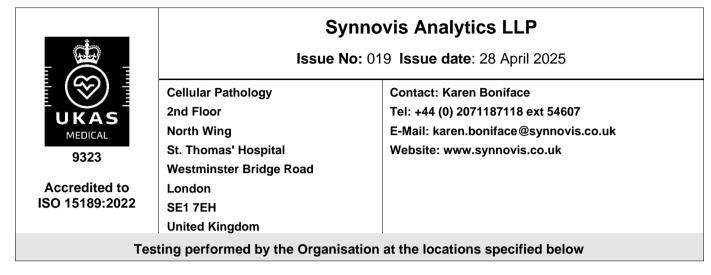
Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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



Locations covered by the organisation and their relevant activities

Laboratory locations:

Location details		Activity	Location code
Address Cellular Pathology 2 nd Floor, North Wing St. Thomas' Hospital Westminster Bridge Road London SE1 7EH	Local contact Karen Boniface (as above)	Histopathology Rapid frozen section for intra-operative diagnosis Microscopic identification of Glomeruli Diagnostic Cytopathology Andrology	ST
Head & Neck / Oral Pathology Laboratory 4 th Floor, Tower Wing Guy's Hospital Great Maze Pond London SE1 9RT	Karen Boniface (as above)	Histopathology Rapid frozen section for intra-operative diagnosis	GHN

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Site activities performed away from the locations listed above:

Location details		Activity	Location code
Gassiot House Andrology Clinic St. Thomas' Hospital	Karen Boniface (as above)	Andrology sample production only	N/A
Fine Needle Aspirate (FNA) Clinics Westminster Bridge Road site	Karen Boniface (as above)	FNA material/slide preparation Cellularity assessment	STFNA
FNA Clinics Great Maze Pond site	Karen Boniface (as above)	FNA material/slide preparation Cellularity assessment	GFNA
Renal Biopsy Theatre/Ward (8 locations) St. Thomas' Hospital	Karen Boniface (as above)	Microscopic identification of Glomeruli	STRB
Renal Biopsy Wards (2 locations) Guy's Hospital	Karen Boniface (as above)	Microscopic identification of Glomeruli	GRB



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DETAIL OF ACCREDITATION

measurement	Equipment/Techniques used	Location Code
Diagnostic Cytology		
Preparation and examination of cellular material to identify or exclude morphological & cytological abnormalities	Preparation/centrifugation In-house procedures: CPC-SOP-112 Non-Gynae Preparation in conjunction with manufacturer's instructions using: Thermo Shandon Cytospins 3 & 4 Heraeus Megafuge 1.0 & Megafuge 40 Hologic T2000processor	ST
	Papanicolaou staining Automated using in-house procedures: CPC-SOP-111 Non-Gynae Staining in conjunction with manufacturer's instructions using: Leica Autostainer ST5020 Leica Autostainer XL	ST
Red & white blood cells	Hemacolor staining Automated using in-house procedures: CPC-SOP-111 Non-Gynae Staining in conjunction with manufacturer's instructions using: Leica Autostainer ST5020 Leica Autostainer XL	ST
	Preparation and examination of cellular material to identify or exclude morphological & cytological abnormalities	Preparation and examination of cellular material to identify or exclude morphological & cytological abnormalitiesPreparation/centrifugation In-house procedures: CPC-SOP-112 Non-Gynae Preparation in conjunction with manufacturer's instructions using: Thermo Shandon Cytospins 3 & 4 Heraeus Megafuge 1.0 & Megafuge 40 Hologic T2000processorPapanicolaou staining Automated using in-house procedures: CPC-SOP-111 Non-Gynae Staining in conjunction with manufacturer's instructions using: Leica Autostainer ST5020 Leica Autostainer XLRed & white blood cellsHemacolor staining Automated using in-house procedures: CPC-SOP-111 Non-Gynae Staining in conjunction with manufacturer's instructions using: Leica Autostainer ST5020 Leica Autostainer XLRed & white blood cellsHemacolor staining Automated using in-house procedures: CPC-SOP-111 Non-Gynae Staining in conjunction with manufacturer's instructions using: Leica Autostainer ST5020 Leica Autostainer ST5020

