

Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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



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Accredited to
ISO 15189: 2022

Norfolk & Norwich University Hospitals NHS Foundation Trust

Issue No: 007 Issue date: 11 November 2024

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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 AND FLUIDS Fixed and fresh tissue, excisional and incisional biopsies and surgical resection specimens Calcified Tissue samples Fixed and fresh tissue, excisional and incisional biopsies and surgical resection specimens Fixed and fresh tissue, excisional and incisional biopsies and surgical resection specimens	<u>Histopathological examination activities for the purposes of clinical diagnosis</u> Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis	Macroscopic and Microscopic examination supported by documented in house methods incorporating manufacturers' instructions where relevant: Specimen dissection: HIS.CUT.P.1& 7 HIS.LT.P.1&2 Decalcification of bony samples to allow subsequent histopathological examination: HIS.CUT.P.09A HIS.CUT.P.11 Macroscopic tissue description, dissection and creation of 'block' size pieces for processing: HIS.BD.P.1-6 HIS.MED.P.04 Routine Paraffin Wax (Xylene and IPA based) processing and tissue sectioning: Leica Peloris & Tissue TEK VIP Tissue Processors Leica HistoCore Multicut Microtomes Leica H&E, following in house procedures:- HIS.PR.P.02 HIS.BL.P.01 HIS.BL.P.02



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<p>HUMAN BODY TISSUE AND FLUIDS (cont'd)</p> <p>Fresh tissue, excisional and incisional biopsies and surgical resection specimens</p> <p>Fresh tissue, excisional and incisional biopsies and surgical resection specimens</p> <p>Fixed and frozen tissue prepared as above</p> <p>Fixed tissue prepared as above</p>	<p><u>Histopathological examination activities for the purposes of clinical diagnosis</u> (cont'd)</p> <p>Visualisation of nuclear detail in cells</p> <p>Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis</p> <p>Demonstration of:</p> <p>Mucins</p> <p>Acid Mucins</p> <p>Amyloid</p>	<p>Macroscopic and Microscopic examination supported by documented in house methods incorporating manufacturers' instructions where relevant:</p> <p>Leica Cryostat CM 1850 UV, Cryostar NX70 Routine Frozen Sections following in house procedures:-HIS.FS.P.01</p> <p>Leica Cryostat CM 1850 UV, Cryostar NX70 MOHs Frozen Sections following in house procedures:- HIS.FS.P.06</p> <p>Automated Haematoxylin and Eosin stain: Leica Autostainer 5020 with Coverslipper CV5030 module, following in house procedures:- HIS.SL.P.1-2</p> <p>Manual special stains -</p> <p>AB PAS/+-D/Hales Mucicarmine HIS.SS.P.1,2,16,21,25 & 26</p> <p>Alcian Blue.</p> <p>Alkaline potassium permanganate Congo red, HIS.SS.P.4 &31</p>



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HUMAN BODY TISSUE AND FLUIDS (cont'd)	Histopathological examination <u>activities for the purposes of clinical diagnosis</u> (cont'd)	Microscopic examination supported by documented in house methods incorporating manufacturers' instructions where relevant:
Fixed tissue prepared as above (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:-
	Demonstration of: (cont'd)	
	Elastin	Elastin van Gieson, Elastin Picro Sirius red HIS.SS.P.8
	Bile Pigment	Fouchet van Gieson HIS.SS.P.9
	Haemopoietic tissue	Giemsa HIS.SS.P.11
	Diferentiation of gram positive and gram negative bacteria	Gram Gram twort HIS.SS.P.12 & 13
	Argyrophil Cells	Grimeilus silver method HIS.SS.P.14
	Connective Tissue	Haematoxylin van Gieson HIS.SS.P.38
	Fibrin	Martius Scarlet Blue HIS.SS.P.18
	Melanin pigment	Masson Fontana, Schmorl's Ferricyanide HIS.SS.P.19&34
	Fungi	Microwave Grocott PAS+D HIS.SS.P.15
	Lipid droplets	Oil red 'o' HIS.SS.P.22



