BED-SOP-809 Diagnostic Cytology Reporting using microscopes as follows: Leica DMLB Leica DM2000 Nikon Eclipse E600</p> <p><u>Semen Analysis</u> In-house procedures following the guidelines below:</p> <p>WHO Laboratory Manual for the Examination of Human Semen and Sperm-Cervical Mucus Interaction 5th Edition.</p> <p>2016 Laboratory guidelines for post vasectomy 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</p>



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Ejaculate	Fertility screening:  Semen pH Semen volume	Manual methods using in-house procedures: BED-SOP-396 Infertility Semen Analysis BED-SOP-655 Preparation of Semen Samples from Andrology
Ejaculate	Sperm concentration Sperm motility Sperm vitality Sperm morphology	Manual microscopy method using in-house procedure s: BED-SOP-396 Infertility Semen Analysis BED-SOP-655 Preparation of Semen Samples from Andrology Using: Leica DMLB Leica DM2000 Nikon Eclipse E600
Ejaculate	Post-vasectomy semen analysis (PVSA):  Detection of sperm	Centrifugation followed by microscopy using in-house procedure: CPC-SOP-83 Semen Analysis (Manual Method) using: Heraeus Megafuge Leica DMLB Leica DM2000 Nikon Eclipse E600
END		