


Schedule of Accreditation

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United Kingdom Accreditation Service

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

 <p>UKAS MEDICAL</p> <p>8698 Accredited to ISO 15189:2012</p>	<h3>NHS Lothian</h3> <p>Issue No: 006 Issue date: 18 February 2020</p>	
	<p>Pathology Royal Infirmary of Edinburgh 51 Little France Crescent Edinburgh EH16 4UX</p>	<p>Contact: Nadine Wilkinson Address: Laboratory Medicine Nine Bio Quarter 9 Little France Road Edinburgh, EH16 4UX Tel: +44 (0)131 242 6809 E-mail: Nadine.wilkinson@nhslothian.scot.nhs.uk</p>
<p>Testing performed by the Organisation at the locations specified below</p>		

Locations covered by the organisation and their relevant activities

Laboratory locations:

Location details	Activity	Location code
<p>Address NHS Lothian- Royal Infirmary of Edinburgh- Pathology Royal Infirmary of Edinburgh 51 Little France Crescent</p> <p>Local Contact Anne Wright Department of Pathology Royal Infirmary of Edinburgh 51, Little France Crescent Edinburgh EH16 4SA Tel: 0131 242 7130 E-mail: anne.wright@nhslothian.scot.nhs.uk</p>	<p>Routine Histopathology Special Stains Immunocytochemistry Frozen Section Histology Cytology (Cervical and Diagnostic)</p>	A
<p>Address Western General NHS Lothian-Western General Hospital Pathology Crewe Road South Edinburgh EH4 2XU</p> <p>Local Contact Scott Maxwell Department of Pathology Western General Hospital Porterfield Road Edinburgh Tel: 0131 537 1959 E-mail: Scott.maxwell@nhslothian.scot.nhs.uk</p>	<p>Neuropathology Immunofluorescence Stain CSF and Urine Cytology Breast FNA Cytology Frozen Section</p>	B
<p>Address St John's Hospital NHS Lothian Howden Road West Livingston West Lothian EH54 6PP</p> <p>Local Contact Anne Wright Department of Pathology Royal Infirmary of Edinburgh 51, Little France Crescent Edinburgh EH16 4SA Tel: 0131 242 7130 E-mail: anne.wright@nhslothian.scot.nhs.uk (site not manned on day to day basis)</p>	<p>Body store</p>	C



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Site activities performed away from the locations listed above:

Location details	Activity	Location code
<p>Address Mortuary RIE NHS Lothian- Royal Infirmary of Edinburgh- Pathology Royal Infirmary of Edinburgh 51 Little France Crescent Edinburgh EH16 4SA</p> <p>Local Contact Alison M Anderson Department of Pathology Royal Infirmary of Edinburgh 51, Little France Crescent Edinburgh EH16 4SA Tel: 0131 242 7179 E-mail: Alison.m.anderson@nhslothian.scot.nhs.uk</p>	Body store	D
<p>Address Western General NHS Lothian-Western General Hospital Mortuary Crewe Road South Edinburgh EH4 2XU</p> <p>Local Contact Anne Wright Department of Pathology Royal Infirmary of Edinburgh 51, Little France Crescent Edinburgh EH16 4SA Tel: 0131 242 7130 E-mail: anne.wright@nhslothian.scot.nhs.uk</p>	Body store	E
<p>Address Mohs Dermatology Clinic 3rd Floor Lauriston Building 39 Lauriston Place EDINBURGH EH3 9EN</p> <p>Local Contact Anne Wright Department of Pathology Royal Infirmary of Edinburgh 51, Little France Crescent Edinburgh EH16 4SA Tel: 0131 242 7130 E-mail: anne.wright@nhslothian.scot.nhs.uk</p>	Frozen Section	F



