


Schedule of Accreditation

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United Kingdom Accreditation Service

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

 <p>Accredited to ISO 15189:2012</p>	Royal Devon and Exeter Hospitals NHS Foundation Trust	
	Issue No: 003 Issue date: 19 November 2018	
	Cellular Pathology Royal Devon & Exeter Hospital Church Lane Exeter Devon EX2 5AD United Kingdom	Contact: Ramzi Rajab Tel: +44 (0)1392 402964 Fax: +44 (0)1392 406402 E-Mail: Ramzi.rajab@nhs.net Website: www.exeterlaboratory.com/cellular-pathology/
Testing performed by the Organisation at the locations specified below		

Locations covered by the organisation and their relevant activities

Laboratory locations:

Location details		Activity	Location code
Address Cellular Pathology Department Royal Devon & Exeter Hospital (Wonford) Church Lane Exeter Devon EX2 5AD United Kingdom	Local contact Dr Ramji Rajab Tel: +44 (0)1392 402964 Fax: +44 (0)1392 406402 Email: Ramzi.rajab@nhs.net	Routine Histopathology Special Stains Immunohistochemistry Immunofluorescence Diagnostic Cytology (Non-Gynae) Cytology (Gynae) HPV Testing Mortuary Services Mohs Clinic Post-Vasectomy Semen Analysis	A

Site activities performed away from the locations listed above:

Location details	Activity	Location code
Mortuary Royal Devon & Exeter Hospital (Wonford) Church Lane Exeter Devon EX2 5AD United Kingdom	Mortuary Services (body receipt, storage and release)	B



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Location details	Activity	Location code
Histology Archives Royal Devon & Exeter Hospital (Heavitree) Gladstone Road Exeter Devon EX1 2ED United Kingdom	Histology Archives Storage of records only Moh's clinic	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
HUMAN BODY TISSUE	<u>Histopathological examination activities for the purposes of clinical diagnosis</u>	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:	A
Tissue: biopsy, excision, resection and post-mortem specimens	Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis	Histology cut up– HISOP058 Monmouth downdraft benches HISOP118	A
		Tissue processing Manual procedures or using VIP or ASP Tissue processor (HISOP108, HISOP003, HISOP082, EXTDOC018, HISOP004, EXTDOC007, EXTDOC025, EXTDOC036)	A
		Tissue Embedding Using Leica and Sakura embedding stations (HISOP016, EXTDOC090, EXTDOC092)	A
Formalin Fixed Paraffin wax blocks of processed tissue.		Tissue Sectioning Using Leica Microtomes, (HISOP030, HISOP028, EXTDOC028, EXTDOC031,)	A
Skin in Michel's Medium Renal tissue in saline Tissue for frozen sections - MOHS	Histopathological examination of common skin malignancies to provide assessment of the circumferential, peripheral and deep margins	Cryotomy Intra-Operative Frozen sections Using Shandon Cryostat (HISOP021, HISOP023, HISOP HISOP014, EXTDOC013) HISOP116 Preparation of slides for MOHs Surgery	A C
FFPE slides (Formalin fixed paraffin embedded) tissue on glass slides		Interpretive/diagnostic microscopy (HISOP065, HISOP095)	A



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HUMAN BODY TISSUE	<u>Histopathological examination activities for the purposes of clinical diagnosis (continued)</u>	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 Leica Autostainer using Haematoxylin and Eosin (H & E) stains – HISOP005, 006, 007, EXTDOC001, 002 & 032 Frozen Section Staining (Handstained H&E) HISOPSS037	A
Frozen Sections	Special stains for the detection of: Lipids	Documented in-house procedures for manual special stains Fat Stains on Frozen Sections (Oil Red O) HISOPSS019	A
FFPE slides	Acid Mucopolysaccharides Acid and Neutral Mucopolysaccharides Amyloid Elastic fibres and connective tissue Helicobacter/Microorganisms Gram positive and Negative microorganisms Basophilic and eosinophilic structures Connective tissue and fibrin	Alcian Blue HISOPSS001 Alcian Blue/PAS HISOPSS002 Congo Red HISOPSS032 Elastic/Haematoxylin Van Gieson (EVG/HVG) HISOPSS017 & 012 Giemsa HISOPSS006 Gram HISOPSS009 Haematoxylin & Eosin (H&E) HISOPSS037 Martius Yellow, Brilliant Crystal Scarlet, Soluble Blue (MSB) HISOPSS014	



