


# Schedule of Accreditation

issued by

## United Kingdom Accreditation Service

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

 <b>Accredited to ISO 15189:2022</b>	<b>The Royal Marsden NHS Foundation Trust</b>	
	<b>Issue No:</b> 009 <b>Issue date:</b> 07 October 2024	
	<b>The Royal Marsden NHS Foundation Trust</b> Department of Histo/Cytopathology Royal Marsden NHS Foundation Trust Fulham Road London SW3 6JJ United Kingdom	<b>Contact:</b> Natalie Peters <b>Tel:</b> +44 (0)208 915 6549 <b>Fax:</b> +44 (0)208 915 6566 <b>E-Mail:</b> Natalie.Peters@rmh.nhs.uk
<b>Testing performed by the Organisation at the locations specified below</b>		

### Locations covered by the organisation and their relevant activities

#### Laboratory locations:

Location details	Activity	Location code
<b>Address:</b> As above  <b>Local contact:</b> Natalie Peters Tel: 0208 915 6549 Fax: 0208 915 6566 E-Mail: natalie.peters@rmh.nhs.uk	Histology Non-Gynae Cytology Immunohistochemistry In-situ Hybridisation OSNA	A
Location details	Activity	Location code
<b>Address:</b> Department of Histo/Cytopathology Royal Marsden NHS Foundation Trust Downs Road Sutton London SM2 5PT  <b>Local contact:</b> Natalie Peters Tel: 0208 915 6549 Fax: 0208 915 6566 Email: natalie.peters@rmh.nhs.uk	Histology Immunohistochemistry In-situ Hybridisation OSNA	B



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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
<b>HUMAN BODY TISSUE AND FLUIDS</b>	<u>Histopathological examination activities for the purposes of clinical diagnosis</u>	In-house documented procedures using manual methods or analysers as specific in conjunction with manufacturers' instructions as specified:	
Tissue samples: Fixed & fresh, including bone marrow trephines.	The examination of tissues to exclude or identify morphological and cytological abnormalities for the purpose of clinical diagnosis	Macroscopic and Microscopic examination  Supported by:	A, B
Non-gynae cytology cell blocks Frozen sections			A
Fresh tissue only		Manual Tissue dissection HIST 164 HIST CMP 146	A, B
		Cryomicrotomy and intraoperative frozen sections using Thermo Scientific HM525NX and FSE Cryostat HIST 17	A
		Tissue Processing using Sakura Tissue Tek VIP6, VIP 6 AI HIST 1A HIST CMP 01	A, B
		Embedding using Sakura Tissue Tec5 HIST SD 06	A, B
		Section Cutting using Leica Microtome RM 2235, Eprelia Slide Mate AS HIST SD 05 HIST 149 HIST CMP 10	A, B



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Stained Formalin-fixed paraffin embedded tissue slides	Morphological assessment and interpretation/diagnosis	Microscopy HIST MAN 09 HIST 261 HIST 124	A, B
Formalin-fixed paraffin embedded tissue slides	<u>Demonstration of:</u>	Special Tinctorial Histochemical Staining (Special Stains) methods using manual techniques:	A, B
	Basophilic and eosinophilic structures	Routine H&E staining Leica Autostainer XL, CV5030 Coverslipper HIST 5 (automated) HIST 131 (manual) HIST 6 (manual) HIST 322 HIST SD 13	A
		Routine H&E staining using manual method and CV5030 coverslipper HIST 131 (manual) HIST SD 13	B
	Acid mucins	Alcian Blue Technique HIST 59	A
	Acid and Neutral mucins	Alcian Blue – Periodic Acid-Schiff ± Diastase HIST SD 01	A, B
	Amyloid	Congo Red (Highman) HIST CMP 70	B
	Bone marrow cell differentiation	Giemsa Stain HIST CMP 67	B



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	<u>Demonstration of:</u> (cont'd)	Special Tinctorial Histochemical Staining (Special Stains) methods using manual techniques:	A, B
	Glycogen	PAS ± Diastase HIST SD 14	A
	M. Tuberculosis	Ziehl Neelsen HIST CMP 91	B
	Haemosiderin	Perl's Prussian Blue Stain HIST CMP 83	B
	Reticulin Fibres	Gordon and Sweet Stain HIST CMP 85	B
	<u>Immunohistochemistry for the detection of:</u>	Automated Immunohistochemistry In conjunction with manufacturer's instructions for: Roche/Ventana Benchmark Ultra – HIST 32 Leica Bond III - HIST CMP 15	A B
	Glandular and stratified squamous epithelium	AE1/3	A, B
	Germ cell tumours, with high frequency in yolk sac tumours	Alpha Fetoprotein	A
	Anaplastic lymphoma kinase large cell lymphoma.	ALK-1 (DAKO)	A, B
	Anaplastic lymphoma kinase large cell lymphoma.	ALK-1 (VMS)	A, B



