


# Schedule of Accreditation

issued by

## United Kingdom Accreditation Service

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

 <b>9727</b> Accredited to ISO 15189:2012	<b>Frimley Health NHS Foundation Trust</b>  <b>Issue No: 012 Issue date: 27 November 2024</b>	
	<b>Department of Histopathology</b> Royal Surrey County Hospital Egerton Road Guildford GU2 7XX	<b>Contact: Governance &amp; Quality Department</b> <b>Tel: +44 (0) 1276 522194 / 01932 723424</b> <b>E-Mail: <a href="mailto:fph-tr.bspsquality@nhs.net">fph-tr.bspsquality@nhs.net</a></b> <b>Website: <a href="http://www.nhspathology.fph.nhs.uk">http://www.nhspathology.fph.nhs.uk</a></b>
Testing performed by the Organisation at the locations specified below		

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

#### Laboratory locations:

Location details		Activity	Location code
<b>Address (hub)</b> Department of Histopathology Royal Surrey County Hospital Egerton Road Guildford GU2 7XX	<b>Local contact</b>  Elaine Inglis 01276 522194 01932 723424	Routine Histopathology Intraoperative frozen sections Special Stains Immunohistochemistry In-situ hybridisation Molecular Pathology including OSNA	RSCH

#### Site activities performed away from the locations listed above:

Location details		Activity	Location code
Frimley Park Hospital Portsmouth Rd Frimley Camberley GU16 7UJ	As above	Macroscopic dissection Microscopic reporting Decalcification	FPH
St Peter's Hospital Guildford Rd Lyne Chertsey KT16 0PZ	As above	Macroscopic dissection (Consultant) Microscopic reporting Decalcification	SPH



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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
HUMAN BODY TISSUE	<u>Histopathological examination activities for the purposes of clinical diagnosis</u>	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:	
Human tissue samples	Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis	Specimen dissection HIS-RSCH-SOP-34 HIS-RSCH-SOP-35 HIS-FPH-SOP-90 HIS-ASPH-SOP-40 HIS-ASPH-SOP-47  Decalcification of bony tissue Manual method using documented procedure: HIS-RSCH/FPH/ASPH-SOP-57: Decalcification  Tissue processing Using Sakura VIP 6 tissue processors HIS-RSCH-SOP-41  Tissue embedding Using Sakura TecV embedding station HIS-RSCH-SOP-59	RSCH FPH SPH  RSCH SPH FPH  RSCH  RSCH
Formalin fixed paraffin wax blocks of processed tissue		Tissue sectioning (microtomy) using Leica RM2035 and RM 2235 HIS-RSCH-SOP-61	RSCH
Fresh human tissue		Cryotomy Intra-operative frozen sections Using: Leica CM3050S HIS-RSCH-SOP-62	RSCH



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HUMAN BODY TISSUE (cont'd)	<u>Histopathological examination activities for the purposes of clinical diagnosis</u> (cont'd)	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:	
Formalin fixed paraffin embedded (FFPE)	Basophilic and eosinophilic tissue structures	Automated and manual Haematoxylin and Eosin (H&E) staining. Documented procedure & manufacturer's instructions using: Roche HE600H&E stainer and coverslipping module, and Myreva Stainer (Mega slide staining). HIS-RSCH-SOP-104	RSCH
Frozen sections	Basophilic and eosinophilic tissue structures	Manual rapid H&E staining HIS-RSCH-SOP-4	RSCH
FFPE sections	Special stains to detect the following:	Documented in-house procedures for manual special stains HIS-RSCH-SOP-4	RSCH
	Elastic fibres	Elastic Van Gieson (EVG)	
	Reticulin fibres	Gordon and Sweet's Retic	
	Connective tissue	Haematoxylin Van Gieson (HVG) commercial kit - Atom Scientific Ltd.	
	Acid Mucins	Hale's Dialysed Iron, commercial kit - Atom Scientific Ltd.	
	Fibrin	Martius Scarlet Blue (MSB) commercial kit - Atom Scientific Ltd.	
	Melanin	Masson's Fontana commercial kit - Atom Scientific Ltd.	
	Connective tissue	Masson's Trichrome	
	Melanin	Melanin Bleach HE	



