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United Kingdom Accreditation Service

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

 Accredited to ISO 15189:2012	Viapath Analytics LLP Issue No: 006 Issue date: 10 December 2021	
	Liver Pathology Denmark Hill London SE5 9RS	Contact: Pradeep Agrawal Tel: +44 (0) 020 3299 2519 E-Mail: Pradeep.agrawal@nhs.net Website: https://liverlabs.kch.nhs.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	Ciclosporin	LP-IDM-SOP-28-Combined therapeutic monitoring of Ciclosporin and Tacrolimus by LC-MS/MS
Blood	Tacrolimus	LP-IDM-SOP-28-Combined therapeutic monitoring of Ciclosporin and Tacrolimus by LC-MS/MS
Blood	Everolimus	LP-IDM-SOP-30Therapeutic Monitoring of Sirolimus and Everolimus by LC-MS/MS
Blood	Sirolimus	LP-IDM-SOP-30Therapeutic Monitoring of Sirolimus and Everolimus by LC-MS/MS
Blood	Mycophenolic acid	LP-IDM-SOP-29-Therapeutic monitoring of MPA by LC-MS
Blood	Ribavirin	LP-IDM-SOP-37Therapeutic monitoring of Ribavirin by LC-MS/MS



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HUMAN BODY FLUIDS (cont'd)	<u>Viral serology for the purpose of clinical diagnosis</u>	Documented in house methods and manufacturer's instructions for Abbott Architect –Chemiluminescent micro particle immunoassay
Blood	HAV Ab (IgM)	LP- HTS-SOP-36 – HAV Ab IgM CMIA ARCHITECT
Blood	HAV Ab (IgG)	LP-HTS-SOP-35 - Hepatitis A Antibody (IgG)
Blood	HBsAg (Qualitative)	LP -HTS-SOP-35 – HBsAg Qualitative II
Blood	HBsAg Confirmatory	LP- HTS-SOP-40 - HBsAg Qualitative Confirmatory
Blood	HBsAg (Quantitative)	LP- HTS-SOP-41 – HBsAg
Blood	HBeAb	LP- HTS-SOP-33 – Anti-HBe
Blood	HBsAb	LP- HTS-SOP-42 – HbsAb
Blood	HBeAg	LP- HTS-SOP-34 – HbeAg
Blood	HBcAb	LP- HTS-SOP-32 - Hepatitis B Core Antibody
Blood	HBcAb (IgM)	LP-HTS-SOP-37- Hepatitis B Core Antibody (IgM)
Blood	HCV Ab	LP- HTS-SOP-39– Anti-HCV CMIA ARCHITECT



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HUMAN BODY FLUIDS (cont'd)	<u>Viral serology for the purpose of clinical diagnosis (cont'd)</u>	Documented in house methods and manufacturer's instructions
Blood	HEV Ab (IgM)	Manual ELISAs using kits listed below, read on Tecan Sunrise LP- HTS-SOP-13- Tecan Sunrise Plate Reader Tecan sunrise Principle: Enzyme-Linked Immunosorbent Assay LP-HTS-SOP-52-Fortress HEV IgM Antibody
Blood	HEV Ab (IgG)	Tecan sunrise Principle: Enzyme-Linked Immunosorbent Assay LP-HTS-SOP-51-Fortress HEV IgG Antibody
Blood	HDV Ab (Total)	DIA-PRO Delta kits LP- HTS-SOP-73-DIA.PRO - Delta Ab assay
Blood	HDV Ab (IgM)	DIA-PRO Delta kits lp-HTS-SOP-74- DIA.PRO Delta IgM assay



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HUMAN BODY FLUIDS (cont'd)	<u>Viral serology for the purpose of clinical diagnosis</u> (cont'd)	Documented in house methods and manufacturer's instructions
Blood	HBV DNA (Quantitative)	Roche COBAS using: Real time PCR and LP- HTS-SOP- 79-Cobas 6800 HBV DNA
Blood	HBV Genotype	Using MagMax RNA extractor, ABI 9700 Thermocycler and Life technologies ABI3130 Genetic Analyser using: Direct DNA sequencing and LP- HTS-SOP-49-HBV Genotyping
Blood	HBV DR Mutation Screen	Using MagMax RNA extractor, ABI 9700 Thermocycler and Life technologies ABI3130 Genetic Analyser using: Direct DNA sequencing and LP- HTS-SOP-50- HBV Drug Resistance Mutation Screen
Blood	HCV RNA (Quantitative)	Roche COBAS using LP- HTS-SOP-80- Cobas 6800 HCV RNA
Blood	HCV Genotype	Siemens AutoBlot 3000 and Hybridization using LP- HTS-SOP-43- VERSANT HCV Genotype 2.0 Assay (LiPA)
Blood	HDV RNA (Quantitative)	Roche COBAS TaqMan Real time PCR using SOP LP- HTS-SOP-44- Quantitative HDV RNA Test
Blood	HEV RNA (Quantitative)	Life Technologies StepOne plus Real-time PCR SOP: LP- HTS-SOP-75-HEV Quant
Blood	HEV RNA (Qualatative)	Roche Cobas 6800 using LP- HTS-SOP- 77- Cobas 6800 HEV RNA qualitative



