

Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 <p>UKAS MEDICAL</p> <p>8162</p> <p>Accredited to ISO 15189:2012</p>	<p>Nottingham University Hospitals NHS Trust</p> <p>Issue No: 006 Issue date: 02 January 2021</p>	
	<p>Cellular Pathology City Hospitals Hucknall Road Nottingham NG5 1PB</p>	<p>Contact: Suzi Wilson Tel: +44 (0) 0115 9249924 Ext 63530/56938 Fax: +44 (0) 115 9709479 E-Mail: Suzanna.wilson@nuh.nhs.uk Website: www.nuh.nhs.uk/healthcare-professionals/pathology/</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 Cellular Pathology Department Queen's Medical Centre Campus Derby Road Nottingham NG7 2UH</p> <p>Local contact Name: Suzi Wilson</p>	<p>Sample reception Dissection Processing including decalcification Embedding Routine Stains Special Stains Immunohistochemistry Frozen Sections Non-Gynae Cytology Neuropathology Paediatric pathology Reporting across all areas of Histology Microscopy Reporting Photographic & Digital Imaging</p>	A
<p>Cellular Pathology Department City Hospital Campus Hucknall Road NG5 1PB</p> <p>As above</p>	<p>Sample reception Dissection Frozen Sections Molecular Diagnostics HMDN including immunophenotyping and morphology Reporting across all areas of Histology</p>	B
<p>Treatment Centre Queen's Medical Centre Campus Derby Road Nottingham NG7 2UH</p> <p>As above</p>	<p>Mohs and intraoperative frozen sections H&E stains Morphological assessment and interpretation/diagnosis</p>	C



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Site activities performed away from the locations listed above:

Location details	Activity
On-site Body Store Queen's Medical Centre Campus Derby Road Nottingham NG7 2UH	Mortuary Services (body receipt, storage and release)
On-site Body Store City Hospital Campus Hucknall Road NG5 1PB	Mortuary Services (body receipt, storage and release)
Renal Clinic City Hospital Campus Hucknall Road NG5 1PB	Adequacy of sample assessment
Renal Clinic Queen's Medical Centre Campus Derby Road Nottingham NG7 2UH	Adequacy of sample assessment



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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 AND FLUIDS</p> <p>Fixed and fresh tissue, excisional and incisional biopsies and surgical resection specimens</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>Macroscopic and Microscopic examination:</p> <p>Documented in house methods incorporating manufacturers' instructions where relevant:</p> <p>Tissue Dissection using SOPs - IN1699, IN1736, IN5732, IN5752, IN5823, IN5824, IN5826, IN5827, IN5828, IN5830, IN5831, IN5832, IN5833, IN5834, IN5835, IN5836, IN5837, IN5838, IN5841, IN5842, IN5843, IN5844, IN5845, IN5846, IN5847, IN5848, IN5849, IN5850, IN5851, IN5852, IN5853, IN5854, IN5857, IN5858, IN5859, IN5861, IN5863, IN5865, IN5869, IN5870, IN5871, IN5872, IN5873, IN5874, IN5875, IN5876, IN5877, IN5878, IN5879, IN5880, IN5881, IN5882, IN5883, IN5884, IN5885, IN5889, IN5890, IN5891, IN5892, IN5893, IN5894, IN5895, IN5897, IN5898, IN5900, IN5901, IN5902, IN5903, IN5904, IN5917, IN5931, IN5932, IN5939, PL155, PR1934, PR1935, PR1936, PR1937, PR3011 and PR3024</p> <p>Tissue processing using Thermo Excelsior ES ME732 using SOP – PR1903</p> <p>Embedding Thermo Histostar Embedding Station – ME752 SOP IN1667</p>	<p>A</p>