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Formalin-fixed paraffin embedded tissue slides (cont'd)	<u>Immunohistochemistry for the detection of:</u> (cont'd)	Automated Immunohistochemistry In conjunction with manufacturer's instructions for: Roche/Ventana Benchmark Ultra – HIST 32 Leica Bond III - HIST CMP 15	A B
	Prostatic carcinoma	Alpha-methylacyl-CoA racemase (AMACR)	A
	Osteosarcoma, and in prostatic carcinoma	Androgen Receptor	A
	Human tumorigenesis, and in colorectal cancer	B-Catenin	A
	Presence and loss of nuclear staining in melanocytes, moderate nuclear staining of epithelial and lymphoid cells	BAP1	A
	Malignant rhabdoid tumour (MRT) of the liver	BAF-47	A
	Follicular and diffused large cell lymphomas from reactive lymph nodes	BCL2	A, B
	Diffuse large B cell lymphomas and Burkitt's lymphoma and Reed Sternberg cells in Hodgkin's disease	BCL6	A, B
	Epithelial Cells of the Colon	BerEP4	A
	B cells, plasma cells	BOB-1	A, B



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	<u>Immunohistochemistry for the detection of: (cont'd)</u>	Automated Immunohistochemistry In conjunction with manufacturer's instructions for: Roche/Ventana Benchmark Ultra – HIST 32 Leica Bond III - HIST CMP 15	A B
	Cytoplasmic staining in BRAF mutated tumour cells	BRAF V600E	A
	Nuclear staining/loss of expression correlates to tumour staging	BRG1	A
	Membranous staining in RCC and normal normal Gall bladder/ Stomach epithelium	CA IX	A
	Seminal vesicle carcinoma and anaplastic lymphoma	CA125	A
	Gastrointestinal and pancreatic cancers	CA19.9	A
	Endocrine tumour, medullary thyroid carcinoma (MTC),	Calcitonin	A
	Smooth muscle tumours	Caldesmon	A
	Smooth muscle of prostate, bowel and aorta	Calponin	A
	Mesothelial cells, steroid producing cells	Calretinin	A
	Carcinomas from malignant tumours of non-epithelial origin	Cam5.2	A, B



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	Langerhans cells in skin	CD1a	B
	T cell lymphomas	CD2	A, B
	Normal and neoplastic T cells from thymocytes to mature T cells	CD3	B
	Inducer T cells both normal and neoplastic	CD4	A, B
	T cell lymphomas and mantle cell lymphoma	CD5	A, B
	Peripheral blood T lymphocytes NK cells Thymocytes	CD7	B
	T cells cytotoxic / suppressor	CD8	A, B
	All germinal centre cells – tonsil Renal cell carcinoma	CD10	A, B
	Hairy cell leukaemia	CD11c	B
	Myeloid antigen	CD13	B
	Monocyte differentiation antigen	CD14	B



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	Granulocytes, Reed-Sternberg cells	CD15	B
	Natural killer cells	CD16	A, B
	Common B cell marker, expressed by B cells and follicular dendritic cells	CD19	B
	B cells	CD20	B
	Follicular dendritic cells	CD21	A, B
	B cell marker	CD22	B
	Small B cell lymphocytic lymphoma	CD23	A, B
	Activated T lymphocytes; Natural Killer cell	CD25	A, B
	Post germinal centre B cell marker	CD27	B
	Reed Sternberg cells in Hodgkin's lymphoma, anaplastic large cell lymphoma and plasma cells	CD30	A, B
	Endothelial cells. Benign and malignant vascular disorders	CD31	A, B





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	Myeloid marker	CD33	B
	Leucocyte differentiation	CD34	A, B
	Erythrocytes, leukocytes, glomerular podocytes and follicular dendritic cells	CD35	A, B
	Thymocytes, germinal centre B cells, activated T cells, plasma cells, monocytes	CD38	B
	T and B cell lymphomas	CD43	A, B
	Malignant cells in epithelial, mesothelial and hemopoiesis tissues	CD44	A
	All Leucocytes	CD45	A, B
	T & B lymphocytes	CD45RO	B
	Neural / neuroendocrine tissue and natural killer cells	CD56	A, B
	Mononuclear cells, natural killer and neuroectodermal cells	CD57	A, B
	Identify platelets, megakaryocytes and platelet thrombi	CD61	B
	Red blood cell marker	CD71	B



