


# Schedule of Accreditation

issued by

## United Kingdom Accreditation Service

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

 <b>8818</b> Accredited to ISO 15189:2012	<b>Synnovis Analytics LLP</b>  <b>Issue No: 008 Issue date: 04 October 2023</b>	
	<b>Department of Histopathology</b> <b>Sydney Street</b> <b>London</b> <b>SW3 6NP</b> <b>United Kingdom</b>	<b>Contact: Pratibha Shah</b> <b>Tel: +44 (0) 207 351 8427</b> <b>E-Mail: pratibha.shah@rbht.nhs.uk</b> <b>Website: www.synnovis.co.uk</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
Royal Brompton Hospital Sydney Street London SW3 6NP  <b>Contact as above</b>	Histology Immunocytochemistry Cytology	RBH
Harefield Hospital Hill End Road Harefield UB9 6JH  <b>Contact as above</b>	Histology-Frozen sections and urgent biopsies only	HH



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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 FLUIDS AND TISSUES</b>	<u>Histopathological examination activities for the purposes of clinical diagnosis</u>	Macroscopic and Microscopic examination supported by in-house documented procedures based on equipment manuals as relevant	
Fixed, fresh and frozen tissue, excisional and incisional biopsies and surgical resection specimens	Examination and preparation of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis	Reception of Histology and Cytology Specimens at RBH HISTINST6 Reception of Histology and Cytology specimens at Harefield HISTINST7	RBH  HH
Fixed, fresh and frozen tissue, excisional and incisional biopsies and surgical resection specimens and cell pellets		<u>Macroanalysis and dissection</u>  Tissue dissection using AFOS downdraft benches HISHSOP1  <u>Decalcification</u> Manual method using procedure HISTINST13  <u>Tissue processing</u> Automated method using HISHSOP2 and Leica ASP6025 tissue processor HISTEQINST4 Leica HistoCore Peloris 3 tissue processor HISTEQINST57	RBH
Formalin fixed tissues		<u>Embedding</u> Manual method using HISHSOP3 and Thermo Scientific Histostar HISTEQINST11	



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HUMAN BODY FLUIDS AND TISSUES	<u>Histopathological examination activities for the purposes of clinical diagnosis</u>	Macroscopic and Microscopic examination supported by in-house documented procedures based on equipment manuals as relevant	
FFPE tissues		<u>Microtomy</u> <u>Manual method</u> using HISHSOP4 and Leica RM 2235 and RM2035 - HISTEQINST3	RBH
Biopsies and tissue samples (Urgent frozen section reporting)	Morphological assessment and interpretation/diagnosis	<u>Rapid frozen section</u> Cryotomy and manual Haematoxylin & Eosin (H&E) staining method using  Frozen Section Procedure at Harefield Hospital HISHSOP6 and Leica CM1860 UV Cryostat - HISTEQINST47	HH
		Frozen Section Procedure at Royal Brompton Hospital HISHSOP7 and Thermo Scientific Cryotome FSE HISTEQINST18 Leica CM1860 UV Cryostat - HISTEQINST47	RB
	Identification of basophilic and eosinophilic cells and tissue structures	Haematoxylin and Eosin for frozen sections (manual only) HISTSTAIN15	RBH HH
FFPE tissue sections	Identification of basophilic and eosinophilic cells and tissue structures	<u>Haematoxylin and Eosin staining and coverslipping</u> Automated method using Modified Haematoxylin and Eosin for paraffin block HISTSTAIN14 And Shandon Gemini stainer HISTEQINST48 with EpreDiaClearvue coverslipper HISTEQINST61	RBH