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HUMAN BODY TISSUE AND FLUIDS (cont'd)	Histopathological examination <u>activities for the purposes of clinical diagnosis</u> (cont'd)	Microscopic examination supported by documented in house methods incorporating manufacturers' instructions where relevant:
Fixed tissue prepared as above (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:-
	Demonstration of: (cont'd)	
	Glycogen (and other PAS +ve substances)	PAS+/- Diastase HIS.SS.P.25 & 26
	Basement membranes	PAS+Diastase, PA Silver HIS.SS.P.23 & 26
	Haemosiderin pigment	Perl's Stain HIS.SS.P.27
	Asbestos Fibres	Perls Stains HIS.SS.P.28
	Muscle Striations	Phosphotungstic acid haematoxylin HIS.SS.P.30
	Reticulin Fibres	Rhodanine HIS.SS.P.32
	Lipofuscin	Schmorl's Ferricyanide HIS.SS.P.34
	Copper Associated Protein	Shikata's Orcein HIS.SS.P.35
	Mast Cells	Toluidine blue HIS.SS.P.36
	Calcium Salts	Von Kossa van Gieson HIS.SS.P.39
	Spirochetes	Warthin Faulkner HIS.SS.P.40



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Fixed tissue prepared as above (cont'd)	Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd)	Special stains using DAKO Artisan automated stainer:-
	Demonstration of: (cont'd)	
	Mycobacteria	Ziehl Neelsen, Modified Ziehl Neelsen HIS.SS.P.41 & 42
	Mucins	AB PAS/+-D HIS SS P 25 & 26
	Amyloid	Alkaline potassium permanganate Congo Red HIS SS P.4 & 31
	Differentiation of gram positive and gram negative bacteria	Gram; Gram twort HIS SS P12 & 114
	Glycogen	PAS+/- Diastase HIS SS P 25 & 26
	Basement Membranes	PAS+/- Diastase HIS SS P 23
	Haemosiderin pigment	Perl's Stain HIS SS P 27
	Asbestos Fibres	Perl's Stain HIS SS P 28
	Copper associated protein	Shikata's Orcein HIS SS P 35
	Detection of:	Immunohistochemistry by detection of antigens using DAKO 48 Stainer: HIS.IM.P.25
Formalin Fixed paraffin processed material	PD-L1 expression	PD-L1



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Fixed tissue prepared as above (cont'd)	Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd)	Immunohistochemistry by detection of antigens using Leica Bond III Autostainers: HIS.IM.P.01-15
	Demonstration of: (cont'd)	
	Basal Cells	34 BE12
	Endocrine Tissue	ACTH
	Pan Cytokeratin	AE1/AE3
	Lymphoma/Non Small Cell Lung Carcinoma	ALK1
	Prostate grading	AMACR (Racemase)
	Amyloid A	Amyloid A
	Salivary Gland Tumour	Androgen
	Hepatocellular Carcinoma	Arginase-1
	Malignant Mesothelioma	BAP 1
	Melanoma BRAF Mutations	BRAF v600E
	Lymphoma/Skin Tumours	bcl-2
	Lymphoma	bcl-6
	Basal Cell Tumours	BER EP4
	Renal Transplant rejection	C4 d
	Gynae Carcinoma	Ca 125
	Gastro intestinal Carcinomas	CA19.9
	Endocrine tissue	Calcitonin



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Fixed tissue prepared as above (cont'd)	Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis	Immunohistochemistry by detection of antigens using Leica Bond III Autostainers: HIS.IM.P.01-15
	Demonstration of: (cont'd)	
	Mesothelial cells	Calretinin
	Renal cell carcinoma	Carbonic Anhydrase IX (CA9)
	Translocation renal cell carcinomas and Micro-granulomas	Cathepsin K
	Lymphoma	CD 2, CD1a, CD20, CD21, CD23, CD3, CD4, CD44, CD5, CD61, CD7, CD79a, CD8, CD6,
	Lymphoma/Renal Tumour	CD10 ,CD15
	Mast Cells /GIST	CD117 (C-KIT)
	Lymphoma/Germ Cell Tumour	CD30
	Endothelial Cells	CD31
	Endothelial Cells / GIST	CD34
	Neuroendocrine/Lymphoma	CD56(N-cam)
	Monocytes	CD68
	Sarcoma/Genital Tract Tumour	CD99
	Sarcoma Typing	CDK4
	Adenocarcinoma Typing	CEA
	Neuroendocrine Cells	CEA
	Pagets Disease	C-erb 2
	Neuroendocrine Cells	Chromagranin A



