

Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 UKAS MEDICAL 8805 Accredited to ISO 15189:2022	Synnovis Analytics LLP Issue No: 015 Issue date: 23 December 2025	
	Liver Pathology Denmark Hill London SE5 9RS	Contact: Karen Boniface Tel: +44 (0) 7188 7188 E-Mail: karen.boniface@synnovis.co.uk Website: www.Synnovis.co.uk

Testing performed by the Organisation at the locations specified below

Locations covered by the organisation and their relevant activities

Laboratory locations:

Location details	Activity
Address Histology Archives King's College Hospital NHS Foundation Trust Denmark Hill London SE5 9RS	Histology Archives Storage of blocks and slides only



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DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
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 manufacturer's instructions as specified
Excision and incisional surgical specimens	Examination of tissues in order to identify or exclude morphological and cytological abnormalities for the purpose of diagnosis	Using SOP: LP-HIS-SOP- 56Specimen reception v3.1 and ventilated grossing station and ventilated specimen table using LP-HIS-SOP-53-Surgical specimen cut-upv5.0
Excision and incisional surgical specimens	Sample processing	Sakura VIP 6 tissue processor using SOP LP-HIS-SOP-100- Use of the VIP 6 Tissue Processor
Excision and incisional surgical specimens	Sample Embedding	Sakura Histocore Arcadia embedding centre using SOP LP-HIS-SOP-50- Embedding in paraffin wax
Formalin fixed paraffin embedded tissue (FFPE)	Microtomy	Leica RM2235 and Leica Biocut microtome Using SOP LP- HIS-SOP-95-Cutting paraffin sections
Fresh tissue	Sample processing (fresh frozen)	Using Bright Clini-RF rapid freezing bath and LP-HIS-SOP-5-freezer bath maintenance LP- HIS-SOP-63-Frozen section preparation-LP -HIS-SOP-64 Freezing tissue in liquid nitrogen
Fresh tissue	Cutting sections (frozen)	Leica CM1950 and Leica CM1860 cryostat using SOP: LP-HIS-SOP-63- Frozen section preparation
Glass slides with fresh tissue	Routine morphological staining for the detection of: Basophilic and Eosinophilic structures	LP-HIS-SOP-83-H&E (Frozen Sections)
Glass slides with FFPE tissue	Basophilic and Eosinophilic structures	LP-HIS-SOP-82-Harris H&E (Paraffin sections)



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<p>HUMAN BODY TISSUE (cont'd)</p> <p>Glass slides with FFPE tissue</p>	<p><u>Histopathological examination activities for the purposes of clinical diagnosis</u> (cont'd)</p> <p>Special stains for the detection of:</p> <p>Acid and neutral mucins</p> <p>Retic</p> <p>Amyloid</p> <p>Elastic fibres and collagen</p> <p>Helicobacter/Microorganisms</p> <p>Connective tissue</p> <p>Gram positive and negative micro-organisms</p> <p>Elastic fibres and connective tissue</p> <p>Elastic fibres and connective tissue</p> <p>Elastic fibres and connective tissue</p> <p>Acid and Neutral Mucopolysaccharides</p> <p>Connective tissue and fibrin</p> <p>Melanin</p> <p>Fungi (Aspergillus) and Pneumocystis</p> <p>Copper, Hepatitis B</p>	<p>In-house documented procedures using manual methods</p> <p>Documented in-house procedures for manual special stains</p> <p>LP-HIS-SOP-72-AB-PAS</p> <p>LP-HIS-SOP-90-Ammoniacal Silver for reticulin fibres</p> <p>LP-HIS-SOP-75-Congo Red</p> <p>LP-HIS-SOP-77--EVG</p> <p>LP-HIS-SOP-78- Giemsa for Helicobacter pylori</p> <p>LP-HIS-SOP-79 Gomori's one step trichrome</p> <p>LP- HIS-SOP-80 Gram Stain</p> <p>LP- HIS-SOP-71-Haemalum van Giesen</p> <p>LP- HIS-SOP-73-Carazzi's Haematoxylin</p> <p>LP- HIS- SOP-74-Celestine blue / Haemalum sequence</p> <p>-LP- HIS-SOP-76-dPAS</p> <p>Martius Yellow, Brilliant Crystal Scarlet, Soluble Blue using LP- HIS-SOP-85 -MSB</p> <p>LP-HIS-SOP-84Masson-Fontana</p> <p>LP- HIS- SOP-81-Grocott's methenamine silver</p> <p>LP- HIS-SOP-86-Orcein</p>