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Fixed and fresh tissue, excisional and incisional biopsies and surgical resection specimens contd	Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis contd.	Documented in house methods incorporating manufacturers' instructions where relevant: Microtomy Thermo Shandon Finesse ME+ sectioning microtomes – ME753 Thermo Scientific Microm HM340E rotary microtome – ME754 and Slee 4060 sectioning microtome – ME735 using IN1668	A
Fixed and fresh tissue, excisional and incisional biopsies and surgical resection specimens	Routine staining for identification of basophilic and eosinophilic structures	Frozen section PR1904 – Frozen section slide production and IN1670 - H&E method instructions PR1978 – Urgent Neuropathology frozen IN1810 -H&E Neuro instructions PR1970 - Production of Frozen Sections for IMF Cryostats – Leica CM1850 UV and Leica CM1950 Routine FFPE H & E staining Haematoxylin and Eosin stain : Automated staining : Surgical (PR 1903): HE600 H&E staining platform (primary) - ME1248, ME1249, IN3448 Leica Autostainer (secondary and mega) ST5020 – ME1173 Set up for Leica ST5020 autostainer – IN3000 MOHS Laboratory Thermo Linistat stainer – ME744 and IN1724 Specialist Laboratory Leica Autostainer ST5020 – ME1173 Set up for Leica ST5020 autostainer - IN1718 and IN1819 Manual staining: QMC Surgical – IN1670 QMC – Specialist – IN1810 City – IN5914	A, B, C



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HUMAN BODY TISSUE AND FLUIDS (cont'd)	<u>Histopathological Examination activities for the purposes of clinical diagnosis.</u> (cont'd)	Macroscopic and Microscopic examination:	
Formalin Fixed Paraffin Embedded Tissue (FFPE) sections on glass slides.	Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis	Documented in house methods incorporating manufacturers' instructions where relevant: Macroscopic and Microscopic examination:	
	Acid fast bacilli	Manual special stains PR1905 – Specials and Extra requests. ZN Method - IN1689	A
	Pneumocystis/Fungi	Grocott method IN1677	A
	Acid mucins	Alcian blue – In1691	A
	Amyloid	Congo red – IN1673	A
	Mucins / glycogen	DAB/PAS method – IN1672	A
	Elastin/collagen/muscle/ RBC	EVG – IN1674	A
	Non-acid fast bacteria	Gram – IN1675	A
	Muscle,Collagen ,Cytoplasm	HVG – IN1678	A
	Basement membranes	Methenamine Silver Method – IN1679	A
	Melanin	Masson Fontana Method – IN1680	A
	Muscle, red blood cells, fibrin, connective tissue	Masson Trichrome Method – IN1681	A
	Fibrin,muscle,collagen,RBC	MSB Method – IN1682	A
	Ferric iron	Perls' method – IN1683	A
	Mucins / glycogen	DPAS Method – IN1684	A
	Reticulin fibres (collagen)	Reticulin Method – IN1685	A



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Formalin Fixed Paraffin Embedded Tissue (FFPE) sections on glass slides. (cont'd)	Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd)	Manual special stains PR1905 – Specials and Extra requests contd.	A
	Hep B surface antigen	Shikata's Orcein Method – IN1686	A
	Helicobacter pylori	Toluidine Blue for HP Method – IN1687	A
	Acid mucins	AB pH 2.5 Method – IN1691	A
	Bleaching melanin	Melanin Bleach Method – IN1692	A
Frozen sections	Lipids	Oil Red O Method – IN1693	A
	<u>Enzyme Histochemistry activities for the purposes of clinical diagnosis</u>	Microscopic examination	
Frozen sections muscle tissue and FFPE muscle sections on glass slides	Examination of tissues to identify or exclude enzymatic abnormalities for the purpose of diagnosis	Manual enzyme histochemistry methods PR 1987	A
	Detection of acid phosphatase	Acid phosphatase IN1998	
	Demonstration of alkaline phosphatase	Alkaline phosphatase IN2000	A
	Demonstration of nerve twigs and acts as a marker for ganglion cells	Cholinesterase (CHE) IN2002	A
	Demonstrate COX positivity in skeletal muscle fibres	Combined Cytochrome oxidase(COX) QMCCEP-LI-NEU010	A



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	Examination of tissues to identify or exclude enzymatic abnormalities for the purpose of diagnosis (cont'd)	Manual enzyme histochemistry methods PR1987	A
	Demonstrates presence of MAD in skeletal muscle fibres	Myoadenylate deaminase (MAD) IN2004	A
	Demonstrates mitochondria and sarcoplasmic reticulum	NADH diaphorase (MTT) IN1800	A
	Demonstrates glycogenoses	PAS for frozen sections IN2006	A
	Demonstrates phosphorylase in skeletal muscle fibres	Phosphorylase IN2008	A
	Demonstrates deficiency in either enzyme	Phosphofructokinase (PFK) and aldolase IN2007	A
HUMAN BODY TISSUE AND FLUIDS (cont'd) Formalin Fixed Paraffin Embedded Tissue (FFPE) sections on glass slides	<u>Immunochemistry examination for the purposes of clinical diagnosis</u>	Microscopic examination supported by automated staining with positive and negative controls:	
		Automated equipment Ventana Benchmark Ultra Immunostainers – ME633 SOPs PR1968 and 1967	A
	Adrenocorticotrophic hormone, pituitary tumours	ACTH	A
	Cytokeratin – classification of tumours of epithelial origin	AE1/AE3	A
Alpha-1-fetoprotein, classifying neoplastic liver disease and germ cell tumours	AFP	A	