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	B cells all stages	CD79a	B
	Red blood cell marker	CD71	A, B
	B cells all stages	CD71	B
	T- Lymphocytes, granulosa cells ovary, pancreatic islet cells, CNS ependymal cells and Sertoli's, Ewing's sarcoma	CD79a	A, B
	Membrane staining of intraepithelial T-cells and some periphery regulatory T cells	CD99	A, B
	KIT protein in gastro-intestinal stromal tumours	CD103 (clone EP206)	B
	Plasma cells	CD117	A, B
	Macrophages	CD138	A, B
	Lung carcinoma	CD163	B
	Surface of the villus, crypts and in sporadic colorectal cancers	CDK4	A
	Mucosal epithelia of the adult colon	CDX2	A
	Neuroendocrine tumours	Carcinoembryonic antigen (CEA)	A
		Chromogranin (CG)	A



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	Epithelial tumour cells	CK5/6	B
	Adenocarcinomas of breast, lung, endometrium, ovary, thyroid and carcinomas of bladder and renal cell	CK7	A
	Neoplasms of squamous cell	CK14	A
	Squamous cell carcinomas of the lung, cervix and oral cavity	CK17	A
	Adenocarcinomas of colon, stomach, pancreas, biliary tract, liver and breast	CK19	A
	Columnar cell epithelium	CK20	A
	Prostate carcinoma	CK903	A
	Cytomegalovirus infected cells	CMV	A
	Oncogene	cMYC	B
	Basement membranes associated with Alport syndrome and Goodpasture's syndrome	Collagen IV	A
	Plasma biomarker for germinal centre activity, peritoneal macrophages, Kupffer cells	CXCL13	B



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	Mantle cell lymphomas and breast	Cyclin D1	B
	Lymphatic vessels	D240	A
	Hairy cell leukaemia	DBA44	A, B
	Smooth and striated muscle tumours	Desmin	B
	Gastro-intestinal stromal tumours	DOG-1	A
	Adenocarcinoma from mesothelioma and ductal vs lobular cancer of the breast	E-Cadherin	A
	Epstein Barr Encoded RNA expressing cells	EBER ISH	A
	Variety of normal and neoplastic epithelia	EMA	A
	Oestrogen receptors breast carcinoma	ER	A, B
	Prostate carcinoma	ERG	A
	Endothelia cells	Factor VIII	A
	Bone marrow dermal dendritic cells, distinct from Langerhans cells	Factor XIIIa	A



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	<u>Immunohistochemistry for the detection of:</u> (cont'd)	Automated Immunohistochemistry In conjunction with manufacturer's instructions for: Roche/Ventana Benchmark Ultra – HIST 32 Leica Bond III - HIST CMP 15	A
	Dendritic cells and Hodgkin's disease	Fascin	B
	Ewing sarcoma, Angiosarcoma	Fli-1	A
	B cell marker	Fox-P1	B
	T cell regulatory cells marker	Fox-P3	B
	Cytoplasmic staining in hepatocytes, loss in germline mutations	Fumarate Hydratase (FH)	A
	T-cells and endothelial cells	GATA-3	A
	Immuno-reactive cells, associated with mucous glands	Gastrin	A
	Breast Carcinoma	GCDFP	B
	Germinal centre B cell marker	GCET-1	B
	Astrocytes, Schwann cells	GFAP	A
	Human pancreatic islets, Glucagonomas	Glucagon	A
	Erythrocytes	Glycophlorin C (Ret 40)	B
	Erythrocytes	Glycophlorin A (CD235a)	A, B
	Cytotoxic granules	Granzyme	B



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	Mesothelial cells benign and malignant	HBME-1	B
	Hepatocellular carcinoma, hepatoblastoma, melanoma, testicular germ cell tumours and Wilms tumour	Glypican 3	A
	Placental secreting trophoblasts	HCG	A, B
	Membrane staining of MHS class II complex	HLA-DR	A
	Leukaemia marker	HLA-DR (TAL-1B5)	B
	Helicobacter pylori protein	H Pylori	A
	Human Herpes Virus 8	HHV8	A, B
	Marker of Her2 amplification in breast tumours.	Her2	A
	Marker of Her2 amplification in breast tumours.	Her2 DDISH	A
	Hepatocellular carcinoma	HepR1	A
	Melanoma cells	HMB45	A
	T cell Follicular helper cells	ICOS	B
	Plasma cells and related lymphoid cells containing IgA	IgA	A, B



