


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 <p>9929</p> <p>Accredited to ISO 15189:2012</p>	<h3>Royal Marsden NHS Foundation Trust</h3> <p>Issue No: 003 Issue date: 11 August 2020</p>	
	<p>The Royal Marsden NHS Foundation Trust Department of Histo/Cytopathology Royal Marsden NHS Foundation Trust Fulham Road London SW3 6JJ United Kingdom</p>	<p>Contact: Glenn Noel-Storr Tel: +44 (0)207 808 2632 Fax: +44 (0)207 808 2578 E-Mail: glen.noel-storr@rmh.nhs.uk</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: As above</p> <p>Local contact: Glenn Noel-Storr Tel: +44 (0)207 808 2632 Fax: +44 (0) 207 808 2578 E-Mail: glen.noel-storr@rmh.nhs.uk</p>	<p>Histology Non-Gynae Cytology Immunohistochemistry In-situ Hybridisation OSNA</p>	A
<p>Address: Department of Histo/Cytopathology Royal Marsden NHS Foundation Trust Downs road Sutton London SM2 5PT</p> <p>Local contact: Natalie Peters Tel: 0208 915 6549 Fax: 0208 915 6566 Email: natalie.peters@rmh.nhs.uk</p>	<p>Histology Non-gynae cytology specimen preparation and staining Immunohistochemistry In-situ Hybridisation OSNA</p>	B



9929
Accredited to
ISO 15189:2012

Schedule of Accreditation
issued by
United Kingdom Accreditation Service
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

Royal Marsden NHS Foundation Trust

Issue No: 003 **Issue date:** 11 August 2020

Testing performed by the Organisation at the locations specified

DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY TISSUE AND FLUIDS	<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 and frozen, including Bone Marrow trephines. Non-gynae cytology cell blocks	The examination of tissues to exclude or identify morphological and cytological abnormalities for the purpose of clinical diagnosis	Macroscopic and Microscopic examination Supported by: Manual Tissue dissection using SOP: HIST 129, HIST 162; HIST 164, HIST CMP 146	A, B
Fresh tissue only		Cryomicrotomy and Intraoperative Frozen Sections by Thermo Scientific HM525NX cryostat using SOP: HIST 17	A
		Tissue Processing: VIP5, VIP6, VIP 6 AI using SOP: HIST 1, HIST CMP 01	A, B
		Embedding: Sakura Tec 5 using SOP: HIST 3, HIST CMP 03	A, B
		Section Cutting: Leica RM 2135, Leica RM 2235, TS slide mate, SOP: HIST 23, HIST CMP 23, HIST 149, HIST CMP 10	
Stained Formalin-fixed paraffin embedded tissue slides	Morphological assessment and interpretation/diagnosis	Microscopy using SOP: HIST MAN 09, HIST 261, HIST 124	A, B



9929
Accredited to
ISO 15189:2012

Schedule of Accreditation
issued by
United Kingdom Accreditation Service
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

Royal Marsden NHS Foundation Trust

Issue No: 003 **Issue date:** 11 August 2020

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) Formalin-fixed paraffin embedded tissue slides	<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>Demonstration of:</u>	Special Tinctorial Histochemical Staining Methods using Manual techniques:	A
	Basophilic and eosinophilic structures	Routine H&E staining Leica Autostainer XL, CV5030 Coverslipper using SOP: HIST 5 (automated) and HIST 131 (manual), HIST 322, HIST 7	A
		Routine H&E staining Leica ST5020 Multi-stainer with CV5030 coverslipper SOP: HIST CMP 5 (automated), HIST 131 (manual)	B
	Acid mucins	Alcian Blue Technique using SOP: HIST 59	A
	Acid and Neutral mucins	Alcian Blue – Periodic Acid-Schiff ± Diastase using SOP: HIST 63, HIST 65 SOP: HIST CMP 63, HIST CMP 65	A B
	Amyloid	Congo Red (Highman) using SOP: HIST CMP 70	B
	Bone marrow cell differentiation	Giemsa Stain using SOP: HIST 67 SOP: HIST CMP 67	A B
	Glycogen	PAS ± Diastase using SOP: HIST 82, HIST 81 SOP: HIST CMP 81, HIST CMP 82	A B
	M. Tuberculosis	Ziehl Neelsen using SOP: HIST 91 SOP: HIST CMP 91	A B