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HUMAN BODY TISSUE (cont'd)	<u>Histopathological examination activities for the purposes of clinical diagnosis</u> (cont'd)	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:	
FFPE sections	Special stains to detect the following:	Documented in-house procedures for manual special stains HIS-RSCH-SOP-4	RSCH
	Copper associated protein and hepatitis B affected cells	Shikata's Orcein	
	Mucins	Mucicarmine, Southgate's stain	
	Mast cells	Toluidine Blue commercial kit - Atom Scientific Ltd.	
	Calcium	Von Kossa commercial kit - Atom Scientific Ltd.	
	Leprosy	Wade Fite	
		Documented in-house procedures for automated special stains using Roche Ventana Special Stainers HIS-RSCH-SOP-4, HIS-RSFT-SOP-126	RSCH
	Mucins	Alcian Blue +/- diastase (ABPAS+/- D)	
	Amyloid	Congo red	
	Bone marrow elements	Giemsa	
	Gram +/- organisms	Gram	
	Fungi	Grocott	
	Basement membranes	Jones Methanamine (Hexamine) Silver	
	Helicobacter pylori	Modified Giemsa	



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FFPE sections	Special stains to detect the following:	Documented in-house procedures for automated special stains using Roche Ventana Special Stainers HIS-RSCH-SOP-4, HIS-RSFT-SOP-126	RSCH
	Glycogen/fungi	Periodic Acid Schiff (PAS) and Diastase PAS (PAS+D)	
	Ferric iron (haemosiderin)	Perls' Prussian Blue	
	reticulenic fibers	Reticulin (Gordon and Sweet's)	
		Southgate's Mucicarmine	
	Spirochetes	Warthin Starry	
	Mycobacterium Tuberculosis	Ziehl Neelsen (ZN)	
FFPE sections (cont'd)	Special stains to detect the following continued: (cont'd)	Documented in-house procedures for manual special stains HIS-RSCH-SOP-4	RSCH
Frozen sections	Lipids	Oil Red O	RSCH FPH SPH
FFPE sections	In-situ hybridisation to detect the following:	Automated method using: HIS-RSCH-SOP-67 Roche Ventana Ultra and Roche Ventana GX and probes as appropriate	RSCH
	Her-2-Neu	HER-2 DDISH	
	Epstein Barr virus infected cells	EBER	



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FFPE sections (cont'd)	Immunohistochemistry to detect the following: (cont'd)	Automated method using: HIS-RSCH-SOP-67 Roche Ventana Ultra IHC platform Using antibodies to:	
	Basal cells	34BE12	
	Alpha-1-anti-trypsin deposits	A-1-AT	
	Epithelial cells	AE 1/3	
	Alfa-foetal protein	AFP	
	Anaplastic lymphoma	ALK-1	
	Alpha-methylacyl-CoA racemase	AMACR	
	Androgen receptor	Androgen	
	Cell adhesion marker	Beta Catenin	
	Epithelial cells	Ber EP4	
	B-Cells	BCL2	
	B-Cells	BCL6	
	CA 125	CA 125	
	Calcitonin (Thyroid)	Calcitonin	
	Smooth muscle	Caldesmon	
	Myoepithelial cells (breast)	Calponin	
	Epithelial cells	Cam 5.2	
	Langerhans cells	CD1a	



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FFPE sections (cont'd)	Immunohistochemistry to detect the following: (cont'd)	Automated method using: HIS-RSCH-SOP-67 Roche Ventana Ultra IHC platform Using antibodies to:	
	T cells	CD2	
	T cells	CD3	
	Helper T cells	CD4	
	T cells	CD5	
	T cells	CD7	
	T cells	CD8	
	Germinal centre B cells	CD10	
	Reed-Sternberg cells	CD15	
	B cells	CD20	
	B cells	CD21	
	Follicular dendritic cells	CD23	
	Activated T cells and NK cells	CD25	
	Reed-Sternberg cells	CD30	
	Endothelial cells	CD31	
	Endothelial cells	CD34	
	B cells	CD38	



