Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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



9902

Accredited to ISO 15189:2012

Northern Care Alliance NHS Foundation Trust

Issue No: 008 Issue date: 10 February 2025

Cellular Pathology Department Contact: Louise Bell – Quality Manager

Level 2 Turnberg Building Tel: +44 (0)161 206 5016

Salford Royal Hospital E-Mail: louise.bell@nca.nhs.uk

Stott Lane Website: www.srft.nhs.uk/paws/cellular-pathology/ Salford

United Kingdom

Testing performed at the above address only

Locations covered by the organisation and their relevant activities

Laboratory locations:

Location details		Activity
Address Cellular Pathology Department Level 2 Turnberg Building Salford Royal Hospital Stott Lane Salford M6 8HD United Kingdom	Local contact David Muskett Tel: +44 (0) 161 206 5011 Email: david.muskett@nca.nhs.uk	Routine Histopathology Special Stains Immunohistochemistry Immunofluorescence Neuropathology Diagnostic Cytology (Non-Gynae) Mortuary Services

Site activities performed away from the locations listed above:

M6 8HD

Location details	Activities
On-site Mortuary and Body Store Salford Royal Hospital	Storage of bodies Viewing facilities Record keeping, body identification and audit trail
Head and neck clinic Thomas Linacre Centre Wigan	Tissue staining and adequacy assessment of tissues sampled at one-stop clinic.
Moh's Clinic Dermatology outpatients Salford Royal Hospital	Preparation and staining of frozen blocks and slides. Histopathological examination for assessment of circumpheral, peripheral and deep margins.

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DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY TISSUE	Histopathological examination activities for the purposes of clinical diagnosis	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:
Tissue: biopsy, excision, resection and post-mortem specimens	Examination of tissues to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis	Macroscopic examination and dissection Numerous organ specific SOPs: CP-MACRO.001 to 027
		Tissue processing using Sakura automated tissue processors. CP-HIST.001
Bone and calcified tissue		Decalcification CP-CUTUP-07
		Embedding using Sakura tissue embedding centres CP-HIST.002
Formalin Fixed Paraffin Embedded (FFPE) wax blocks of processed tissue.		Microtomy using Thermo, Leica and Sakura microtomes CP-HIST.003
FFPE slides	Basophilic and eosinophilic tissue structures	Haematoxylin & eosin staining Automated: Sakura Autostainer CP-CYTO.016
Frozen sections		Cryotomy using Leica CM1950 CP-EQUIP.016
FFPE slides	Morphological assessment and interpretation/diagnosis	Interpretive/diagnostic microscopy using Leica, Nikon & Olympus microscopes CP-EQUIP.008 Olympus, Leica, Nikon CP-MPROC.002
FFPE slides	Tinctorial/Special morphological staining for the detection of: Amyloid	In-house documented procedures using manual methods with the following stains: Sirius red CP-STAINS.030 Thioflavine T CP-STAINS.042 Congo red CP-STAINS.004

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activities diagnosis FFPE slides (cont'd) Tinctoria	nological examination for the purposes of clinical s (cont'd) //Special staining (cont'd) Int membranes	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified: In-house documented procedures using manual methods with the following stains:
		using manual methods with the
Basemer	nt membranes	
		Methenamine Silver CP- STAINS.017
Basophil structure	ic and eosinophilic tissue s	Haematoxylin & eosin Manual: CP-STAINS.012
Calcium	deposits	Von Kossa CP-STAINS.034
Connecti	ve tissue	HVG CP-STAINS.013 Masson trichrome CP-STAINS.016
Copper,	Hep B sAg	Orcein CP-STAINS.023
Elastic fil	ores	Elastic Van Gieson CP-STAINS.044
Ferric iro	n	Perls CP-STAINS.025
Fibrin		MSB CP-STAINS.021
Fungi, P	neumocystis	Grocott CP-STAINS.011
Gram po	sitive and negative bacteria	Gram CP-STAINS.009
Helicoba	cter pylori	Giemsa CP-STAINS.007
M. leprae	9	Wade Fite CP-STAINS.035
M. tubero	culosis	Ziehl Neelsen CP-STAINS.038
Mast cell	s	Toluidine blue CP-STAINS.032
Melanin		Masson Fontana CP-STAINS.015