9929
Accredited to
ISO 15189:2012

Schedule of Accreditation
issued by
United Kingdom Accreditation Service
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

Royal Marsden NHS Foundation Trust

Issue No: 003 **Issue date:** 11 August 2020

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 (cont'd)</u>	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)	Demonstration of:	Special Tinctorial Histochemical Staining Methods using Manual techniques:	B
	Haemosiderin	Perl's Prussian Blue Stain using SOP: HIST CMP 83	
	Reticulin Fibres	Gordon and Sweet Stain using SOP: HIST CMP 85	
Formalin-fixed paraffin embedded tissue slides (cont'd)	<u>Immunohistochemistry for the detection of:</u>	Automated Immunohistochemistry In conjunction with manufacturer's instructions for Roche/Ventana Benchmark Ultra SOP: HIST 32 incorporating the following antibodies.	A
	Germ cell tumours, with high frequency in yolk sac tumours	Alpha Fetoprotein	
	Prostatic carcinoma	Alpha-methylacyl-CoA racemase (AMACR)	
	Osteosarcoma, and in prostatic carcinoma	Androgen Receptor	
	Human tumorigenesis, and in colorectal cancer	B-Catenin	
	Malignant rhabdoid tumour (MRT) of the liver	BAF-47	
	Epithelial Cells of the Colon	BerEP4	
	Cervical carcinoma	BRACHYURY	
	Seminal vesicle carcinoma and anaplastic lymphoma	CA125	



9929
Accredited to
ISO 15189:2012

Schedule of Accreditation
issued by
United Kingdom Accreditation Service
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

Royal Marsden NHS Foundation Trust

Issue No: 003 **Issue date:** 11 August 2020

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 (cont'd)</u>	In-house documented procedures using manual methods or analysers as specific in conjunction with manufacturers' instructions as specified:	A
Formalin-fixed paraffin embedded tissue slides (cont'd)	<u>Immunohistochemistry for the detection of:</u>	Automated Immunohistochemistry In conjunction with manufacturer's instructions for Roche/Ventana Benchmark Ultra SOP: HIST 32 incorporating the following antibodies.	
	Gastrointestinal and pancreatic cancers	CA19.9	
	Endocrine tumour, medullary thyroid carcinoma (MTC),	Calcitonin	
	Smooth muscle tumours	Caldesmon	
	Smooth muscle of prostate, bowel and aorta	Calponin	
	Mesothelial cells, steroid producing cells	Calretinin	
	B cell chronic lymphocytic leukaemia's	CD21	
	Malignant cells in epithelial, mesothelial and hemopoiesis tissues	CD44	
	Lung carcinoma	CdK4	
	Surface of the villus, crypts and in sporadic colorectal cancers	CDX2	
	Mucosal epithelia of the adult colon	Carcinoembryonic antigen (CEA)	
	Neuroendocrine tumours	Chromogranin (CG)	



9929
Accredited to
ISO 15189:2012

Schedule of Accreditation
issued by
United Kingdom Accreditation Service
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

Royal Marsden NHS Foundation Trust

Issue No: 003 **Issue date:** 11 August 2020

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 (cont'd)</u>	In-house documented procedures using manual methods or analysers as specific in conjunction with manufacturers' instructions as specified:	A
Formalin-fixed paraffin embedded tissue slides (cont'd)	<u>Immunohistochemistry for the detection of:</u>	Automated Immunohistochemistry In conjunction with manufacturer's instructions for Roche/Ventana Benchmark Ultra SOP: HIST 32 incorporating the following antibodies.	
	Epithelial tumour cells	CK5/6	
	Adenocarcinomas of breast, lung, endometrium, ovary, thyroid and carcinomas of bladder and renal cell	CK7	
	Neoplasms of squamous cell	CK14	
	Squamous cell carcinomas of the lung, cervix and oral cavity	CK17	
	Adenocarcinomas of colon, stomach, pancreas, biliary tract, liver and breast	CK19	
	Columnar cell epithelium	CK20	
	Prostate carcinoma	CK903	
	Cytomegalovirus infected cells	CMV	
	Basement membranes associated with Alport syndrome and Goodpasture's syndrome	Collagen IV	
	Smooth and striated muscle tumours	Desmin	