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Histopathological examination activities for the purposes of clinical diagnosis</u> (cont'd)	Macroscopic and Microscopic examination supported by in-house documented procedures based on equipment manuals as relevant	RBH
FFPE tissue sections	<u>Special staining of histopathology examinations to assist in detection of clinical abnormalities:</u>	<u>Special staining</u> Manual methods using -Special Staining Process HISHSOP5 and individual staining methods	
	Acid mucins	Modified Alcian Blue stain HISTSTAIN1	
	Acid mucins and neutral mucins	Modified Alcian Blue Periodic Acid Schiff HISTSTAIN3	
	Amyloid	Modified Alkaline Congo Red for amyloid HISTSTAIN4	
	Diastase digestion	Diastase Periodic Acid Schiff (DPAS) HISTSTAIN6	
	Elastic	Modified Alcian Blue Elastic Van Gieson (AB EVG) HISTSTAIN7	
	Helicobacter pylori and other organisms	Modified Giemsa (Modified) for Helicobacter Pylori HISTSTAIN9	
	Gram stain	Modified GRAM HISTSTAIN11-	
	Gram Twort	Modified Gram Twort Staining Method HISTSTAIN12	
	Fungi including Pneumocystis	Modified Grocott – Microwave Method HISTSTAIN13	
	Fibrin and connective tissues	Modified Martius Scarlet Blue for fibrin and connective tissues HISTSTAIN18	



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FFPE tissue sections	<u>Special staining of histopathology examinations to assist in detection of clinical abnormalities:</u>  Argentaffin and melanin  Elastic fibres  Mucin, glycogen, basement membranes, etc  Haemosiderin  Mycobacteria	<u>Special staining</u> Manual methods using -Special Staining Process HISHSOP5 and individual staining methods  Modified Masson Fontana HISTSTAIN19  Modified Miller's Elastic Van Gieson (EVG) for elastic fibres HISTSTAIN21  Modified Periodic Acid Schiff for mucin, glycogen, basement membranes HISTSTAIN24 -  Modified Perl's Prussian Blue for haemosiderin HISTSTAIN25  Modified Ziehl-Neelsen staining method HISTSTAIN31	RBH



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Histopathological examination activities for the purposes of clinical diagnosis</u> (cont'd)	Macroscopic and Microscopic examination supported by in-house documented procedures based on equipment manuals as relevant	RBH
FFPE tissue sections	<u>Immunocytochemistry to detect the following</u>	<u>Immunohistochemistry</u> In-house documented procedures using Leica Bond III The Bond III automated ICC procedure HISISOP1 Bond III solutions and antibody titres IMMHINST4	
	Anaplastic lymphoma kinase (Human p80 protein)	Anaplastic lymphoma kinase receptor (CD246)-ALK1	
	Expression of Alphafetoprotein	Alpha Fetoprotein	
	Mantle zone B lymphocytes & interfollicular T lymphocytes and other rare tumour types	BCL 2	
	Malignant mesothelioma	BAP-1	
	Cell membrane glycoproteins expressed on healthy epithelia and in various carcinomas	Ber-EP4	
	Gastrin releasing peptide (cancers of the lung, colon, stomach, pancreas, breast, and prostate)	Bombesin	
	Special tissue marker for humoral immunity	C4d	
	Calcium binding protein structurally related to S100 and inhibin	Calretinin	
	Glandular cells	CAM 5.2	



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HUMAN BODY FLUIDS AND TISSUES	<u>Histopathological examination activities for the purposes of clinical diagnosis</u>	Macroscopic and Microscopic examination supported by in-house documented procedures based on equipment manuals as relevant	
Paraffin section (cont'd)	<u>Immunocytochemistry to detect the following</u> (cont'd)	<u>Immunohistochemistry</u> In-house documented procedures using Leica Bond III The Bond III automated ICC procedure HISISOP1 - Bond III solutions and antibody titres IMMINST4	
	MHC class 1 related cell surface glycoprotein thymic lymphocytes; Langerhan's cells; interdigitating reticulum cells	CD1a	
	T lymphocytes; helper/inducer T lymphocytes	CD3	
	Germinal centre T lymphocytes; B lymphocyte subset	CD5	
	Normal, early progenitor lymphoid cells; B lymphocytes in germinal centres	CD10	
	Hodgkin's & Reed-Sternberg cells	CD15	
	B lymphocytes	CD20	
	Follicular dendritic cells	CD21	
	Hodgkin's & Reed-Sternberg cells	CD30	
	Endothelial cells; macrophages	CD31	



