


# Schedule of Accreditation

issued by

## United Kingdom Accreditation Service

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

 <b>UKAS</b> MEDICAL <b>8914</b>  Accredited to <b>ISO 15189:2012</b>	<b>Torbay and South Devon NHS Foundation Trust</b>	
	<b>Issue No: 003    Issue date: 25 February 2019</b>	
	<b>Histopathology Department</b> <b>South Devon Healthcare NHS</b> <b>Foundation Trust</b> <b>Lowes Bridge</b> <b>Torquay</b> <b>Devon</b> <b>TQ2 7AA</b>	<b>Contact: Nikki Harwood</b> <b>Tel: +44 (0)1803 655261</b> <b>E-Mail: <a href="mailto:nikki.harwood@nhs.net">nikki.harwood@nhs.net</a></b> <b>Website: <a href="http://www.sdhct.nhs.uk">http://www.sdhct.nhs.uk</a></b>
<b>Testing performed at the above address only</b>		

### Locations covered by the organisation and their relevant activities

#### Laboratory locations:

Location details	Activity
<p>Histopathology Department South Devon Healthcare NHS Foundation Trust Lowes Bridge Torquay Devon TQ2 7AA</p> <p><b>Local contact</b> Peter Foot Tel: +44 (0)1803 655215 Email: <a href="mailto:peterfoot@nhs.net">peterfoot@nhs.net</a></p>	<p>Routine Histopathology Special Stains Immunohistochemistry Diagnostic Cytology Mortuary Services Frozen Section Histology Screening (bowel cancer) Mortuary Services (body receipt, storage and release) OSNA FNA - Slide production, staining &amp; mounting of fine needle aspirates for diagnostic cytology</p>



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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>Tissue: biopsy, excision, resection and post-mortem specimens</p> <p>Formalin Fixed Paraffin wax blocks of processed tissue.</p> <p>Skin in Michel's Medium Renal tissue in saline Tissue for frozen sections</p> <p>FFPE slides (Formalin fixed paraffin embedded) tissue on glass slides</p>	<p><u>Histopathological examination activities for the purposes of clinical diagnosis</u></p> <p>Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis</p>	<p>In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:</p> <p>Specimen dissection using Astecair Down-flow Cut-up Table, Cassette printers and in-house documented procedures: Specimen Reception LP HIS 17 BMS Cut Up LP HIS 18 Handling of High Risk Specimens LP HIS 11 PrintMate User Guide LP HIS 14 PrintMate Set Up Guide LP HIS 13</p> <p>Tissue processing Routine Use of Excelsior Tissue Processor LP HIS 2 Reprocessing of Tissue Blocks LP HIS 21</p> <p>Decalcification LP HIS 22</p> <p>Tissue Embedding Using Histostar Embedding Centre and in-house documented procedure LP HIS 3</p> <p>Tissue Sectioning Using Leica Microtomes, Microtomy LP HIS 4</p> <p>Cryotomy Intra-operative Frozen sections Using Thermo FS and FSE cryostat Cryotomy LP HIS 5</p> <p>Interpretive/diagnostic microscopy Standard Microscope LP CEL 3 Routine Use of the Olympus Fluorescent Microscope LP HIS 7 Internal Quality Control QP CEL 2</p>



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HUMAN BODY TISSUE (cont'd)	<u>Histopathological examination activities for the purposes of clinical diagnosis (cont'd)</u>	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:
FFPE slides (Formalin fixed paraffin embedded) and frozen sections	Detection of Basophilic and eosinophilic structures	Morphological staining; Tissue Tek Prisma stainer and Thermo Linistat stainer using Haematoxylin and Eosin (H & E) stains and Rapid H&E for Frozen Section staining, using in-house documented procedure: Operation and Maintenance of the Tissue Tek Prisma Automated Slide Stainer LP CEL 13 Cryotomy LP HIS 5
FFPE slides	Detection of:	Documented in-house procedures for manual special stains:
	Acid Mucopolysaccharides	Alcian Blue SOP LP HIS 26
	Acid and Neutral Mucopolysaccharides	Alcian Blue/PAS SOP LP HIS 27
	Amyloid	Congo Red (SOP LP HIS 28)
	Elastic fibres and connective tissue	Elastic/Haematoxylin Van Gieson (EVG/HVG) (SOP LP HIS 29)
	Haematopoietic cells	Giemsa (SOP LP HIS 30)
	Gram positive and negative bacteria	Gram (SOP LP HIS 31)
	Nuclei and connective tissue	HVG (SOP LP HIS 33)
	Melanin	Masson Fontana (SOP LP HIS 36)
	Connective Tissue	Masson Trichrome (SOP LP HIS 35)
		Documented in-house procedures for manual special stains
FFPE slides	Removal of melanin pigment	Schmorl's (SOP LP HIS 38)
	Lipofucshin / Melanin	Schmorl's (SOP LP HIS 38)



