


# Schedule of Accreditation

issued by

## United Kingdom Accreditation Service

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

 <p><b>UKAS</b> MEDICAL</p> <p>9727</p> <p>Accredited to ISO 15189:2012</p>	<p><b>Frimley Health NHS Foundation Trust</b></p> <p>Issue No: 003 Issue date: 06 September 2020</p>	
	<p>Department of Histopathology Royal Surrey County Hospital Egerton Road Guildford GU2 7XX</p>	<p>Contact: Governance &amp; Quality Department Tel: +44 (0) 1276 522194 / 01932 723424 E-Mail: <a href="mailto:fph-tr.bspsquality@nhs.net">fph-tr.bspsquality@nhs.net</a> Website: <a href="http://www.nhspathology.fph.nhs.uk">http://www.nhspathology.fph.nhs.uk</a></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><b>Address</b> Department of Histopathology Royal Surrey County Hospital Egerton Road Guildford GU2 7XX</p>	<p><b>Local contact</b>  Elaine Inglis 01276 522194 01932 723424</p>	<p>Routine Histopathology Intraoperative frozen sections Special Stains Immunohistochemistry In-situ hybridisation OSNA Molecular including next generation sequencing</p>	<p>RSCH</p>

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

Location details		Activity	Location code
<p>Frimley Park Hospital Portsmouth Rd Frimley Camberley GU16 7UJ</p>	<p>As above</p>	<p>Macroscopic dissection Microscopic reporting Decalcification Intraoperative frozen sections OSNA</p>	<p>FPH</p>
<p>St Peter's Hospital Guildford Rd Lyne Chertsey KT16 0PZ</p>	<p>As above</p>	<p>Macroscopic dissection Microscopic reporting Intraoperative frozen sections Decalcification</p>	<p>SPH</p>
<p>Ashford Hospital London Rd Stanwell Ashford TW15 3AA</p>	<p>As above</p>	<p>OSNA</p>	<p>Ashford</p>



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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	RSCH FPH SPH
		Decalcification of bony tissue Manual method using documented procedure: HIS-SPS-SOP-57	RSCH SPH FPH
		Tissue processing Using Sakura VIP 5 and VIP 6 tissue processors HIS-RSCH-SOP-41	RSCH
		Tissue embedding Using Sakura TecV embedding station HIS-RSCH-SOP-59	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
		Shandon Cryotome HIS-ASPH-SOP-46	SPH
		Bright OTF5000 HIS-FPH-SOP-53	FPH



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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. HIS-RSCH-SOP-104	RSCH
Frozen sections	Basophilic and eosinophilic tissue structures	Manual rapid H&E staining HIS-RSCH-SOP-4	RSCH SPH FPH
FFPE sections	Special stains to detect the following:	Documented in-house procedures for manual special stains HIS-RSCH-SOP-4	RSCH
	Mucins	Alcian Blue +/- diastase (ABPAS+/- D)	
	Amyloid	Congo red	
	Elastic fibres	Elastic Van Gieson (EVG)	
	Bile pigment	Fouchet	
	Bone marrow elements	Giemsa	
	Reticulin fibres	Gomori's Retic	
	Reticulin fibres	Gordon and Sweet's Retic	
	Gram +/- organisms	Gram	
	Agyrophil cells	Grimelius	
	Fungi	Grocott	



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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:	RSCH	
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		
	Connective tissue	Haematoxylin Van Gieson (HVG)		
	Basement membranes	Jones Hexamine Silver		
	Fibrin	Martius Scarlet Blue (MSB)		
	Melanin	Masson's Fontana		
	Connective tissue	Masson's Trichrome		
	Melanin	Melanin Bleach HE		
	Helicobacter pylori	Modified Giemsa		
	Lipids	Oil Red O		
Frozen sections	Lipids	Oil Red O		RSCH FPH SPH
	Glycogen/fungi	Periodic Acid Schiff (PAS) and Diastase PAS (PAS+D)		
	Ferric iron (haemosiderin)	Perls' Prussian Blue		
	Copper associated protein and hepatitis B affected cells	Shikata's Orcein		
	Mucins	Southgate's mucicarmine		
	Mast cells	Toluidine Blue		
	Calcium	Von Kossa		
	Leprosy	Wade Fite		



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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
	Spirochetes	Warthin Starry	
	Mycobacterium Tuberculosis	Ziehl Neelsen (ZN)	
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	
	Her-2-Neu	HER-2 ISH	
	Chromosome 17 to assess Her-2-Neu ratio	C17	
	Epstein Barr virus infected cells	EBER	
FFPE sections	Immunohistochemistry to detect the following:	Automated method using: HIS-RSCH-SOP-67 Roche Ventana Ultra IHC platform and Roche Ventana GX Using antibodies to:	RSCH
	Basal cells	34BE12	
	Alpha-1-anti-trypsin deposits	A-1-AT	
	Epithelial cells	AE 1/3	
	Alfa-foetal protein	AFP	
	Anaplastic lymphoma	ALK-1	



