


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 Accredited to ISO 15189:2012	King's College Hospital NHS Foundation Trust	
	Issue No: 001 Issue date: 30 November 2017	
	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	Local contact	
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	SOP: KCH-LP-SOP-IDM K6-Combined therapeutic monitoring of Ciclosporin and Tacrolimus by LC-MS/MS
Blood	Tacrolimus	SOP: KCH-LP-SOP-IDM K6-Combined therapeutic monitoring of Ciclosporin and Tacrolimus by LC-MS/MS
Blood	Everolimus	SOP: KCH-LP-SOP IDM K5- Therapeutic Monitoring of Sirolimus and Everolimus by LC-MS/MS
Blood	Sirolimus	SOP: KCH-LP-SOP IDM K5- Therapeutic Monitoring of Sirolimus and Everolimus by LC-MS/MS
Blood	Mycophenolic acid	KCH-LP-SOP-IDM K4-Therapeutic monitoring of MPA by LC-MS
Blood	Ribavirin	SOP: KCH-LP-SOP IDM Q1- Therapeutic monitoring of Ribavirin by LC-MS/MS



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HUMAN BODY FLUIDS	<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)	KCH-LP-SOP-HTS-ASY-37A – HAV Ab IgM CMIA ARCHITECT
Blood	HAV Ab (IgG)	KCH-LP-SOP-HTS-ASY-39A - Hepatitis A Antibody (IgG)
Blood	HBsAg (Qualitative)	KCH-LP-SOP-HTS-ASY-35A – HBsAg Qualitative II
Blood	HBsAg Confirmatory	KCH-LP-SOP-HTS-ASY-41A - HBsAg Qualitative Confirmatory
Blood	HBsAg (Quantitative)	KCH-LP-SOP-HTS-ASY- 45 – HBsAg
Blood	HBeAb	KCH-LP-SOP-HTS-ASY-33A – Anti-HBe
Blood	HBsAb	KCH-LP-SOP-HTS-ASY-53 – HbsAb
Blood	HBeAg	SOP KCH-LP-SOP-HTS-ASY-34A – HbeAg
Blood	HBcAb	KCH-LP-SOP-HTS-ASY-32A - Hepatitis B Core Antibody
Blood	HBcAb (IgM)	KCH-LP-SOP-HTS-ASY-38A - Hepatitis B Core Antibody (IgM)
Blood	HCV Ab	KCH-LP-SOP-HTS-ASY-40A – Anti-HCV CMIA ARCHITECT



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HUMAN BODY FLUID	<u>Viral serology for the purpose of clinical diagnosis</u> (cont'd)	Documented in house methods and manufacturer's instructions
Blood	HEV Ab (IgM)	Manual ELISAs using kits listed below, read on Tecan Sunrise KCH-LP-SOP-HTS-Eq-58- Tecan Sunrise Plate Reader Fortress Diagnostics kit
Blood	HEV Ab (IgG)	SOP: KCH-LP-SOP-HTS-ASY-52- Fortress HEV IgM Antibody Fortress Diagnostics kit
Blood	HDV Ab (Total)	KCH-LP-SOP-HTS-ASY-51- Fortress HEV IGM Antibody DiaSorin Delta kits
Blood	HDV Ab (IgM)	SOP KCH-LP-SOP-HTS-ASY-18- Delta Ab (Total) EIA DiaSorin Delta kits KCH-LP-SOP-HTS-ASY-20- Delta Ab (IgM) EIA



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HUMAN BODY FLUID	<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 Ampliprep/COBAS TaqMan using: Real time PCR and SOP: KCH-LP-SOP-HTS-ASY-44- Roche COBAS Ampliprep/COBAS TaqMan HBV Test
Blood	HBV Genotype	Using MagMax RNA extractor, ABI 97000 Thermocycler and Life technologies ABI3130 Genetic Analyser using: Direct DNA sequencing and SOP KCH-LP-SOP-HTS-ASY-48-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 KCH-LP-SOP-HTS-ASY-49- HBV Drug Resistance Mutation Screen
Blood	HCV RNA (Quantitative)	Using MagMax RNA extractor, ABI 9700 Thermocycler, Roche COBAS Ampliprep/COBAS TaqMan and Real time PCR using SOP: KCH-LP-SOP-HTS-ASY-43- Roche COBAS Ampliprep/COBAS TaqMan HCV Test
Blood	HCV Genotype	Siemens AutoBlot 3000 and Hybridization using SOP KCH-LP-HTS-ASY-27- VERSANT HCV Genotype 2.0 Assay (LiPA)
Blood	HDV RNA (Quantitative)	Roche COBAS TaqMan Real time PCR using SOP KCH-LP-SOP-HTS-ASY-47- Quantitative HDV RNA Test