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HUMAN BODY TISSUE	<u>Histopathological examination activities for the purposes of clinical diagnosis (continued)</u>	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:	A
FFPE slides	Special stains for the detection of:	Documented in-house procedures for manual special stains	A
	Melanin, Argentaffin cells and Lipofuscin pigment	Masson Fontana HISOPSS015	
	Connective tissue	Masson's Trichrome HISOPSS016	
	Neutral Mucopolysaccharides, glycogen and fungus	Periodic Acid Schiff (PAS) & Diastase PAS (D/PAS) HISOPSS021	
	Haemosiderin and ferric iron	Perl's Prussian Blue HISOPSS022	
	Reticulin fibres	Reticulin HISOPSS008	
	Mast cells	Toluidine Blue HISOPSS026	
	Tubercle bacilli	Ziehl Nielsen (ZN) HISOPSS031	
	Calcium	Von Kossa HISOPSS028	
	Copper assoc Protein and Hepatitis B	Orcein HISOPSS020	
	Fungi (Aspergillus) and Pneumocystis	Grocott HISOPSS011	
	Helicobacter Pylori	Cresyl Fast Violet HISOPSS005	
	Leprosy	Wade Fite HISOPSS029	
	Plasma Cells e.g. BMT, parasites/bacteria	Giemsa HISOPSS006	
	Carcinoid Tumour	Grimelius HISOPSS010	



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FFPE slides	Special stains for the detection of: Spirochetes	Documented in-house procedures for manual special stains Warthin & Starry HISOPSS035	A
FFPE slides	IDENTIFICATION OF: Antigens and antibodies in various auto-immune skin diseases Reacts with C3c fragment, native C3 and C3b Specific for alpha chains of human IgA Specific for gamma chains of human IgG Specific for mu chains of human IgM Fibrinogen (Skin only) Specific for fibrinogen (Skin only)	Immunofluorescence technique Documented in-house procedures in conjunction with manufacturer's instructions for Fluorescent Microscope SOPS HISOP025, HISOP026, EXTDOC048, EXTDOC074 C3c complement/FITC IgA/FITC IgG/FITC IgM/FITC C1a Kappa Lambda	A



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HUMAN BODY TISSUE	<u>Histopathological examination activities for the purposes of clinical diagnosis (continued)</u>	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:	A
FFPE slides and cytospin slides	Immunohistochemistry to detect the following:	DAKO IHC OMNIS (HISOPIHC010, HISOPIHC011, HISOPIHC012, HISOPIHC013, HISOPIHC014) Dako Omnis Advanced User Guide EXTDOC097	A
	Macrophages, neutrophils, A1AT accumulation	Alpha 1 Antitrypsin	
	Anaplastic lymphoma kinase receptor (CD246)	ALK- 1	
	Embryonic cell in normal tissues and germ tumours	Alpha Fetoprotein	
	HGPIN, prostate adenocarcinoma	AMACR, Prostate combo, PROSTEIN	
	Amyloid	Amyloid A – MC1	
	Androgen Receptor eg breast tumours	AR	
	Alpha Smooth Muscle Actin	ASMA -	
	Diffuse lymph-proliferative disease and neoplastic cells of follicular lymphomas.	BCL2, BCL6	
	Epithelial cell types	Ber EP4, AE1/3	
	Range of B cell Lymphocytes	BOB-1	
	T Helper Cells	CD4	
	Ovarian cancer	CA 125	
	Parafollicular cells in thyroid and medullary thyroid carcinomas	Calcitonin	



