### **Schedule of Accreditation**

### **United Kingdom Accreditation Service**

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



10011

Accredited to ISO 15189:2022

### **Dorset County Hospital NHS Foundation Trust**

Issue No: 008 Issue date: 17 February 2025

**Department of Cellular Pathology Dorset County Hospital** 

Williams Avenue Dorchester

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#### Testing performed at the above address only

#### **DETAIL OF ACCREDITATION**

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS	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.	Examination of cellular material in order to identify or exclude morphological and cytological abnormalities	Diagnostic cytology (non-gynae) inhouse documented manual procedures for preparation Screening and Reporting CYT/NG SOP 0005, CYT/NG SOP 0006, CYT/NG SOP 0008, CYT/NG SOP 0009, CYT/NG SOP 0011, CYT/NG SOP 0013, CYT/NG SOP 0014, CYT/NG SOP 0016, CYT/NG SOP 0017, CYT/NG SOP 0018
	Demonstration of: Cells (nuclei and cytoplasm) and micro organisms	Papanicolaou stain for Non-Gynae Specimens CYT/NG SOP 0026 Rapid Grocott method for Pneumocystis and Fungi CYT/NG HIST/STAIN SOP0008 Rapid Hema-Gurr staining CYT/NG SOP 0024 H&E Staining HIST/GEN SOP0014 CYT/NG SOP 0010 CYT/NG SOP0012

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HUMAN BODY FLUIDS (cont'd)	Cytopathology (Non-Gynae) 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:
Slides prepared in-house from sample types listed above	Morphological assessment and interpretation/diagnosis	Diagnostic cytology (non-gynae) inhouse documented manual procedures for preparation Screening and Reporting CYT/NG SOP 0005, CYT/NG SOP 0006, CYT/NG SOP 0008, CYT/NG SOP 0009, CYT/NG SOP 0011, CYT/NG SOP 0013, CYT/NG SOP 0014, CYT/NG SOP 0015, CYT/NG SOP 0016, CYT/NG SOP 0017, CYT/NG SOP 0018

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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 samples (including breast; gastrointestinal; skin; urological; bronchial/lung/thoracic; endocrine including thyroid, parathyroid, adrenal; lymphoreticular including lymph nodes, spleen, and bone marrow trephines [processing only for bone marrow trephines]; liver; bone and soft tissues; gynaecological; and head and neck)		Specimen dissection: Cut-up Manual – Routine HIST/CU-SOP 0001 – Appendix HIST/CU-SOP 0002 – Small Cut-up HIST/CU-SOP 0004 – Breast HIST/CU-SOP 0005 – Colectomy tumour HIST/CU-SOP 0006 – Colectomy (non-tumour) HIST/CU-SOP 0007 – Urinary bladder HIST/CU-SOP 0008 – Fallopian tubes HIST/CU-SOP 0009 – Femoral Head HIST/CU-SOP 0011 – Gallbladder HIST/CU-SOP 0013 – Kidney (non- tumour) HIST/CU-SOP 0014 – Kidney (tumour) HIST/CU-SOP 0015 – Lip HIST/CU-SOP 0017 – Lymph Node HIST/CU-SOP 0021 – Ovary HIST/CU-SOP 0025 – Prostate Gland HIST/CU-SOP 0026 – Salivary Gland HIST/CU-SOP 0027 – Skin HIST/CU-SOP 0029 – Spleen HIST/CU-SOP 0029 – Spleen HIST/CU-SOP 0030 – Orchidectomy HIST/CU-SOP 0031 – Thyroid Gland HIST/CU-SOP 0032 – Uterus & Cervix HIST/CU-SOP 0033 – Vas & Fallopian Tube