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HUMAN BODY TISSUE (cont'd)	Histopathological examination activities for the purposes of clinical diagnosis (cont'd)	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:
FFPE slides (cont'd)	Tinctorial/Special staining (cont'd)	In-house documented procedures using manual methods with the following stains:
	Mucins and carbohydrates	Alcian blue CP-STAINS.001 Hale's colloidal iron CP-STAINS.0 ABPAS CP-STAINS.002 PAS CP-STAINS.024 PASD CP-STAINS.006
	Myelin in CNS	Luxol fast blue CP-STAINS.014
	Nissl substance	Cresyl fast violet CP-STAINS.003
	Reticulin fibres	Gordon & Sweet's reticulin CP- STAINS.008
Muscle biopsy specimens	Basophilic and eosinophilic tissue structures	Haematoxylin &Eosin CP-MUSC.010
Muscle biopsy specimens	Fibrosis, rods, mitochondria	Gomori's Trichrome CP-MUSC.011
Muscle biopsy specimens	Lipid	Sudan Black CP-MUSC.016
Muscle biopsy specimens	Glycogen	PAS+/-D CP-MUSC.013

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HUMAN BODY TISSUE (cont'd)	Histopathological examination activities for the purposes of clinical diagnosis (cont'd)	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:
	Immunohistochemistry examination activities to detect the following:	Automated qualitative immunohistochemistry using the Roche Ventana Benchmark Ultra and the following monoclonal, polyclonal and cocktail antibodies: CP-IMM.025/CP-IMM.005
	Cells of the anterior pituitary and in neurons in brain	Adrenocorticotrophic hormone
	Acidic and basic cytokeratin; glandular epithelium of prostate, skin, breast, thyroid. Squamous epithelium, columnar epithelium of skin tonsil, cervix, stomach, intestine	AE1/AE3 cytokeratins
	Germ cell tumours, foetal liver cells	α-Fetoprotein
	Prostate adenocarcinoma, kidney tubules	Methyl acyl CoA racemase
	Amyloid β/A4, pre A4 in damaged neurones, senile plaques in Alzheimer's disease	Alzheimer precursor protein
	Senile plaques in Alzheimer's disease	β-Amyloid

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HUMAN BODY TISSUE (cont'd)	Histopathological examination activities for the purposes of clinical diagnosis (cont'd)	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:
	Immunohistochemistry (cont'd)	Automated qualitative immunohistochemistry using the Roche Ventana Benchmark Ultra and the following monoclonal, polyclonal and cocktail antibodies: CP-IMM.025/CP-IMM.005
FFPE slides (cont'd)	Immature enteric ganglion and diffuse large cell lymphoma	bcl-2
	Germinal centre marker Marker for follicular lymphoma	bcl-6
	Desmoplastic small round cell Carcinoma	Ber-EP4
	Braf V600E mutation	Braf V600E
	C1Q compliment protein	C1q complement
	C3 compliment protein	C3 complement
	C4d complement protein	C4d complement
	Peripheral nerves (ganglion cells and axons) and macrophages in the appendix, cortical epithelial cells, mesothelioma	Calretinin
	Simple and glandular epithelium. Classifying malignant cells of epithelial origin (carcinomas). Distinguishing carcinoma from malignant tumour of non-epithelial origin	CAM5.2 cytokeratin
	Langerhans cells	CD1a
	T cells	CD3
	T cell helper/inducer subset	CD4

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HUMAN BODY TISSUE (cont'd)	Histopathological examination activities for the purposes of clinical diagnosis (cont'd)	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:
FFPE slides (cont'd)	Immunohistochemistry (cont'd)	Automated qualitative immunohistochemistry using the Roche Ventana Benchmark Ultra and the following monoclonal, polyclonal and cocktail antibodies: CP-IMM.025/CP-IMM.005
	T cells and a small number of B cells	CD5
	T cells, NK cells	CD7
	Cytoxic / suppressor T cells	CD8
	immature B cells, fibroblasts. Myoepithelium	CD10
	Human myelomonocytic antigen. Granulocytes and monocytes	CD15
	B cells	CD20
	Follicular dendritic cells, mature B cells	CD21
	B cell subset, some monocytes & dendritic cells	CD23
	Anaplastic large-cell lymphoma, Hodgkin's Reed-Sternberg cells	CD30
	Endothelial cells, platelets, monocytes, some B cells	CD31
	Capillary endothelial cells	CD34
	T lymphocytes, monocytes, granulocytes, and some B lymphocytes	CD43