9929
Accredited to
ISO 15189:2012

Schedule of Accreditation
issued by
United Kingdom Accreditation Service
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

Royal Marsden NHS Foundation Trust

Issue No: 003 **Issue date:** 11 August 2020

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 (cont'd)</u>	In-house documented procedures using manual methods or analysers as specific in conjunction with manufacturers' instructions as specified:	A
Formalin-fixed paraffin embedded tissue slides (cont'd)	<u>Immunohistochemistry for the detection of:</u>	Automated Immunohistochemistry In conjunction with manufacturer's instructions for Roche/Ventana Benchmark Ultra SOP: HIST 32 incorporating the following antibodies.	
	Gastro-intestinal stromal tumours	DOG-1	
	Adenocarcinoma from mesothelioma and ductal vs lobular cancer of the breast	E-Cadherin	
	Prostate carcinoma	ERG	
	Endothelia cells	Factor VIII	
	Bone marrow dermal dendritic cells, distinct from Langerhans cells	Factor XIIIa	
	Ewing sarcoma, Angiosarcoma	Fli-1	
	T-cells and endothelial cells	GATA-3	
	Immuno-reactive cells, associated with mucous glands	Gastrin	
	Breast Carcinoma	GDCFP	
	Astrocytes, Schwann cells	GFAP	
	Human pancreatic islets, Glucagonomas	Glucagon	



9929
Accredited to
ISO 15189:2012

Schedule of Accreditation
issued by
United Kingdom Accreditation Service
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

Royal Marsden NHS Foundation Trust

Issue No: 003 **Issue date:** 11 August 2020

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 (cont'd)</u>	In-house documented procedures using manual methods or analysers as specific in conjunction with manufacturers' instructions as specified:	A
Formalin-fixed paraffin embedded tissue slides (cont'd)	<u>Immunohistochemistry for the detection of:</u>	Automated Immunohistochemistry In conjunction with manufacturer's instructions for Roche/Ventana Benchmark Ultra SOP: HIST 32 incorporating the following antibodies.	
	Hepatocellular carcinoma, hepatoblastoma, melanoma, testicular germ cell tumours and Wilms tumour	Glypican 3	
	Mesothelial cells benign and malignant	HBME-1	
	Placental secreting trophoblasts	BHCG	
	Hepatocellular carcinoma	HepR1	
	Melanoma cells	HMB45	
	Leydig and Sertoli cells testis	Inhibin	
	Islets of Langerhans in the pancreas	Insulin	
	Small cell lung cancers	Laminin	
	Melanoma	Melan A	
	Colorectal carcinoma	MLH-1	
	Colorectal carcinoma	MSH2	
	Colorectal carcinoma	MSH6	



9929
Accredited to
ISO 15189:2012

Schedule of Accreditation
issued by
United Kingdom Accreditation Service
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

Royal Marsden NHS Foundation Trust

Issue No: 003 Issue date: 11 August 2020

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 (cont'd)</u>	In-house documented procedures using manual methods or analysers as specific in conjunction with manufacturers' instructions as specified:	A
Formalin-fixed paraffin embedded tissue slides (cont'd)	<u>Immunohistochemistry for the detection of:</u>	Automated Immunohistochemistry In conjunction with manufacturer's instructions for Roche/Ventana Benchmark Ultra SOP: HIST 32 incorporating the following antibodies.	
	Breast carcinoma	MUC-1	
	Gastric carcinoma	MUC-2	
	Epithelial cells	MUC-4	
	Gastric carcinoma	MUC-5ac	
	Epithelial cells	MUC-6	
	Expressed in plasma cells germinal centre B cells activated T cells and Reed Sternberg cells	MUM-1	
	Normal and neoplastic skeletal and cardiac muscle cells	MyoD1	
	Rhabdomyosarcomas, Wilms tumour	Myogenin	
	Napsin A, expressed in type II pneumocytes, kidney and foetal lung	Napsin A	
	Neuroblastoma and small round cell tumours	NB84	
	Neuronal intermediate filament	Neurofilament	



9929
Accredited to
ISO 15189:2012

Schedule of Accreditation
issued by
United Kingdom Accreditation Service
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

