


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 UKAS MEDICAL 9344 Accredited to ISO 15189:2012	Unilabs Ltd	
	Issue No: 005 Issue Date: 20 August 2021	
	24-32 Stephenson Way London NW1 2HD	Contact: Ms Jayne Holloway Tel: +44 (0)207 299 4490 Fax: +44 (0)207 299 4491 E-Mail: jayne.holloway@unilabs.com Website: http://www.unilabs.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	Location code	
Address 24-32 Stephenson Way London NW1 2HD	Local contact Andrew Coutts andrew.coutts@unilabs.com	Histopathology: Special Stains Interpretive microscopy Diagnostic Cytology (Non-Gynae): Interpretive microscopy Cytology (Gynae) Interpretive microscopy HPV Testing Storage of Records Covid 19 RNA testing Covid 19 Sampling Clinic (PCR swabs)	STEP
Address 100a New Cavendish Street London W1W 6NR	Local contact Andrew Coutts andrew.coutts@unilabs.com	Covid 19 Antibody testing- Serum	CAVE
Address BMI Ross Hall Hospital 221 Crookston Road Glasgow G52 3NQ	Local contact Gary Doig +44 (0)141 810 3151 ext 391	Histopathology Special Stains	ROSS



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Site activities performed away from the locations listed above:

Location details	Activity	Location code
<p>Address Harley Street Breast Clinic 3rd Floor 148 Harley Street London W1G 7LG</p> <p>Local contact Andrew Coufts andrew.coufts@unilabs.com</p>	Sample preparation, slide production, staining & mounting of fine needle aspirates with ROSE (Rapid On-Site Evaluation) by light microscopy of preparation for adequacy, for diagnostic cytology	FNA-HAR
<p>Address 31 Old Broad Street London EC2N 1HT</p> <p>Local contact Andrew Coufts andrew.coufts@unilabs.com</p>	Sample preparation, slide production, staining & mounting of fine needle aspirates with ROSE (Rapid On-Site Evaluation) by light microscopy of preparation for adequacy, for diagnostic cytology	FNA-OLD
<p>Address The Cadogan Clinic 120 Sloane Street London SW1X 9BW</p> <p>Local contact Andrew Coufts andrew.coufts@unilabs.com</p>	Frozen section (Mohs)	FS-CAD
<p>Address The London Clinic of Dermatology 152 Harley Street London W1G 7LH</p> <p>Local contact Andrew Coufts andrew.coufts@unilabs.com</p>	Frozen Section (Mohs)	FS-LCL
<p>Address The Parkside Hospital 53 Parkside Wimbledon London SW19 5NX</p> <p>Local contact Andrew Coufts andrew.coufts@unilabs.com</p>	Frozen section	FS-PRK
<p>Address BMI Alexandra Hospital Mill Lane Cheadle Stockport SK8 2PX</p> <p>Local contact Andrew Coufts andrew.coufts@unilabs.com</p>	Specimen reception	ALEX



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Address Clients Premises	Local contact Andrew Coutts andrew.coutts@unilabs.com	Covid 19 PCR sampling	CUST
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DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
<p>HUMAN BODY TISSUE</p> <p>Fixed, fresh and frozen tissue; excisional and incisional biopsies and surgical resection specimens</p> <p>Formalin fixed tissue Tissue samples (including breast; gastrointestinal; skin; urological; bronchial/lung/thoracic; endocrine including thyroid, parathyroid, adrenal; lymphoreticular including lymph nodes, spleen, and bone marrow trephine biopsies, liver; bone and soft tissues; gynaecological; head and neck.</p>	<p><u>Histopathological examination activities for the purposes of clinical diagnosis</u></p> <p><u>Routine Histopathology</u></p> <p>Examination of tissues to identify or exclude morphological and cytological abnormalities for the purposes of diagnosis</p>	<p>In house documented procedures (listed) in conjunction with manufacturer's instructions for equipment as specified:</p> <p><u>Specimen dissection</u> Manual method using:</p> <p>Thermo printmate Dragon Dictation system/LIS Balances –Ohaus & Denver XP3000 Labcaire Downflow workstation AFOS workstation Thermo Grosslab Senior cut up bench SOP H49, H55, H56, D007</p> <p>Balance-CoulourMatch AEG cut up bench SOP RH03, RH04, RH05</p>	<p>STEP</p> <p>ROSS</p>