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		Automated equipment Ventana Benchmark Ultra Immunostainers – ME633 SOPs PR1968 and 1967	A
	Classification of anaplastic large cell lymphoma	ALKProtein (CD246)	A
	Associated with Alzheimer's	Alpha-1 anti-Chymotrypsin	A
	Identification of alpha-1 antitrypsin accumulation in hepatocytes of A1AT deficient liver	Alpha-1 anti-Trypsin	A
	Classification of ovarian sex cord and stromal tumours	Alpha Inhibin	A
	Limb-girdle muscular dystrophy – expressed in skeletal muscle	Alpha-Sarcoglycan	A
	Identification and classification of AA-amyloidosis	Amyloid A	A
	Follicular lymphoma. Various B and T cell lymphoproliferative diseases	BCL 2	A
	Classification of B cell lymphomas, follicular lymphomas and Burkitts lymphoma	BCL 6	A
Labels most epithelial cells, differentiation of adenocarcinoma versus malignant mesothelioma	BerEP4	A	
Identification of senile plaques in brain / Alzheimer's disease	Beta-Amyloid (βA4)	A	



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		Automated equipment Ventana Benchmark Ultra Immunostainers – ME633 SOPs PR1968 AND PR1967	
	ID of desmoid tumours and colorectal cancer / adenoma	Beta (β)-Catenin	
	Identification of B-cells in germinal centres, differentiation of lymphomas	BOB1	
	Complement C3 demonstration	C3c/FITC	
	Complement C4 demonstration	C4D	
	Tumour marker – pancreatic adenocarcinoma	CA 19.9	
	Mucin-like glycoproteins – variety of tumours, classification of adenocarcinomas.	CA125	
	Expressed primarily in carcinoma cells	CA IX	
	Calcitonin producing C cells – medullary thyroid carcinoma	Calcitonin	
Classification of tumours of smooth muscle	Caldesmon	A	
Smooth muscle cells Normal and neoplastic mesothelial cells	Calponin Calretinin	A	



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		Automated equipment Ventana Benchmark Ultra Immunostainers – ME633 SOPs PR1968 and PR1967	A
	Cytokeratin 7&8 on secretory epithelium – identifies tumours of epithelial origin	CAM 5.2	A
	CD1a positive cells in normal and neoplastic tissue	CD1a	A
	Labels normal T-Cells and related neoplasms and differentiation of T cell lymphomas	CD2	A
	Classification of T-Cell neoplasms	CD3	A
	Thymocytes and T helper cells – identifying anaplastic T-Cell lymphoma	CD4	A
	ID of B and T cell malignancies	CD5	A
	Peripheral blood T cells, NK cells, and all thymocytes	CD7	A
	Cytotoxic suppressor T Cells	CD8	A
ID of Burkitts' lymphoma, follicular lymphoma, ALL and renal carcinoma (clear cell)	CD10	A	
B cells and identification of neoplasms of B cell derivation	CD20	A	



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	Follicular dendritic cells and mature B cells, lymphoma	CD21	A
	B cell activator proteins	CD25	A
	Normal B lymphocytes and malignant lymphomas	CD30	A
	Activated T and B cells	CD31	A
	Anaplastic large cell Lymphoma, Reed-Sternberg cells, Hodgkin's	CD34	A
	Endothelial cells, benign and malignant vascular disorders	CD22	A
	CD34 is a useful marker for the identification of vascular and lymphatic tumours and for the sub classification of leukaemia's	CD23	A
	The antibody may be a useful tool for characterization of histiocytic/dendritic cell neoplasms, follicular dendritic and cell sarcomas	CD35	A
	Low-grade B-cell lymphomas and myeloid disorders.	CD43	A
T and B cells, monocytes, granulocytes, erythrocytes, epithelial cells and mast cells	CD44	A	