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	Type of test/Properties			

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HUMAN TISSUES AND FLUIDS (cont'd)	Diagnostic Cytology (cont'd)		
Slides prepared in-house from sample types listed above	Morphological assessment and interpretation/diagnosis	Microscopy (qualitative analysis) In-house procedures: CPC-SOP-117 Non-Gynae Screening using microscopes as follows: Olympus BX40F Olympus BX40 Olympus BX41 Olympus BX45 Olympus BX46 Olympus BX53 Nikon	ST
Fine needle aspirations (FNA)	Cellularity assessment (sample adequacy confirmation) followed by subsequent processing and analysis in the Cytopathology Laboratory (ST)	Material/slide preparation followed by microscopy Manual methods using: CPC-SOP-73 FNA and: Olympus BX40, BX41 microscopes Flexible scope protocols: CP-SOP-27 Flexible scope limited to the application of these methods for commissioning & operation of FNA clinics listed in CPC-REC-31 FNA Clinic Log	STFNA GFNA

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Materials/Products tested	Type of test/Properties	Standard specifications/	Location	

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN TISSUES AND FLUIDS (cont'd)	Histopathology Preparation and examination to identify or exclude morphological & cytological abnormalities	Macroscopic and Microscopic examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant)	
Formalin fixed tissues		Macroanalysis and dissection Manual method using: CPH-SOP-60 Cut-up and Processing CPH-SOP-17 Urological Histopathology (Dissection) CPH-SOP-15 Respiratory Histopathology (Dissection) CPH-SOP-28 Breast Pathology (Dissection) CPH-SOP-12 Endocrine Histopathology CPH-SOP-4 General Histopathology (Dissection) CPH-SOP-7 GI Histopathology (Dissection) CPH-SOP-9 Gynae Histopathology (Dissection) CPH-SOP-5 Haematopathology (Dissection) CPH-SOP-11 Perinatal Pathology (Dissection) CPH-SOP-18 Prostatic Histopathology (Dissection)	ST
		Decalcification Manual method using: CPH-SOP-60 Cut-up and Processing	ST
		Tissue Processing Automated method using: CPH-SOP-26 Processing Room and: Sakura VIP6 & VIP6 AI tissue processors	ST

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN TISSUES AND FLUIDS (cont'd)	Histopathology (cont'd) Preparation and examination to identify or exclude morphological & cytological abnormalities (cont'd)	Macroscopic and Microscopic examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant)	
Formalin fixed tissues		Embedding Manual method using: CPH-SOP-109 Main Laboratory – Embedding and: Sakura Tissue Tek 5 & TEC 6 embedding centres	ST
		<u>Microtomy</u> Manual method using: CPH-SOP-110 Main Laboratory - Microtomy and: Leica RM2235 microtomes Microm HM 325 microtomes	ST
		PCR sectioning Manual method using: CPH-SOP-82 Preparation of Molecular Requests and: Leica RM2235 microtomes Microm HM 325 microtomes	ST
Fresh tissue Frozen tissue	Intra-operative diagnosis	Rapid frozen section Cryotomy and manual Haematoxylin & Eosin (H&E) staining method using:	
		CPH-SOP-29 Frozen Section Room and: Leica CM1950 Cryostat Bright Cryostat	ST
		CPH-SOP-30 Frozen Section Room (GH) and: Thermo Scientific FSE Cryostat	GHN

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	Type of test/Properties		Location	

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN TISSUES AND FLUIDS (cont'd)	Histopathology (cont'd) Preparation and examination to identify or exclude morphological & cytological abnormalities (cont'd)	Macroscopic and Microscopic examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant)	
Formalin fixed, paraffin embedded (FFPE) tissue	Basophilic and eosinophilic tissue structures	Routine Haematoxylin & Eosin (H&E) staining and coverslipping Automated method using: CPH-SOP-111 Main Laboratory – Staining, Correlation & Verification and: Leica XL ST5010 stainer Leica CV5030 coverslipper	ST
FFPE tissue	Detection of the following:	<u>Special staining</u> Manual methods using: CPH-SOP-23 Special Stains Manual and the following stains:	ST
	Acid and sulphated mucins	Alcian Blue	
	Foetal cells in amniotic fluid	Attwood's	
	Elastic fibres & collagen	Miller's Elastic Van Gieson (EVG)	
	Differentiating between haemopoetic cells	Giemsa	
	Gram positive and gram negative organisms	Gram's	
	Amyloid	Highman's Congo Red	
	Collagen and fibrosis	Haematoxylin Van Gieson (HVG)	