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HUMAN BODY TISSUE (cont'd)	<u>Histopathological examination activities for the purposes of clinical diagnosis (cont'd)</u>  <i>H. pylori</i>  Fibrin connective tissue  Polysaccharides including glycogen  Hemosiderin  Reticulin fibres  Hepatitis B surface antigen and copper associated protein  Mast Cells  <i>Mycobacterium leprae</i>  <i>Mycobacterium spp including tuberculosis</i>  Spirochetes	Documented in-house procedures for manual special stains (cont'd)  Modified Giemsa (SOP LP HIS 30)  MSB (SOP LP HIS 34)  PAS (SOP LP HIS 27)  Perls Russian Blue (SOP LP HIS 37)  Reticulin (SOP LP HIS 44)  Shikata's Orcein (SOP LP HIS 40)  Toluidine Blue (SOP LP HIS 39)  Wade Fite (SOP LP HIS 43)  Ziehl Neelsen (SOP LP HIS 42)  Warthin Starry (SOP LP HIS 41)
FFPE slides	<u>Immunohistochemistry</u>          Detection of : Foetal Liver Cells Large cell Lymphoma Epithelial Cells	Documented in-house methods used in accordance with manufacturer's operating instructions for the use of Benchmark Ultra automated immunostainers. User Maintenance and Decontamination of Ventana Ultras LP HIS 23 New IHC Antibody or ISH Probe Procedure/Modification LP HIS 25 Ordering and Stock Control of the Ventana Benchmark Ultras LP HIS 9 Registering Reagents on the Ventana Ultra Inventory LP HIS 12 IHC and ISH Using the Ventana Benchmark Ultra System LP HIS 16 Incorporating the following antibodies : AFP ALK 1 BerEp4



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<p>HUMAN BODY TISSUE (cont'd)</p> <p>FFPE slides</p>	<p><u>Histopathological examination activities for the purposes of clinical diagnosis (cont'd)</u></p> <p><u>Immunohistochemistry (cont'd)</u></p> <p>T-cells, B-cells in the mantle zone Follicular centre B-cells Luminal cells of the fallopian tube Parafollicular (C-Cells) Mesothelial cell lining Low molecular weight marker T-cell marker T-helper cells T-cells, B-cells in the mantle zone Cytotoxic T-cells Immature B Lymphocytes B-cell marker Mature B-cells and FDC FDC and EBV transformed blasts RS Cells Endothelial Marker Plasma cells and activated T-Cell T-cell and myeloid cells Leukocyte common antigen Neural cell adhesion molecule Neuroendocrine Macrophages Intestinal epithelial B-Cell marker Mast cells and GIST Carcinoembryonic antigen Plasma cells Mantle cell lymphoma Broad-range cytokeratin</p>	<p>Documented in-house methods used in accordance with manufacturer's operating instructions for the use of Benchmark Ultra automated immunostainers. User Maintenance and Decontamination of Ventana Ultras LP HIS 23 New IHC Antibody or ISH Probe Procedure/Modification LP HIS 25 Ordering and Stock Control of the Ventana Benchmark Ultras LP HIS 9 Registering Reagents on the Ventana Ultra Inventory LP HIS 12 IHC and ISH Using the Ventana Benchmark Ultra System LP HIS 16</p> <p>Bcl-2 oncoprotein Bcl-6 Ca125 Calcitonin Calretinin Cam 5.2 CD3 CD4 CD5 (407) CD8 CD15 CD20 (L26) CD21 CD23 CD30 (Ber-H2) CD34 CD38 CD43 CD45 (LCA) CD56 ChromograninA CD68 CDX2 CD79a CD117 (c-kit) CEA (Poly) CD138 CyclinD1 Cytokeratin AE1/AE3</p>



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<p>HUMAN BODY TISSUE (cont'd)</p> <p>FFPE slides</p>	<p><u>Histopathological examination activities for the purposes of clinical diagnosis (cont'd)</u></p> <p><u>Immunohistochemistry (cont'd)</u></p> <p>Squamous and myoepithelial Gastrointestinal epithelia Glandular, transitional epithelia Mesenchymal marker Oestrogen Receptor Epithelial membrane antigen Epithelial cells Cell adhesion molecule GIST Intermediate filament Monocytes Lung adenocarcinoma Prostate specific antigen Progesterone Receptor Seminoma Placental Alkaline Phosphatase Basal cell marker Melanoma, neuroendocrine Mesenchymal marker Non squamous epithelium / adenocarcinoma Fibromatosis Neutral metalloendopeptidase Neoplastic plasma cells Cytomegalovirus DNA binding protein Ebstein Barr Virus Hepatocytes</p>	<p>Documented in-house methods used in accordance with manufacturer's operating instructions for the use of Benchmark Ultra automated immunostainers.</p> <p>User Maintenance and Decontamination of Ventana Ultras LP HIS 23 New IHC Antibody or ISH Probe Procedure/Modification LP HIS 25 Ordering and Stock Control of the Ventana Benchmark Ultras LP HIS 9 Registering Reagents on the Ventana Ultra Inventory LP HIS 12 IHC and ISH Using the Ventana Benchmark Ultra System LP HIS 16</p> <p>Cytokeratin 5/6 Cytokeratin 20 Cytokeratin 7 Muscle specific actin ER EMA Cytokeratin 19 E-Cadherin DOG-1 Desmin Myeloperoxidase Napsin PSA Progesterone Receptors Oct 4 PLAP P63 S100 SMA Ber EP4</p> <p>Beta Catenin CD10 CD138 CMV c-MYC Eber ISH Hepatocyte</p>