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HUMAN BODY TISSUE	<u>Histopathological examination activities for the purposes of clinical diagnosis (continued)</u>	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:	A
FFPE slides and cytospin slides (Cont'd)	Immunohistochemistry to detect the following:	DAKO IHC OMNIS (HISOPIHC010, HISOPIHC011, HISOPIHC012, HISOPIHC013, HISOPIHC014) Dako Omnis Advanced User Guide EXTDOC097	A
	Reacts with human calretinin and intracellular calcium binding protein. Marker for mesotheliomas	Calretinin	
	Smooth Muscle Cells	Caldesmon h-CD	
	Smooth Muscle Cells	Calponin	
	Glandular cells	CAM 5.2	
	T cells	CD3	
	T cells (helper+mature)	CD4	
	Mature T cells, T cell lymphomas	CD5	
	Mature B cells, follicular dendritic cells, CALLA	CD8	
	Granulocytes Reed-Sternberg cells	CD10	
	T Cell, NK cells	CD7	
	Reed-Sternberg and lymphomas	CD15	
	Mature B cells, Follicular dendritic cells	CD20	
	B cells, some T cells	CD21	
	B Cells, Reed-Sternberg cells	CD23	



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HUMAN BODY TISSUE	<u>Histopathological examination activities for the purposes of clinical diagnosis (continued)</u>	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:	A
FFPE slides and cytospin slides (Cont'd)	Immunohistochemistry to detect the following:	DAKO IHC OMNIS (HISOPIHC010, HISOPIHC011, HISOPIHC012, HISOPIHC013, HISOPIHC014) Dako Omnis Advanced User Guide EXTDOC097	A
	Reed-Sternberg cells and ALCL	CD30	
	Haematopoietic cells, vascular endothelium	CD31	
	T cells and some soft tissue	CD34	
	Plasma cells and activated T-cells	CD38	
	Reactive urothelium and Lymphocytes	CD44	
	Leukocyte common antigen	CD45	
	Neuroendocrine cells	CD56	
	Hodgkin's and T cell marker	CD57	
	Macrophages	CD68 (KPI)	
	B lymphocytes	CD79 alpha, PAX-5, PAX-8	
	Ewings sarcoma and thymic tumour marker	CD99	
	GIST	CD117/CKIT	
	Plasma cells	CD138	
	Adenocarcinoma and carcinoid (intestinal epithelium)	CDX2	
	Megakaryocytes	CD61	



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HUMAN BODY TISSUE	<u>Histopathological examination activities for the purposes of clinical diagnosis (continued)</u>	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:	A
FFPE slides and cytospin slides (Cont'd)	Immunohistochemistry to detect the following:	DAKO IHC OMNIS (HISOPIHC010, HISOPIHC011, HISOPIHC012, HISOPIHC013, HISOPIHC014) Dako Omnis Advanced User Guide EXTDOC097	A
	CEA glycoproteins in adenocarcinoma	CEA-m / CEA-p	
	Tissues of neuroendocrine origin	Chromogranin	
	CMV	CMV	
	Expressed in variety tumours Eg Mantle cell lymphoma	Cyclin D1	
	Basal cells, filamentous keratins form glandular to stratified squamous, prostate adenocarcinoma	Cytokeratin (HMWCK/34βE12)	
	Epithelial tissue from glandular to stratified squamous	Cytokeratin (MNF116)	
	Stratified squamous epithelium, basal cells, mesotheliomas	Cytokeratin 5/6	
	Normal and neoplastic epithelia	Cytokeratin 7	
	Epithelial cells	Cytokeratin 14	
	Identification of specific tumour cells	Cytokeratin 19	
	Malignant transformation of squamous cells	EGFR	
	Adenocarcinomas, columnar epithelial cells	Cytokeratin 20	



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FFPE slides and cytospin slides (Cont'd)	Immunohistochemistry to detect the following:	DAKO IHC OMNIS (HISOPIHC010, HISOPIHC011, HISOPIHC012, HISOPIHC013, HISOPIHC014) Dako Omnis Advanced User Guide EXTDOC097	A
	Striated and smooth muscle cells	Desmin	
	Normal duct epithelial cells, ductal carcinoma	E-Cadherin	
	Normal and neoplastic epithelium	EMA	
	V.W factor in endothelial cells	Factor VIII	
	Mesothelial Cells	HBME1	
	Placental trophoblasts	HCG	
	Melanoma, melanocyte differentiation	HMB45	
	Sex chord stromal tumours	Inhibin	
	B cells and plasma cells	Kappa	
	Proliferating Cells	Ki 67 (MIB-1)	
	B cells and plasma cells	Lambda	
	Epstein-Barr Virus	LMP	
	Melanoma marker	Melan-A	
	Neutrophil granulocytes, monocytes	Myeloperoxidase	
	Colon carcinomas	MLH1, MSH2	