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HUMAN BODY TISSUE (cont'd)	Histopathological examination activities for the purposes of clinical diagnosis (cont'd)	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:
FFPE slides (cont'd)	Immunohistochemistry (cont'd)	Automated qualitative immunohistochemistry using the Roche Ventana Benchmark Ultra and the following monoclonal, polyclonal and cocktail antibodies: CP-IMM.025/CP-IMM.005
	Neuroendocrine cells and neurones	CD56
	Monocytes, macrophages, neutrophils	CD68
	Neuroendocrine cells and neurones	CD79
	T lymphocytes, granulosa cells of the ovary, CNS ependymal cells, Leydig cells & Sertoli cells in testes.	CD99
	Mast cells, melanocytes, intestinal Cajal cells	CD117
	Plasma cells, late B cells, squamous epithelium	CD138
	Normal enzyme that is oncogenic in anaplastic large-cell lymphoma, lung adenocarcinoma	CD246
	Epithelial cells in intestine	CDX2
	Epithelial cells, macrophages identify adenocarcinomas of the digestive tract, to distinguish between malignant mesothelioma and peripheral pulmonary adenocarcinoma, to distinguish between endocervical and endometrioid endometrial adenocarcinoma, and to distinguish hepatocellular carcinoma from cholangiocarcinoma and metastatic liver adenocarcinoma	Carcinoembryonic antigen

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HUMAN BODY TISSUE (cont'd)	Histopathological examination activities for the purposes of clinical diagnosis (cont'd)	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:
FFPE slides (cont'd)	Immunohistochemistry (cont'd)	Automated qualitative immunohistochemistry using the Roche Ventana Benchmark Ultra and the following monoclonal, polyclonal and cocktail antibodies: CP-IMM.025/CP-IMM.005
	Neural tissue & endocrine cells. pituitary adenomas, parathyroid and pancreatic islet cell tumours medullary thyroid carcinoma, and carcinoid tumours of e.g., respiratory and gastrointestinal tract.	Chromogranin
	Human cytomegalovirus in infected cells	Cytomegalovirus
	Cells in G1 phase of the cell cycle. Differentiation of mantle cell lymphoma from other B-cell lymphomas	Cyclin D1
	Simple, complex and transitional epithelia including biliary, pancreatic ducts, lung alveoli and endometrium. Identification of adenocarcinomas of the lung, breast and endometrium, thyroid gland, ovary, transitional cell carcinomas and chromophobe renal cell carcinoma.	Cytokeratin7
	Stratified squamous and non- squamous epithelium. Identification of basal and squamous cell carcinomas. Distinguishing stratified and simple epithelial cells	Cytokeratin 14

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HUMAN BODY TISSUE (cont'd)	Histopathological examination activities for the purposes of clinical diagnosis (cont'd)	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:
FFPE slides (cont'd)	Immunohistochemistry (cont'd)	Automated qualitative immunohistochemistry using the Roche Ventana Benchmark Ultra and the following monoclonal, polyclonal and cocktail antibodies: CP-IMM.025/CP-IMM.005
	Gastric small and large bowel epithelium, urothelium, Merkel cells. Characterization of carcinoma originating from urothelium, intestinal epithelium and Merkel cells	Cytokeratin 20
	Cytokeratin in human epidermis and non-keratinising epithelium. Distinguishes low differentiated squamous cell carcinoma and adenocarcinoma.	Cytokeratin 5/6
	HMW cytokeratin's; epithelium in skin, breast, lung, kidney, pancreas, tonsil. Identifying normal squamous, ductal and other complex epithelia.	Cytokeratin 34βE12
	Smooth, cardiac and striated muscle cells, more abundant in parenchymal smooth muscle than vascular. Reactive mesothelial cells	Desmin
	Gastric epithelium, interstitial cells of Cajal, breast epithelium, epithelium of salivary glands, stomach, prostate, liver, pancreas, testis, gallbladder, GIST, pancreatic and oesophageal neoplasms	DOG1