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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:	RSCH
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:	
	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	
	Mesothelial cells	Calretinin	
	Myoepithelial cells (breast)	Calponin	
	Epithelial cells	Cam 5.2	
	Langerhans cells	CD1a	
	T cells	CD2	
	T cells	CD3	
	Helper T cells	CD4	



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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 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	
	T and B lymphocytes, monocytes, granulocytes, erythrocytes, fibroblasts, epithelial, and mast cells	CD44	



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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:	
	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	
	Breast epithelial cells	CK7	
	Squamous epithelial cells	CK14	
	Epithelial cells	CK19	





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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:	
	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	
	Mantle zone lymphocytes	DBA -44	
	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	
	Luminal epithelial cells (breast)	GATA 3	
	Epithelial cells of sweat glands	GCDFP-15	



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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:	
	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	
	IgG4 positive cells	IgG4	
	Mantle zone B cells	IgM	



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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:	
	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 and Roche Ventana GX 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 and Roche Ventana GX 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 and Roche Ventana GX 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 SOP HIS-SPS-SOP-86	RSCH SPH FPH
Sentinel lymph node tissue	Detection of Cytokeratin 19 (CK 19) mRNA	One step nucleic acid amplification (OSNA) HIS-SPS-SOP-37 Using sysmex RD210 analyser	RSCH FPH Ashford



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HUMAN TISSUE AND FLUIDS  Whole blood Buccal swabs FFPE Plasma	<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:  Automated DNA extraction MOLBIO-RSCH-SOP-00020 MOLBIO-RSCH-SOP-00018 MOLBIO-RSCH-SOP-00045 MOLBIO-RSCH-SOP-00053 Using: Maxwell QIACUBE QIAsymphony	RSCH
Genomic DNA	Names of disease, analysed gene(s) or mutation:  Factor V Leiden mutation Prothrombin gene mutation MTHFR gene mutation HLAB27 genotyping Jak 2 mutation analysis Coeliac exclusion (HLADQ2/8) ApoE genotyping Lactose intolerance Cell-free DNA testing for EGFR PVL gene detection Haemochromatosis mutation	PCR amplification and detection MOLBIO-RSCH-SOP-00055 Using: Rotorgene QIAgility Roche Cobas 480 MOLBIO-RSCH-SOP-00027 MOLBIO-RSCH-SOP-00027 MOLBIO-RSCH-SOP-00027 MOLBIO-RSCH-SOP-00026 MOLBIO-RSCH-SOP-00028 MOLBIO-RSCH-SOP-00038 MOLBIO-RSCH-SOP-00029 MOLBIO-RSCH-SOP-00043 MOLBIO-RSCH-SOP-00031  MOLBIO-RSCH-SOP-00051 MOLBIO-RSCH-SOP-00037	RSCH
Genomic DNA	Names of disease, analysed gene(s) or mutation:  Clonal gene rearrangements Cystic fibrosis mutation screen	PCR amplification and detection MOLBIO-RSCH-ED-00017 Using QIAgility liquid handling robot ABI 2720 thermocycler QiaExcel MOLBIO-RSCH-SOP-00033 MOLBIO-RSCH-SOP-00055 MOLBIO-RSCH-SOP-00001	RSCH



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HUMAN TISSUE AND FLUIDS (cont'd)  Genomic DNA	<u>Molecular genetic examination for the purposes of clinical diagnosis (cont'd)</u>  Targeted sequencing for the following diseases: Colorectal cancer Melanoma NSCLC (lung cancer) GIST	In-house documented procedures using manual methods or analysers in conjunction with manufacturers' instructions as specified:  Next generation sequencing MOLBIO-RSCH-SOP-00002 MOLBIO-RSCH-SOP-00002 Appendix 1 using Ion Chef Ion Torrent PGM Qubit spectrophotometer GEN-BSPS-SOP-022	RSCH
Genomic DNA	Sequencing of variations in a targeted panel of genes – Alpha Panel	Next generation sequencing MOLBIO-RSCH-SOP-00002 using Ion Chef, Ion Torrent S5 and Alpha Panel	RSCH
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-RSCH-SOP-00063 MOLBIO-RSCH-SOP-00013	RSCH
RNA	PROSIGNA Breast cancer prognostic assay - assessment of the number of molecules of RNA present in breast tumours	Nanostring nCounter system and subsequent generation of a risk score MOLBIO-RSCH-SOP-00100	RSCH
END			