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FFPE slides and cytospin slides (Cont'd)	Immunohistochemistry to detect the following:	DAKO IHC OMNIS (HISOPIHC010, HISOPIHC011, HISOPIHC012, HISOPIHC013, HISOPIHC014) Dako Omnis Advanced User Guide EXTDOC097	A
	Granulocytes, monocytes and histiocytes	Lysozyme	
	Breast ductal carcinoma	Mammaglobin	
	Rhabdomyosarcoma and Wilm's tumour	Myogenin	
	Neural tissue	Neurofibrillary protein NFP	
	Peripheral nerves, neuroendocrine tumours	NSE	
	Nuclei of cells containing a high level of oestrogen	Oestrogen Receptors	
	Neoplastic cells in epithelium	P53	
	Squamous epithelium	P63	
	Glandular epithelium	PAP	
	Neurones, melanocytes, neuroendocrine cells	PGP 9.5	
	Germ cell tumours	PLAP	
	Pneumocystis carinii	P. carinii	



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HUMAN BODY TISSUE	<u>Histopathological examination activities for the purposes of clinical diagnosis (continued)</u>	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:	A
FFPE slides and cytospin slides (Cont'd)	Immunohistochemistry to detect the following:	DAKO IHC OMNIS (HISOPIHC010, HISOPIHC011, HISOPIHC012, HISOPIHC013, HISOPIHC014) Dako Omnis Advanced User Guide EXTDOC097	A
	Nuclei of cells showing expression of Progesterone	Progesterone Receptors	
	Lung Carcinoma	P40	
	Pro/pre/Mature B cells	PAX 5 (BSAP)	
	Prostate secretory and ductal epithelium	PSA-P PSA-M PSMA	
	Schwann cells, nerve processes, S100 +ve neoplasms eg Melanoma	S100	
	Smooth muscle cells, myoepithelial cells	Smooth Muscle Myosin (SMM)	
	Neuroendocrine cells	Synaptophysin	
	Lining blood vessels, lymphatic vessels, mesothelial cells	Thrombomodulin	
	Thyroglobulin containing cells	Thyroglobulin	
	TTF-1 found in lung and thyroid (thyroid follicular cells)	TTF-1	
	Cells of mesenchymal origin	Vimentin	
	Epithelial cells and smooth muscle in fallopian tube. Wilms tumour	WT-1	



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HUMAN BODY TISSUE	<u>Histopathological examination activities for the purposes of clinical diagnosis (continued)</u>	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:	A
FFPE slides and cytospin slides (Cont'd)	Immunohistochemistry to detect the following:	DAKO IHC OMNIS (HISOPIHC010, HISOPIHC011, HISOPIHC012, HISOPIHC013, HISOPIHC014) Dako Omnis Advanced User Guide EXTDOC097	
	Renal rejection markers	C4d, CMV	
	Langerhans cells	CD1a	
	Subtyping germ cell tumours and molar pregnancies	CD61	
	Lymphoid cells	D2-40	
	Collagen V	COL	
	Identification of HPV associated neoplastic lesions, cervix and oral cavity	F13A	
	Breast carcinoma	GCDFP, GATA3	
	Malignant prostatic gland/breast glands and SCC	GFAP	
	Glycogen	GLYC	
	H.pylori	HP	
	Herpes Simplex Virus	HSV	
	Hepatocyte specific Antigen	HSA	
	Thyroid epithelium – normal/neoplastic	IgA, IgG, IgM, IgD	
	Primary adenocarcinoma lung/thyroid epithelium normal/neoplastic	IgG4	



