


# 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>	<b>Country Durham and Darlington NHS Foundation Trust</b>	
	<b>Issue No: 001    Issue date: 07 March 2018</b>	
	<b>Cellular Pathology Department</b> University Hospital of North Durham North Road Durham County Durham DH1 5TW	<b>Contact: Jen Siddall</b> Tel: +44 (0) 191 333 2447 E-Mail: <a href="mailto:jennifersiddall@nhs.net">jennifersiddall@nhs.net</a> Website: <a href="http://cddft.nhs.uk">cddft.nhs.uk</a>
<b>Testing performed by the Organisation at the locations specified below</b>		

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

#### Laboratory locations:

Location details	Activity	Location code
<b>Address</b> Cellular Pathology Department University Hospital of North Durham North Road Durham DH1 5TW	<b>Local contact</b> Jen Siddall Tel: 01913332447 Email: <a href="mailto:jennifersiddall@nhs.net">jennifersiddall@nhs.net</a>	Histopathology Cytology Non-gynae Cytology  A

#### Site activities performed away from the locations listed above:

Location details	Activity	Location code
University Hospital of North Durham North Road Durham DH1 5TW	Jen Siddall Tel: +44 (0)191 3332447 Email: <a href="mailto:jennifersiddall@nhs.net">jennifersiddall@nhs.net</a>	Mortuary Services (body receipt, storage and release)  A
Darlington Memorial Hospital Hollyhurst Road Darlington Durham DI3 6HX	Jen Siddall Tel: +44 (0)191 3332447 Email: <a href="mailto:jennifersiddall@nhs.net">jennifersiddall@nhs.net</a>	Mortuary Services (body receipt, storage and release)  B
ENT Ultrasound Clinic Darlington Memorial Hospital Hollyhurst Road Darlington Durham DI3 6HX	Jen Siddall Tel: +44 (0)191 3332447 Email: <a href="mailto:jennifersiddall@nhs.net">jennifersiddall@nhs.net</a>	Preparation of FNA, staining and sample adequacy check.  C



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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
<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>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 – LP/ND/HP/CU00020 Tissue Sampling LP/ND/HP/RH00006</p> <p>Specimen Decalcification Decalcification &amp; the determination of end point using Ammonium Oxalate test. LP/ND/HP/RH00007</p> <p>Tissue processing using VIP Tissue processors LP/ND/HP/SH000076</p> <p>Tissue Embedding Using Auto Tec 120 automated embedding stations (X2) LP/ND/HP/RH000017 LP/ND/HP/RH000094</p> <p>Tissue Sectioning Using Leica Microtomes LP/ND/HP/RH000018</p> <p>Cryotomy Intra-operative Frozen sections Using Leica Cryostat LP/ND/HP/FS00002</p> <p>Interpretive/diagnostic microscopy LP/ND/HP/RH000097</p>	<p>A</p>



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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
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:	A
FFPE slides (Formalin fixed paraffin embedded) and frozen sections	Routine morphological staining For the detection of:  Basophilic and eosinophilic structures	Routine morphological staining Prisma automatic using: LP/ND/HP/RH000059  Haematoxylin and Eosin (H & E) stains LP/ND/HP/SH00001  Frozen Section Staining (Rapid H&E) LP/ND/HP/FS00003	
Trephine on glass slides	Basophilic and eosinophilic structures	Haematoxylin and Eosin (H & E) stains LP/ND/HP/SH00001	
	Special stains for the detection of:	Documented in-house procedures for manual special stains	
FFPE slides	Connective tissue	Van Gieson method (LP/ND/HP/SH00002)	
	Connective tissue	Masson Trichrome method LP/ND/HP/SH00003	
	Connective tissue and fibrin	Martius Yellow, Brilliant Crystal Scarlet, Soluble Blue (MSB) LP/ND/HP/SH00004	
	Reticulin fibres	Gordon & Sweets method LP/ND/HP/SH00005	
	Elastic fibres	Modified Weigert LP/ND/HP/SH00006	