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	Identification of NK cells, neural / neuroendocrine tissue, carcinoid	CD56	A
	T Cells, oligodendromas and neuroendocrine tumours	CD57	A
	Detection of activated platelets, neutrophils and basophils	CD68	A
	Mononuclear phagocytes	CD79a	A
	B cells and B Cell neoplasms	CD99 (Mic2)	A
	Ewing's sarcoma marker	CD117 (C kit)	A
	Transmembrane tyrosine kinase receptors	CD138	A
	Terminally differentiated plasma cells	CDX2	A
	CEA expressing cells	CerbB2	A
	Prognostic indicator for breast cancer	Chromogranin A	A
	Neuroendocrine differentiation	CD63 see NKIC3	A
	Differentiation between squamous cell carcinoma and adenocarcinoma	CK5/6	A
Glandular and transitional epithelial cells	CK7	A	



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	Basal cell compartments of stratified and combined epithelia	CK14	A
	Differentiation and identification of epithelial tumours (1) and epithelioid hemangioendotheliomas	CK18	A
	Identification of epithelial tumours, and may be useful in identifying cholangiocellular carcinomas	CK19	A
	Normal and abnormal gastric and intestinal epithelium, urothelium and Merkel cells	CK20	A
	Identification of basement membranes	Collagen IV Collagen IV MAB 1 (KIT) Collagen IV MAB 3 (KIT) Collagen IV MAB 5 (KIT)	A
	Identification of mantle cell lymphomas	Cyclin D1	A
	Identification of lymphatic invasion	D240 (Podoplanin)	A
	Labels smooth and striated muscle cells as well as mesothelial cells, identification of rhabdomyosarcomas, leiomyomas and mesotheliomas	Desmin	A



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	Differential diagnosis of gastrointestinal stromal tumours	Dog1	A
	Limb-girdle muscular dystrophy	Dysferlin	A
	Duchenne muscular dystrophy	Dystrophin N-term (DYS 3)	A
	Labels Epstein-Barr virus-infected cells expressing the latent membrane protein (LMP), identification of tumor cells in Epstein-Barr virus-associated Hodgkin's disease and nasopharyngeal carcinoma	EBV	A
	E-cadherin-positive cells in normal and neoplastic tissues	E-Cadherin	A
	Labels epithelial cells in a wide variety of tissues and is a useful tool for the identification of neoplastic epithelia	EMA	A
	Emery-Dreifuss muscular dystrophy	Emerin	A
	Labels estrogen receptor α -positive cells and is useful in the assessment of estrogen receptor status in human breast carcinomas	ER	A



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Formalin Fixed Paraffin Embedded Tissue (FFPE) sections on glass slides (cont'd)		Automated equipment Ventana Benchmark Ultra Immunostainers – ME633 SOPs PR1968 and PR1967	A
	Angiogenesis in neoplasms such as breast cancer and for the identification of epithelioid hemangio-endothelioma	FACTOR VIII (Von Willebrand's Factor)	A
	Fibrinolytic, skin disorders	Factor XIIIa	A
	Found in acute lymphoblastic leukaemia	FOXP1	A
	Labels follicle stimulating hormone in normal and neoplastic tissue	FSH	A
	Limb-girdle muscular dystrophy	Gamma-Sarcoglycan	A
	Labels cells producing gastrin or structural gastrin analogues	Gastrin	A
	Expressed in mammary gland and several exocrine tissues	GCDFP15	A
	Glial fibrillary acidic protein (GFAP) is the principal intermediate filament of mature astrocytes	GFAP	A



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		<p>Automated equipment Ventana Benchmark Ultra Immunostainers – ME633 SOPs PR1968 and PR1967</p>	A
	<p>Insulin positive cells in normal and neoplastic tissues using immunohistochemical</p>	<p>Glucagon</p>	A
	<p>Intrinsic membrane protein of erythrocytes</p>	<p>Glycophorin A</p>	A
	<p>Labels erythroid cells at almost all stages of differentiation and is a useful tool for the ID of erythroleukaemia</p>	<p>Glypican 3</p>	A
	<p>Activated human cytotoxic T lymphocytes (CTL) and natural killer (NK) cells</p>	<p>Granzyme B</p>	A
	<p>Mesothelial cells both benign and malignant</p>	<p>HBME1</p>	A
	<p>Labels hCG-containing cells and used for the demonstration of trophoblastic elements, e.g. in germ cell tumours</p>	<p>HCG</p>	A
	<p>Identification of hairy cell leukaemia and lymphomas</p>	<p>HCL</p>	A
	<p>Antibody labels hepatocytes and is a useful tool for the differential diagnosis of hepatocellular tumours in general</p>	<p>Hepatocyte</p>	A
<p>Determine HER2 gene amplification in formalin-fixed, paraffin-embedded breast cancer tissue specimens</p>	<p>HER2</p>	A	