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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 manufacturer's instructions as specified
Glass slides with FFPE tissue	Special stains for the detection of: Glycogen Haemosiderin and ferric iron Copper Collagen Nuclear stain used as part of Sirius Red and EVG Tubercle bacilli	Documented in-house procedures for manual special stains LP-HIS-SOP-87-PAS LP-HIS-SOP-88-Perls Prussian blue LP-HIS-SOP-91-Rhodanine LP- HIS-SOP-89-PicroSirius Red LP- HIS-SOP-93-Weigert's Iron haematoxylin LP- HIS-SOP-94-Ziehl Neelsen
Glass slides with FFPE tissue	In situ hybridisation to detect the following: Epstein Barr virus	In situ hybridisation using Leica Bond III immunostainer and SOP LP-HIS-SOP-103 Antibody dilutions and protocols for Bond III EBER (ISH)
Glass slides with FFPE tissue	Immunohistochemistry to detect the following: A1AT accumulation in diagnosis of A1AT deficiency Adenovirus Multi-cytokeratin to confirm epithelial origin	Leica Bond-III immunostainer using SOP: LP-HIS-SOP-68- Immunohistochemistry using the Leica Bond III autostainer, and SOP LP-HIS-SOP-103 Antibody dilutions and protocols for Bond III A1AT Adenovirus AE1/AE3



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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 and manufacturer's instructions, using Leica Bond-III immunostainer
Glass slides with FFPE tissue	Fetal antigen used for diagnosis of hepatoblastoma and germ cell tumours	AFP
	Cholangiocyte cilia marker	Acetylate alpha tubulin
	Amyloid	Amyloid A
	Detection of Hepatocellular origin for poorly differentiated tumours	Arginase1
	Diagnosis of hepatocellular malignancies and solid pseudopapillary neoplasms of pancreas	B-catenin
	Cytoplasmic staining of B lymphocytes. Anti-apoptotic marker	BCL2
	Diagnosis of pancreatic acinar cell carcinoma	BCL10
	Bile salt export protein expression in liver canaliculi used in diagnosis of BSEP deficiency (ABCB11 disease)	BSEP
	Detection of ganglia/nerves, mesothelial cells and mast cells	Calretenin
	Detection of cytokeratin 8 in carcinomas	CAM 5.2
	Expressed in biliary and pancreatic cancer	CA19-9



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<p>HUMAN BODY TISSUE (cont'd)</p> <p>Glass slides with FFPE tissue (cont'd)</p>	<p><u>Histopathological examination activities for the purposes of clinical diagnosis</u> (cont'd)</p> <p>Component of complement associated with vascular damage. Used as part of diagnosis of humoral rejection in allografts</p> <p>Langerhans cells – used for diagnosis of Langerhans cell histiocytosis</p> <p>T cell marker in tonsil, lymph node and colon</p> <p>Helper T cell marker in tonsil, lymph node and colon</p> <p>Immature T cell marker in tonsil, lymph node and colon</p> <p>Cytotoxic T cell marker in tonsil, lymph node and colon</p> <p>Granulocytes Reed-Sternberg cells</p> <p>Hepatic canalicular marker</p> <p>Plasma cell marker</p> <p>Mature B cells, Follicular dendritic cells</p> <p>Vascular endothelium</p> <p>Gastrointestinal Stromal Tumours</p> <p>Neuroendocrine cells</p> <p>Macrophages</p> <p>B lymphocytes</p> <p>GIST</p>	<p>In-house documented procedures and manufacturer's instructions, using Leica Bond-III immunostainer</p> <p>C4d</p> <p>CD1a</p> <p>CD3</p> <p>CD4</p> <p>CD5</p> <p>CD8</p> <p>CD10</p> <p>CD13</p> <p>CD138</p> <p>CD20 (L26)</p> <p>CD31</p> <p>CD34</p> <p>CD56 (NCAM)</p> <p>CD68</p> <p>CD79a</p> <p>CD117</p>