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HUMAN BODY TISSUE (cont'd)	Histopathological examination activities for the purposes of clinical diagnosis (cont'd)	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:
FFPE slides (cont'd)	Immunohistochemistry (cont'd)	Automated qualitative immunohistochemistry using the Roche Ventana Benchmark Ultra and the following monoclonal, polyclonal and cocktail antibodies: CP-IMM.025/CP-IMM.005
	Glandular epithelium, adenocarcinomas of lung, GI tract and ovary.	E-cadherin
	Distal tubules of normal kidney, DSRCT (desmoplastic small round cell carcinoma). Present in all epithelial cells except superficial layers of squamous epithelium, hepatocytes and parietal cells	Epithelial membrane antigen
	Platelets, megakaryocytes and fibroblast-like mesenchymal or histiocytic cells in the placenta, uterus, prostate, monocytes and macrophages and dermal dendritic cells.	Factor XIIIa
	Fibrinogen glycoprotein	Fibrinogen
	FoxP1 protein. Identification and sub-classification of diffuse large B-cell lymphoma	FOXP1
	Mesothelial cells. Marker of thyroid papillary and follicular carcinoma	HBME-1
	Classification of pituitary tumours and the study of pituitary disease	Follicle Stimulating Hormone

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HUMAN BODY TISSUE (cont'd)	Histopathological examination activities for the purposes of clinical diagnosis (cont'd)	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:
FFPE slides (cont'd)	Immunohistochemistry (cont'd)	Automated qualitative immunohistochemistry using the Roche Ventana Benchmark Ultra and the following monoclonal, polyclonal and cocktail antibodies: CP-IMM.025/CP-IMM.005
	Marker of mammary carcinoma and carcinoma of salivary and sweat glands.	GCDFP15
	Chondrocytes, Kupffer cells, Schwann cells, retinal Muller cells, astrocytes, ependymal cells, oligodendrocytes. Peripheral nerve sheath tumours, mixed tumours of salivary and sweat glands and some chondroid tumours.	Glial fibrillary acidic protein
	GH-producing cells, Acidophilic cells of the anterior lobe of the pituitary gland. Hepatocellular carcinoma and various benign and malignant cutaneous lesions.	Growth hormone
	Over expression of Her2 protein	Gastric Her2
	Immature melanosomes. Normal breast and sweat gland epithelium. Malignant melanoma, Angiomyolipomas, Clear Cell lung tumours and Lymphangioleiomyomatosis.	HMB-45

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HUMAN BODY TISSUE (cont'd)	Histopathological examination activities for the purposes of clinical diagnosis (cont'd)	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:
FFPE slides (cont'd)	Immunohistochemistry (cont'd)	Automated qualitative immunohistochemistry using the Roche Ventana Benchmark Ultra and the following monoclonal, polyclonal and cocktail antibodies: CP-IMM.025/CP-IMM.005
	HSV type I specific antigens	Herpes simplex virus
	HHV8 associated Kaposi sarcoma, primary effusion lymphoma, multicentric Castleman disease	Human herpes virus 8
	Astrocytomas, oligoastrocytomas and oligodendrogliomas.	Isocitrate dehydrogenase
	Evaluation of glomerular disease, detection of plasma cells and related lymphoid cells containing IgA; classification of B-cell neoplasia, distinguishing neoplastic monoclonal proliferation from reactive hyperplasia of plasma cells	IgA, IgG, IgM
	Identification of ovarian granulosa cell tumours and Sertoli cell tumours	Inhibin
	Lymphoma marker	Kappa light chains
	Proliferation marker	Ki67
	Lymphoma marker	Lambda light chains
	Marker of cells of a haematopoietic origin except erythrocytes; B and T cells, granulocytes, monocytes, macrophages.	Leucocyte common antigen
	Marker of Pituitary Tumours	Luteinising Hormone
	Marker of neuronal differentiation and detection of ganglion cells	Microtube associated protein