Royal Marsden NHS Foundation Trust

Issue No: 003 **Issue date:** 11 August 2020

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 (cont'd)</u>	In-house documented procedures using manual methods or analysers as specific in conjunction with manufacturers' instructions as specified:	A
Formalin-fixed paraffin embedded tissue slides (cont'd)	<u>Immunohistochemistry for the detection of:</u>	Automated Immunohistochemistry In conjunction with manufacturer's instructions for Roche/Ventana Benchmark Ultra SOP: HIST 32 incorporating the following antibodies.	
	Seminiferous ducts	NUT	
	Central and peripheral neuroendocrine cells	NSE	
	Seminoma / germ cell tumour	OCT-3/4	
	P40 protein in squamous cell carcinomas (lung, urothelial, head and neck)	P40	
	Thyroid follicular carcinomas and atypical follicular thyroid adenomas.	Pax8	
	Normal proliferating cells; poorly differentiated squamous cell carcinoma, basal cells; abluminal cells	P63	
	Hepatocellular carcinoma	PCEA	
	PD-L1 protein expression	PDL-1	
	Placental trophoblasts	PLAP	
	Breast carcinoma	PMS2	
	Prostate secretory and ductal epithelium	PSA	



9929
Accredited to
ISO 15189:2012

Schedule of Accreditation
issued by
United Kingdom Accreditation Service
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

Royal Marsden NHS Foundation Trust

Issue No: 003 **Issue date:** 11 August 2020

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 (cont'd)</u>	In-house documented procedures using manual methods or analysers as specific in conjunction with manufacturers' instructions as specified:	A
Formalin-fixed paraffin embedded tissue slides (cont'd)	<u>Immunohistochemistry for the detection of:</u>	Automated Immunohistochemistry In conjunction with manufacturer's instructions for Roche/Ventana Benchmark Ultra SOP: HIST 32 incorporating the following antibodies.	
	Glandular prostatic epithelium	PSAP	
	Renal tumours	RCC	
	Schwann cells, adipocytes, cartilage	S100p	
	Squamous cell carcinoma	SALL-4	
	Gastrointestinal carcinoma	Serotonin	
	Smooth muscle, myoepithelial and other contractile cells	Smooth muscle actin (SMA)	
	Somatostatin	Somatostatin	
	Melanoma marker- especially spindle cell type	Sox-10	
	Stat6 (signal transducers and activators of transcription)	STAT-6	
	Synaptic vesicle protein (neurones; neuroendocrine cells)	Synaptophysin	
	Thyroid follicular epithelial cells	Thyroglobulin	
	TLE1 gene	TLE-1	



9929
Accredited to
ISO 15189:2012

Schedule of Accreditation
issued by
United Kingdom Accreditation Service
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

Royal Marsden NHS Foundation Trust

Issue No: 003 **Issue date:** 11 August 2020

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 (cont'd)</u>	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> Lymphomas in lung and thyroid. Cells of mesenchymal origin Mesenchymal cells, Wilms tumour, Serous ovarian adenocarcinoma	Automated Immunohistochemistry In conjunction with manufacturer's instructions for Roche/Ventana Benchmark Ultra SOP: HIST 32 incorporating the following antibodies. TTF-1 Vimentin WT-1	A
Formalin-fixed paraffin embedded tissue slides (cont'd)	<u>Immunohistochemistry for the detection of:</u> Oestrogen receptors breast carcinoma Breast carcinoma Marker of Her2 amplification in breast tumours. Marker of Her2 amplification in breast tumours.	Automated Immunohistochemistry In conjunction with manufacturer's instructions for Roche/Ventana Benchmark XT SOP: HIST 43, HIST 118, HIST 55 incorporating the following antibodies. ER Progesterone receptor Her2 (IHC) Her2 DDISH	A
	Epstein Barr Encoded RNA expressing cells	EBER ISH	A, B



9929
Accredited to
ISO 15189:2012

Schedule of Accreditation
issued by
United Kingdom Accreditation Service
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