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FFPE slides	<u>Immunohistochemistry (cont'd)</u>  Heavy chain muscle Cell cycle regulator linked to HPV Neuroendocrine marker Early B-Cell, thymocytes marker Lumen of thyroid follicles Thyroid Transcription factor-1 Mesenchymal Marker Wilms tumour gene product	Myosin P16 Synaptophysin Tdt Thyroglobulin TTF-1 Vimentin WT-1
frozen tissue	Identification of auto-immune skin diseases  Gamma Chains  Alpha Chains  Mu Chains	Manual method using in-house documented procedures: Routine Use of the Olympus Fluorescent Microscope LP HIS 7 Immunofluorescence using the Ventana Benchmark Ultra LP HIS 6 IHC & IHS using the Ventana Benchmark Ultra LP HIS 16  Incorporating the following antibodies:  IgG fluorescein isothiocyanate  IgA fluorescein isothiocyanate  IgM fluorescein isothiocyanate



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HUMAN BODY TISSUE (cont'd)	<u>Histopathological examination activities for the purposes of clinical diagnosis (cont'd)</u>	Documented in-house methods used in accordance with manufacturer's operating instructions for the use of Benchmark Ultra automated immunostainers. User Maintenance and Decontamination of Ventana Ultras LP HIS 23 New IHC Antibody or ISH Probe Procedure/Modification LP HIS 25 Ordering and Stock Control of the Ventana Benchmark Ultras LP HIS 9 Registering Reagents on the Ventana Ultra Inventory LP HIS 12 IHC and ISH Using the Ventana Benchmark Ultra System LP HIS 16
frozen tissue	Identification of auto-immune skin diseases  C3c fragment of complement	Immunofluorescence using the Ventana Benchmark Ultra LP HIS 6  C3c fluorescein isothiocyanate
Fine needle aspirates – Breast, sputum, urine CSF, oesophageal washings and brushings, Conventional Bronchial Brushings, Serous fluids, Bronchial washings and Bronchial Alveolar lavage samples.	<u>Cytopathology (Non-Gynae) examination activities for the purposes of clinical diagnosis</u>  Examination of cellular material in order to identify or exclude morphological and cytological abnormalities  Demonstration of : Cells (nuclei and cytoplasm) and micro organisms	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:  Diagnostic cytology (non-gynae) in-house documented manual procedures for preparation Clinician Prepared FNA and Brush Smears LP CYT 6 Fluid Cytology Preparation LP CYT 14 May Grunwald Giemsa LP CYT 7 Pretreatment of Respiratory Samples for Thinprep Processing LP CYT 8 Supported FNAs LP CYT 9 Rapi-Diff Staining LP CYT 10 Cytofoam Disk LP CYT 11 Sending of cervical samples to RD&E LP CYT 12 Operation and Maintenance of the Tissue Tek Prisma Automated Slide Stainer LP CEL 13





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<p>HUMAN BODY FLUIDS (cont'd)</p> <p>Fresh surgical lymph node – CK19</p> <p>Mortuary Service</p>	<p><u>Cytopathology (Non-Gynae) examination activities for the purposes of clinical diagnosis (cont'd)</u></p> <p>Molecular analysis of sentinel lymph nodes</p> <p>Admission and release of deceased Post mortem procedure</p>	<p>In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:</p> <p>Documented in house procedure in conjunction with manufacturer's instructions for the operation of Sysmex RD100i OSNA Amplification LP HIS 15 OSNA EQA QP HIS 1</p> <p>Admission, Storage and Release of Deceased in the Mortuary LP MOR 1 Post Mortem LP MOR 2 Management of Deceased Bariatric Patients LP MOR 3 Out of Hours Service MP MOR 1 Viewing of Deceased LP MOR 4 Pacemaker Removal LP MOR 5 Spinal Cord Removal LP MOR 6 Brain Fixation LP MOR 8 Eye Nucleation LP MOR 9 Foetus and Stillborn Policy LP MOR 11 ICD Removal LP MOR 11 Post Mortem Consent LP MOR 14 HTA Reportable Incident (HTARI) Process MP MOR 3 Monitoring in the Mortuary MP MOR 4</p>
END		