


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 Accredited to ISO 15189:2012	Southern Health and Social Care Trust	
	Issue No: 003 Issue date: 24 February 2020	
	Cellular Pathology Craigavon Area Hospital 68 Lurgan Road BT63 5QQ United Kingdom	Contact: James Heaney Tel: +44 (0)28 38612541 E-Mail: James.heaney@southerntrust.hscni.net Website: http://www.southerntrust.hscni.net/
Testing performed at the above address only		

Locations covered by the organisation and their relevant activities

Additional site activity performed away from the laboratory:

Location details	Activities
On-site Body Store	Mortuary Services (body receipt, storage and release)
Fine Needle Aspiration Clinic	EUS and EBUS FNA slide preparation, staining and provisional diagnosis

Site activities performed away from the locations listed above:

Location details	Activities
Daisy Hill Hospital Mortuary – body store 5 Hospital Road Newry BT35 8DR United Kingdom	Mortuary Services (body receipt, storage and release)
South Tyrone Hospital tissue block store Carland Road Dungannon BT71 4AU United Kingdom	Tissue block store



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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 resection and biopsy specimens from the following sites: Head and Neck Cardiorespiratory Breast Gastrointestinal Female genital tract. Urology Skin Osteoarticular and soft tissue Lymph nodes (non-haematological malignancies)</p> <p>Calcified and hard fibrous tissue</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>Tissue Dissection Down flow AFOS dissecting workstations x 5.</p> <p>Balances VWR LPC-213I X4 Operator manual: LPC-213IOPERATORMANUAL Sartorius BL6 x1 Operator manual: SARTORIUSOPMAN</p> <p>Pathlite Macro Camera Station Operator manual: PATHLITE</p> <p>Thermo Printmate AS 450 Cassette Printer x2 SOP:SLIDEPRINTERSOPMANUAL</p> <p>Slicing of calcified and keratinized tissue using band saw Gryphon Diamond Band Saw C-40 SOPs: BANDSAWOPERATORMANUAL; BANDSAWUSE</p>



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<p>HUMAN BODY TISSUE (cont'd)</p> <p>Calcified and hard fibrous tissue</p> <p>Tissue blocks</p> <p>Paraffin wax impregnated tissue blocks and cytology cellblocks</p>	<p><u>Histopathological examination activities for the purposes of clinical diagnosis</u> (cont'd)</p>	<p>In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:</p> <p>Rapid fixation/decalcification and softening of tissue KOS Microwave Multifunction Tissue Processor SOP: KOSMICROWAVEOPERATORMANUAL; DISSECT</p> <p>Tissue processing Fixation, dehydration, clearing and impregnation in paraffin wax in preparation for tissue embedding.</p> <p>Excelsior AS Tissue Processor Operator Manual: EXCELSIOROPMAN Reference SOP TPROCESSEXCEL</p> <p>Tissue paraffin wax manual embedding</p> <p>Paraform and standard cassettes. Operator guide: PARAFORMUSERGUIDE</p> <p>Shandon Histocentre C Operator manual: SHANDONHISTOCENTREOPMAN</p> <p>Thermo Scientific Microme EC 350 Operator manual: TISSUEMBEDCENTHERMOMICROM M Thermo Scientific Histo Star Operator manual: EMBEDCENTHISTOSTAROPMAN</p> <p>Para Trimmer SOP: EMBEDDINGPROTOCO</p>



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<p>HUMAN BODY TISSUE (cont'd)</p> <p>Paraffin embedded tissue and cytology cell blocks.</p> <p>Fresh unfixed tissue</p>	<p><u>Histopathological examination activities for the purposes of clinical diagnosis</u> (cont'd)</p>	<p>In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:</p> <p>Trimming and cutting of tissue sections SOP: SECTIONCUT</p> <p>Biocut 2035, Microm HM325 Leica RM 2125 RTF, RM2125 RTS microtomes</p> <p>Operator manuals: BIOCUT2035OPMAN MICROMHM325OPMAN LEICARTSOPERATORMANUAL</p> <p>Leica HI1210 digitally andthermostatically controlled tissue section floatation water baths. Operator Manuals: WATERBATHOPMAN WATERBATHBOEKEL</p> <p>Electric cold plates TCP100 Cold Plate Operator Manual: COLDPLATEOPERATORMANUAL</p> <p>Thermo Scientific Slidemate AS Printers Operator manual: SLIDEPRINTER; SOPMANUAL</p> <p>Frozen Section preparation: Cryostat OFT/AS Operator manual: CRYOSTATEOFT/ASOPMAN SOP: FROZENSECTION</p>