Royal Marsden NHS Foundation Trust

Issue No: 003 **Issue date:** 11 August 2020

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 (cont'd)</u>	In-house documented procedures using manual methods or analysers as specific in conjunction with manufacturers' instructions as specified:	B
Formalin-fixed paraffin embedded tissue slides (cont'd)	<u>Immunohistochemistry for the detection of:</u>	Automated Immunohistochemistry In conjunction with manufacturer's instructions for Roche/Ventana Benchmark Ultra SOP: HIST CMP 35 incorporating the following antibodies.	
	Hairy Cell Leukaemia	Annexin	
	Hairy Cell Leukaemia	CD11c	
	Interleukin 3 receptor a-chain in Monocytes; neutrophils; basophils	CD123	
	Myeloid antigen	CD13	
	Monocyte differentiation antigen	CD14	
	Natural killer cells	CD16	
	Macrophages	CD163	
	Common B cell marker, expressed by B cells and follicular dendritic cells	CD19	
	Circulating T lymphocytes	CD2	
	B cell marker	CD22	
	Post germinal centre B cell marker	CD27	
	Myeloid marker	CD33	



9929
Accredited to
ISO 15189:2012

Schedule of Accreditation
issued by
United Kingdom Accreditation Service
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

Royal Marsden NHS Foundation Trust

Issue No: 003 **Issue date:** 11 August 2020

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 (cont'd)</u>	In-house documented procedures using manual methods or analysers as specific in conjunction with manufacturers' instructions as specified:	B
Formalin-fixed paraffin embedded tissue slides (cont'd)	<u>Immunohistochemistry for the detection of:</u>	Automated Immunohistochemistry In conjunction with manufacturer's instructions for Roche/Ventana Benchmark Ultra SOP: HIST CMP 35 incorporating the following antibodies.	
	Multifunctional enzyme, identify plasma cells and plasmablastic differentiation	CD38	
	T & B lymphocytes	CD45RA	
	T & B lymphocytes	CD45RO	
	Identify platelets, megakaryocytes and platelet thrombi	CD61	
	Peripheral blood T lymphocytes; NK cells; thymocytes	CD7	
	Red blood cell marker	CD71	
	Oncogene	cMYC	
	T Cell follicular helper cell marker	CXCL-13	
	Dendritic cells and Hodgkin's disease	Fascin	
	B cell marker	Fox-P1	
	T cell regulatory cells marker	Fox-P3	



9929
Accredited to
ISO 15189:2012

Schedule of Accreditation
issued by
United Kingdom Accreditation Service
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

Royal Marsden NHS Foundation Trust

Issue No: 003 **Issue date:** 11 August 2020

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 (cont'd)</u>	In-house documented procedures using manual methods or analysers as specific in conjunction with manufacturers' instructions as specified:	B
Formalin-fixed paraffin embedded tissue slides (cont'd)	<u>Immunohistochemistry for the detection of:</u>	Automated Immunohistochemistry In conjunction with manufacturer's instructions for Roche/Ventana Benchmark Ultra SOP: HIST CMP 35 incorporating the following antibodies.	
	Germinal centre B cell marker	GCET-1	
	Erythrocytes	Glycophlorin C (Ret 40)	
	Cytotoxic granules	Granzyme	
	Leukaemia marker	HLA-DR (TAL-1B5)	
	T cell Follicular helper cells	ICOS	
	Immunoglobulins	J Chain	
	Langerhans cells	Langerin	
	Mast cells	MCT	
	Systemic lupus erythematosus, T-cells in germinal centres, mantle zones and interfollicular zones	PD1	
	Cytotoxic granules	Perforin	
	Mantle cell lymphoma	Sox11	
	T cell subtyping	TCR beta	
	Cytotoxic granules	TIA1	



9929
Accredited to
ISO 15189:2012

Schedule of Accreditation
issued by
United Kingdom Accreditation Service
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

Royal Marsden NHS Foundation Trust

Issue No: 003 **Issue date:** 11 August 2020

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 (cont'd)</u>	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>	Automated Immunohistochemistry In conjunction with manufacturer's instructions for Roche/Ventana Benchmark Ultra SOP: HIST 32, HIST CMP 35 incorporating the following antibodies.	A, B
	Glandular and stratified squamous epithelium	AE1/3	
	Anaplastic lymphoma kinase large cell lymphoma.	ALK-1 (DAKO)	
	Anaplastic lymphoma kinase large cell lymphoma.	ALK-1 (VMS)	
	Follicular and diffused large cell lymphomas from reactive lymph nodes	BCL2	
	Diffuse large B cell lymphomas and Burkitt's lymphoma and Reed Sternberg cells in Hodgkin's disease	BCL6	
	B cells, plasma cells	BOB-1	
	Carcinomas from malignant tumours of non-epithelial origin	Cam5.2	
	Langerhans cells in skin	CD1a	
	Normal and neoplastic T cells from thymocytes to mature T cells	CD3	