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HUMAN BODY TISSUE (cont'd)	Histopathological examination activities for the purposes of clinical diagnosis (cont'd)	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:
FFPE slides (cont'd)	Immunohistochemistry (cont'd)	Automated qualitative immunohistochemistry using the Roche Ventana Benchmark Ultra and the following monoclonal, polyclonal and cocktail antibodies: CP-IMM.025/CP-IMM.005
	Mast cells marker	Mast cell Tryptase
	Melanocytes; melanomas, adrenocortical carcinomas and angiomyolipomas	Melan-A
	Rhabdomyosarcoma marker	Myogenin
	Myeloid cells	Myeloperoxidase
	Mismatch repair defect	MMR
	Neurons of the central and peripheral nervous system,	Neurofilament protein
	Normal and neoplastic cells of neuronal and neuroendocrine origin	Neurone specific enolase
	Embryonic stem cells and germ cells	OCT3/4
	p53 oncogene associated with malignancy	p53

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HUMAN BODY TISSUE (cont'd)	Histopathological examination activities for the purposes of clinical diagnosis (cont'd)	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:
FFPE slides (cont'd)	Immunohistochemistry (cont'd)	Automated qualitative immunohistochemistry using the Roche Ventana Benchmark Ultra and the following monoclonal, polyclonal and cocktail antibodies: CP-IMM.025/CP-IMM.005
	Marker of molar pregnancy	p57
	Neurofibrillary tangles and in Lewy bodies. Rosenthal fibres of pilocytic astrocytoma	p62
	Basal or progenitor layers of epithelial tissues. Lung squamous cell carcinomas and differentiation of lung adenocarcinomas. Identifies breast/prostate tumours	p63
	Marker of organogenesis in the thyroid, kidney and Mullerian system. B lymphocytes, kidney, liver, RCC and spleen marker.	PAX-8
	Marker of PLAP expressing cells. Ovarian, testicular and extra gonadal germ cell tumours. Skeletal and smooth muscle and other tumours	Placental alkaline phosphatase
	Pituitary hormone	Prolactin
	Marker of normal/malignant prostate	Prostate specific antigen

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HUMAN BODY TISSUE (cont'd)	Histopathological examination activities for the purposes of clinical diagnosis (cont'd)	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:
FFPE slides (cont'd)	Immunohistochemistry (cont'd)	Automated qualitative immunohistochemistry using the Roche Ventana Benchmark Ultra and the following monoclonal, polyclonal and cocktail antibodies: CP-IMM.025/CP-IMM.005
	Marker of normal/malignant prostate	Prostate specific acid phosphatase
	Distinction of melanoma	PRAME
	Differentiation of primary or metastatic RCC from non-renal tumours	Renal cell carcinoma
	Marker of neural tissue / lesions and melanoma. Identifying Schwannomas, ependymomas, astrogliomas, and almost all benign and malignant melanomas and metastases	S100
	Smooth muscle, myofibroblasts, myoepithelial cells, leiomyomas, leiosarcomas, pleomorphic adenoma, myoepithelial cells in breast lesions	SM Actin
	Simian virus 40 tumour marker	SV40 T antigen
	Normal neuroendocrine cells and neuroendocrine neoplasms. Dense, granular cytoplasmic staining	Synaptophysin
	Tangles in Alzheimer's disease	Tau
	Follicular epithelial cells of thyroid, colloid	Thyroglobulin

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HUMAN BODY TISSUE (cont'd)	Histopathological examination activities for the purposes of clinical diagnosis (cont'd)	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:
FFPE slides (cont'd)	Immunohistochemistry (cont'd)	Automated qualitative immunohistochemistry using the Roche Ventana Benchmark Ultra and the following monoclonal, polyclonal and cocktail antibodies: CP-IMM.025/CP-IMM.005
	Syphilis marker	Treponema pallidum
	Pituitary hormone	Thyroid stimulating hormone
	Marker of normal thyroid/lung tumours	Thyroid transcription factor
	Mesenchymal tumours	Vimentin
	Wilms tumour/mesothelioma	WT1 gene product
	Marker of pituitary corticotrophs	ACTH
	Detection of ALK protein in non- small cell lung carcinoma (NSCLC)	ALK-1
	Detection of Small Focal Prostate Carcinoma	AMACR / 34Be12 dual stain
	Marker of ischaemic or traumatic axonal injury	APP
	Diagnostic and prognostic marker in astrocytomas	ATRX