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Fixed tissue prepared as above (cont'd)	Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd)	Immunohistochemistry by detection of antigens using Leica BondIII Autostainers: HIS.IM.P.01-15
	Demonstration of: (cont'd)	
	Basal Cells/Carcinoma Invasion	CK 5
	Adenocarcinoma typing	CK 7
	Pan Cytokeratin	CK(MNF116)
	Basal Cells/Carcinoma Invasion	CK14
	Basal/Immature epithelium	CK17
	Adenocarcinoma Typing	CK20, CK8/18 (CAM 5.2)
	Lymphoma	C-Myc
	Cytomegalo Virus Infection	CMV
	Basement membranes	Collagen IV
	Myocardial Infarction	Complement C9
	Lymphoma	Cyclin D1
	Lymphatics	D2 40
	Muscle related intermediate filaments	DESMIN
	Tumour grading	IMP 3
	Breast Cancer Differentiation	E-Cadherin
	Adenocarcinoma / mesothelioma / Squamous Cell carcinoma	EMA



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Fixed tissue prepared as above (cont'd)	Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd)	Immunohistochemistry by detection of antigens using Leica Bond III Autostainers: HIS.IM.P.1-15
	Demonstration of: (cont'd)	
	Breast/Gynae Tumour Tamoxifen grading	ER
	Sarcoma	ERG
	Fibrohistocytic Tumour	Factor 13
	Endothelial cells	FACTOR 8
	Fibrinogen	Fibrinogen
	Carcinoma	GATA-3
	Adenocarcinoma Typing (Breast/Salivary Gland)	GCDFP 15
	Brain Tumours	GFAP
	Endocrine Tumours	Glucagon
	Lymphoma	Glycophorin
	Hepatocellular carcinoma	Glutamine Synthetase
	Lymphoma	Granzyme
	Sarcoma Typing	h-Caldesmon
	Hep B virus	Hep B core Ag
	Hep B Virus	Hep B surface Ag
	Clear cell carcinoma	HNF-1B



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Fixed tissue prepared as above (cont'd)	Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd)	Immunohistochemistry by detection of antigens using Leica Bond III Autostainers: HIS.IM.P.1-15
	Demonstration of: (cont'd)	
	Lymphoma/Mastocytosis	Mast Cell Tryptase
	Hepatocytes (tumours)	Hepatocyte
	Herpes Virus	Herpes virus
	Germ Cell Tumours	HCG
	Human Herpes Virus 8 / Kaposi's Sarcoma	HHV8
	H. pylori	HLO (H.pylori)
	Melanoma	HMB 45
	Lymphoma/Renal Disease	IgG
	Gynae Tumours	Inhibin
	Endocrine tissue	Insulin
	Lymphoma	Kappa / Lambda B Cell
	Proliferation Marker	Ki-67 (MIB-1)
	Lymphoma/Autoimmune Diseases	Kappa / Lambda Plasma Cell
	Basement Membrane	Laminin
	Lymphoma	LCA (CD45)
	Monocytes	MAC 387
	Melanoma	Melan A
	Liposarcoma	MDM2



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Fixed tissue prepared as above (cont'd)	Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd)	Immunohistochemistry by detection of antigens using Leica Bond III Autostainers: HIS.IM.P.01-15
	Demonstration of: (cont'd)	
	Melanoma/Salivary Gland Tumour	MITF
	Adenocarcinoma Typing	Muc-1
	Sarcoma	MUC 4
	Adenocarcinoma Typing	MUC-5AC
	Lymphoma	MUM-1
	Lymphoma	Myeloperoxidase
	Myogenic Tumour	MyoD
	Myogenic Tumour	Myogenin
	Myogenic Tumour	Myoglobin
	Myogenic Tumour	Myosin
	Neural Crest Tumour	N-Cadherin
	Germ Cell Tumours	OCT3/4
	Neural Crest Tumour	NFP
	Prostate adenocarcinoma	NKX3.1
	Neuroendocrine Cells	NSE
	Tumour Grading (Gynae, Head & Neck)	P16
	Tumour Grading (Gynae Upper GI)	P53



