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United Kingdom Accreditation Service

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

 Accredited to ISO 15189:2012	Synnovis Analytics LLP Issue No: 012 Issue date: 30 October 2024	
	Liver Pathology Denmark Hill London SE5 9RS	Contact: Simon Hammond Tel: +44 (0)203 299 4814 E-Mail: Simon.Hammond@nhs.net 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 FLUIDS	<u>Therapeutic drug monitoring examination activities for the purposes of clinical diagnosis:</u>	Documented in house methods and manufacturer's instructions for Waters LC-MSMS using Liquid Chromatography – Tandem Mass Spectrometry
Blood	Mycophenolic acid	LP-IDM-SOP-29-Therapeutic monitoring of MPA by LC-MS



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



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



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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)	Adenocarcinoma and carcinoid (intestinal epithelium)	CDX2
	Peroxisomal enzyme, used for diagnosis of peroxisomal disorders	Catalase
	GCEA glycoproteins in adenocarcinoma	pCEA
	Tissues of neuroendocrine origin	Chromogranin A
	Pancreatic acinar cell enzyme Canalicular marker to assess integrity of canalicular membrane during diagnosis of Familial cholestatic disorders	Chymotrypsin (F) cMOAT
	CMV	CMV
	Basal cells, filamentous keratins form glandular to stratified squamous, prostate adenocarcinoma	Pan Cytokeratin
	Normal and neoplastic epithelia	CK 7
	Cytokeratin accumulation in Mallory Denk bodies	CK 8/18
	Ductal and glandular epithelia	CK19
	Adenocarcinomas, columnar epithelial cells	CK 20
	Late cycle stage of proliferating cells, pancreatic exocrine cells	CyclinD



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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)	Hepatocyte marker – clone OCH1E5	HepPar-1
	Liver cells infected with hepatitis B – surface antigen staining	HBs
	Liver cells infected with hepatitis B – core antigen staining	HBc
	Nuclear marker for infected cells	HHV8
	Melanoma, melanocyte differentiation PComas	HMB-45
	Herpes Simplex virus 1 Herpes Simplex virus 2	HSV1 (cocktail with HSV2) HSV2 (cocktail with HSV1)
	Specific for gamma chains of human IgG	IgG
	Detection of IgG4 related disease	IgG4
	Diagnosis of mucinous cystic neoplasms of the pancreas	Inhibin
	Beta cells of pancreatic islets	Insulin
	Islet cell marker / diagnosis of pancreatic endocrine tumours	ISL-1
	Kappa light chains restricted B lymphocytes and plasma cells	Kappa Light Chain
	Proliferating Cells	Ki-67 (MIB-1)
	Lambda light chains restricted B lymphocytes and plasma cells	Lambda light chain



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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
	Canalicular staining in normal liver	MDR1
	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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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)	Gastric pyloric epithelium and Brunners glands epithelial tissue	MUC-6
	Islet cell marker / diagnosis of pancreatic endocrine tumours	NKX6-1
	Peripheral nerves, neuroendocrine tumours	NSE
	Nuclear staining, positive in renal distal	PAX 8
	Neoplastic cells in epithelium	P53
	Nuclear staining in basal epithelial cells, squamous cells and Squamous cell carcinoma	P63
	Nuclear positivity in most cells – loss of expression in some tumour types convoluted tubules and collecting duct (and derived tumours). Pancreatic neuroendocrine tumours	PMS2
	Cytoplasm of lymphatic endothelial cells	Podoplanin
	Prostate secretory and ductal epithelium	PSA
	Nuclear staining in some Hepatocellular carcinomas	SALL4
	Smooth muscle cells, myoepithelial cells	SMA



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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
Glass slides with FFPE tissue (cont'd)	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 Hologic Thin Prep 2000 using SOP LP-HIS-SOP-43-Cytology FNA preparation
Slides prepared above	Demonstration of basophilic and eosinophilic structures	LP-HIS-SOP-46-H&E for cytology preparations
Slides prepared above	Demonstration of: Cells (nuclei and cytoplasm) and micro organisms	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