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<p>HUMAN BODY TISSUE (cont'd)</p> <p>Glass slides with FFPE tissue (cont'd)</p>	<p><u>Histopathological examination activities for the purposes of clinical diagnosis</u> (cont'd)</p> <p>Adenocarcinoma and carcinoid (intestinal epithelium)</p> <p>Peroxisomal enzyme, used for diagnosis of peroxisomal disorders</p> <p>GCEA glycoproteins in adenocarcinoma</p> <p>Tissues of neuroendocrine origin</p> <p>Pancreatic acinar cell enzyme Canalicular marker to assess integrity of canalicular membrane during diagnosis of Familial cholestatic disorders</p> <p>CMV</p> <p>Basal cells, filamentous keratins form glandular to stratified squamous, prostate adenocarcinoma</p> <p>Normal and neoplastic epithelia</p> <p>Cytokeratin accumulation in Mallory Denk bodies</p> <p>Ductal and glandular epithelia</p> <p>Adenocarcinomas, columnar epithelial cells</p> <p>Late cycle stage of proliferating cells, pancreatic exocrine cells</p>	<p>In-house documented procedures and manufacturer's instructions, using Leica Bond-III immunostainer</p> <p>CDX2</p> <p>Catalase</p> <p>pCEA</p> <p>Chromogranin A</p> <p>Chymotrypsin (F) cMOAT</p> <p>CMV</p> <p>Pan Cytokeratin</p> <p>CK 7</p> <p>CK 8/18</p> <p>CK19</p> <p>CK 20</p> <p>CyclinD</p>



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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 and manufacturer's instructions, using Leica Bond-III immunostainer
Glass slides with FFPE tissue (cont'd)	Striated and smooth muscle cells	Desmin
	Inflammatory adenoma marker Cholangiocyte cilia marker	CRP DCDC2
	Normal and neoplastic epithelium	EMA
	Diagnosis of tufting enteropathy	EPCAM
	Liver fatty acid binding protein in liver – HCC, NAFLD. Identifies inflammatory subtype HCA HNF1A inactivated hepatic adenoma subtype	FABP (F)
	V.W factor in endothelial cells	Factor 8
	Thrombi in placenta, fibrinogen granules within hepatocytes in fibrinogen storage disease	Fibrinogen
	Stomach neuroendocrine cell (G cell) marker	Gastrin
	Gamma glutamyl transferase in canaliculi- used to help diagnose PFIC type 1 (ATP8B1 disease)	GGT (F)
	Zonal expression pattern differentiates hepatocellular adenoma from hepatic focal nodular hyperplasia	Glutamine Synthetase (F)
	Hepatocellular carcinoma	Glypican 3



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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 and manufacturer's instructions, using Leica Bond-III immunostainer
Glass slides with FFPE tissue (cont'd)	B cells, T cells, monocytes, macrophages	LCA (CD45)
	Membrane Attack Complex, terminal complement cascade. Inflammatory hepatocyte membrane positive in neonatal haemochromatosis	MAC
	Multidrug resistant 3 protein – stains canaliculi in normal liver, absent in progressive familial intrahepatic cholestasis type 3(ABCB4 disease)	MDR3 (F)
	Cytoplasmic staining of melanocytes and melanomas	Melan A
	Nuclear positivity in ost cells with loss of expression in some tumour types	MLH1
	Epithelial tissue from glandular to stratified squamous	MNF116 (pan cytok)
	Nuclear positivity in most cells with loss of expression in some tumour types	MSH2
	Nuclear positivity in most cells with loss of expression in some tumour types	MSH6
	Neoplastic pancreatic ductal superficial epithelium	MUC-1
	Intestinal epithelium	MUC-2
	Gastric superficial epithelium	MUC-5AC