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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:
Tissue samples (including breast; gastrointestinal; skin; urological; bronchial/lung/thoracic; endocrine including thyroid, parathyroid, adrenal; lymphoreticular including lymph nodes, spleen, and bone marrow trephines [processing only for bone marrow trephines]; liver; bone and soft tissues; gynaecological; and head and neck) (cont'd)		Specimen dissection: Cut-up Manual – Routine HIST/CU-SOP 0034 – Lymph nodes for clearance HIST/CU-SOP 0035 – Radical prostatectomy (for tumour) HIST/CU-SOP 0037 – Bilateral prophylactic oophorectomy/salpingectomy HIST/CU-SOP 0040 – LLETZ
		Decalcification using HIST/GEN- SOP 0009 and HIST/GEN-SOP 0009 - Rapid Decalcifier Solution and 10% Formic Acid, Faxitron
Formalin fixed tissue		Tissue Processing: Leica Peloris using HIST/GEN-SOP 0034, HIST/GEN-SOP 0066 Thermo Shandon Excelsior using HIST/GEN-SOP 0072 and HIST/GEN-SOP 0073 – Tissue Tek VIP-5, HIST/GEN-SOP 0088 – Tissue Tek VIP-6
		Tissue embedding: 2 x Sakura TEC 5 Tissue Embedding Console Systems using HIST/GEN-SOP 0010
Formalin Fixed Paraffin Embedded Tissue (FFPE)		Microtomy: Leica RM2125, Leica RM2235 x 3, Microm ZIP using HIST/GEN-SOP 0012
Formalin Fixed Paraffin Embedded Tissue (FFPE) sections on glass slides	Basophilic and eosinophilic structures	Sakura Tissue-Tek H&E staining HIST/GEN SOP 0014

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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:
Fresh tissue		Cryotomy: Leica CM1950 Cryostat using HIST/GEN-SOP 0011
Fresh tissue on glass slides	Basophilic and eosinophilic structures	H&E staining HIST/GEN SOP 0011
Formalin Fixed Paraffin Embedded Tissue (FFPE) sections on glass slides	Special stains for the detection of:	Documented in-house procedures for automated special stains using Sakura Tissue-Tek
	Acid and Neutral Mucopolysaccharides	Alcian Blue/Periodic Acid Schiff HIST/STAIN SOP 0002
	Neutral Mucopolysaccharides, glycogen and fungus	Periodic Acid Schiff (PAS) HIST/STAIN SOP 0017
	Acid Mucopolysaccharides	Alcian Blue HIST/STAIN SOP 0001
	Amyloid	Congo Red HIST/STAIN SOP 0003
	Elastic fibres and connective tissue	Elastic Van Gieson (EVG) Millers HIST SOP 0013
	Helicobacter/Microorganisms	Giemsa HIST/STAIN SOP 0005
	Gram positive and negative micro- organisms	Gram HIST/STAIN SOP 0006
	Connective tissue and fibrin	Martius Yellow, Brilliant Crystal Scarlet, Soluble Blue (MSB) HIST/STAIN SOP 0009
	Melanin, Argentaffin cells and Lipofuscin pigment	Melanin Bleach HIST/STAIN SOP 0011
	Connective tissue	Masson's Trichrome HIST/STAIN SOP 0010

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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:
Formalin Fixed Paraffin Embedded Tissue (FFPE) sections on glass slides prepared in house (cont'd)	Special stains for the detection of: (cont'd)	Documented in-house procedures for manual special stains
	Haemosiderin and ferric iron	Perl's Prussian Blue HIST/STAIN SOP 0018
	Reticulin fibres	Reticulin (James) HIST/STAIN SOP 0020
	Copper-associated protein and Hepatitis B-affected cells	Orcein HIST/STAIN SOP 0016
	Tubercle bacilli	Ziehl Neelsen (ZN) HIST/STAIN SOP 0030
	Calcium	Modified Von Kossa HIST/STAIN SOP 0027
	Fungi (Aspergillus) and Pneumocystis	Grocott HIST/STAIN SOP 0008
	Elastic fibres and connective tissue	Van Gieson HIST/STAIN SOP 0026
	Leprosy	Wade Fite HIST/STAIN SOP 0028
	Melanin, Argentaffin cells and Lipofuscin pigment	Masson Fontana HIST/STAIN SOP 0032