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<p>HUMAN BODY TISSUE</p> <p>FFPE slides and cytospin slides (Cont'd)</p>	<p><u>Histopathological examination activities for the purposes of clinical diagnosis (continued)</u></p> <p>Immunohistochemistry to detect the following:</p> <p>Mismatch repair genes and proteins</p> <p>Mitochondria</p> <p>Gastrointestinal stromal tumours, mast cells and their disorders</p> <p>Programmed death marker/ ligand</p> <p>c-Myc regulator gene</p> <p>B cells normal/neoplastic</p> <p>B cells/ B Cell derived lymphomas</p> <p>COS-1 and WOP cells transfected with CD68 cDNA</p> <p>Renal Cell carcinoma</p> <p>Precursor B/T cell ALL and thymoma</p> <p>T-cell diseases</p>	<p>In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:</p> <p>DAKO IHC OMNIS (HISOPIHC010, HISOPIHC011, HISOPIHC012 HISOPIHC013 HISOPIHC014) Dako Omnis Advanced User Guide EXTDOC097</p> <p>MSH6, PMS2</p> <p>MIT</p> <p>MOC-31</p> <p>PD1 / PDL-1</p> <p>C-MYC</p> <p>MUM-1</p> <p>OCT 2, OCT 3/4</p> <p>PG-M1</p> <p>RCC</p> <p>TdT</p> <p>TIA-1</p>	<p>A</p>



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HUMAN BODY TISSUE	<u>Histopathological examination activities for the purposes of clinical diagnosis (continued)</u>	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:	
FFPE slides	Immunohistochemistry to detect the following: ALK Lung HPV driven tumour eg Squamous cell carcinoma Mast cells Pan melanoma Cocktail B lymphocytes Renal rejection marker Vascular endothelial cells (homeostasis and angiogenesis)	ROCHE Ventana ULTRA HISOPIHC016-Routine Ultra operation ALK-1 P16 DOG-1 PMC PAX-8 SV-40 (BKV) ERG (Erthrocyte transformation specific ETS related gene)	A
Semen (Post Vasectomy)	<u>Andrology examination activities for the purposes of clinical diagnosis</u> Detection of spermatozoa	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified: Documented in house manual method CYNG14, CYSA09, CY01, CYNG24, CYNG27 for examination of direct wet preparation and centrifuged pellet based on WHO Manual 2010 (5th Edition)	A A



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HUMAN BODY FLUIDS	<u>Cytopathology (Non-Gynae) examination activities for the purposes of clinical diagnosis</u>	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:	A
Fine needle aspirates – sputum, urine CSF, oesophageal washings and brushings, Conventional Bronchial Brushings, Serous fluids, Bronchial washings and Bronchial Alveolar lavage samples.	Examination of cellular material in order to identify or exclude morphological and cytological abnormalities	Diagnostic cytology (non-gynae) in-house documented manual procedures for preparation Screening and Reporting CYNG02, CYNG03, CYNG04, CYNG05, CYNG06, CYNG07, CYNG08, CYNG09, CYNG10, CYNG11, CYNG11a, CYNG15, CYNG24, CYNG26, Cell Block Preparation CYNG20, Gelatin Foam Cell Block Preparation CYNG29 Preparation of LBC bronchial brushing specimens CYNGLBC01 Screening and reporting of non gynae cytology slides CYNG01	A
	Demonstration of: Cells (nuclei and cytoplasm) and micro organisms	Papanicolaou stain for Non-Gynae Specimens CYNG24 May-Grunwald & Giemsa stain for air dried slides CYNG08 Diff-Quick Staining Technique CYNG18 Papanicolaou staining on the Leica autostainer/ coverslipper CYLBC03	A
Synovial Aspirate (Synovial Fluid for Cytology)	Detection and identification of Crystals	Preparation and examination of joint fluids -CYNG 19 using polarising microscopy	A



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HUMAN BODY FLUIDS	<u>Cytopathological (Gynae) examination activities for the purposes of clinical diagnosis</u>	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:	
Liquid Based Cervical Cytology Samples	Examination of cellular material in order to identify or exclude morphological and cytological abnormalities	Gynae-cytology preparation, Hologic T2000 Processor CYLBC01 Hologic T5000 autoloader Processor CYLBC10. Screening and reporting of cervical cytology slides CY05, CYG02, CYG04	A
Liquid Based Cervical Cytology Samples	Molecular Techniques Detection of high-risk HPV DNA	Roche Cobas 4800 HR CYHPV1, CYHPV3.	A
END			