9929
Accredited to
ISO 15189:2012

Schedule of Accreditation
issued by
United Kingdom Accreditation Service
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

Royal Marsden NHS Foundation Trust

Issue No: 003 **Issue date:** 11 August 2020

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 (cont'd)</u>	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>	Automated Immunohistochemistry In conjunction with manufacturer's instructions for Roche/Ventana Benchmark Ultra SOP: HIST 32, HIST CMP 35 incorporating the following antibodies.	A, B
	Inducer T cells both normal and neoplastic	CD4	
	T cell lymphomas and mantle cell lymphoma	CD5	
	T cells cytotoxic / suppressor	CD8	
	All germinal centre cells – tonsil Renal cell carcinoma	CD10	
	Granulocytes, Reed-Sternberg cells	CD15	
	B cells	CD20	
	Follicular dendritic cells	CD21	
	Small B cell lymphocytic lymphoma	CD23	
	Activated T lymphocytes; Natural Killer cell	CD25	
	Reed Sternberg cells in Hodgkin's lymphoma, anaplastic large cell lymphoma and plasma cells	CD30	



9929
Accredited to
ISO 15189:2012

Schedule of Accreditation
issued by
United Kingdom Accreditation Service
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

Royal Marsden NHS Foundation Trust

Issue No: 003 **Issue date:** 11 August 2020

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 (cont'd)</u>	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>	Automated Immunohistochemistry In conjunction with manufacturer's instructions for Roche/Ventana Benchmark Ultra SOP: HIST 32, HIST CMP 35 incorporating the following antibodies.	A, B
	Endothelial cells. Benign and malignant vascular disorders	CD31	
	Leucocyte differentiation	CD34	
	Erythrocytes, leukocytes, glomerular podocytes and follicular dendritic cells	CD35	
	T and B cell lymphomas	CD43	
	All Leucocytes	CD45	
	Neural / neuroendocrine tissue and natural killer cells	CD56	
	Mononuclear cells, natural killer and neuroectodermal cells	CD57	
	T cells. Natural killer cells, thymocytes	CD68 (KPI)	
	T cells. Natural killer cells, thymocytes	CD68 (PGM1)	
	B cells all stages	CD79a	



9929
Accredited to
ISO 15189:2012

Schedule of Accreditation
issued by
United Kingdom Accreditation Service
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

Royal Marsden NHS Foundation Trust

Issue No: 003 **Issue date:** 11 August 2020

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 (cont'd)</u>	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> T- Lymphocytes, granulosa cells ovary, pancreatic islet cells, CNS ependymal cells and Sertoli's, Ewing's sarcoma	Automated Immunohistochemistry In conjunction with manufacturer's instructions for Roche/Ventana Benchmark Ultra SOP: HIST 32, HIST CMP 35 incorporating the following antibodies. CD99	A, B
	KIT protein in gastro-intestinal stromal tumours	CD117	
	Plasma cells	CD138	
	Mantle cell lymphomas and breast	Cyclin D1	
	Lymphatic vessels	D240	
	Hairy cell leukaemia	DBA44	
	Variety of normal and neoplastic epithelia	EMA	
	Erythrocytes	Glycophlorin A (CD235a)	
	Helicobacter pylori protein	H Pylori	
	Human Herpes Virus 8	HHV8	
	Plasma cells and related lymphoid cells containing IgA	IgA	
	Plasma cells and related lymphoid cells containing IgD	IgD	



9929
Accredited to
ISO 15189:2012

Schedule of Accreditation
issued by
United Kingdom Accreditation Service
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