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FFPE sections (cont'd)	Immunohistochemistry to detect the following: (cont'd)	Automated method using: HIS-RSCH-SOP-67 Roche Ventana Ultra IHC platform and Roche Ventana GX Using antibodies to:	
	T and B lymphocytes, monocytes, granulocytes, erythrocytes, fibroblasts, epithelial, and mast cells	CD44	
	Neurons, astrocytes, Schwann cells, NK cells and a subset of activated T lymphocytes.	CD56	
	NK cells	CD57	
	Megakaryocytes	CD61	
	Macrophages	CD68	
	B cells	CD79a	
	Islet cells	CD99	
	GIST	CD117	
	Plasma cells	CD138	
	Intestinal epithelial cells	CDX2	
	Intestinal epithelial cells	CEA (m)	
	Intestinal epithelial cells	CEA (p)	
	Pancreatic Islet cells	Chromogranin A	
	Squamous epithelial cells	CK 5/6	





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FFPE sections (cont'd)	Immunohistochemistry to detect the following: (cont'd)	Automated method using: HIS-RSCH-SOP-67 Roche Ventana Ultra IHC platform Using antibodies to:	
	Breast epithelial cells	CK7	
	Squamous epithelial cells	CK14	
	Epithelial cells	CK19	
	Epithelial cells	CK20	
	CMV	CMV	
	Basement membrane	Collagen IV	
	Squamous epithelium (tonsil)	Cyclin D1	
	Lymphatic endothelial cells, follicular dendritic cells and basal squamous endothelial cells	D2-40	
	Muscle cells	Desmin	
	Epithelial cells	E-Cadherin	
	Epithelial cells	EMA	
	ER +ve cells	Oestrogen Receptor (ER)	
	Placental macrophages and mesenchymal cells	Factor 13a	
	Gastrin producing cells (stomach/small bowel)	Gastrin	



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FFPE sections (cont'd)	Immunohistochemistry to detect the following: (cont'd)	Automated method using: HIS-RSCH-SOP-67 Roche Ventana Ultra IHC platform Using antibodies to:	
	Luminal epithelial cells (breast)	GATA 3	
	Epithelial cells of sweat glands	GCDFP-15	
	Ganglion cells/astrocytes	GFAP	
	Pancreatic islet cells	Glucagon	
	Red blood cells	Glycophorin A	
	Trophoblasts	Glypican 3	
	Cytotoxic T lymphocytes/NK cells	Granzyme B	
	Trophoblasts	Human Chorionic Gonadotrophin (HCG)	
	Hepatocytes	Hepatocyte	
	HHV8 infected cells	HHV 8	
	Antigen presenting cells	HLA DR	
	Melanoma	HMB45	
	Mesothelial cells	HBME-1	
	Plasma cells	IgA	
	Mantle zone B cells	IgD	
	Plasma cells	IgG	



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FFPE sections (cont'd)	Immunohistochemistry to detect the following: (cont'd)	Automated method using: HIS-RSCH-SOP-67 Roche Ventana Ultra IHC platform Using antibodies to:	
	IgG4 positive cells	IgG4	
	Mantle zone B cells	IgM	
	Trophoblasts and syncytiotrophoblasts or Leydig cells and Sertoli cells	Inhibin	
	B cells in the islets of Langerhans	Insulin	
	Mantle zone B cells/germinal centre Plasma cells	Kappa	
	Mantle zone B cells/germinal centre Plasma cells	Lambda	
	Lymphocytes	LCA	
	Melanoma/melanocytes	Melan A	
	Germinal centre B cells	MIB 1 (Ki-67)	
	Intestinal crypts/ lymphocytes	MLH 1	
	Epithelial cells	MNF 116	
	Epithelial cells	MOC 31	
	Neutrophils/eosinophils/germinal centre macrophages	MPO	
	Intestinal crypts/ lymphocytes	MSH 2	
	Intestinal crypts/ lymphocytes	MSH 6	