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HUMAN BODY TISSUE (cont'd)	Immunohistochemical examination activities for the purposes of clinical diagnosis	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:
FFPE slides prepared in house	Demonstration of:	Ventana Benchmark ULTRA immunostainers HIST/ICC-SOP- 0001, 0002, 0006, 0010, 0017, 0018 and 0019
	Acid and basic cytokeratin's	AE1/AE3
	Embryonic cell in normal tissues and germ tumours	Alpha Fetoprotein
	Nuclear expression of B-Catenin in cancer tumorigenesis	B-Catenin
	Diffuse lymph-proliferative disease and neoplastic cells of follicular lymphomas.	Bcl2 oncoprotein
	Germinal centre cells	Bcl6
	Epithelial cell types	Ber Ep4
	Ovarian cancer	CA 125
	Reacts with human calretinin and intracellular calcium binding protein. Marker for mesotheliomas	Calretinin
	Adenocarcinoma and carcinoid (intestinal epithelium)	CDX2
	T cells	CD3
	T cells (helper+mature)	CD4
	Mature T cells, T cell lymphomas	CD5
	Cytotoxic and suppressor T cells	CD8
	Precursor B&T cells, germinal centre B-cells, granulocytes, liver canaliculi, myoepithelial cells, endometrial stroma	CD10

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HUMAN BODY TISSUE (cont'd)	Immunohistochemical 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 prepared in house (cont'd)	Demonstration of: (cont'd)	Ventana Benchmark ULTRA immunostainers HIST/ICC SOP 0018, HIST/ICC SOP 0019
	Reed-sternberg and lymphomas	CD15
	Mature B cells, Follicular dendritic cells	CD20
	B cells, some T cells	CD21
	B cells, follicular dendritic cells, monocytes	CD23
	Reed-Sternberg cells and ALCL	CD30
	Haematopoietic cells, vascular endothelium	CD31
	Neuroendocrine cells	CD56
	Macrophages	CD68
	B lymphocytes	CD79alpha
	GIST	CD117
	Plasma cells	CD138
	CEA glycoproteins in adenocarcinoma	CEA
	Tissues of neuroendocrine origin	Chromogranin
	Cyto Megalo Virus	CMV
	Expressed in variety tumours e.g. Mantle cell lymphoma	Cyclin D1
	Stratified squamous epithelium, basal cells, mesotheliomas	CK5

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HUMAN BODY TISSUE (cont'd)	Immunohistochemical 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 prepared in house (cont'd)	Demonstration of: (cont'd)	Ventana Benchmark ULTRA immunostainers HIST/ICC SOP 0018, HIST/ICC SOP 0019
	Stratified squamous epithelium, basal cells, mesotheliomas and Squamous epithelium cocktail	CK5 + P63 cocktail
	Normal and neoplastic epithelia	CK7
	Low-molecular weight keratins present in simple (non-squamous) epithelia	CK8/18
	Low-molecular weight keratin used as a part of an antibody panel for the characterization of normal and malignant cells of epithelial origin	CK19
	Adenocarcinomas, columnar epithelial cells	CK20
	Striated and smooth muscle cells	Desmin
	Normal duct epithelial cells, ductal carcinoma	E-Cadherin
	Normal and neoplastic epithelium	EMA
	T cells and some soft tissue	END/CD34
	Nuclei of cells containing a high level of oestrogen	ER
	Bladder and breast cancers, determine response to hormone therapy and to refine the prognosis of breast cancer	GATA3