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	Plasma cells and related lymphoid cells containing IgD	IgD	B
	Plasma cells and related lymphoid cells containing IgG	IgG	A, B
	Plasma cells and related lymphoid cells containing IgG4	IgG4	A, B
	Plasma cells and related lymphoid cells containing IgM	IgM	A, B
	Leydig and Sertoli cells testis	Inhibin	A
	Islets of Langerhans in the pancreas	Insulin	A
	Immunoglobulins	J chain	B
	B cells and plasma cells	Kappa	A, B
	B cells and plasma cells	Lambda	A, B
	Small cell lung cancers	Laminin	A
	Langerhans cells	Langerin	B
	Nuclear staining associated with chromosomal aberration in T-ALL	LMO2	
	Monocytic leukaemia	Lysozyme	A, B
	Melanoma	Melan A	A



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	Mast cells	MCT	B
	Chronic lymphocytic B cell leukaemia	LEF1	B
	Proliferating cells in germinal B cells	MIB-1	A, B
	Colorectal carcinoma	MLH-1	A
	Cytokeratins 5, 6, 8, 17, 19 (All epithelia)	MNF116	A, B
	Myeloperoxidase in Neutrophils, eosinophils, monocytes	MPO	A, B
	Colorectal carcinoma	MSH2	A
	Colorectal carcinoma	MSH6	A
	Breast carcinoma	MUC-1	A
	Gastric carcinoma	MUC-2	A
	Epithelial cells	MUC-4	A
	Gastric carcinoma	MUC-5ac	A
	Epithelial cells	MUC-6	A





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	Expressed in plasma cells germinal centre B cells activated T cells and Reed Sternberg cells	MUM-1	A, B
	Epithelial cells	MUC-6	A
	Expressed in plasma cells germinal centre B cells activated T cells and Reed Sternberg cells	MUM-1	A, B
	Normal and neoplastic skeletal and cardiac muscle cells	MyoD1	A
	Rhabdomyosarcomas, Wilms tumour	Myogenin	A
	Napsin A, expressed in type II pneumocytes, kidney and foetal lung	Napsin A	A
	Neuronal intermediate filament	NF	A
	Seminiferous ducts	NUT	A
	Central and peripheral neuroendocrine cells	NSE	A
	B Cell lymphomas, germinal centre derived lymphomas	OCT-2	A, B
	Seminoma / germ cell tumour	OCT-4	A



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**The Royal Marsden NHS Foundation Trust**

**Issue No: 009    Issue date: 07 October 2024**

**Testing performed by the Organisation at the locations specified**

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/Equipment/Techniques used	Location Code
HUMAN BODY TISSUE AND FLUIDS (cont'd)	<u>Histopathological examination activities for the purposes of clinical diagnosis</u> (cont'd)	In-house documented procedures using manual methods or analysers as specific in conjunction with manufacturers' instructions as specified:	
Formalin-fixed paraffin embedded tissue slides (cont'd)	<u>Immunohistochemistry for the detection of:</u> (cont'd)	Automated Immunohistochemistry In conjunction with manufacturer's instructions for: Roche/Ventana Benchmark Ultra – HIST 32 Leica Bond III - HIST CMP 15	A
	Pre-B cells	PAX5	B
	Human immunodeficiency virus disease	P24	A, B
	P40 protein in squamous cell carcinomas (lung, urothelial, head and neck)	P40	B
	Thyroid follicular carcinomas and atypical follicular thyroid adenomas.	Pax8	A
	Pancreas islets of Langerhans cells positive	PGP 9.5	A
	Membranous and nuclear staining	PRAME	A
	Cytoplasmic/nuclear staining of tumour cells	P16	A
	Wild type and mutant forms of human p53	P53	A
	Normal proliferating cells; poorly differentiated squamous cell carcinoma, basal cells; abluminal cells	P63	A, B
	Breast carcinoma	PGR	A
	Hepatocellular carcinoma	PCEA	A



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<p><b>HUMAN BODY TISSUE AND FLUIDS (cont'd)</b></p> <p>Formalin-fixed paraffin embedded tissue slides (cont'd)</p>	<u>Histopathological examination activities for the purposes of clinical diagnosis (cont'd)</u>	In-house documented procedures using manual methods or analysers as specific in conjunction with manufacturers' instructions as specified:	
	<u>Immunohistochemistry for the detection of: (cont'd)</u>	Automated Immunohistochemistry In conjunction with manufacturer's instructions for: Roche/Ventana Benchmark Ultra – HIST 32 Leica Bond III - HIST CMP 15	A
	Systemic lupus erythematosus, T-cells in germinal centres, mantle zones and interfollicular zones	PD1	B
	PD-L1 protein expression	PD-L1 (SP142 & SP263)	A
	Cytoplasmic granules of cytolytic T-lymphocytes	Perforin	B
	Placental trophoblasts	PLAP	A
	Plasma cells	Plasma cell (V538c)	B
	Breast carcinoma	PMS2	A
	Breast carcinoma	Progesterone receptor	A
	Prostate secretory and ductal epithelium	PSA	A
	Glandular prostatic epithelium	PSAP	A
	Renal tumours	RCC	A
	Squamous cell carcinoma	SALL-4	A
	Gastrointestinal carcinoma	Serotonin	A
	Schwann cells, adipocytes, cartilage	S100	A, B