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FFPE sections (cont'd)	Immunohistochemistry to detect the following: (cont'd)	Automated method using: HIS-RSCH-SOP-67 Roche Ventana Ultra IHC platform Using antibodies to:	
	Activated B cells/ intrafollicular plasma cells	MUM 1	
	Rhabdomyosarcoma	Myogenin	
	Skeletal/cardiac muscle	Myoglobin	
	Epithelial cells of kidney	Napsin A	
	Ganglion cells/axons	Neurofilament	
	Langerhans islets	NSE	
	B cells/ plasma cells	OCT 2	
	Embryonic stem cells/ germ cells	OCT 3/4	
	P16 +ve tumour cells	P16	
	P53 +ve tumour cells	P53	
	Basal epithelial cells	P63	
	Breast tumour	P120	
	Germinal centre/mantle zone B cells	PAX 5	
	Thyroid follicular cells	PAX 8	
	Intestinal nerves	PGP 9.5	



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FFPE sections (cont'd)	Immunohistochemistry to detect the following: (cont'd)	Automated method using: HIS-RSCH-SOP-67 Roche Ventana Ultra IHC platform Using antibodies to:	
	Placental brush border	PLAP	
	Intestinal crypts/lymphocytes	PMS2	
	PR +ve cells	Progesterone Receptor (PR)	
	Prostate luminal epithelial cells	PSA	
	Prostate luminal epithelial cells	PSAP	
	Epithelial cells of proximal tubules	RCC	
	Intestinal nerve cells/macrophages	S100	
	Carcinoid tumour	Serotonin	
	Smooth muscle	SMA (Actin)	
	Islet D cells	Somatostatin	
	Melanocytes/melanoma	SOX 10	
	Pancreatic Islet cells	Synaptophysin	
	Subcapsular/cortical thymocytes or perisinusoidal cells in interfollicular zone of tonsil	TDT	
	Syncytiotrophoblasts in placenta	Thombomodulin	



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FFPE sections (cont'd)	Immunohistochemistry to detect the following: (cont'd)	Automated method using: HIS-RSCH-SOP-67 Roche Ventana Ultra IHC platform Using antibodies to:	
	Follicular epithelial cells/ extracellular colloid of thyroid	Thyroglobulin	
	Tonsil dendritic cells	TRAP	
	Mast cells	Tryptase	
	Thyroid follicular epithelial cells	TTF 1	
	Most cells of mesenchymal origin	Vimentin	
	Wilms tumour	WT 1	
	Isolated germinal centre T cells	ZAP 70	
	GIST	DOG 1	
	Her 2 protein	Her 2 4b5	
FFPE and frozen sections	Morphological assessment and interpretation/diagnosis	Interpretive/diagnostic microscopy using microscopes: including Nikon, Olympus and Leica HIS-RSFT/FPH/ASPH-SOP-86	RSCH SPH FPH



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HUMAN TISSUE AND FLUIDS	<u>Molecular genetic examination for the purposes of clinical diagnosis</u>	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:	RSCH
Sentinel lymph node tissue	Detection of Cytokeratin 19 (CK 19) mRNA	One step nucleic acid amplification (OSNA) HIS-RSFT/FPH/SPH-SOP-37 Using Sysmex RD210 analyser	RSCH
Whole blood Buccal swabs FFPE Plasma		Automated DNA extraction MOLBIO-RSFT-SOP-00020 MOLBIO-RSFT-SOP-00018 MOLBIO-RSFT-SOP-00045 MOLBIO-RSFT-SOP-00053 Using: Maxwell 48 QIACUBE Connect QIAsymphony	
Genomic DNA	Names of disease, analysed gene(s) or mutation:	PCR amplification and detection MOLBIO-RSCH-SOP-00055 Using: Rotorgene Myra	RSCH
	Factor V Leiden mutation Prothrombin gene mutation MTHFR gene mutation HLAB27 genotyping Jak 2 mutation analysis Coeliac exclusion (HLADQ2/8) ApoE genotyping PVL gene detection Haemochromatosis mutation	QIAsymphony Roche Cobas 480 MOLBIO-RSFT-SOP-00027 MOLBIO-RSFT-SOP-00027 MOLBIO-RSFT-SOP-00027 MOLBIO-RSFT-SOP-00026 MOLBIO-RSFT-SOP-00028 MOLBIO-RSFT-SOP-00038 MOLBIO-RSFT-SOP-00029 MOLBIO-RSFT-SOP-00051 MOLBIO-RSFT-SOP-00037	