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		Automated equipment Ventana Benchmark Ultra Immunostainers – ME633 SOPs PR1968 and PR1967	A
	Identification of HHV, the likely aetiological agent of Kaposi's sarcoma	HHV-8	A
	Classification of thymomas and malignancies of T-cell precursors	HLA Class I (MHC)	A
	Classification of melanomas and melanocytic lesions and also aid in distinguishing metastatic amelanotic melanomas from other poorly differentiated tumours of uncertain origin	HMB-45	A
	Marker for differentiation of high grade invasive urothelial carcinoma from prostate cancer	HMWCK	A
	Detection of HPV infected cells	HPV	A
	Detection of HSV in human cellular material	HSV I	A
	Glioma differentiation, low grade astrocytoma	IDH-1	A
	Labels plasma cells and related lymphoid cells containing IgA	IgA	A
Detection of antigens to IgA	IgA/FITC	A	



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<p>HUMAN BODY TISSUE AND FLUIDS (cont'd)</p> <p>Formalin Fixed Paraffin Embedded Tissue (FFPE) sections on glass slides (cont'd)</p>	<p><u>Immunochemistry examination for the purposes of clinical diagnosis</u> (cont'd)</p>	<p>Microscopic examination supported by automated staining with positive and negative controls:</p> <p>Automated equipment Ventana Benchmark Ultra Immunostainers – ME633 SOPs PR1968 and PR1967</p>	A
	<p>Labels delta-chains of human IgD in splenic marginal zone lymphoma, mantle cell lymphoma, B-cell lymphocytic lymphoma and rare subsets of multiple myeloma</p>	IgD	A
	<p>Plasma cells and related lymphoid cells containing IgG, and it is a useful tool for the classification of patients with B-cell neoplasia</p>	IgG	A
	<p>Detection of antigens to IgG in renal tissue</p>	IgG/FITC	A
	<p>Labels plasma cells and related lymphoid cells containing IgM, and it is a useful tool for the classification of patients with B-cell neoplasia</p>	IgM	A
	<p>Detection of antigens to IgM</p>	IgM/FITC	A
	<p>Insulin positive cells in normal and neoplastic tissues</p>	Insulin	A
	<p>Labels plasma cells and related lymphoid cells containing kappa light chains</p>	Kappa	A
<p>Detection of antigens to kappa -</p>	Kappa/FITC	A	



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<p>HUMAN BODY TISSUE AND FLUIDS (cont'd)</p> <p>Formalin Fixed Paraffin Embedded Tissue (FFPE) sections on glass slides (cont'd)</p>	<p><u>Immunochemistry examination for the purposes of clinical diagnosis</u> (cont'd)</p>	<p>Microscopic examination supported by automated staining with positive and negative controls:</p>	
		<p>Automated equipment Ventana Benchmark Ultra Immunostainers – ME633 SOPs PR1968 and PR1967</p>	A
	<p>Ki-67 antigen in normal and neoplastic cells e.g soft-tissue sarcoma, prostatic adenocarcinoma, and breast carcinoma</p>	Ki67	A
	<p>Labels plasma cells and related lymphoid cells containing lambda light chains</p>	Lambda	A
	<p>Detection of antigens to Lambda</p>	Lambda/FITC	A
	<p>Defects in LAMA2 cause of merosin-deficient congenital muscular dystrophy</p>	Laminin Alpha 2 300 kD	A
	<p>Identifies uteinizing hormone in normal and neoplastic tissue</p>	LH	A
	<p>Labels normal and neoplastic cells, and is a useful tool for identifying T-cell lymphomas, and for the differentiation of low-grade B-cell from T-cell lymphomas</p>	LCA (CD45)	A
	<p>Myelin basic protein positive cells in normal and neoplastic tissues</p>	MBP (Myelin Basic Protein)	A
	<p>Marker of mast cell activation</p>	MCT (Mast Cell Tryptase)	A
<p>Labels melanocytes and identification of melanomas, and, if melanoma is ruled out, for adrenocortical carcinomas</p>	Melan A (Mart 1)	A	