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HUMAN BODY TISSUE (cont'd)	Histopathological examination activities for the purposes of clinical diagnosis (cont'd)	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:
FFPE slides (cont'd)	Immunohistochemistry (cont'd)	Automated qualitative immunohistochemistry using the Roche Ventana Benchmark Ultra and the following monoclonal, polyclonal and cocktail antibodies: CP-IMM.025/ CP-IMM.005
	Differential diagnosis of Chordoma & Hemangioblastoma vs neoplastic histological mimickers Marker for chordoma	Brachyury
	Lymphatic endothelium marker podoplanin in normal and neoplastic tissues.	D2-40 (Podoplanin)
	Identify fibrohistiocytic lesions (soft tissue lesions) such as benign fibrous histiocytomas. Differentiatation of neurofibroma from neurotised melanocytic naevus	FVIII
	Breast carcinoma and urothelial carcinoma. Differentiation of unknown primary carcinoma.	GATA-3
	Differential diagnosis of astrocytomas, oligoastrocytomas and oligodendrogliomas.	IDH1
	Identification of tumours with neuronal differentiation, Hirschsprungs and allied enteric nervous system malformations Marker of neuronal / nerve intermediate filaments	Neurofilament Protein (NFP)

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HUMAN BODY TISSUE (cont'd)	Histopathological examination activities for the purposes of clinical diagnosis (cont'd)	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:
FFPE slides (cont'd)	Immunohistochemistry (cont'd)	Automated qualitative immunohistochemistry using the Roche Ventana Benchmark Ultra and the following monoclonal, polyclonal and cocktail antibodies: CP-IMM.025/ CP-IMM.005
	G1-S-phase transition in precancerous and cancerous tissues associated with HPV. Identification of precancerous cervical lesions associated with HPV. Differentiation between CIN2 and 3, high and low grade lesions.	P16
	Pulmonary squamous cell carcinoma of head and neck and urothelial carcinomas. Differentiation between benign and malignant glands.	P40
	Classification of pituitary adenomas	PIT-1
	Classification of pituitary gonadotroph adenomas	SF-1
	Marker for malignant melanoma, including spindle cell and desmoplastic melanomas.	SOX-10
	Investigation of pituitary corticotroph adenomas	TPIT

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HUMAN BODY TISSUE (cont'd)	Histopathological examination activities for the purposes of clinical diagnosis (cont'd)	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:
Muscle biopsy specimens (cont'd)	Immunohistochemistry (cont'd)	Automated qualitative immunohistochemistry using the Roche Ventana Benchmark Ultra and the following monoclonal, polyclonal and cocktail antibodies: SOP: CP-IMM.025
Muscle biopsy specimens	Normal/abnormal muscle fibre	Dystrophins1,2 & 3
	elements	Sarcoglycans α, β, γ, & δ
		Emerin
		Dysferlin
		Utrophin
		Spectrin
		Merosin
		Troponin
		Human leucocyte antigen -1
		Complement C5-9
		Slow Heavy Chain Myosin
		Fast Heavy Chain Myosin
		Neonatal Heavy Chain Myosin
	<u> </u>	

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY TISSUE (cont'd)	Histopathological examination activities for the purposes of clinical diagnosis (cont'd)	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:
Muscle biopsy specimens (cont'd)	Immunohistochemistry (cont'd)	Automated qualitative immunohistochemistry using the Roche Ventana Benchmark Ultra and the following monoclonal, polyclonal and cocktail antibodies: SOP: CP-IMM.025
	Immunofluorescence (IF) for identification/demonstration of:	Qualitative immunofluorescence using Roche Ventana Benchmark Ultra SOPs: CP-IMM.003, CP-IMM.010
Frozen tissue specimens	IgA	
	IgG	
	IgM	
	Complement C3	
	Fibrinogen	
	Kappa light chains	
	Lambda light chains	