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HUMAN TISSUES AND FLUIDS (cont'd)	Histopathology (cont'd) Preparation and examination to identify or exclude morphological & cytological abnormalities (cont'd)	Macroscopic and Microscopic examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant)	
	Detection of the following: (cont'd)	<u>Special staining</u> (manual, cont'd)	ST
FFPE & Cytological fluids	Fungi	Grocott Gomori Methanamine Silver	
	Myelin sheath	Luxol Fast Blue	
	Connective tissue and fibrin	Lendrum's Martius, Scarlet, Blue (MSB)	
	5HT in melanin and lipofuscins	Masson Fontana	
	Collagen and smooth muscle	Masson Trichrome	
	Helicobacter pylori	Modified Giemsa	
	Hepatitis B surface antigen	Shikata's Orcein	
	Basement membranes	PAMS: Jones Methenamine Silver	
	Liberated aldehydes	Periodic Acid Schiff's (+/- diastase)	
	Haemosiderin	Perls' Prussian Blue	
	Weakly acidic mucins	Southgate's Mucicarmine	
	Mast cell granules	Toluidine Blue Metachromatic	
	Calcium salts	Von Kossa	
	Acid fast bacilli, e.g. <i>M. leprae</i>	Wade-Fite	
FFPE and cytological fluids	Acid fast bacilli, e.g. <i>M. tuberculosis</i>	Ziehl-Neelsen	

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HUMAN TISSUES AND FLUIDS (cont'd)	Histopathology (cont'd) Preparation and examination to identify or exclude morphological & cytological abnormalities (cont'd)	Macroscopic and Microscopic examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant)	
FFPE tissue	Detection of the following:	Special staining Automated methods using: CPH-SOP-95 Dako Artisan Link Pro and: Dako Artisan Link Pro with the following stains:	ST
	Fungi	Grocott Methenamine Silver	
	Haemosiderin	Perls' Prussian Blue	
	Reticulin fibres	Reticulin method	
	Reticulin fibres	Untoned Reticulin Method	
	Spirochetes	Warthin-Starry	
Fresh frozen tissue	Detection of the following:	<u>Special staining</u> Manual methods using: CPH-SOP-23 and the following stains:	ST
	ACE expression in nerves	Acetyl cholinesterase	
	Hydrophobic (neutral) lipids	Oil Red O	

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HUMAN TISSUES AND FLUIDS (cont'd)	-	Macroscopic and Microscopic examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant) Flexible Scope protocols: CPHN-SOP-1 Management of UKAS Flexible Scope: Immunohistochemistry and in-situ hybridisation testing using: <u>Ventana Benchmark Ultra</u> <u>Immunostainer with:</u>	ST
		 Antigen Retrieval Methods Ultra Cell Conditioning Solution 1 (CC1) Ultra Cell Conditioning Solution 2 (CC2) Protease 1 Detection Kits UltraView DAB Optiview DAB Ultraview Amplification Kit Optiview DAB Amplification Kit 	
		 Use of the Leica Bond III Immunostainer with: Antigen retrieval methods Bond Epitope Retrieval 1 (ER1) Bond Epitope Retrieval 2 (ER2) Bond Enzyme Pretreatment Detection Kits Bond Polymer Refine Chromoplex 1 Dual Detection 	ST

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HUMAN TISSUES AND FLUIDS (cont'd)	Histopathology (cont'd) Preparation and examination to identify or exclude morphological & cytological abnormalities (cont'd)	Macroscopic and Microscopic examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant)	
FFPE tissue (cont'd)	Target antigens in tissue sections (cont'd)	 Flexible Scope protocols: CPHN-SOP-1 Management of UKAS Flexible Scope: Immunohistochemistry and in-situ hybridisation testing using: <u>Ventana Benchmark Ultra</u> Immunostainer with: Antigen Retrieval Methods Ultra Cell Conditioning Solution 1 (CC1) Ultra Cell Conditioning Solution 2 (CC2) Protease 1 Protease 3 Detection Kits UltraView DAB Optiview DAB Ultraview Amplification Kit Optiview DAB Amplification Kit iView Blue Kit iView Blue Kit iView Blue Plus Kit Flexible scope limited to the application of these methods for the detection of target antigens in tissue sections CPH-INST-395 (Site ST) and HN-INST-138 (Site GHN) record of changes within flexible scope	GHN