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HUMAN BODY TISSUE AND FLUIDS (cont'd)	<u>Histopathological examination activities for the purposes of clinical diagnosis</u> (cont'd)	In-house documented procedures using manual methods or analysers as specific in conjunction with manufacturers' instructions as specified:	
Formalin-fixed paraffin embedded tissue slides (cont'd)	<u>Immunohistochemistry for the detection of:</u> (cont'd)	Automated Immunohistochemistry In conjunction with manufacturer's instructions for: Roche/Ventana Benchmark Ultra – HIST 32 Leica Bond III - HIST CMP 15	A
	Nuclear and cytoplasmic staining of tissue expressing S100A and S100B	S100	B
	Smooth muscle, myoepithelial and other contractile cells	Smooth muscle actin (SMA)	A
	Somatostatin	Somatostatin	A
	Melanoma marker- especially spindle cell type	Sox-10	A
	Mantle cell lymphoma	Sox11	B
	Stat6 (signal transducers and activators of transcription)	STAT-6	A
	Synaptic vesicle protein (neurones; neuroendocrine cells)	Synaptophysin	A
	T cell subtyping	TCR beta	B
	Leukaemia's, acute lymphoblastic	Tdt	B
	Cytotoxic granules	TIA1	B
	Tartrate resistant acid phosphatase in Hairy cell leukaemia	TRAP	A



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HUMAN BODY TISSUE AND FLUIDS (cont'd)	<u>Histopathological examination activities for the purposes of clinical diagnosis</u> (cont'd)	In-house documented procedures using manual methods or analysers as specific in conjunction with manufacturers' instructions as specified:	
Formalin-fixed paraffin embedded tissue slides (cont'd)	<u>Immunohistochemistry for the detection of:</u> (cont'd)	Automated Immunohistochemistry In conjunction with manufacturer's instructions for: Roche/Ventana Benchmark Ultra – HIST 32 Leica Bond III - HIST CMP 15	A B
	Lymphomas in lung and thyroid.	TTF-1	A
	Cells of mesenchymal origin	Vimentin	A
	Mesenchymal cells, Wilms tumour, Serous ovarian adenocarcinoma	WT-1	A
Formalin-fixed paraffin embedded tissue slides	PDL-1	Documented in-house procedure in conjunction with manufacturer's instructions for Dako Autostainer 48 and Dako PT Link HIST CMP 6	B
Sentinel lymph node tissue	Detection of Cytokeratin 19 (CK19) mRNA in breast carcinoma (OSNA)	OSNA (One Step Nucleic Acid Amplification)  Documented in-house procedures In conjunction with manufacturer's instructions for Sysmex RD210 , Eppendorf minispin. HIST SD 08	A, B



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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY TISSUE AND FLUIDS (cont'd)	<u>Cytopathological (Non-Gynae) examination activities for the purposes of clinical diagnosis</u>	Macroscopic and microscopic examination	
Serous fluids Fine Needle Aspirations Cerebro-spinal fluid (CSF) Sputum Bronchio-alveolar lavage Bronchial washings	The examination of body fluid/fine needle aspirate samples to exclude or identify morphological and cytological abnormalities for the purpose of clinical diagnosis	Documented in-house procedures in conjunction with manufacturer's instructions for Cytopsin, Gemini Shandon Varistain CYTO 23 CYTO 3 CYTO 4 CYTO 9 CYTO 2	A
TIC sentinel lymph node	Demonstration of cells (nuclei and cytoplasm) and micro-organisms	Tinctorial stains (Special Stains): <ul style="list-style-type: none"><li>• Papanicolaou (PAP)</li><li>• May-Grunwald Giemsa (MGG)</li><li>• Diff Quick</li></ul> Shandon Varistain Gemini CYTO 16 CYTO 15 CYTO 17  Manual staining CYTO 17	A
Samples as above	Preparation of cell blocks for histology processing and staining	CYTO 38	A
Body fluids Fine Needle Aspirations	Routine cytology of non-gynae: One stop Breast Clinic	Macroscopic and microscopic examination HIST 124	A
END			