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Genomic DNA from whole blood	Most common 61 cystic fibrosis mutations in the European and UK populations	DNA extracted using Maxwell 48, PCR using SimpliAmp PCR, and Genotyping using capillary electrophoresis with Elucigene CF-EU2v1 and CF-UK panels on the Spectrum Compact using GeneMarker	
FFPE Tissue	Presence of oncogenic fusions (ALK, RET and ROS1 gene fusions and MET exon 14 skipping).	FFPE liquefaction and cell lysis to liberate nucleic acids, followed by real-time PCR using Biocartis Idylla System  MOLBIO-RSFT-SOP-00102: Idylla Gene Fusions	
cDNA synthesised in-house from whole blood or received as primary sample type from an external source	BCR-ABL1 (p210) Diagnosis and therapy monitoring	Quantitative measurement of BCR-ABL1 mRNA transcripts (p210) e13a2 or e14a2 and ABL1 using the GeneXpert Realtime PCR platform MOLBIO-RSFT-SOP-00063 MOLBIO-RSFT-SOP-00013	RSCH





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DNA extracted from primary samples (saliva, blood).	Production of DNA sequence data for subsequent analysis, interpretation and reporting of clinical significance by an external organisation	Instrumentation: Maxwell 48 SimpliAmp Illumina MiSeq Measurement Principle: Next generation sequencing: TWIST/Centogene Library Prep and Enrichment;  MOLBIO-RSFT-SOP-00020: USING THE MAXWELL 48 FOR DNA/ RNA EXTRACTION MOLBIO-RSFT-SOP-00302: Twist/Centogene Library prep and enrichment protocol MOLBIO-RSFT-SOP-00304: Next Generation Sequencing using the Illumina MiSeq	RSCH
Biopsy material	PROSIGNA Breast cancer prognostic assay - assessment of the number of molecules of RNA present in breast tumours	Manual RNA extraction, hybridisation and Nanostring nCounter system, and subsequent generation of a risk score MOLBIO-RSFT-SOP-00100	RSCH



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HUMAN TISSUE AND FLUIDS	<u>Molecular genetic examination for the purposes of clinical diagnosis</u>	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:	RSCH
Whole Blood	<p>DPYD genotyping for 4 genotypes: c.1905+1G&gt;A (p.?) (DPYD*2A) c.1679T&gt;G (p.I560S) (DPYD13*) c.2846A&gt;T (p.D949V) (D949V) c.1236G&gt;A (p.E412E) (E412E)</p> <p>Beta panel detection of somatic mutations in hotspot regions of the CALR, MPL and Jak2 exon 12 genes</p> <p>Oncomine Focus panel to sequence 35 hotspot genes</p>	<p>MIC Myra Loop mediated isothermal amplification (LOOP) PCR</p> <p>MOLBIO-RSFT-SOP-00064: DPYD genotyping</p> <p>Next Generation Sequencing using Instrumentation: Maxwell 48 Ion Chef S5</p> <p>MOLBIO-RSFT-SOP-00002: Next Generation Sequencing Beta Panel MOLBIO-RSFT-SOP-00056: NGS Bioinformatics Analysis SOP</p> <p>Next Generation Sequencing using Qiacube Ion Chef S5</p> <p>MOLBIO-RSFT-SOP-00039: Somatic Next Generation Sequencing using the Oncomine Focus panel</p>	RSCH
END			