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Paraffin section (cont'd)	<u>Immunocytochemistry to detect the following</u> (cont'd)	<u>Immunohistochemistry</u> In-house documented procedures using Leica Bond III The Bond III automated ICC procedure HISISOP1 - Bond III solutions and antibody titres IMMINST4	
	Haemopoietic precursor cells; endothelial cells; fibroblasts; other cell types in various solid tumours	CD34	
	T & B lymphocytes	CD45	
	Peripheral nerves; NK cells; neuroendocrine differentiation	CD56	
	Macrophages; monocytes; granulocytes	CD68	
	Thymic T lymphocytes; islet cells; endothelial cells, Ewing's sarcoma; other rare spindle cell tumours	CD99	
	Carcino-embryonic antigen (Adenocarcinomas, epithelial cells of the glandular lumen)	Carcinoembryonic Antigen (CEA)	
	Chromogranin A (neuroendocrine cells and tumours)	Chromogranin	
	Stratified squamous epithelium, basal cells, mesotheliomas	Cytokeratin 5	
	Normal and neoplastic epithelia	Cytokeratin 7	





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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Histopathological examination activities for the purposes of clinical diagnosis</u> (cont'd)	Macroscopic and Microscopic examination supported by in-house documented procedures based on equipment manuals as relevant	RBH
Paraffin section (cont'd)	<u>Immunocytochemistry to detect the following</u> (cont'd)	<u>Immunohistochemistry</u> In-house documented procedures using Leica Bond III The Bond III automated ICC procedure HISISOP1 Bond III solutions and antibody titres IMMINST4	
	GI epithelia	Cytokeratin 20	
	Cytomegalovirus viral inclusions	Cytomegalovirus	
	Lymphatic endothelial cells	D2-40	
	Smooth & striated muscle cells	Desmin	
	Epithelial membrane antigen (Glandular & ductal epithelia, perineurium; other cell types in various tumours)	Epithelial Membrane Antigen (EMA)	
	Cellular estrogen receptor expression	Oestrogen Receptor (ER)	
	Human Chorionic Gonadotropin (Trophoblastic elements, e.g. in germ cell tumours)	HCG (beta)	
	Human melanoma black 45 antigen (Activated melanocytes; melanocytic tumours)	HMB 45	



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Paraffin section (cont'd)	<u>Immunocytochemistry to detect the following</u> (cont'd)	<u>Immunohistochemistry</u> In-house documented procedures using Leica Bond III The Bond III automated ICC procedure HISISOP1 - Bond III solutions and antibody titres IMMINST4	
	Plasma cells and related lymphoid cells containing IgG4)	IgG4	
	Plasma cells and related lymphoid cells containing Kappa light chains	Kappa	
	Ki-67 nuclear antigen (Proliferating cells; cells in cycle)	Ki-67	
	Plasma cells and related lymphoid cells containing Lambda light chains	Lambda	
	Malignant Mesothelioma	MTAP	
	Acidic and basic human cytokeratins	Multi-cytokeratin (AE1/AE3)	
	Epithelial tissue from glandular to stratified squamous	MNF116	
	Napsin A, expressed in type II pneumocytes, kidney and foetal lung	Napsin (A)	
	Nuclear protein of testis in NUT-midline carcinomas (head, neck and mediastinum tumours)	NUT-midline	



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Paraffin section (cont'd)	<u>Immunocytochemistry to detect the following</u> (cont'd)	<u>Immunohistochemistry</u> In-house documented procedures using Leica Bond III The Bond III automated ICC procedure HISISOP1 Bond III solutions and antibody titres IMMHINST4	
	P40 protein in squamous cell carcinomas (lung, urothelial, head and neck)	P40	
	Placental Alkaline Phosphatase in germ cell tumours, particularly seminomas; also breast, lung, ovarian carcinomas	Placental AP (PLAP)	
	Cellular progesterone receptor expression	Progesterone Receptor (PR)	
	Prostate specific antigen	Prostate Specific Antigen (PSA)	
	Lung adenocarcinomas	ROS-1	
	Normal and neoplastic melanocytes; macrophages; adipocytes; nerve fibres; many tumour types	S100	
	Smooth muscle, myoepithelial and other contractile cells	Smooth Muscle Actin	
	Solitary fibrous tumor (SFT) fibroblastic neoplasm	STAT6	RBH
	Synaptic vesicle protein (neurones; neuroendocrine cells)	Synaptophysin	RBH