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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 FLUIDS and TISSUES	<u>Cervical Cytology examinations to assist in clinical investigations</u>	In House documented procedure & manufacturer's instructions using the following equipment	A
Cervical Smears	Cervical smear abnormalities	Hologic T5000 AL – SOP-EXT-60 Hologic T2000 – SOP-CYT-21, CYT-44, CYT-46 Prisma staining machine – SOP-CYT-69 Prisma coverslipper – SOP-PATH-171 Hologic Imaging System – SOP-EXT-108, CYT-51 CYT-66, CYT-37	
Wet Fixed Preparations – Body fluids, urine, CSFs, aspirates, washings, brushings, EUS/EBUS FNA, FNA	<u>Diagnostic Cytology examinations to assist in clinical investigations</u>	May Grunwald Giemsa (MGG) Manual method using documented procedure SOP-CYT-68, CYT-57	A
Air Dried Preparations - Body fluids, CSFs		Papanicolau-Manual method using documented procedure SOP- CYT-57, CYT-68, CYT-69	
FNA Wet Fixed Preparations Breast, Thyroid, Lymph nodes		RAL 55-Rapid Giemsa Manual method using documented procedure SOP- CYT-57, CYT-68, CYT-69	
FNA Air Dried Preparations - Breast, Thyroid, Lymph nodes		Rapid Papanicolau Documented procedure & manufacturers instructions using Hologic T2000 sample processor – CYT-57	



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HUMAN BODY FLUIDS and TISSUES (cont'd)	<u>Diagnostic Cytology examinations to assist in clinical investigations</u> (cont'd)	In House manual methods and manufacturer's instructions documented	
Air Dried Preparations- Paediatric BAL, Stool		Oil Red O Manual method using documented procedure SOP- CYT-57, CYT-68, CYT-69	A
FNA		Stainer SOP-CYT-69	B
Muscle	<u>Neuropathology examinations to assist in clinical investigations</u> Detection of abnormal cells	SOP_PATH-W-26 ATPases PH 9.4, 4.6,4.3 Cytochrome C oxidase NADH Phosphofructokinase+ adolase Phosphorylase Acid Phosphatase Myoadenylate deaminase reaction Succinic dehydrogenase H&E Periodic acid schiffs Gomoris trichrome Sudan black 4	B
Skin Immunofluorescence	Skin and blood serum	Immunofluorescence Stain SOP_PATH-W-24 FITC Ig_A, G, M, C3 Novalite Monkey Oesohagus IFA kit Direct ImP staining method Blood and serum Specimen for indirect IMF Blood indirect staining protocol	



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HUMAN BODY FLUIDS and TISSUES (cont'd)	<u>Neuropathology examinations to assist in clinical investigations</u> (cont'd)	In House manual methods and manufacturer's instructions documented	
CSF	Cerebrospinal fluids	H&E SOP-CYT-68	B
Tissue samples	<u>Frozen Section Histology examinations to assist in clinical investigations</u> Detection of abnormal cells	Using the Leica Cryostats and SOPs;- in SOP- PATH-165,167,187, 211 PATH-W-23, 26,32, ICC-R36 And SOP- EXT-266, PATH-41, PATH-167,PATH-200	A,B, F
Tissue samples	<u>Routine Histopathology examinations to assist in clinical investigations</u> Detection of abnormal cells	Specimen Dissection Manual method using documented procedures in the range PATH-165,176,185,186,187,205,206 210,PATH-W-43,PATH-W-32 Tissue processing Documented procedure & manufacturer's instructions using Leica Peloris, Leica ASP300 & Thermo Shandon Excelsior PATH-190, PATH-R-34 Tissue embedding Manual method using documented procedure Sakura embedding centres PATH-29	A