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Materials/Products tested	measured/Range of measurement	Equipment/Techniques used
HUMAN BODY TISSUE (cont'd)	Histopathological examination activities for the purposes of clinical diagnosis (cont'd)	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:
		Semiquantitative immunohistochemistry using Roche Ventana Benchmark Ultra
Tissue (Breast primary)	HER2 protein	HER2 protein CP-IMM.008
	Oestrogen receptor	Summary of Breast Receptor Demonstration CP-IMM.018
	Progesterone receptor	Summary of Breast Receptor Demonstration CP-IMM.018
Tissue (Breast primary)	HER2 protein	Semiquantitative chromogenic in situ hybridisation (DDISH) using Roche Ventana Benchmark Ultra CP-IMM.030
FFPE slide preparations from gastric cancer samples	HER2 protein expression	Automated immunocytochemistry method using Roche Ventana Benchmark Ultra CP-Imm. 025 CP-IMM.038 HER2 Testing using VENTANA anti-HER2/neu (4B5) EX-CP-MEM.084 Interpretation Guide for Ventana HER2/neu (4B5)
		HER2 Testing using VENTANA anti-HER2/neu (4B5) Qualitative microscopic interpretation CP-Imm.005
FFPE slides	HER2 gene expression on Chromosome 17	Chromogenic in-situ hybridisation test using automated immunocytochemistry method using Roche Ventana Benchmark Ultra CP-Imm. 025 Qualitative microscopic interpretation CP-Imm.005 Interpretation of HER2 ISH results CP-Imm.030

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HUMAN BODY TISSUE (cont'd)	Histopathological examination activities for the purposes of clinical diagnosis (cont'd)	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:
	Muscle Histopathology	
Muscle		Muscle Biopsy Handling and preparation of frozen sections CP-MUSC.001 and CP-HIST.017
		Tinctorial staining using the following:
Slides prepared from fresh / frozen tissue or formalin fixed, paraffin embedded (FFPE) Muscle biopsy tissue specimens	Basophilic and eosinophilic tissue structures	Haematoxylin & Eosin CP-MUSC.010
Slides prepared from fresh / frozen tissue or formalin fixed, paraffin embedded (FFPE) Muscle biopsy specimens	Fibrosis, rods, mitochondria	Gomori's Trichrome CP-MUSC.011
Slides prepared from fresh / frozen tissue Muscle biopsy specimens	Lipid	Sudan Black CP-MUSC.016
Slides prepared from fresh / frozen tissue or formalin fixed, paraffin embedded (FFPE) Muscle biopsy specimens	Glycogen	PAS+/-D CP-MUSC.013

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HUMAN BODY TISSUE (cont'd)	Histopathological examination activities for the purposes of clinical diagnosis (cont'd)	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:
	Muscle Histopathology (cont'd)	
		Enzyme histochemistry using the following SOPs:
Muscle biopsy specimens	Cytochrome oxidase activity	CP-MUSC.003
	Succinate dehydrogenase activity	CP-MUSC.004
	NADH tetrazolium reductase activity	CP-MUSC.005
	Adenosine triphosphatase activity	CP-MUSC.009
	Myophosphorylase activity	CP-MUSC.007
	Acid phosphatase activity	CP-MUSC.006
	Phosphofructokinase	CP-MUSC.008

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HUMAN BODY FLUIDS	Diagnostic Cytopathology (Non- Gynae) examination activities for the purposes of clinical diagnosis	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:	
Fine needle aspirates –Breast, sputum, urine, CSF, oesophageal washings and brushings, Conventional Bronchial Brushings, Serous fluids, Bronchial washings and Bronchial Alveolar lavage samples.	Preparation and examination of cellular material to identify or exclude morphological and cytological abnormalities	Cytopreparation and staining using: Hologic T 2000 Processor; Cytospin 4 Centrifuge; Rotina Centrifuge; Leica Autostainer. CP-CYTO.015; CP-CYTO.016	
Slides prepared in-house from sample types listed above	Morphological assessment and interpretation/diagnosis	Interpretive/diagnostic microscopy using Leica, Nikon & Olympus microscopes CP-EQUIP.008 Olympus, Leica, Nikon CP-MPROC.002	
END			

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