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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: KCH-LP-SOP- HIS- Specimen reception v3.1 and Propath CTiBT downdraft dissection table using SOP: KCH-LP-SOP-HIS-Surgical specimen cut-upv5.0
Excision and incisional surgical specimens	Sample processing	Sakura VIP 6-E2 tissue processor using SOP KCH-LP-SOP-HIS- Use of the VIP 6 Tissue Processor
Excision and incisional surgical specimens	Sample Embedding	Sakura Tissue Tek Tec 5 embedding centre using SOP KCH-LP-SOP-HIS- Embedding in paraffin wax
Formalin fixed paraffin embedded tissue (FFPE)	Microtomy	Leica RM2235 microtome Using SOP KCH-LP-SOP-HIS-Cutting paraffin sections
Fresh tissue	Sample processing (fresh frozen)	Using Bright Clini-RF rapid freezing bath and SOP: KCH-LP-SOP-HIS- freezer bath KCH-LP-SOP-HIS-Frozen section preparation KCH-LP-SOP-HIS-liquid nitrogen
Fresh tissue	Cutting sections (frozen)	Leica CM1950 cryostat using SOP: KCH-LP-SOP-HIS-Frozen section preparation
Glass slides with fresh tissue	Routine morphological staining For the detection of:	
	Basophilic and Eosinophilic structures	KCH-LP-SOP-HIS-H&E (Frozen Sections)
Glass slides with FFPE tissue	Basophilic and Eosinophilic structures	KCH-LP-SOP-HIS-Harris H&E (Paraffin sections)



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HUMAN BODY TISSUE	<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
	Retic	KCH-LP-SOP-HIS-Ammoniacal Silver for reticulin fibres
	Amyloid	KCH-LP-SOP-HIS-Congo Red
	Helicobacter/Microorganisms	KCH-LP-SOP-HIS- Giemsa for Helicobacter pylori
	Connective tissue	KCH-LP-SOP-HIS-Gomori's one step trichrome
	Gram positive and negative micro-organisms	KCH-LP-SOP-HIS-Gram Stain
	Elastic fibres and connective tissue	KCH-LP-SOP-HIS-Haemalum van Giesen
	Elastic fibres and connective tissue	KCH-LP-SOP-HIS-Carazzi's Haematoxylin
	Elastic fibres and connective tissue	KCH-LP-SOP-HIS- Celestine blue / Haemalum sequence
	Acid and Neutral Mucopolysaccharides	KCH-LP-SOP-HIS-dPAS
	Connective tissue and fibrin	Martius Yellow, Brilliant Crystal Scarlet, Soluble Blue using SOP KCH-LP-SOP-HIS-MSB
	Fungi (Aspergillus) and Pneumocystis	KCH-LP-SOP-HIS- Grocott's methenamine silver
	Copper, Hepatitis B	KCH-LP-SOP-HIS-Orcein
	Haemosiderin and ferric iron	KCH-LP-SOP-HIS-Perls Prussian blue
	Copper	KCH-LP-SOP-HIS-Rhodanine



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	Collagen	KCH-LP-SOP-HIS-Sirius Red
	Nuclear stain used as part of Sirius Red and EVG	KCH-LP-SOP-HIS-Weigert's Iron haematoxylin
	Tubercle bacilli	KCH-LP-SOP-HIS-Ziehl Neelsen
Glass slides with FFPE tissue	In situ hybridisation to detect the following:	In situ hybridisation using Leica Bond immunostainer and SOP KCH-LP-SOP-HIS-Antibody dilutions and protocols for BondMax
	Epstein Barr virus	EBER (ISH)
Glass slides with FFPE tissue	Immunohistochemistry to detect the following:	Leica Bond-Max immunostainer using SOP: KCH-LP-SOP-HIS- and SOP KCH-LP-SOP-HIS-Antibody dilutions and protocols for Bond Max
	A1AT accumulation in diagnosis of A1AT deficiency	A1AT
	Adenovirus	Adenovirus
	Multi-cytokeratin to confirm epithelial origin	AE1/AE3
	Fetal antigen used for diagnosis of hepatoblastoma and germ cell tumours	AFP
	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