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HUMAN BODY TISSUE (cont'd)	<u>Histopathological examination activities for the purposes of clinical diagnosis</u> (cont'd)	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:
3-4µm paraffin embedded tissue sections	Identification of basophilic and acidophilic intra- and extracellular structures	Automated H&E staining Ventana HE600, Sakura Prisma. HE600 stainer and coverslipper Prisma automated H&E stainer and coverslipper. Operator manual PRISMAOPERATORMAN SOP: STAINAUTOSTAIN
6-7µm embedded fresh frozen tissue sections	Identification of basophilic and acidophilic intra- and extracellular structures	Staining of frozen sections Prisma automated H&E stainer and coverslipper. Operator manual PRISMAOPERATORMAN SOP: STAINAUTOSTAIN
Slides prepared in house as above	Morphological assessment and interpretation/diagnosis	Immunohistochemical staining using the following equipment and primary antibodies: Light microscopy SOP: MICROSCOPEADJUST
3-4µm paraffin embedded tissue sections	IHC stains for the detection of:	Ventana Benchmark Ultra SOP: IMMUNOSTAIN
	Liver marker	α-1-Fetoprotein
	Apoptosis marker	BCL-2
	Lymphoid marker	BCL-6
	Epithelial marker	Ber EP4
	Ovarian tumour marker	CA125



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HUMAN BODY TISSUE (cont'd)	<u>Histopathological examination activities for the purposes of clinical diagnosis</u> (cont'd)	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:
3-4µm paraffin embedded tissue sections (cont'd)	IHC stains for the detection of: (cont'd)	Immunohistochemical staining (cont'd)
	GI tract and pancreatic marker	CA19.9
	Thyroid tumour marker	Calcitonin
	Smooth muscle marker	Caldesmon
	Smooth muscle marker	Calponin
	Mesothelioma marker	Calretinin
	T lymphocyte marker	CD3
	T helper lymphocyte marker	CD4
	Lymphoid marker	CD5
	T cell lymphocyte marker	CD8
	Lymphoid and endometrial tumour marker	CD10
	Hodgkin's lymphoma marker	CD15
	B lymphocyte marker	CD20
	B cell lymphocyte marker	CD23
	Hodgkin's lymphoma marker	CD30
	Endothelial marker	CD31
	Endothelial marker	CD34
	Lymphocyte marker	CD45



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HUMAN BODY TISSUE (cont'd)	<u>Histopathological examination activities for the purposes of clinical diagnosis</u> (cont'd)	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:
3-4µm paraffin embedded tissue sections (cont'd)	IHC stains for the detection of: (cont'd)	Immunohistochemical staining (cont'd)
	Nerve and neuroendocrine tumour marker	CD56
	Histiocyte/macrophage marker	CD68
	B lymphocyte marker	CD79a
	Ewing's sarcoma marker	CD99
	Plasma cell marker	CD138
	GI tract tumour marker	CDX2
	Epithelial marker	CEA mono
	Epithelial marker and liver tumour marker	CEA poly
	Neuroendocrine cell marker	Chromogranin
	Pre/malignant cervical tumour marker	CINTEC p16
	Secretory epithelial marker	CK-CAM5.2
	Epithelial marker	CK-Pan K (AE1/AE3)CK 7
	Epithelial marker	CK5/6
	Epithelial marker	CK14
	Epithelial marker	CK19
	Epithelial marker	CK20



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<p>HUMAN BODY TISSUE (cont'd)</p> <p>3-4µm paraffin embedded tissue sections (cont'd)</p>	<p><u>Histopathological examination activities for the purposes of clinical diagnosis</u> (cont'd)</p> <p>IHC stains for the detection of: (cont'd)</p> <p>Epithelial marker</p> <p>Gastrointestinal stromal marker</p> <p>Mantle cell lymphoma and breast tumour marker</p> <p>Cytomegalovirus marker</p> <p>Pan muscle marker</p> <p>GI tract stromal tumour marker</p> <p>Lymphocyte channel marker</p> <p>Cell adhesion molecule marker</p> <p>Epithelial marker</p> <p>Prostate Marker</p> <p>Endothelial marker</p> <p>Breast and urothelial marker</p> <p>Mesothelial marker</p> <p>Lung epithelial marker</p> <p>HER2 amplification marker</p> <p>Hepatocyte marker</p> <p>Melanoma marker</p> <p>Granulosa cell and mucinous epithelial ovarian tumour marker</p>	<p>In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:</p> <p>Immunohistochemical staining (cont'd)</p> <p>CK34BE12</p> <p>C-KIT</p> <p>Cyclin D1</p> <p>Cytomegalovirus (CMV)</p> <p>Desmin</p> <p>DOG 1</p> <p>D2-40</p> <p>E-Cadherin</p> <p>EMA</p> <p>ERG</p> <p>Factor V111</p> <p>GATA 3</p> <p>HBME-1</p> <p>HCG</p> <p>HER2</p> <p>Hepatocyte Specific Antigen</p> <p>HMB45</p> <p>Inhibin</p>