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HUMAN BODY FLUIDS and TISSUES (cont'd)	<u>Routine Histopathology examinations to assist in clinical investigations</u> (cont'd)	In House manual methods and manufacturer's instructions documented	A
Tissue samples (cont'd)	Detection of abnormal cells (cont'd)	Tissue sectioning Manual method using documented procedure- Leica Microtomes PATH-167,172,175	
	<u>Special staining of Histopathology examinations to assist in detection of clinical abnormalities</u>	Routine staining (H&E) Documented procedure & manufacturer's instructions using Sakura Prisma stainer and Leica Autostainer CV5030 coverslipper, PATH-R-48, PATH-R-31, PATH-R-32,PATH-171	
Tissue samples		Using series SOPs and Microscopy PATH-R-37,38,39	A
	Acid and Neutral Mucins	Alcian Blue paS	
	Acid Fast Tubercle Bacilli	Zeihl Neelsen	
	Acid Mucins/Mast Cells	Azure A Metachromatic Technique	
	Amyloid	Congo Red (Highmans) Modified Congo Red (ResinSections) Sirius Red	
	Argentaffin Cells/Carcinoid Tumour	Alkaline Diazo	
	Basement Membranes	Jones Methenamine Sliver	
	Basophil/Eosinophol/ Neutorphil granules	Giemsa	



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HUMAN BODY FLUIDS and TISSUES (cont'd)	<u>Special staining of Histopathology examinations to assist in detection of clinical abnormalities (cont'd)</u>	In House manual methods and manufacturer's instructions documented	
Tissue samples (cont'd)	Calcium	Von Kossa	A
	Connective tissue / Collagen / Muscle	Masson Trichrome Picro Sirius Red Van Gieson	
	Connective tissue / Collagen / Muscle / Fibrin	Martius Scarlet Blue (MSB)	
	DNA	Feulgen	
	Elastic Fibres	Elastic Haematoxylin & Eosin Elastic Stain	
	Fungi	Grocott Gomori Methenamine Silver	
		Using series SOPs and Microscopy-PATH-R-37,38,39	
	General Architecture	Paragon Stain (Resin Sections)	A
	Glycogen/Neutral Mucins/Fungi	Periodic Acid Schiffs (PAS) +/- Diastase	
	Gram +ve & Gram -ve Organisms	Gram Stain	
	Haemosiderin	Perls Prussian Blue	
	Helicobacter/Micro-organisms	Modified Giemsa	
	Hepatitis B affected Cells /Copper associated protein	Shikata's Orcein	
	Lipid	Oil Red O	



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Tissue samples (cont'd)	Mast Cells	Toluidine Blue	
	Melanin / Argentaffin / Chromaffin / some Lipofuscin	Masson Fontana	
	Mucin	Lisons Alcian Blue	
	Mycobacterium Leprae	Wade-Fite	
	Nuclei	Celestin Blue-Haematoxylin	
	pH1 Sulphated Acid Mucins/pH2.5 Acid Mucins	Alcian Blue (pH1 & pH2.5)	
	Reticulin Fibres	Gordon & Sweet's Reticulin	
	Spirochetes	Warthin Starry	
	<u>Immunocytochemistry of Histopathology examinations to assist in detection of clinical abnormalities</u>		
Tissue samples & Cell blocks		In house documented procedures & manufacturer's instructions using Leica Bond III system – SOP ICC-R-36,R8,28,29,34	A
	Embryonic cells in normal tissues and germ tumours	Using antibodies to and microscopy;-	
	ACTH producing corticotrophs in pituitary	a-1-Fetoprotein	
	Smooth muscle cells, myoepithelial cells	ACTH	
	Anaplastic Large Cell Lymphoma's (ALCL's)	Actin, smooth muscle	