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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:	A
	Acid and Neutral Mucopolysaccharides	Alcian Blue/PAS LP/ND/HP/SH00008	
	Carbohydrates and mucins	Period acid Schiffs LP/ND/HP/SH00009	
	Amyloid	Improved Congo red LP/ND/HP/SH000010	
	Amyloid	Sirius Red LP/ND/HP/SH000012	
	Gram positive and negative microorganisms	Grams method LP/ND/HP/SH000015	
	Fungi	Grocott-Gomori Methenamine Silver LP/ND/HP/SH000016	
	Helicobacter/Microorganisms	Giemsa stain LP/ND/HP/SH000017	
	Tubercle bacilli	Ziehl Neelsen LP/ND/HP/RH000019	
	Haemosiderin and ferric iron	Perls Prussian Blue LP/ND/HP/SH000021	
	Melanin, Argentaffin cells and Lipofuscin pigment	Masson Fontana LP/ND/HP/SH000023	
	Melanin bleached	Melanin Bleach LP/ND/HP/SH000024	
	Mast cells	Toluidine Blue LP/ND/HP/SH000027	
	Basement membrane	Methenamine – Silver LP/ND/HP/SH000028	



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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:	A
	Copper associated Protein and Hepatitis B	Shikata's Orcein method LP/ND/HP/SH000029	
	Leprosy	Wade Fite LP/ND/HP/SH000033	
FFPE slides	<u>Immunohistochemistry to detect the following:</u>	Dako Autostainer Link 48 Immuno Stainer and SOP LP/ND/HP/IC00005	
	Epithelial cells	AE1/AE3	
	Differential diagnosis-malignant mesothelioma /adenocarcinoma	BCL2	
	Epithelial cell types	BerEP4	
	Reacts with human calretinin and intracellular calcium binding protein. Marker for mesotheliomas	CALRETININ	
	T cells in mantle zone	CD3	
	T and B cells -leukaemia	CD5	
	Childhood ALL, follicular lymphoma	CD10	
	Reed Sternberg cells, Hodgkins	CD15	
	B cells lymphoma	CD20	
	Reed Sternberg cells, Hodgkins	CD30	
	Endothelial cells, malignancy	CD31	



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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:	A
FFPE slides (cont'd)	<u>Immunohistochemistry to detect the following:</u> (cont'd)	Dako Autostainer Link 48 Immuno Stainer and SOP LP/ND/HP/IC00005	
	Vascular epithelium	CD34	
	B & T cells	CD45	
	Neuroectodermal cells	CD56	
	Macrophages	CD68	
	B cells	CD79	
	GIST tumours	CD117 (c-kit)	
	Carcinoid/metastatic Adenocarcinoma differentiation	CDX2	
	Epithelial malignancy	CEA (MONO)	
	Epithelial malignancy	CEA (POLY)	
	Neuroendocrine cells	CHROMOGRANIN	
	Epithelial cells	CK-PAN	
	Prostatic basal cells	CK-34BE12	
	Epithelial neoplasms	CK5/6	
	Differentiating primary/metastatic pulmonary adenocarcinoma	CK7	
	Differentiating primary/metastatic pulmonary adenocarcinoma	CK20	



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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:	A
FFPE slides (cont'd)	<u>Immunohistochemistry to detect the following:</u> (cont'd)	Dako Autostainer Link 48 Immuno Stainer and SOP LP/ND/HP/IC00005	
	Lymphatic endothelium	D2-40	
	Smooth and striated muscle	DESMIN	
	Epithelial cell Ca	E-CADHERIN	
	Epithelial cell	EMA	
	Oestrogen receptor - breast	OESTROGEN RECEPTOR	
	Melanoma panel marker	HMB45	
	Proliferating cells	KI67	
	Melanoma panel marker	MELAN A	
	Germ cell tumour	OCT3/4	
	Transcription factor kidney, thyroid	PAX-8	
	Cervical Ca	P16	
	Tumour suppressor	P53	
	Benign/malignant prostate tumour	P63	
	Progesterone receptor breast	Progesterone Receptor	
	Prostate neoplasms	Prostatic Acid Phosphatase	
	Prostate neoplasms	Prostate Specific Antigen (Poly)	