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HUMAN BODY TISSUE (cont'd)	<u>Histopathological examination activities for the purposes of clinical diagnosis</u> (cont'd)	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:
3-4µm paraffin embedded tissue sections (cont'd)	IHC stains for the detection of: (cont'd)	Immunohistochemical staining (cont'd)
	Lymphoma marker	KAPPA
	Proliferation marker	Ki67
	Lymphoma marker	Lambda
	Melanoma marker	Melan A
	Lung adenocarcinoma marker	Napsin A
	Germ cell marker	OCT 3/4
	Oestrogen receptor/prognostic breast marker	Oestrogen Receptor(ER)
	Epithelial gynae tumour marker	PAX8
	Nerve and neurocrine marker	PG P9.5
	Germ cell tumour marker	PLAP
	Progesterone receptor/prognostic breast marker	Progesterone Receptor (PR)
	Prostate marker	PSA
	Prostate marker	PSAP
	Prostate and breast tumour marker	P40
	Prostate and tumour marker	P504S
	Wild type P53 tumour marker	P53
	Molar pregnancy marker	P57



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<p>HUMAN BODY TISSUE (cont'd)</p> <p>3-4µm paraffin embedded tissue sections (cont'd)</p> <p>3-4µm paraffin embedded tissue sections</p>	<p><u>Histopathological examination activities for the purposes of clinical diagnosis</u> (cont'd)</p> <p>IHC stains for the detection of: (cont'd)</p> <p>Marker of squamous and urothelial cells / tumours and basal/myoepitheial cells</p> <p>Neural and nerve sheath marker</p> <p>Smooth muscle marker</p> <p>Smooth muscle marker</p> <p>Neural marker</p> <p>Neural cell and neuroendocrine marker</p> <p>Thyroid marker</p> <p>Thyroid and lung marker</p> <p>Mesenchymal tumour marker</p> <p>Wilm's and mesothelioma tumour marker</p> <p>Special stains for the detection of:</p>	<p>In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:</p> <p>Immunohistochemical staining (cont'd)</p> <p>P63</p> <p>S100</p> <p>SM Actin</p> <p>SM Myosin</p> <p>SOX-10</p> <p>Synaptophysin</p> <p>Thyroglobulin</p> <p>TTF-1</p> <p>Vimentin</p> <p>WT-1</p> <p>Special stains - manual</p> <p>WS-6 Downflow Workstation Operator Manual</p> <p>WS-6DOWNFLOWOPMAN</p>



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HUMAN BODY TISSUE (cont'd)	<u>Histopathological examination activities for the purposes of clinical diagnosis</u> (cont'd)	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:
3-4µm paraffin embedded tissue sections (cont'd)	Special stains for the detection of: (cont'd)	Special stains - automated
	Mycobacterium Acid Fast Bacilli	Ventana Benchmark Automated Stainer and the following kits: AFB 3 Kit
	Acid Mucins	Alcian Blue Kit
	Differential identification acid and neutral mucins	Alcian Blue PAS Kit
	Helicobacter	Alcian Yellow Kit
	Amyloid	Congo Red Kit
	Glycogen	Diastase Kit
	Elastin Fibres	Elastin Staining Kit
	Fungi and other opportunistic organisms	GMS 2 Kit
	Gram negative and gram positive bacteria	Gram Kit
	Iron pigment	Iron Staining Kit
	Acid muco-polysaccharides	Mucicarmine Kit
	Glycogen	PAS Kit
	Reticulin fibres	Reticulin Staining Kit
	Spirochetes and helicobacter	Steiner Kit
	Connective tissue and collagen	Trichrome Staining Kit



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<p>HUMAN BODY TISSUE AND FLUIDS</p> <p>Liquid Based Cervical Cell Samples, Human body fluids (except CSF and joint fluids)</p> <p>Respiratory tract specimens (including sputa and bronchoscopy)</p> <p>Urinary tract specimens</p> <p>Liquid Based Cell Samples</p>	<p><u>Gynae and non-gynae cytopathological examination activities for the purposes of clinical diagnosis</u></p> <p>Examination of cellular material to identify or exclude morphological and cytological abnormalities</p> <p>Production of cell monolayer preparations free from red blood cells</p>	<p>In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:</p> <p>Automated gynae and non-gynae LBC slide production SOPs: CYTLBCPROCESSING CYTNGPROCESSING</p> <p>T5000ThinPrep automated LBC Processor and autoloader</p> <p>Operator manual: T5000OPERATORMANUAL</p> <p>MSE Harrier 15/80 Centrifuge Operator manual CENTRIFUGEMSEHARRIER</p> <p>Automated gynae LBC slide production post acid treatment</p> <p>T5000ThinPrep automated LBC Processor and autoloader Operator manual: T5000OPERATORMANUAL SOP: CYTLBCPROCESSING</p> <p>IKA Vibrax Vortexor Operator manual: VORTEXOPERMAN</p> <p>MSE Harrier 15/80 Centrifuge Operator manual: CENTRIFUGEMSEHARRIER</p>