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<p>HUMAN BODY TISSUE (cont'd)</p> <p>Glass slides with FFPE tissue (cont'd)</p>	<p><u>Histopathological examination activities for the purposes of clinical diagnosis</u> (cont'd)</p> <p>Gastric pyloric epithelium and Brunners glands epithelial tissue</p> <p>Islet cell marker / diagnosis of pancreatic endocrine tumours</p> <p>Nuclear staining, positive in renal distal</p> <p>Neoplastic cells in epithelium</p> <p>Nuclear staining in basal epithelial cells, squamous cells and Squamous cell carcinoma</p> <p>Nuclear positivity in most cells – loss of expression in some tumour types convoluted tubules and collecting duct (and derived tumours). Pancreatic neuroendocrine tumours</p> <p>Cytoplasm of lymphatic endothelial cells</p> <p>Prostate secretory and ductal epithelium</p> <p>Nuclear staining in some Hepatocellular carcinomas</p> <p>Smooth muscle cells, myoepithelial cells</p>	<p>In-house documented procedures and manufacturer's instructions, using Leica Bond-III immunostainer</p> <p>MUC-6</p> <p>NKX6-1</p> <p>PAX 8</p> <p>P53</p> <p>P63</p> <p>PMS2</p> <p>Podoplanin</p> <p>PSA</p> <p>SALL4</p> <p>SMA</p>



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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 and manufacturer's instructions, using Leica Bond-III immunostainer
Glass slides with FFPE tissue (cont'd)	Nuclear and cytoplasmic positivity in most cell types. Tumour suppressor protein, loss of expression in some tumour types (pancreatic adenocarcinomas)	SMAD4
	Schwann cells, nerve processes, S100 +ve neoplasms eg Melanoma	S-100
	Cytoplasmic staining in pancreatic adenocarcinoma	S-100P
	Neuroendocrine cells	Synaptophysin
	Tight junctions between cells	TJP 2
	Trypsin in exocrine cells of the pancreas – diagnosis of acinar cell carcinoma of pancreas	Trypsin (F)
	TTF-1 found in lung and thyroid (thyroid follicular cells)	TTF-1
	Cells of mesenchymal origin	Vimentin



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HUMAN BODY FLUIDS	<u>Cytopathology (Non-Gynae) examination activities for the purposes of clinical diagnosis</u>	In-house documented procedures using manual methods or analysers in conjunction with manufacturer's instructions as specified:
Bile duct brushings Fine needle aspirate biopsies of the pancreas Pancreatic cyst fluids	Examination of cellular material in order to identify or exclude morphological and cytological abnormalities	Thermo electron Cytospin4 using SOP LP-HIS-SOP-43-Cytology FNA preparation
Slides prepared above	Demonstration of basophilic and eosinophilic structures	Hologic Thin Prep 2000 using SOP LP-HIS-SOP-43-Cytology FNA preparation
Slides prepared above	Demonstration of: Cells (nuclei and cytoplasm) and micro organisms	LP-HIS-SOP-46-H&E for cytology preparations LP-HIS-SOP-48Papanicolaou - LP-HIS-SOP-47-MGG for cytology
FFPE slides, frozen tissue on glass slides, non-gynae cytology slides	Morphological assessment and interpretation/diagnosis	Interpretive/diagnostic microscopy LP-HIS-SOP-32-Histopathology reporting LP-HIS-SOP-28-Cytology reporting
END		