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<p>HUMAN TISSUES AND BODY FLUIDS</p> <p>Genomic DNA</p> <p>Genomic DNA extracted in-house from the sample types listed above or received as primary sample type from an external source</p>	<p><u>Molecular Genetics activities for the purpose of clinical diagnosis</u></p> <p>DNA quantification</p> <p><i>DNA variant detection (substitutions and small indels)</i></p> <p><i>Cholestasis (R171)</i> <i>Wilson's Disease (R172)</i> <i>Polycystic liver disease (R173)</i> <i>Pancreatitis (R175)</i> <i>Gilbert Syndrome (R176)</i> <i>Hirschsprung disease (R177)</i> <i>Intestinal failure/Congenital diarrhoea (R331)</i></p>	<p>Documented in-house methods incorporating manufacturer's instructions (where relevant)</p> <p>NanodropOne for DNA Quantification</p> <p>Analysis of PCR amplified DNA by Sanger sequencing to identify abnormal sequences using PCR Veriti , ABI 3730, TapeStation 4200, Qubit fluorimeter and Illumina MiSeq. Amplicon PCR and agarose gel electrophoresis followed by Sanger sequencing. Using SOP: LP-LMG-SOP-33- Sequencing clean up and use of the ABI 3130 LP-LMG-SOP-30-Mutation surveyor LP-LMG-SOP-32-Sanger sequencing LP-LMG-SOP-15-Thermal cyclers LP-LMG-SOP-31 PCR for Sanger sequencing LP-LMG-SOP-34- LMG Family Mutation Analysis Multiple probe and PCR based library preparation followed by next-generation sequencing using SOP LP-LMG-SOP-27-Next generation sequencing on the MiSeq LP-LMG-SOP-35-LMG NGS data import and analysis using the CLC Genomics workbench LP-LMG-SOP-23 Qubit Measurement LP-LMG-SOP-15-Thermal cyclers</p>



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<p>HUMAN TISSUES AND BODY FLUIDS (cont'd)</p> <p>Genomic DNA extracted in-house from the sample types listed above or received as primary sample type from an external source</p>	<p><u>Molecular Genetics activities for the purpose of clinical diagnosis</u> (cont'd)</p> <p><i>DNA variant detection for clinical indications in the NHSE National Genomic Test Directory for Rare and Inherited diseases:</i> <i>Cholestasis (R171)</i> <i>Wilson's Disease (R172)</i> <i>Polycystic liver disease (R173)</i> <i>Pancreatitis (R175)</i> <i>Gilbert Syndrome (R176)</i> <i>Hirschsprung disease (R177)</i> <i>Intestinal failure/Congenital diarrhoea (R331)</i></p> <p>Gene/exon copy number variation detection using qPCR</p> <p>Inherited conditions-detection of clinically relevant nucleic acid sequence variants (including SNVs, indels, CNVs down to exon level)</p>	<p>Documented in-house methods incorporating manufacturer's instructions (where relevant)</p> <p>Analysis of PCR amplified DNA by Next Generation Sequencing (NGS) (Automated with manual backup) to identify variant sequences using PCR Veriti, Qubit fluorimeter, TapeStation 4200, Agilent Magnis NGS Prep System and Illumina Miseq and SQVD (bioinformatics)</p> <p>Using SOP: LP-LMG-SOP-23 Qubit Measurement LP-LMG-SOP-54 Next Generation Sequencing using SureSelect XT HS LP-LMG-SOP-56 Automated Next Generation Sequencing using SureSelect XT HS LP-LMG-SOP-55 Analysis of NGS data using SQVD</p> <p>Documented in house methods incorporating manufacturers methods where relevant. Analysis of copy number variation in NGS reads followed by confirmation using qPCR on an ABI StepOnePlus platform. Applied Biosystems StepOnePlus LP-LMG-SOP-48 Dosage LP-LMG-SOP-46 qPCR for copy number variants</p>
END		