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HUMAN TISSUES AND FLUIDS (cont'd)	Histopathology (cont'd) Preparation and examination to identify or exclude morphological & cytological abnormalities (cont'd)	Macroscopic and Microscopic examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant)	
FFPE renal biopsies	Detection of the following:	Immunohistochemistry Manual methods using: CPH-SOP-24 Renal IHC Staining Manual and the following antibodies:	ST
	Fibrin in tissue sections	Fibrinogen	
	Plasma cells and related lymphoid cells containing Kappa light chains	Kappa light chains	
	Plasma cells and related lymphoid cells containing Lambda light chains	Lambda light chains	
	Plasma cells and related lymphoid cells containing IgG	IgG	
	Plasma cells and related lymphoid cells containing IgA	IgA	
	Plasma cells and related lymphoid cells containing IgM	IgM	
	Complement 3	C3	
	Complement 1q	C1q	

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HUMAN TISSUES AND FLUIDS (cont'd)	<u>Histopathology</u> (cont'd) Preparation and examination to identify or exclude morphological & cytological abnormalities (cont'd)	Macroscopic and Microscopic examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant)	
Slides prepared in-house from sample types listed above	Morphological assessment and interpretation/diagnosis	Microscopy (qualitative analysis) In-house procedures: CPH-SOP-64 Consultant Reporting using: Olympus BX40 Olympus BX50 Olympus BX51 Nikon 80i Nikon 50i Leica DM2500	ST
		CPH-SOP-64 Consultant Reporting using: Nikon E400 Olympus BH2	GHN
Fresh renal biopsies	Identification of Glomeruli	<u>Microscopy (qualitative analysis)</u> In-house procedure: CPH-SOP-13 Renal Histopathology and: Vickers Dissecting Microscope	ST STRB GRB
Tissue samples from head and neck	Preparation and examination to identify or exclude morphological & cytological abnormalities (cont'd)	Macroanalysis and dissection Manual method using: HN-SOP-45 HN-SOP-20 HN-SOP-84	GHN
		Decalcification Manual method using: HN-SOP-46	GHN
		<u>Tissue processing</u> Automated method using: HN-SOP-47 and: Sakura Tissue Tek VIP6	GHN

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HUMAN TISSUES AND FLUIDS (cont'd)	Histopathology (cont'd) Preparation and examination to identify or exclude morphological & cytological abnormalities (cont'd)	Macroscopic and Microscopic examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant)	
Tissue samples from head and neck	Preparation and examination to identify or exclude morphological & cytological abnormalities (cont'd)	Embedding Manual method using: HN-SOP-48 and: Leica EG1150 Embedding Centre	GHN
		Microtomy Manual method using: HN-SOP-48 and: Reichert Jung 2030 & Leica RM2235 rotary microtomes	GHN
FFPE tissue	Basophilic and eosinophilic tissue structures	Routine Haematoxylin & Eosin (H&E) staining Automated method using: HN-SOP-80 and: Leica Autostainer XL	GHN
FFPE tissue	Carbohydrates	Special staining Partially automated method using: HN-SOP-49 and: PAS +/-diastase stain with counterstaining using: Leica Autostainer XL	GHN

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HUMAN TISSUES AND FLUIDS (cont'd)	Histopathology (cont'd) Preparation and examination to identify or exclude morphological & cytological abnormalities (cont'd)	Macroscopic and Microscopic examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant)	
FFPE tissue	Detection of the following:	<u>Special staining</u> Manual methods using: HN-SOP-49 and the following stains:	GHN
	Acid mucins (sulphomucins & sialomucins); neutral mucins; mixed mucins	Alcian Blue/PAS +/-diatase	
	Acid mucins (sulphomucins & sialomucins); neutral mucins; mixed mucins	Long ABPAS	
	Amyloid	Highman's Congo Red	
	Gram positive/negative bacteria	Gram's stain	
	Fungi	Grocott	
	All tissue structures	Haematoxylin & Eosin (manual)	
	Connective tissue; muscle	Heamatoxylin Van Gieson	
	Fibrin	Martius, Scarlet & Blue (MSB)	
	Melanin	Masson Fontana	
	Melanin	Melanin Bleach	
	Elastic fibres	Miller's Elastic Van Gieson	
	Haemosiderin	Perls' Prussian Blue	
	Mycobacterium tuberculosis	Ziehl Neelsen	