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HUMAN BODY TISSUE (cont'd)	<u>Histopathological examination activities for the purposes of clinical diagnosis (cont'd)</u>	In house documented procedures (listed) in conjunction with manufacturer's instructions for equipment as specified	
Formalin fixed tissues samples (as above)		<u>Tissue Processing</u> Thermo Excelsior processor Thermo Excelsior As processor SOP H23 Tissue processing Thermo Excelsior As processor SOP RH08	STEP ROSS
Processed tissue samples (as above)		<u>Tissue embedding</u> Thermo Histostar embedding centres SOP 51 Tissue Tek embedding centre SOP RH07	STEP ROSS
Paraffin waxed tissue samples (as above)		<u>Tissue sectioning (microtomy)</u> Cutting of 3u sections using: Thermo Finesse microtomes Thermo HM325 rotary microtome Leitz base sledge Thermo HM255S automatic microtome SOP 51 Thermo Finesse microtomes SOP RH07	STEP ROSS
Fresh Tissue		<u>Cryotomy</u> Leica Cryostat CM1510 & Leica Portable Cryostat CM1100 SOPH 53 Leica CM1850 cryostat SOP RH14 Leica Cryostat CM1510S SOP H53	STEP ROSS FS-CAD FS-LCL FS-PRK



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HUMAN BODY TISSUE (cont'd)	<u>Histopathological examination activities for the purposes of clinical diagnosis (cont'd)</u>	In house documented procedures (listed) in conjunction with manufacturer's instructions for equipment as specified	
Frozen Section Tissue on glass slides	H&E staining for tissue architecture and nuclear detail/ Identification of basophilic and eosinophilic structures	<u>H&E staining</u> <u>Manual method</u> SOP H53	STEP FS-CAD FS-LCL FS-PRK
Formalin Fixed Paraffin Embedded Tissue (FFPE) sections on glass slides		SOP RH14	ROSS
Formalin Fixed Paraffin Embedded Tissue (FFPE) sections on glass slides		<u>Automated staining</u> Leica Auto Stainer and CV5030 coverslipper Thermo Hyperclean TRUAIR Hood SOP H51 SOP RH07	STEP ROSS STEP ROSS
Formalin Fixed Paraffin Embedded Tissue (FFPE) sections on glass slides	<u>Special staining</u> Examination of tissues to identify or exclude morphological and cytological abnormalities for the purposes of diagnosis (cont'd)	Documented in-house procedures for manual tinctorial hand staining	
	Acid Mucopolysaccharides	SOP H52 SOP RH11 Using stains: Alcian blue	STEP ROSS
	Acid and Neutral Mucopolysaccharides	Alcian Blue/Periodic Acid Schiff	STEP ROSS
	Amyloid	Congo Red	STEP
	H.Pylori	Cresyl fast Violet	ROSS
	Elastic tissue fibres-black	EVG - Miller's Elastic Tissue Stain	STEP
	Muscle-yellow		ROSS
	Collagen-red		



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HUMAN BODY TISSUE (cont'd)	<u>Histopathological examination activities for the purposes of clinical diagnosis (cont'd)</u>	In house documented procedures (listed) in conjunction with manufacturer's instructions for equipment as specified	
Formalin Fixed Paraffin Embedded Tissue (FFPE) sections on glass slides	<u>Special staining Cont'd)</u>	Documented in-house procedures for manual tinctorial hand staining (cont'd)	
	Gram +/- organisms	Grams stain	STEP ROSS STEP
	Fungi and Pneumocystis carinii	Grocott- Hexamine Silver	STEP ROSS STEP
	Connective tissue	Haematoxylin Van Gieson	STEP ROSS STEP ROSS STEP ROSS STEP ROSS
	Melanin pigment	Masson Fontana	
	Connective tissue	Masson Trichrome	
	Fibrin	MSB	
	Hepatitis B surface antigen	Shikata Orcein	
	PAS +ve substances e.g. fungi, glycogen (and cells of pituitary)	Periodic Acid Schiff with and without diastase	
	Haemosiderin and ferric iron	Perls Prussian Blue	STEP ROSS STEP ROSS STEP ROSS STEP ROSS
	Reticulin	Reticulin method – Gordon & Sweets	
	Metachromatic substances	Toluidine Blue	
	Calcium	Von Kossa	
	Copper	Rhodanine	
	Tubercle bacilli (TB)	Ziehl-Neelsen	
	Leprosy	Wade Fite	
Formalin Fixed Paraffin Embedded Tissue (FFPE) sections on glass slides	Morphological assessment and interpretation/diagnosis	Microscopy (qualitative analysis) In-house procedures using light microscopy Olympus BX45 microscope SOP H31 Nikon Microscope SOP RH18	STEP ROSS