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HUMAN BODY TISSUE (cont'd)	Immunohistochemical 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 prepared in house (cont'd)	Demonstration of: (cont'd)	Ventana Benchmark ULTRA immunostainers HIST/ICC SOP 0018, HIST/ICC SOP 0019,
	Her2 gene amplification or	HER2 using Ventana 4B5 assay
	HER2 Expression testing for Breast and Gastric Carcinoma	(Roche)
	Mesothelial Cells	HMBE1
	Melanoma, melanocyte differentiation	HMB45
	B cells and plasma cells	Kappa ISH
	Proliferating Cells	Ki67
	B cells and plasma cells	Lambda ISH
	B cells, T cells, monocytes, macrophages	LCA/CD45
	Melanoma marker	Mel A
	Classification of tumours of the intestinal tract; Identification of Lynch Syndrome	MMR panel (MLH-1, MSH-2, MSH-6, PMS-2)
	Epithelial tissue from glandular to stratified squamous	MNF 116
	Neutrophil granulocytes, monocytes	MPO (Myeloperoxidase)
	Detection of human multiple myeloma oncogen 1 in normal and neoplastic tissues	MUM1
	Alveolar macrophages, plasma cells, lung adenocarcinoma	Napsin A

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HUMAN BODY TISSUE (cont'd)	Immunohistochemical 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 prepared in house (cont'd)	Demonstration of: (cont'd)	Ventana Benchmark ULTRA immunostainers HIST/ICC SOP 0018, HIST/ICC SOP 0019
	Identification of renal cell carcinoma, thyroid carcinoma and ovarian non-mucinous carcinoma Metastatic panel)	PAX8
	HPV driven tumour eg Squamous cell carcinoma	P16
	Neoplastic cells in epithelium	P53
	Squamous epithelium	P63
	Germ cell tumours	PLAP
	Preferentially expressed antibody in melanoma	PRAME
	Nuclei of cells showing expression of Progesterone	Progesterone Receptors
	Prostate specific antigen	PSA
	Prostatic carcinoma	Racemase
	prostatic carcinoma + proliferating cells	Racemase + Ki67 cocktail
	Schwann cells, nerve processes, S100 +ve neoplasms e.g. Melanoma	S100
	Smooth muscle cells, myoepithelial cells	SMA
	Smooth muscle cells, myoepithelial cells	Smooth Muscle Myosin (SMM)
	Neuroendocrine cells	Synaptophysin

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HUMAN BODY TISSUE (cont'd)	Immunohistochemical 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 prepared in house (cont'd)	Demonstration of: (cont'd)	Immunohistochemistry: Ventana Benchmark ULTRA immunostainers HIST/ICC SOP 0018, HIST/ICC SOP 0019
	TTF-1 found in lung and thyroid (thyroid follicular cells)	TTF-1
	Cells of mesenchymal origin	Vimentin
	Epithelial cells and smooth muscle in fallopian tube. Wilms tumour	WT-1/Wilms'
Stained slides prepared in-house from sample types listed above	Morphological assessment and interpretation/diagnosis	Interpretive Microscopy Using SOP HIST/GEN-SOP 0036 – Using the microscope

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HUMAN BODY FLUIDS	Andrological examination activities for the purposes of clinical diagnosis	
Semen	Post vasectomy:  Detection of sperm	Based on 2016 Laboratory guidelines for post vasectomy semen analysis: Association of Biomedical Andrologists, the British Andrology Society and the British Association of Urological Surgeons) Manual method using wet prep and centrifugation and documented inhouse procedure SOP CYT NG 0012
Semen	Fertility testing:	Based on WHO laboratory manual for the examination and processing of human semen (Sixth edition 2021) and manual method and documented in-house procedure SOP CYT NG 0010
	Volume	Volume/weight
	рН	Colorimetric strips
	Sperm morphology excluding TZI scoring	Stained slides (Papanicolau) microscopy (Bright field)
	Sperm concentration	Improved Neubauer counting chambers and Microscopy (Phase contrast)
	Sperm motility	Microscopy (Phase contrast)
	Sperm vitality	Stained slide (Eosin/Nigrosin dye exclusion test) microscopy (Bright field)
END		

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