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Fixed tissue prepared as above	Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis	Immunohistochemistry by detection of antigens using Leica Bond III Autostainers: HIS.IM.P.01-15
	Demonstration of: (cont'd)	
	Myoepithelial Cells- Invasion Squamous Cell Carcinoma	P63
	Parathyroid	Parathyroid
	Parvovirus	Parvovirus
	Germ Cell Tumours	PLAP
	Endometrial hyperplasia	PAX2
	Pneumocystis	PNC (PCP)
	Breast Tumour (Tamoxifen treatment)	PR
	Melanoma	PRAME
	Prostate Tumour	PSA
	Endometrial hyperplasia	PTEN
	Renal Tumour	RCC
	Neural Crest derived cells/Tumours	S100
	Colorectal carcinoma	SAT B 2
	Smooth Muscle and Tumours	SMA
	Myoepithelial Cells Invasion	SMM-HC
	Endocrine Tissue	Somatostatin



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Fixed tissue prepared as above (cont'd)	Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd)	Immunohistochemistry by detection of antigens using Leica Bond III Autostainers: HIS.IM.P.1-15
	Demonstration of: (cont'd)	
	Solitary Fibrous Tumours	STAT6
	JC / BK virus	SV-40
	Neuroendocrine cells	Synaptophysin
	Lymphoma	TdT
	Endothelial/Mesothelium	Thrombomodulin
	Thyroid Tumour	Thyroglobulin
	Lymphoma	TIA-1
	Translocation renal cell carcinomas	TFE3
	Synovial Sarcoma	TLE1
	Lung / Thyroid Tumours	TTF1
	Sarcoma	Vimentin
	Lymphoma / Plasma Cells	CD138
	Mesothelioma/Ovarian Serous Adenocarcinoma	WT-1
	Germ Cell Tumours	α FP
	Hepatitis	α 1AT
	Colorectal Adenocarcinoma	β catenin
	Myoepithelial Cells / Invasion	Calponin



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Fixed tissue prepared as above (cont'd)	Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd)	Immunohistochemistry by detection of antigens using Leica Bond III Autostainers: HIS.IM.P.1-15
	Demonstration of: (cont'd)	
	Lymphoma	CD25
	GI Tract Tumours	CDX2
	GIST	DOG-1
	Epstein Barr Virus	EBER
	Auto immune disease	IgG4
	Mycobacterium	M-Bovis
	Adenocarcinoma Typing	Muc-2
	Hydatidiform moles	P57
	Breast/ Salivary Gland Adenocarcinoma	Mammaglobin
	HNPCC	MSI Markers (MSH2, MSH6, MLH1 and PMS2)
	Lung Adenocarcinoma	Napsin A
	Spirochetes	Spirochete
	Prostate cancer	CK5 / AMACR (double)
	Upper GI Lesions	P53 / IMP3 (double)
	Squamous Cell Carcinoma	P 40
	Renal /Ovarian Serous Adenocarcinoma	PAX 8
	Mesothelioma	SOX 10



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Fixed tissue prepared as above (cont'd)	Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis (cont'd)	Immunohistochemistry by detection of antigens using Leica Bond III Autostainers: HIS.IM.P.1-15
Tissue samples and cell blocks	Demonstration of: (cont'd) Breast Tumour Her 2 status	Her 2
	Demonstration of:	ISH Probes demonstrated using a combination of a pre treatment and the Leica Bond III detection system according to in house procedures HIS.IM.P.01-11 based on manufacturers instructions and guidelines and incorporating the following probes:
	Antibody light chains	kappa/lambda
	Epstein Barr virus	EBV
Fixed breast tissue	HER 2 gene amplification	Leica HER2 FISH System for BOND Following in house procedure HIS.IM.P.14 based on manufacturers instructions and guidelines



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HUMAN BODY TISSUE AND FLUIDS (cont'd)	<u>Histopathological examination activities for the purposes of clinical diagnosis</u> (cont'd)	Microscopic examination supported by documented in house methods incorporating manufacturers' instructions where relevant:
Slides prepared as above	Morphological assessment and interpretation/diagnosis.	HIS.MED.P.01 Guidelines for Reporting in Histopathology HIS.MED.P.02 Consultant Discrepancy, Incident and Near Miss Recording HIS.MED.P.09 Histopathology Reporting in Cervical Cytology HIS.MED.P.10 Histopathology Reporting of Gynaecological Cancers HIS.MED.P.11 Histopathology Reporting of Bowel Cancer Screening HIS.MED.P.12 Histopathology Reporting of Renal Biopsies HIS.MED.P.13 Histopathology Reporting of Colorectal Tumours HIS.MED.P.14 Histopathology Reporting in Uropathology HIS.MED.P.15 Histopathology Reporting of Thyroid and Parathyroid HIS.MED.P.16 Histopathology Reporting in Breast Pathology HIS.MED.P.17 Histopathology Reporting of Upper Gastrointestinal Tumours HIS.MED.P.18 Histopathology Reporting of Hepatobiliary Tumours HIS.MED.P.19 Histopathology Reporting of Skins
Fixed tissue prepared as above	<u>Molecular Pathology examination activities for the purposes of clinical diagnosis:</u> Detection of mutations: BRAF KRAS NRAS EGFR	Real time PCR using Biocartis Idylla System HIS.IM.P.21 Tumour Mutation Analysis on the Idylla System