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Histopathological examination activities for the purposes of clinical diagnosis</u> (cont'd)	Macroscopic and Microscopic examination supported by in-house documented procedures based on equipment manuals as relevant	
Paraffin section (cont'd)	<u>Immunocytochemistry to detect the following</u> (cont'd)	<u>Immunohistochemistry</u> In-house documented procedures using Leica Bond III The Bond III automated ICC procedure HISISOP1 Bond III solutions and antibody titres IMMINST4	RBH
	Diagnostic marker and indicator for lung carcinoma	Thyroid Transcription Factor 1 (TTF1)	RBH
	Thyroglobulin containing cells	Thyroglobulin	RBH
	Vimentin intermediate filament	Vimentin	RBH
	Von Willebrand Factor (endothelial cells)	VWF (F8)	RBH
	Epithelial cells and smooth muscle in fallopian tube. Wilms tumour	Wilms Tumour 1 (WT-1)	RBH
	Immune System Molecule	<u>Immunohistochemistry</u> In-house documented procedures using Autostainer Plus Dako & PT Link PD-L1 (22C3) HISTEQINST20 PD-L1 Staining Procedure IMMINST6	RBH



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Paraffin section (cont'd)	<u>Immunocytochemistry to detect the following</u> (cont'd)	In-house documented procedures using Roche Ventana Benchmark Ultra Ventana BenchMark Ultra HISTEQINST55 Operator Guide for Ventana BenchMark Ultra HISTEXDOC62 Ventana BenchMark Ultra Solutions & Antibody Titres IMMINST7	
	Anaplastic Lymphoma Kinase (Human p80 protein)	ALK1	
	Lung Adenocarcinomas	ROS-1	RBH HH
Slides prepared in-house from sample types listed above	Morphological assessment and interpretation/diagnosis	Reporting Pathology Results HISDSOP4 using Microscopes - HISTEQINST6.	



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<p><b>HUMAN BODY FLUIDS</b></p> <p>Fine needle aspirates – sputum, urine CSF, , oesophageal washings and brushings, Conventional Bronchial Brushings, Serous fluids, Bronchial washings and Bronchial Alveolar lavage samples.</p> <p>Fragments, clots, cell pellets from various cytological fluids. TBNA samples processed to paraffin section Non-gynae cytology Smear or cyto-centrifuge preparation</p> <p>Air-dried cyto-centrifuge preparation</p>	<p><u>Diagnostic Cytology examination activities for the purposes of clinical diagnosis</u></p> <p>Examination of cellular material in order to identify or exclude morphological and cytological abnormalities</p> <p>Basophilic and acidophilic intra- and extracellular structures</p> <p>Identification of eosinophils</p> <p>Morphological assessment &amp; detection of cytological abnormalities</p> <p>Morphological assessment &amp; detection of cytological abnormalities</p>	<p><u>Diagnostic Cytology</u> In-house documented procedures using Preparation of Cytology Specimens HISCSOP1 Preparation of all Cytology Specimens and specified CYTOINST6 In combination with the following procedures</p> <p>Lymphoprep CYTOINST8 Preparation of Sputum CYTOINST10 Preparation of BAL for Differential Cell Count CYTOINST3</p> <p>Preparation of Cell Pellet CYTOINST4</p> <p>Special Staining Process HISHSOP5 in combination with:</p> <p>Modified Carbol Chromotrope CYTSTAIN1</p> <p>CYTSTAIN5 - Modified Papanicolaou Stain-Manual method</p> <p>Modified May-Grunwald Giemsa-Manual method CYTSTAIN2 Oil Red O Fat-laden macrophages CYTSTAIN4</p>	<p>RBH</p>



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HUMAN BODY FLUIDS  Slides prepared in-house from sample types listed above	<u>Diagnostic Cytology examination activities for the purposes of clinical diagnosis</u>  Cytological assessment and interpretation/diagnosis	<u>Diagnostic Cytology</u> In-house documented procedures using Preparation of Cytology Specimens HISCSOP1 Preparation of all Cytology Specimens and specified CYTOINST6 In combination with the following procedures  <u>Microscopy qualitative analysis</u> Microscopes HISTEQINST6	RBH
END			