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<p>HUMAN BODY TISSUE AND FLUIDS (cont'd)</p> <p>Formalin Fixed Paraffin Embedded Tissue (FFPE) sections on glass slides (cont'd)</p>	<p><u>Immunochemistry examination for the purposes of clinical diagnosis (cont'd)</u></p>	<p>Microscopic examination supported by automated staining with positive and negative controls:</p> <p>Automated equipment Ventana Benchmark Ultra Immunostainers – ME633 SOPs PR1968 and PR1967</p>	A
	<p>Differential identification of colorectal carcinoma</p>	MLH1	A
	<p>Epithelial tissues from simple glandular to stratified squamous epithelium and identification of normal and neoplastic cells of epithelial origin</p>	MNF116	A
	<p>Differential identification of colorectal carcinomas</p>	MSH2 MSH6	A
	<p>Positive cells in normal and neoplastic tissues</p>	Myo D1	A
	<p>Myeloperoxidase-positive cells in normal and neoplastic tissues and discrimination between lymphoid and myeloid disorders</p>	MPO (Myeloperoxidase)	A
	<p>Identification of mucinous adenocarcinoma of gastrointestinal origin and intestinal metaplasia in Barrett's esophagus</p>	Muc-2	A
	<p>Differentiation between primary mucinous ovarian cancer and colon adenocarcinoma metastatic to the ovary</p>	Muc-5AC	A



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<p>HUMAN BODY TISSUE AND FLUIDS (cont'd)</p> <p>Formalin Fixed Paraffin Embedded Tissue (FFPE) sections on glass slides (cont'd)</p>	<p><u>Immunochemistry examination for the purposes of clinical diagnosis (cont'd)</u></p>	<p>Microscopic examination supported by automated staining with positive and negative controls:</p> <p>Automated equipment Ventana Benchmark Ultra Immunostainers – ME633 SOPs NUHCEP-LP-IMM009 and NUHCEP-LP-IMM014</p>	A
	<p>Labels the MUM1 protein, which is expressed in a subset of B cells in the light zone of the germinal centre plasma cells, activated T cells, and a wide spectrum of related haematolymphoid neoplasms</p>	MUM1	A
	<p>Skeletal muscle – classification of rhabdosarcomas / Wilms tumour</p>	Myogenin	A
	<p>Serves as a reserve supply of oxygen within muscles</p>	Myoglobin	A
	<p>Neuronal tumours</p>	NFP	A
	<p>Labels both normal and neoplastic cells of neuronal and neuroendocrine origin</p>	NSE	A
	<p>Lymphoid restricted immunoglobulin octamer binding antibody</p>	OCT 2	A
	<p>Expressed in developing brain</p>	OCT 3-4	A
	<p>Tumour suppressor gene</p>	P16	A
	<p>Identification of p53 in normal and neoplastic tissue</p>	P53	A



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HUMAN BODY TISSUE AND FLUIDS (cont'd) Formalin Fixed Paraffin Embedded Tissue (FFPE) sections on glass slides (cont'd)	<u>Immunochemistry examination for the purposes of clinical diagnosis (cont'd)</u>	Microscopic examination supported by automated staining with positive and negative controls: Automated equipment Ventana Benchmark Ultra Immunostainers – ME633 SOPs PR1968 and PR1967	A
	A basal epithelial cell proliferation regulator, identification of prostate adenocarcinoma as an aid in the differentiation between benign prostate lesions and prostate adenocarcinoma	P63	A
	Differentiated neuronal tumours.	Pan NFP	A
	B-cell-specific activator protein ID of pro-, pre-, and mature B cells and in the classification of lymphomas	PAX-5	A
	Plays a key role in secretory granule-dependent cell death, and in defense against virus-infected or neoplastic cells	Perforin	A
	Differentiation of neuroendocrine tumours	PGP	A
	Prostate needle cores differentiation between HGPIN and adenocarcinoma	PIN4	A
	identification of seminomas and desmoplastic small round cell tumors and identification of germ cell tumours	PLAP	A
	Differential identification of colorectal carcinomas	PMS2	A



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		Automated equipment Ventana Benchmark Ultra Immunostainers – ME633 SOPs PR1968 and PR 1967	A
	Classification of pituitary adenomas	Prolactin	A
	Prostatic epithelium and is a useful tool for the identification of benign and malignant cells of prostatic origin	PSA	A
	Identification of prostate adenocarcinoma	Racemase (AMACR)	A
	Identification of S100-positive neoplasms, such as malignant melanoma, Langerhans' histiocytosis, chondroblastoma and schwannoma	S-100	A
	Cells expressing serotonin – useful in characterisation of carcinoids	Serotonin 5HT	A
	Smooth muscle cells, myofibroblasts and myoepithelial cells, and leiomyosarcomas and pleomorphic adenomas	Smooth Muscle Actin	A
	Classification of breast tumours	Smooth Muscle Myosin	A
Erythrocyte structure / actin cytoskeleton	Spectrin	A	