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HUMAN BODY FLUIDS and TISSUES (cont'd)	<u>Immunocytochemistry of Histopathology examinations to assist in detection of clinical abnormalities</u> (cont'd)	In house documented procedures & manufacturer's instructions using Leica Bond III system – SOP ICC-R-36,R8,28,29,34	A
Tissue samples & Cell blocks (cont'd)	B cells, lymphomas	Bcl-2 (Dako) Bcl-6 Protein	
	B cells, plasma cells	Bob-1 (C20)	
	Complement C4d in allograft rejection	C-4d	
	Ovarian epithelial malignancies, seminal vesical carcinoma, anaplastic lymphoma	CA125	
	Parafollicular cells in thyroid and medullary thyroid carcinomas	Calcitonin Caldesmon	
	Smooth muscle cells	Calponin (cell marque) Calretinin	
	Marker for mesotheliomas	CCD43 (Qbend10)	
	Mature B cells, follicular dendritic cells, CALLA	CD10 (CALLA)	
	Various - mast cells, stem cells, Cajal cells, melanocytes, basal cells (skin) and mammary duct epithelium	CD117 (c-kit)	
	Plasma cells	CD138 (Syndecan-1)	



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HUMAN BODY FLUIDS and TISSUES (cont'd)	<u>Immunocytochemistry of Histopathology examinations to assist in detection of clinical abnormalities</u> (cont'd)	In house documented procedures & manufacturer's instructions using Leica Bond III system – SOP ICC-R-36,R8,28,29,34	A
Tissue samples & Cell blocks (cont'd)	Granulocytes, Reed-Sternberg cells	CD15 (Leu-M1)	
	Monocytes	CD163	
	Langerhans cells	CD1aCD2(LFA-2)	
	T cells	CD3	
	B cell	CD20 (CD20cy)	
	Mature B cells, Follicular dendritic cell	CD21	
	B cells, some T cell	CD23	
	Reed-Sternberg cells, plasma cells	CD30 (Ki-1)	
	Endothelial cells	CD31 Dako	
	Myeloid cells	CD33	
	Erythrocytes, leukocytes, glomerular podocytes and follicular dendritic cells	CD35	
	T cells (helper & mature)	CD4 (poly/mono)	
	T and B cell Lymphoma's	CD43 (Qbend10)	
	Leucocytes	CD45(LCA)	



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Tissue samples & Cell blocks (cont'd)	Mature T cells, T cell lymphomas	CD5	
	Natural killer cells, neuroendocrine tissues	CD56(N-CAM) and	
	Platelets, megakaryocytes, macrophages, endothelial cells	CD57	
	Macrophages, monocytes, myeloid cells	CD61	
	T cells. Natural killer cells, thymocytes	CD68 (Routine PG M1)	
	B cells	CD7	
	T cells	CD79a	
	Tumours including Ewings Sarcoma, & T cell lymphoma Intestinal epithelial cells, colorectal + other adenocarcinomas	CD8 CD99 (MIC2) CDX2	
	CEA glycoproteins	CEA	
	Tissues of neuroendocrine origin	Chromagranin A	
	Basal cells, filamentous keratins form glandular to stratified squamous, prostate adenocarcinoma	CK, HMW (34BE12)	
	Expressed in variety tumours	Cyclin D1	
	Pan cytokeratin (broad range)	Cytokeratin , MNF116	



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HUMAN BODY FLUIDS and TISSUES (cont'd)	<u>Immunocytochemistry of Histopathology examinations to assist in detection of clinical abnormalities</u> (cont'd)	In house documented procedures & manufacturer's instructions using Leica Bond III system – SOP ICC-R-36,R8,28,29,34	A
Tissue samples & Cell blocks (cont'd)	Epithelial cells	Cytokeratin 14	
	Epithelial cells including ductal and glandular epithelia	Cytokeratin 19	
	Adenocarcinomas, columnar epithelial cells	Cytokeratin 20	
	Stratified squamous epithelium, basal cells, mesotheliomas	Cytokeratin 5/6	
	Normal and neoplastic epithelia	Cytokeratin 7	
	Pan cytokeratin (broad range)	Cytokeratin AE1/AE3	
	Epithelial cells	Cytokeratin, Cam 5.2	
	Cytomegalovirus	Cytomegalovirus	
	Lymphatic vessels	D2-40	
	Striated and smooth muscle cells	Desmin	
	Gastro Intestinal Stromal tumours (GIST)	DOG-1	
	Epstein Barr Encoded RNA expressing cells	EBER ISH	
	Epstein-Barr Virus	EBV, LMP1	
	Normal duct epithelial cells, ductal carcinoma	E-Cadherin	