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<p>HUMAN BODY TISSUE (cont'd)</p> <p>Unfixed body fluids cell brushings, cell washings, Ascitic, pleural, pericardial, and peritoneal Cell Blocks CSF Urine Cyst fluids FNA; - Lymph Node Salivary Gland Submandibular Parotid Liver Kidney Thorax Abdomen Pancreatic brushings Synovial Fluids Bronchial specimens, including bronchial brushings, bronchial washings, sputum, transbronchial FNA</p> <p>Unstained slides prepared from above</p>	<p><u>Cytopathological examination activities for the purposes of clinical diagnosis</u></p> <p><u>Non-Gynaecological Cytology</u></p> <p>Examination of cellular material in order to identify or exclude morphological and cytological abnormalities</p>	<p>In house documented procedures (listed) in conjunction with manufacturer's instructions for equipment as specified</p> <p>Diagnostic cytology (non-gynae) in-house documented manual procedures for preparation using: Thermo Cytospin Hologic ThinPrep 2000 processor SOP CC1 SOP CC2 SOP CC4 SOP CC6 SOP CC8 SOP CC11 SOP CP13</p> <p><u>Romanowsky staining</u> Manual method SOP CC5</p> <p><u>Papanicolaou staining</u> Automated staining using Sakura Tissue Tek Prisma Automated Stainer and ST5030 coverslipper SOP CP12</p>	<p>STEP</p> <p>STEP</p>



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HUMAN BODY TISSUE (cont'd)	<u>Cytopathological examination activities for the purposes of clinical diagnosis (cont'd)</u>	In house documented procedures (listed) in conjunction with manufacturer's instructions for equipment as specified	
Fine needle aspirates (FNA)	Rapid on-site evaluation (ROSE) of cellular material in order to identify or exclude morphological and cytological abnormalities	Documented in-house procedures for FNA slide preparation, production and evaluation. Rapid stain (Rapi Diff) by manual method SOP CC5 SOP CC12 SOP CC20	FNA-HAR FNA-OLD
Formalin Fixed Paraffin Embedded Tissue (FFPE) sections on glass slides	Morphological assessment and interpretation/diagnosis	Microscopy (qualitative analysis) In-house procedures using light microscopy Olympus BX45 microscope SOP H31	STEP
Joint fluids (synovial fluids)	Assessment of birefringent crystals of monosodium urate and calcium pyrophosphate crystals	Microscopic examination: Olympus BX45 microscope with polarising filter SOP CC1	STEP
Liquid based cytology samples	<u>Gynaecological Cytology</u> Examination of tissues to identify or exclude morphological and cytological abnormalities for the purposes of diagnosis		
Liquid based cytology samples containing cervical/vaginal cells		<u>Preparation of slides for staining</u> Documented in-house procedures in conjunction with manufacturer's instructions using: Hologic Thinprep 5000 benchtop processor Hologic Thinprep 2000 processor SOP CS1 SOP CS2 SOP CP1	STEP



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HUMAN BODY TISSUE (cont'd) Unstained slides prepared from above	<u>Cytopathological examination activities for the purposes of clinical diagnosis (cont'd)</u>	In house documented procedures (listed) in conjunction with manufacturer's instructions for equipment as specified <u>Papanicolaou staining</u> Automated staining using Sakura Prisma Automated Stainer and ST5030 coverslipper SOP CP 12	
Formalin Fixed Paraffin Embedded Tissue (FFPE) sections on glass slides	Morphological assessment and interpretation/ diagnosis	Microscopy (qualitative analysis) In-house procedures using light microscopy Olympus microscopes BX45 Olympus microscopes BX51 SOP H31	STEP
Liquid based cytology samples containing cervical/ vaginal cells	<u>High-Risk Human Papilloma Virus (HR-HPV) testing</u> Detection of high-risk HPV genotypes 16 and 18 and 12 others pooled together	Detection of ribosomal RNA from: HPV by Nucleic acid amplification technique (NAAT) using Roche COBAS 480 plus analyser SOP CP14 HPV	STEP
Serum	<u>Serological examination activities for the purposes of clinical diagnosis</u> Covid 19 Antibody IgM	In house documented procedures (listed) in conjunction with manufacturer's instructions for equipment as specified Siemens Atellica using the Atellica IM COV2T assay, sandwich immunoassay- chemiluminescence BIO 001 and BIO 002	CAVE
Nasopharyngeal swabs	<u>Molecular detection for the purposes of clinical diagnosis</u> Covid 19 RNA – N1 and E gene detection	In house documented procedures (listed) in conjunction with manufacturer's instructions for equipment as specified MGSIP 960 extraction and LineGene 9600 analyser RT PCR using the Nonoacus PCR assay	STEP



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HUMAN BODY FLUIDS. Combined Nasopharyngeal & Oropharyngeal (Nose & Throat) in VTM	<u>Sampling with subsequent testing at STEP location code above</u> Sampling For: -General Population including Fit to Fly - Detection of SARS-CoV-2 (COVID-19) virus RNA using molecular methods -Test to Release 5 Day Detection of SARS-CoV-2 (COVID-19) virus RNA using molecular methods	In house documented procedures (listed) in conjunction with manufacturer's instructions for equipment as specified In house method based on PHE Guidance for COVID-19 Sampling for testing purposes	STEP CUST
END			