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<p>HUMAN BODY TISSUE AND FLUIDS (cont'd)</p> <p>Cervical/vaginal cells (Liquid Based Cytology/LBC sample)</p>	<p><u>Cytological examination activities for the purposes of clinical diagnosis:</u></p> <p>Preparation and screening to identify or exclude gynae-cytological abnormalities for the purpose of diagnosis</p>	<p>Use of ThinPrep T5000, Prisma Stainer & Coverslipper according to in house procedures:- C.SR.P.408 – Minimum Standards for Acceptance of Cervical Samples & Requests C.SR.P.407 – Checking & Labelling Vials & Forms C.SR.P.415 – Operation of the Cytoc ThinPrep 5000 C.SR.P.421 – Operation of the Prisma Staining & Coverslipper C.SR.P.424 – Papanicolaou Staining Protocol C.SR.P.405 – Rejection of Samples Taken Outside Recommended Recall Intervals</p>
<p>Cervical/vaginal cells (Liquid Based Cytology/LBC sample)</p>	<p>Morphological assessment and interpretation/diagnosis</p>	<p>Microscopy. according to in house procedures:- C.SC.P.801 – Primary Screening of LBC Samples C.SC.P.806 – Standardised Reporting C.SC.P.805 – Computer (LabTrak) Reporting of Cervical Samples</p>
<p>Cervical/vaginal cells (Liquid Based Cytology/LBC sample)</p>	<p>Detection of High-Risk Human Papilloma Viral (HR HPV) DNA</p>	<p>Real Time PCR amplification and detection using Roche Cobas 6800 and 8800 systems C.H.P.1001 – Testing for HR-HPV</p>



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

Norfolk & Norwich University Hospitals NHS Foundation Trust

Issue No: 007 Issue date: 11 November 2024

Testing performed at main address only

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
<p>HUMAN BODY TISSUE AND FLUIDS (cont'd)</p> <p>Fine needle aspirates, Blood, Serous and Non-serous fluids, Respiratory samples, CSFs)</p>	<p><u>Cytological examination activities for the purposes of clinical diagnosis:</u> (cont'd)</p> <p>Examination to identify or exclude non-gynae cytological abnormalities for the purpose of diagnosis:</p>	<p>Microscopic examination supported by documented in house methods incorporating manufacturers' instructions where relevant:</p> <p>Preparation of blood films/ direct smears and cytopsin slides to look for presence of malignant cells. Stained with Giemsa, Papanicolaou or combination of both stains. Clots made on fluids using in house procedures in conjunction with manufacturers instructions: Class 1 Safety cabinet CP.HS.P.6005 Heraeus centrifuge (megafuge/ biofuge) or Shandon Cytospin 2 or 4 C.SP.P.581 Use Of The Centrifuge And Cytospin</p> <p>Specific Preparation SOPs: C.SP.P.553 Prep of a Clot C.SP.P.566 Urine and Ureteric/Bladder Washing samples C.SP.P.563 Sentinel Node Imprints C.SP.P.555 Preparation of Bronchial and Sputum Samples C.SP.P.561 FNAs – Breast, Thyroid, Parotid and Solid Masses C.SP.P.570 Serous Fluid Preparation C.SP.P.571 Non-serous Fluid Preparation C.SP.P.556 Samples received in LBC Fixative C.SP.P.557 CSF and TSE/CJD samples Stained either by Giemsa method (hand-stained) or Papanicolaou stained using Tissue Tek Prisma Stainer C.SP.P.532 Preparation of Reagents and Giemsa Stain Solution</p>



8405
Accredited to
ISO 15189:2022

Schedule of Accreditation
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