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		<p>Automated equipment Ventana Benchmark Ultra Immunostainers – ME633 SOPs PR1968 and PR1967</p>	A
	<p>Identification of neuroendocrine neoplasms, including neoplasms of epithelial type, ID of nervous system neoplasms with neuronal differentiation and ID of adrenocortical neoplasm</p>	<p>Synaptophysin</p>	A
	<p>Classification of precursor B- and T-cell acute lymphoblastic lymphoma/leukemia (ALL) and thymoma</p>	<p>TdT</p>	A
	<p>Lining of blood and lymphatic vessels, mesothelial cells – classification of mesothelioma</p>	<p>Thrombomodulin</p>	A
	<p>Well differentiated thyroid carcinomas</p>	<p>Thyroglobulin</p>	A
	<p>Labels thyroid stimulating hormone in normal and neoplastic tissue</p>	<p>TSH</p>	A
	<p>Thyroid transcription factor-1 in normal and malignant cells</p>	<p>TTF1</p>	A
	<p>Neurodegenerative diseases including Alzheimer's disease, Parkinson's disease and Creutzfeldt Jakob disease</p>	<p>Ubiquitin</p>	A
<p>Cells of mesenchymal origin in normal and neoplastic tissues, and is of value in tumour diagnosis</p>	<p>Vimentin</p>	A	



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	<p>Classification of Will's tumour, malignant mesothelioma and serous ovarian adenocarcinoma</p>	<p>WT1</p>	A
<p>HUMAN BODY TISSUE AND FLUIDS (cont'd)</p> <p>Frozen tissue (Skin and Renal)</p>	<p><u>Immunofluorescence examination for the purposes of clinical diagnosis</u></p>	<p>Microscopic examination supported by manual labelling of tissue with fluorescent antibodies based on SOP PR1965 and PR1991</p>	
	<p>Detection of antigens to IgG</p> <p>Detection of antigens to IgM</p> <p>Detection of antigens to IgA</p> <p>Detection of antigens to C3</p> <p>Detection of antigens to C4</p> <p>Detection of antigens to C1q</p> <p>Detection of antigens to Lamda</p> <p>Detection of antigens to Kappa</p>	<p>IgG</p> <p>IgM</p> <p>IgA</p> <p>C3</p> <p>C4</p> <p>C1q</p> <p>Lamda</p> <p>Kappa</p>	<p>A</p> <p>A</p> <p>A</p> <p>A</p> <p>A</p> <p>A</p> <p>A</p>
<p>Fresh tissue samples</p>	<p>Basophilic and Eosinophilic tissue structures</p>	<p>Frozen sections (intraoperative and Mohs) using Leica CM1950 Sectioning Cryostat and H & E staining using: documented in house procedures – PR1901 and PR1902 In conjunction with manufacturer's instructions for: Linistainer autostainer</p>	C



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<p>HUMAN BODY TISSUE AND FLUIDS (cont'd)</p> <p>Slides prepared in house from the sample types listed above.</p>	<p><u>Histopathological Examination activities for the purposes of clinical diagnosis.</u> (cont'd)</p> <p>Morphological assessment and interpretation/diagnosis</p>	<p>Microscopic examination:</p> <p>Documented in house methods incorporating manufacturers' instructions where relevant:</p> <p>Microscopy (qualitative analysis) In house procedures: PR1870 – Production of reports – surgical and post mortem. PR1879 – Skin specimens – reporting guidelines PR2015 – Gyneacological reporting procedures PR2016 – Head and neck reporting procedures PR2017 – Reporting Paediatric GI specimens PR2018 – Placental reporting – surgical Using Leica, Nikon and Olympus Microscopes</p>	A, B
<p>HUMAN BODY FLUIDS (cont'd)</p> <p>Fine Needle Aspirations, Sputa, Bronchial Washings, Bronchial Brushings, Urines, Joint, Cyst And Serous Fluids, Serous Effusions, CSF</p>	<p><u>Non-Gynaecological (Diagnostic) Cytopathology Preparation and screening for detection or exclusion of pathological abnormalities</u></p>	<p>Macroscopic and Microscopic examination:</p> <p>Documented in house methods incorporating manufacturers' instructions where relevant:</p> <p>Sample preparation using Megafuge centrifuge Thermo cytopspin Prisma staining machine Class II cabinets at QMC Leica Microscopes Nikon Microscopes Olympus Microscopes Preparing FNA, smears and brushings and cytoblocks – PR1816 NUH Cell Path Production of Diagnostic Cytology Slides plus IN1514, IN1516, IN1518, IN3093, IN3790</p>	A, A A