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<u>Histopathology</u> (cont'd) Preparation and examination to identify or exclude morphological & cytological abnormalities (cont'd)	Macroscopic and Microscopic examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant)	
Frozen section examination to identify or exclude morphological & cytological abnormalities	<u>Cryotomy</u> using: HN-SOP-18 and: Leica CM1850 Cryostat	GHN
Basophilic and eosinophilic tissue structures	Routine H&E staining Manual method using: HN-SOP-48 Automated method using: HN-SOP-18 HN-EXT-84 and Thermo Shandon Linistat	GHN
Morphological assessment and interpretation/diagnosis	Microscopy (qualitative analysis) using: HN-SOP-26 and microscopes : Olympus BX50 Olympus BX51 Olympus BX53 Olympus BH2 Nikon Eclipse E400	GHN
	measured/Range of measurementHistopathology (cont'd)Preparation and examination to identify or exclude morphological & cytological abnormalities (cont'd)Frozen section examination to identify or exclude morphological & cytological abnormalitiesBasophilic and eosinophilic tissue structuresMorphological assessment	Measured/Range of measurementStandard specifications/ Equipment/Techniques usedHistopathology (cont'd)Macroscopic and Microscopic examination using in-house procedures (listed) in conjunction with manufacturer's instructions for the following methods (where relevant)Frozen section examination to identify or exclude morphological & cytological abnormalitiesCryotomy using: HN-SOP-18 and: Leica CM1850 CryostatBasophilic and eosinophilic tissue structuresRoutine H&E staining Manual method using: HN-SOP-48Morphological assessment and interpretation/diagnosisMicroscopy (qualitative analysis) using: HN-SOP-26 and microscopes : Olympus BX50 Olympus BX50 Olympus BH2

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Tissue samples from oral mucosa	Ploidy examination to identify or exclude chromosomal instability indicative of malignant transformation for the purpose of diagnosis	Preparation of monolayers Manual methods using: HN-SOP-59 and: Aquatron Shaking Water Bath, Dade Microfuge Immunofuge II, and Thermo Shandon Cytospin IV	GHN
	Chromosomal material	<u>Feulgen staining</u> Manual method using: HN-SOP-59	GHN
Slides prepared in house from samples listed above	Assessment and interpretation/diagnosis	Scanning monolayers, qualitative and histogram analysis using: HN-SOP-59 and: Zeiss Axioplan microscope DNA Image Ploidy System Prior Scientific robotic stage & controller Zeiss Axiocam Rev3 computer	GHN

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HUMAN BODY FLUIDS	Andrological examination activities for the purposes of clinical diagnosis		
Semen	Post vasectomy: Detection of sperm	Based on 2016 Laboratory guidelines for post vasectomy semen analysis: Association of Biomedical Andrologists, the British Andrology Society and the British Association of Urological Surgeons) Manual method using large volume chambers/ manual microscopy and documented in-house procedure CPC-SOP-128	ST
Semen	Fertility testing:	Based on WHO laboratory manual for the examination and processing of human semen (Sixth edition 2021) and manual method and documented in-house procedure CPC-SOP-128	ST
	Volume	Volume/weight	
	рН	Colorimetric strips	
	Sperm morphology excluding TZI scoring	Stained slides (Papanicolau) microscopy (Bright field)	
	Sperm concentration	Improved Neubauer counting chambers and Microscopy (Phase contrast)	
	Sperm motility	Microscopy (Phase contrast)	
	Sperm vitality	Stained slide (Eosin/Nigrosin dye exclusion test) microscopy (Bright field)	
	Sperm concentration Sperm motility	Automated using Sperminator CASA system	
END			