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Tissue samples & Cell blocks (cont'd)	Normal and neoplastic epithelium	EMA (Dako E29)	
	Epithelial cells, most adenocarcinomas	EP4	
	Nuclei of cells containing a high level of oestrogen	Estrogen Receptor	
	V.W factor in endothelial cells	Factor XIIIa	
	Folicle Stimulating Hormone	FSH (Novacastra)	
	G Cell hyperplasia	Gastrin	
	Breast carcinoma's	GCDFP-15	
	Schwann cells, enteric glial cells, astrocytomas, ependymomas	GFAP	
	Glucagonomas	Glucagon	
	Erythrocytes	Glycophorin A and Glycophorin C	
	T cell lymphoma's	GMP-17 (TIA-1)	
	Cytotoxic T Lymphocytes, Natural Killer cells	Granzyme B	
	Growth Hormone	Growth Hormone	
	Hairy cell leukaemia's	Hairy Cell Leukaemia	
	Placental trophoblasts	hCG	



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Tissue samples & Cell blocks (cont'd)	B cells, monocytes, macrophages, myeloid/erythroid precursors, activated T cells and some epithelial cells	HLA-DR	
	Melanoma, melanocyte differentiation	HMB45	
	Herpes Simplex Virus type I	HSV1	
	Herpes Simplex Virus type II	HSV2	
	Sex chord stromal tumours	Inhibinin, alpha	
	Insulin	Insulin	
	Proliferating Cells	Ki67/p16-MIB-1(Ki67) Dako	
	B cells and plasma cells	Kappa	
	B cell follicles	Lambda	
	Non Small Cell Lung Carcinoma's (NSCLC)	Lung ALK	
	Lutenising Hormone	Lutinising Hormone	
	Melanoma marker	Melan A	
	Granulocytes and monocytes	MPO	
	Urothelium	MUC-4	
	Lympho-haemopoietic tumours	MUM1	
	Rhabdomyosarcoma	MyoD1 and Myogenin	



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HUMAN BODY FLUIDS and TISSUES (cont'd)	<u>Immunocytochemistry of Histopathology examinations to assist in detection of clinical abnormalities</u> (cont'd)	In house documented procedures & manufacturer's instructions using Leica Bond III system – SOP ICC-R-36,R8,28,29,34	A
Tissue samples & Cell blocks (cont'd)	Smooth muscle cells	Myosin (Skeletal Fast)	
	myoepithelial cells	Myosin Heavy Chain (Smooth muscle)	
	Epithelial and endothelial cells	Neuroblastoma(NB84)	
	Neuro, endocrine and neuro-endocrine tumours	NFP	
	Peripheral nerves, neuroendocrine tumours	NSE	
	B Cell lymphomas, germinal centre derived lymphomas	Oct 2	
	Germ cell tumours, seminomas	OCT 3/4	
	Various tumours	P16 Protein	
	Squamous and Basal Cell Carcinoma's	P40	
	Breast, colon, lung and urothelial carcinoma's	P53 (DO-7)	
	Prostate basal cells, proliferative cells, glandular epithelium	P63	
	Non-small cell lung carcinonoma differentiation	P63/CK7	
	B Cells	PAX-5	