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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	Documented in-house procedures for manual special stains LP-HIS-SOP-87-PAS
	Haemosiderin and ferric iron	LP-HIS-SOP-88-Perls Prussian blue
	Copper	LP-HIS-SOP-91-Rhodanine
	Collagen	LP- HIS-SOP-89-PicroSirius Red
	Nuclear stain used as part of Sirius Red and EVG	LP- HIS-SOP-93-Weigert's Iron haematoxylin
	Tubercle bacilli	LP- HIS-SOP-94-Ziehl Neelsen
Glass slides with FFPE tissue	In situ hybridisation to detect the following:	In situ hybridisation using Leica Bond III immunostainer and SOP LP-HIS-SOP-103 Antibody dilutions and protocols for Bond III
	Epstein Barr virus	EBER (ISH)
Glass slides with FFPE tissue	Immunohistochemistry to detect the following:	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 accumulation in diagnosis of A1AT deficiency	A1AT
	Adenovirus	Adenovirus
	Multi-cytokeratin to confirm epithelial origin	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
	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 cytokeratin 8 in carcinomas	CAM 5.2
	Expressed in biliary and pancreatic cancer	CA19-9
	Component of complement associated with vascular damage. Used as part of diagnosis of humoral rejection in allografts	C4d



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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)	Langerhans cells – used for diagnosis of Langerhans cell histiocytosis	CD1a
	Granulocytes Reed-Sternberg cells	CD10
	Hepatic canalicular marker	CD13
	Plasma cell marker	CD138
	Mature B cells, Follicular dendritic cells	CD20 (L26)
	Vascular endothelium	CD31
	Gastrointestinal Stromal Tumours	CD34
	Neuroendocrine cells	CD56 (NCAM)
	Macrophages	CD68
	B lymphocytes	CD79a
	GIST	CD117
	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



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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)	Pancreatic acinar cell enzyme	Chymotrypsin (F)
	Canalicular marker to assess integrity of canalicular membrane during diagnosis of Familial cholestatic disorders	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
	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)



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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)	V.W factor in endothelial cells	Factor 8
	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
	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
	Melanoma, melanocyte differentiation PEComas	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
	Islet cell marker / diagnosis of pancreatic endocrine tumours	ISL-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 and manufacturer's instructions, using Leica Bond-III immunostainer
Glass slides with FFPE tissue (cont'd)	Proliferating Cells	Ki-67 (MIB-1)
	B cells, T cells, monocytes, macrophages	LCA (CD45)
	Multidrug resistant 3 protein – stains canaliculi in normal liver, absent in progressive familial intrahepatic cholestasis type 3(ABCB4 disease)	MDR3 (F)
	Epithelial tissue from glandular to stratified squamous	MNF116 (pan cytok)
	Neoplastic pancreatic ductal superficial epithelium	MUC-1
	Intestinal epithelium	MUC-2
	Gastric superficial epithelium	MUC-5AC
	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
	Neoplastic cells in epithelium	P53
	Prostate secretory and ductal epithelium	PSA
	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)	Schwann cells, nerve processes, S100 +ve neoplasms eg Melanoma	S-100
	Neuroendocrine cells	Synaptophysin
	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
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 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>Fresh, frozen or fixed human tissue or cells (Blood, saliva, amniotic fluid, chorionic villi, placental biopsies)</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) Full coding region of genes: Wilson disease genetics panel (ATP7B) and Cholestasis Gene panel (incorporating Progressive Familial Inherited Cholestasis, Alagille Syndrome, Nieman Pick Disorder Type C, Bile Acid Synthesis Disorder, UGT1A1 associated disease, ARC syndrome, MYO5B associated disease, Neonatal ichthyosis-cholangitis syndrome, GRACILE syndrome, Transaldolase deficiency, Dubin-Johnson Syndrome, Neonatal Sclerosing Cholangitis, Citrin Deficiency).</i></p>	<p>Documented in-house methods incorporating manufacturer's instructions (where relevant)</p> <p>DNA extraction using automated extraction. Equipment used Promega Maxwell DNA Extractor with automated magnetic bead DNA isolation using SOP LP-LMG-SOP-20-LMG DNA Extraction - blood LP-LMG-SOP-19-DNA extraction – donor tissue</p> <p>NanodropOne for DNA Quantification</p> <p>Analysis of PCR amplified DNA by Sanger sequencing or Next generation 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><u>Molecular Genetics activities for the purpose of clinical diagnosis</u> (cont'd)</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>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>
<p>END</p>		