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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:	A
FFPE slides (cont'd)	<u>Immunohistochemistry to detect the following:</u> (cont'd)	Dako Autostainer Link 48 Immuno Stainer and SOP LP/ND/HP/IC00005	
	Melanoma panel marker	S100	
	Smooth muscle	SMA	
	Smooth muscle myosin	SMMhc	
	Neuroendocrine cells	SYNAPTOPHYSIN	
	Thyroid/lung	TTF1	
	Mesenchymal cells	VIMENTIN	
	Renal tumours, mesothelioma	WT-1	
Slides as prepared above	<u>Morphological assessment and interpretation/diagnosis</u>	Documented in house methods incorporating manufacturers' instructions where relevant:	A
	Morphological assessment and interpretation/diagnosis	Interpretive microscopy:  Microscopes: - Nikon & Nikon Eclipse - Olympus BH2 - Leica  Key SOP's: - Interpretive/diagnostic microscopy LP/ND/HP/RH000097 - Pathologist reporting CP/PA/SOP6	





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<p>HUMAN BODY FLUIDS (cont'd)</p> <p>Fine needle aspirations (various sites) Serous effusions (pleural, ascitic, pericardial) Respiratory fluids and brushings Urine Gastrointestinal brushings Cyst Fluids Synovial Fluid CSF Peritoneal washings</p>	<p><u>Cytopathological (Non-Gynae) examination activities for the purposes of clinical diagnosis</u></p> <p>Examination of cellular material in order to identify or exclude morphological and cytological abnormalities</p>	<p>In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions based on Thinprep T2000 equipment and SOP's</p> <p>ThinPrep 2000 – CYEQ014 Cytocentrifugation – CYEQ004 Use of Leica Autostainer – CYEQ008 Sputum Prep – CYPR001 Bronchial Brushings – CYPR002 Bronchioalveolar Lavage- CYPR003 Serous Fluid/Cyst Prep – CYPR004 Breast FNA – CYPR005 Urine Prep – CYPR007 CSF Prep – CYPR008 Joint Fluids – CYPR009 Thrombin Cell Block Prep – CYPR010 Miscellaneous endoscopic brushings –CYPR019 Diff Quick Staining – CYPR011</p>	A
<p>Fine needle aspirations from ENT/ultrasound clinics</p>	<p>Examination of samples in order to assess adequacy for diagnosis</p>	<p>Manual slide preparation and staining using Diffquik</p> <p>LP/ND/CY/CYRE008 LP/ND/CY/CYPR011</p>	C



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<p>HUMAN BODY FLUIDS (cont'd)</p> <p>Cervical/vaginal cells</p> <p>Slides prepared as above</p>	<p><u>Cytopathological (Gynae) examination activities for the purposes of clinical diagnosis</u></p> <p>Examination of cellular material in order to identify or exclude morphological and cytological abnormalities</p> <p><u>Morphological assessment and interpretation/diagnosis</u></p>	<p>In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions based on SurePath LBC system and SOP's</p> <p>Preparation and Staining of cervical samples by SurePath Liquid Based Cytology in conjunction with manufacturer's instructions</p> <p>Reception of LBC Samples – CYRE027 Prep and Staining of LBC Samples – CYPR-017 Procedure for the use of the Leica Coverslipper – CYPR- 0018</p> <p>Screening by light microscopy (qualitative analysis)</p> <p>Interpretive microscopy:</p> <p>Microscope: - Nikon &amp; Nikon Eclipse - Olympus BX45 - Leica</p> <p>Key SOP's - MP/ND/CY/SOP69-Reporting-Classification of Inadequate and Negative Smears. - MP/ND/CY/SOP76 – Dealing with Positive Smears and/or HRHPV Results. - MP/ND/CY/SOP67- Cervical Cytology Reporting for BMS's and Cytoscreeners. - LP/ND/CY/SOP75- Routine Cervical Screening/Checking Procedure</p>	A
END			