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HUMAN BODY TISSUE	<u>Histopathological examination activities for the purposes of clinical diagnosis</u> (cont'd)	In-house documented procedures and manufacturer's instructions, using Leica Bond-Max immunostainer
Glass slides with FFPE tissue	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
	Langerhans cells – used for diagnosis of Langerhans cell histiocytosis	CD1a
	Granulocytes Reed-Sternberg cells	CD10
	Hepatic canalicular marker	CD13
	Mature B cells, Follicular dendritic cells	CD20 (L26)



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HUMAN BODY TISSUE	<u>Histopathological examination activities for the purposes of clinical diagnosis</u> (cont'd)	In-house documented procedures and manufacturer's instructions, using Leica Bond-Max immunostainer
Glass slides with FFPE tissue	Vascular endothelium	CD31
	Gastrointestinal Stromal Tumours	CD34
	Neuroendocrine cells	CD56 (NCAM)
	Macrophages	CD68
	B lymphocytes	CD79a
	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	Chymotrypsin (F)
	Canalicular marker to assess integrity of canalicular membrane during diagnosis of Familial cholestatic disorders	cMOAT
	CMV	CMV



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HUMAN BODY TISSUE	<u>Histopathological examination activities for the purposes of clinical diagnosis</u> (cont'd)	In-house documented procedures and manufacturer's instructions, using Leica Bond-Max immunostainer
Glass slides with FFPE tissue	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
	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



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HUMAN BODY TISSUE	<u>Histopathological examination activities for the purposes of clinical diagnosis</u> (cont'd)	In-house documented procedures and manufacturer's instructions, using Leica Bond-Max immunostainer
Glass slides with FFPE tissue	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	HSV1 (cocktail with HSV2)
	Herpes Simplex virus 2	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



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HUMAN BODY TISSUE	<u>Histopathological examination activities for the purposes of clinical diagnosis</u> (cont'd)	In-house documented procedures and manufacturer's instructions, using Leica Bond-Max immunostainer
Glass slides with FFPE tissue	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
	Peripheral nerves, neuroendocrine tumours	NSE
	Neoplastic cells in epithelium	P53
	Prostate secretory and ductal epithelium	PSA
	Smooth muscle cells, myoepithelial cells	SMA
	Schwann cells, nerve processes, S100 +ve neoplasms eg Melanoma	S-100



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HUMAN BODY TISSUE	<u>Histopathological examination activities for the purposes of clinical diagnosis</u> (cont'd) Neuroendocrine cells Trypsin in exocrine cells of the pancreas – diagnosis of acinar cell carcinoma of pancreas TTF-1 found in lung and thyroid (thyroid follicular cells) Cells of mesenchymal origin	In-house documented procedures and manufacturer's instructions, using Leica Bond-Max immunostainer Synaptophysin Trypsin (F) TTF-1 Vimentin
HUMAN BODY FLUIDS Bile duct brushings Fine needle aspirate biopsies of the pancreas Pancreatic cyst fluids Slides prepared above Slides prepared above FFPE slides, frozen tissue on glass slides, non-gynae cytology slides	<u>Cytopathology (Non-Gynae) examination activities for the purposes of clinical diagnosis</u> Examination of cellular material in order to identify or exclude morphological and cytological abnormalities Demonstration of basophilic and eosinophilic structures Demonstration of: Cells (nuclei and cytoplasm) and micro organisms Morphological assessment and interpretation/diagnosis	In-house documented procedures using manual methods or analysers in conjunction with manufacturer's instructions as specified: Thermo electron Cytospin4 using SOP KCH-LP-SOP-HIS-Cytology FNA preparation KCH-LP-SOP-HIS-H&E KCH-LP-SOP-HIS-Papanicolaou KCH-LP-SOP-HIS-MGG for cytology Interpretive/diagnostic microscopy KCH-LP-SOP-HIS-Histopathology reportingv4.0 KCH-LP-SOP-HIS-Cytology reportingv1.1
END		