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HUMAN BODY FLUIDS Slides prepared in house from the sample types listed above.	<u>Non-Gynaecological (Diagnostic) Cytopathology Preparation and screening for detection or exclusion of pathological abnormalities</u> Staining for the purposes of: Cell differentiation Morphological assessment and interpretation/diagnosis	Macroscopic and Microscopic examination: Documented in house methods incorporating manufacturers' instructions where relevant: Automated: Papanicalou Stain May Grunwald Giemsa using Prisma staining machine PR1816 – Production of Diagnostic Cytology slides Microscopy (qualitative analysis) In house procedures: PR1870 – Production of reports – surgical and post mortem.	A A, B
HUMAN BODY TISSUE AND FLUIDS Blood, bone marrow films, fluid aspirates, tissue samples	Haematological examinations for the purpose of haematological malignancy diagnosis Aspirate morphology	Documented in house methods incorporating manufacturers' instructions where relevant: RAL/MGG staining Shandon Varistain Gemini Semi Automated Stainer and preparation of MGG Stain PR3355 Perl's Iron Stain using Sigma Aldrich Accustain Iron Stain Kit HT20 PR3499	



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<p>HUMAN BODY TISSUE AND FLUIDS</p>	<p>Haematological examinations for the purpose of haematological malignancy diagnosis</p> <p>Immunophenotyping of the following markers/antigens to diagnose the following disorders –</p> <ul style="list-style-type: none"> • Acute Leukaemia – AML, B-ALL and T-ALL • Chronic Myeloid disorders- MDS • Mature Lymphoid Disorders- B & T Lymphoproliferative disorders <p>CD34 CD7; CD33 CD15; CD13 HLADr; CD64 CD14; CD19 CD56; MPO CD117 CD3; CD235a CD5; CD10; CD20; CD22; CD23; CD38; CD43; CD45; CD79b; FMC7; Kappa Lambda</p>	<p>Documented in house methods incorporating manufacturers' instructions where relevant:</p> <p>Beckman Coulter "Navios" 8 colour flow cytometer using appropriate monoclonal antibody panels Flow cytometry on the Beckman Coulter NAVIOS cytometer PR1851</p> <p>Integrated reporting using IN5656 Winpath v5.</p>	<p>B</p>



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HUMAN BODY TISSUE AND FLUIDS (cont'd)	<u>Molecular genetics examinations for the purpose of haematological malignancy diagnosis</u>	In house documented methods incorporating manufacturers' instructions where relevant:	
Human blood, bone marrow films, fluid aspirates, tissue samples, FFPE sections		Automated extraction of DNA and RNA using Promega Maxwell System – PR1860 and PR2853	B
RNA extracted from above		Manual extraction using Quiagen DNA Tissue Kit and microcentrifuges PR1844	
		Reverse transcription of RNA into cDNA using in house RT PCR and thermal cyclers PR1824	B
		Quantitation of nucleic acid using Spectrostar Nano system – IN1535	B
DNA extracted as detailed above	<u>Molecular genetic testing for the purpose of haematological malignancy diagnosis, prognosis, predictive profiling and monitoring</u>	In house documented methods incorporating manufacturers' instructions where relevant:	
	CALR exon 9 indels NPM1 mutations Ig gene rearrangements TCR Gene rearrangements Chimerism	Fluorescent PCR/Fragment Analysis PR 1859 PR 1858 PR 1831 PR 1832 PR 1841	B
	IDH1 and IDH2 mutations	In-house pyrosequencing, Pyromark Q24 PR2931	B
	BRAF V600	QIAGEN Therascreen Pyrosequencing Pyromark Q24 PR 1850	B



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DNA extracted from the above	EGFR mutations BRAF V600 mutations NRAS mutations KRAS mutations	Pyrosequencing, Pyromark Q24, Qiagen therascreen pyro kits PR1850	
END			