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<p>HUMAN BODY TISSUE AND FLUIDS (cont'd)</p> <p>Human body fluids and tissues including upper GI endoscopy specimens</p> <p>Fine needle aspirates: Soft tissue, abdomen, head and neck, lymph node, breast, lung, hepatobiliary</p> <p>Liquid Based Cervical Cell Samples</p> <p>Liquid Based Cervical Cell Samples</p>	<p><u>Gynae and non-gynae cytopathological examination activities for the purposes of clinical diagnosis (cont'd)</u></p> <p>Production of cell monolayer preparations</p> <p>IHC stains for the detection of: Marker for high grade CIN</p>	<p>In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:</p> <p>Automated non-gynae LBC slide production SOP: CYTNGPROCESSING T2000 ThinPrep Processor Operator manual: T2000OPERATORMANUAL</p> <p>Microflow Class I Operator manual: MICROFLOWCLASS1OPERMAN</p> <p>IKA Vibrax Vortexor Operator manual: VORTEXOPERMAN</p> <p>MSE Harrier 15/80 Centrifuge Operator manual: CENTRIFUGEMSEHARRIER</p> <p>Production of direct smears, cytopspins from non-gynae fluid specimens and centrifuged cellular deposits SOP: CYTNGPROCESSING</p> <p>Microflow Class I Operator manual: MICROFLOWCLASS1OPERMAN</p> <p>MSE Harrier 15/80 Centrifuge Operator manual: CENTRIFUGEMSEHARRIER</p> <p>Cytospin 2 Operator manual: CYTOSPINOPMAN</p> <p>Immunohistochemical staining using Ventana Benchmark Ultra SOP: IMMUNOSTAIN</p> <p>CINtec PLUS</p>



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<p>HUMAN BODY TISSUE AND FLUIDS (cont'd)</p> <p>Non-gynae body fluid/semi fluid specimens (see above)</p> <p>Protein/blood clots in body fluids and centrifuged deposits</p> <p>Gynae and non-gynae cytology cellular slide preparations</p>	<p><u>Non-gynae cytopathological examination activities for the purposes of clinical diagnosis</u></p> <p>Basophilic and acidophilic intra- and extracellular structures</p>	<p>In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:</p> <p>Removal of red blood cells using Histopaque in the 'Density Gradient Centrifugation Technique' and mucin using Dithiothreitol (DTT) SOP: CYTNGPROCESSING</p> <p>Microflow Class I Operator manual: MICROFLOWCLASS1OPERMAN</p> <p>MSE Harrier 15/80 Centrifuge Operator manual: CENTRIFUGEMSEHARRIER</p> <p>IKA Vibrax Vortexor Operator manual: VORTEXOPERMAN</p> <p>Production of cell blocks for H&E and immunocytochemical staining using Thrombin or agar SOP: CYTNGPROCESSING</p> <p>Microflow Class I Operator manual: MICROFLOWCLASS1OPERMAN</p> <p>MSE Harrier 15/80 Centrifuge Operator manual: CENTRIFUGEMSEHARRIER</p> <p>Automated staining Papanicolaou (PAP) staining technique. SOP: STAINAUTOSTAIN</p>



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<p>HUMAN BODY TISSUE AND FLUIDS (cont'd)</p> <p>Gynae and non-gynae cytology cellular slide preparations (cont'd)</p> <p>Alcohol fixed cellular slide preparations</p> <p>Non-gynae cytology air fixed cellular slide preparations.</p> <p>Slides prepared in house as above</p>	<p><u>Non-gynae cytopathological examination activities for the purposes of clinical diagnosis</u> (cont'd)</p> <p>Basophilic and acidophilic intra- and extracellular structures (cont'd)</p> <p>Basophilic and acidophilic intra- and extracellular structures</p> <p>Cytological assessment and interpretation/diagnosis</p>	<p>In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:</p> <p>Sakura Prisma stainer and coverslipper Operator manual: PRISMAOPERATORMAN</p> <p>Non-automated non-gynae PAP staining SOP : CYTNGPROCESSING</p> <p>WS-6 Downflow Workstation Operator Manual: WS-6DOWNFLOWOPMAN</p> <p>Rapi-diff 11 for rapid differential staining of cellular slide preparations SOP: NGSTAINRAPDIFF</p> <p>Light microscopy SOP: MICROSCOPEADJUST</p>
END		