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Tissue samples & Cell blocks (cont'd)	Neurones and neuro-endocrine cells	PGP9.5	
	Germ cell tumours, seminomas	Placental Alkaline Phosphatase	
	Nuclei of cells showing expression of Progesterone	Progesterone	
	Prolactin	Prolactin	
	Metastatic prostatic tumours	Prostatic Acid Phosphatase	
	Prostate secretory and ductal epithelium	PSA poly	
	Prostate adenocarcinoma	Racemace (P504s)	
	High Grade PIN	S-100	
	Schwann cells, nerve processes, S100 +ve neoplasms		
	Somatostatin	Somatostatin	
	Simian Virus 40	SV40	
	Neuroendocrine cells	Synaptophysin	
	Leukaemias, acute lymphocytic lymphomas	TdT	
	Thyroglobulin containing cells	Thyroglobulin	
	Thyroid stimulating hormone	TSH	



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Tissue samples & Cell blocks (cont'd)	TTF-1 found in lung and thyroid (thyroid follicular cells)	TTF-1	A
	Small cell differentiation in Lung cancer	TTF-1/CK5/6	
	Small cell differentiation in Lung Cancer	Vimentin	
	Cells of mesenchymal origin Epithelial cells and smooth muscle in fallopian tube	Wilm's Tumour (WT1)	
Formalin-fixed, paraffin-embedded human breast and gastric cancer tissue	Breast and gastric carcinomas expressing HER-2	HER – 2 using monoclonal anti-HER2 clone	
Tissue samples & Cell blocks	Immunocytochemistry in Histopathology examinations to assist in detection of clinical abnormalities	Flexible scope of the Leica Bond III system with ER1, ER2 enzyme retrieval or no retrieval using polymer refine detection DAB and Bond polymer refined red detection using SOP:QUAL-106, and spreadsheet L:drive/Laboratory Specialities/Pathology/ICC Lab/ Antibodies.	A
Lung bx	Metastatic non-small cell lung cancer (NSCLC)	PD-L1 via DAKO Autostainer system using SOP: ICC-R79	A



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HUMAN BODY FLUIDS and TISSUES (cont'd)	<u>FISH analysis to assist in detection of clinical abnormalities</u>	In House manual methods and manufacturer's instructions documented	A
FFPE tissue samples and cell blocks	ALK1 rearrangement for therapy stratification in NSCLC	FISH Analysis Manual staining procedures: ICC-R41 Fluorescence Microscopy Interpretation and scoring: ICC-R46	
	DDIT3 rearrangement for sarcoma classification (myxoid liposarcoma)	FISH Analysis Manual staining procedures: ICC-R41 Fluorescence Microscopy Interpretation and scoring: ICC-R46	
	EWSR1 rearrangement for sarcoma classification (Ewing's sarcoma)	FISH Analysis Manual staining procedures: ICC-R41 Fluorescence Microscopy Interpretation and scoring: ICC-R46	
	FOXO1 rearrangement for sarcoma classification (alveolar rhabdomyosarcoma)	FISH Analysis Manual staining procedures: ICC-R41 Fluorescence Microscopy Interpretation and scoring: ICC-R46	
	FUS rearrangement for sarcoma classification (myxoid/fibromyxoid sarcoma)	FISH Analysis Manual staining procedures: ICC-R41 Fluorescence Microscopy Interpretation and scoring: ICC-R46	
	HER2 amplification for therapy stratification in breast and gastric cancer	FISH Analysis Manual staining procedures (gastric): ICC-R41 Leica Bond automated staining procedures (breast): ICC-R39 Fluorescence Microscopy Interpretation and scoring: ICC-R46	
	MDM2 amplification for sarcoma classification (well differentiated liposarcoma)	FISH Analysis Manual staining procedures: ICC-R41 Fluorescence Microscopy Interpretation and scoring: ICC-R46	



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Testing performed by the Organisation at the locations specified

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS and TISSUES (cont'd)	<u>FISH analysis to assist in detection of clinical abnormalities (cont'd)</u>	In House manual methods and manufacturer's instructions documented	A
FFPE tissue samples and cell blocks	SS18 rearrangement for sarcoma classification (synovial sarcoma)	FISH Analysis Manual staining procedures: ICC-R41 Fluorescence Microscopy Interpretation and scoring: ICC-R46	
END			