Royal Marsden NHS Foundation Trust

Issue No: 003 **Issue date:** 11 August 2020

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 (cont'd)</u>	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>	Automated Immunohistochemistry In conjunction with manufacturer's instructions for Roche/Ventana Benchmark Ultra SOP: HIST 32, HIST CMP 35 incorporating the following antibodies.	A, B
	Plasma cells and related lymphoid cells containing IgG	IgG	
	Plasma cells and related lymphoid cells containing IgG4	IgG4	
	Plasma cells and related lymphoid cells containing IgM	IgM	
	B cells and plasma cells	Kappa	
	B cells and plasma cells	Lambda	
	Monocytic leukaemia	Lysosome	
	Proliferating cells in germinal B cells	MIB-1	
	Cytokeratins 5, 6, 8, 17, 19 (All epithelia)	MNF116	
	Myeloperoxidase in Neutrophils, eosinophils, monocytes	MPO	
	Expressed in plasma cells germinal centre B cells activated T cells and Reed Sternberg cells	MuM1	



9929
Accredited to
ISO 15189:2012

Schedule of Accreditation
issued by
United Kingdom Accreditation Service
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

Royal Marsden NHS Foundation Trust

Issue No: 003 **Issue date:** 11 August 2020

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 (cont'd)</u>	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> B Cell lymphomas, germinal centre derived lymphomas Pre-B cells Wild type and mutant forms of human p53 Schwann cells, adipocytes, cartilage Leukaemia's, acute lymphoblastic Tartrate resistant acid phosphatase in Hairy cell leukaemia	Automated Immunohistochemistry In conjunction with manufacturer's instructions for Roche/Ventana Benchmark Ultra SOP: HIST 32, HIST CMP 35 incorporating the following antibodies. OCT-2 PAX5 P53 S100 TdT TRAP	A, B
Formalin-fixed paraffin embedded tissue slides	PDL-1	Documented in-house procedure using SOP HIST CMP 6 in conjunction with manufacturer's instructions for Dako Autostainer 48 and Dako PT Link	B
Sentinel lymph node tissue	Detection of Cytokeratin 19 (CK19) mRNA in breast carcinoma	Documented in-house procedures using SOP: HIST 169 In conjunction with manufacturer's instructions for Sysmex RD100i, Eppendorf minispin. OSNA (One Step Nucleic Acid Amplification)	A, B



9929
Accredited to
ISO 15189:2012

Schedule of Accreditation
issued by
United Kingdom Accreditation Service
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

Royal Marsden NHS Foundation Trust

Issue No: 003 **Issue date:** 11 August 2020

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)	<p><u>Histopathological examination activities for the purposes of clinical diagnosis (cont'd)</u></p> <p><u>Cytopathological (Non-Gynae) examination activities for the purposes of clinical diagnosis</u></p>	<p>In-house documented procedures using manual methods or analysers as specific in conjunction with manufacturers' instructions as specified:</p> <p>Macroscopic and microscopic examination</p>	
Serous fluids/Fine Needle Aspirations, Cerebro-spinal fluid (CSF), Sputum, Bronchio-alveolar lavage Bronchial washings, synovial fluid.	<p>The examination of body fluid/fine needle aspirate samples to exclude or identify morphological and cytological abnormalities for the purpose of clinical diagnosis</p> <p>Demonstration of:</p>	<p>documented in-house procedures SOP Non Gynae Cytology In conjunction with manufacturer's instructions for Cytosin, Gemini Shandon Varistain: SOP CYTO 23, CYTO 19, CYTO 3, CYTO 29, CYTO 4, CYTO 13, CYTO 9, CYTO 2</p>	
TIC sentinel lymph node	<p>Cells (nuclei and cytoplasm) and micro organisms</p> <p>Preparation of cell blocks for histology processing and staining</p>	<p>Tinctorial stains:</p> <ul style="list-style-type: none"> • Papanicolaou (PAP) • May-Grunwald Giemsa (MGG) • Diff Quick <p>by Shandon Varistain Gemini (automated) using SOP: CYTO 16, CYTO 15, CYTO 17 Manual staining – SOP CYTO 33</p> <p>SOP: CYTO 38</p>	A, B
Body fluids/Fine Needle Aspirations	<p>Routine cytology of non-gynae: One stop Breast Clinic</p>	<p>Macroscopic and microscopic examination: SOP HIST 124</p>	
END			