


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 9344 Accredited to ISO 15189:2012	Unilabs Ltd	
	Issue No: 007 Issue Date: 10 March 2023	
	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 IHC Diagnostic Cytology (Non-Gynae): Interpretive microscopy Digital Pathology Cytology (Gynae) Interpretive microscopy HPV Testing Storage of Records	STEP
Address 100a New Cavendish Street London W1W 6NR	Local contact Andrew Coutts andrew.coutts@unilabs.com	Biochemistry Haematology Coagulation	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
Address Harley Street Breast Clinic 3 rd Floor 148 Harley Street London W1G 7LG	Local contact Andrew Coutts andrew.coutts@unilabs.com	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
Address 31 Old Broad Street London EC2N 1HT	Local contact Andrew Coutts andrew.coutts@unilabs.com	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
Address The Cadogan Clinic 120 Sloane Street London SW1X 9BW	Local contact Andrew Coutts andrew.coutts@unilabs.com	Frozen section (Mohs)	FS-CAD
Address The London Clinic of Dermatology 152 Harley Street London W1G 7LH	Local contact Andrew Coutts andrew.coutts@unilabs.com	Frozen Section (Mohs)	FS-LCL
Address The Parkside Hospital 53 Parkside Wimbledon London SW19 5NX	Local contact Andrew Coutts andrew.coutts@unilabs.com	Frozen section	FS-PRK
Address BMI Alexandra Hospital Mill Lane Cheadle Stockport SK8 2PX	Local contact Andrew Coutts andrew.coutts@unilabs.com	Specimen reception	ALEX



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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 <u>Automated staining</u> Leica Auto Stainer and CV5030 coverslipper Thermo Hyperclean TRUAIR Hood SOP H51 SOP RH07	ROSS 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
	Fungi and Pneumocystis carinii	Grocott- Hexamine Silver	STEP
	Connective tissue	Haematoxylin Van Gieson	STEP ROSS
	Melanin pigment	Masson Fontana	STEP
	Connective tissue	Masson Trichrome	STEP ROSS
	Fibrin	MSB	STEP
	Hepatitis B surface antigen	Shikata Orcein	STEP ROSS
	PAS +ve substances e.g. fungi, glycogen (and cells of pituitary)	Periodic Acid Schiff with and without diastase	STEP ROSS
	Haemosiderin and ferric iron	Perls Prussian Blue	STEP ROSS
	Reticulin	Reticulin method – Gordon & Sweets	STEP ROSS
	Metachromatic substances	Toluidine Blue	STEP ROSS
	Calcium	Von Kossa	STEP
	Tubercle bacilli (TB)	Ziehl-Neelsen	STEP ROSS
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
FFPE slides	Scanning and subsequent Morphological assessment and interpretation/diagnosis	Using Digital Pathology- Scanner Philips Intellisite Ultra Fast Scanners SOP H58	STEP



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<p>HUMAN BODY TISSUE (cont'd)</p> <p>Formalin Fixed Paraffin Embedded (FFPE) human tissue and cell block sections on adhesive glass slides</p>	<p><u>Histological examinations for the purpose of clinical diagnosis</u></p> <p>Examination of tissues to identify or exclude morphological and cytological abnormalities for the purpose of clinical diagnosis</p> <p>Basal cells and Alpha methyacyl CoA racemase</p> <p>B cells of the mantle zone and interfollicular T cells</p> <p>B-lymphocytes, mostly located in germinal centers</p> <p>Epithelial Cells</p> <p>Smooth muscle tissue and myoepithelium</p> <p>Smooth muscle</p> <p>Neural tissues, normal and reactive mesothelium, eccrine glands of skin, Sertoli cells of the testis, ovarian stromal cells and adrenal cortical cells</p> <p>Early lymphoid cells, and various nonlymphoid tissues including breast myoepithelial cells, endometrium, bile canaliculi, fibroblasts, kidney tubular brush borders and small intestine epithelium</p>	<p>Documented in-house procedures SOP's IC01 and IC02 in conjunction with manufacturer's instructions for antibodies and using Ventana Benchmark Ultra :</p> <p>Basal Cell (p63+34be12) + Racemase</p> <p>BCL-2</p> <p>BCL-6</p> <p>BEREP4 (Ep-Cam)</p> <p>Calponin-1</p> <p>Caldesmon</p> <p>Calretinin</p> <p>CD10</p>	<p>STEP</p>



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	Hematopoietic stem cells, melanocytes, mast cells, Cajal cells, germ cells, basal cells of skin, and mammary ductal epithelia	CD117	
	Plasma cells	CD138	
	Reed-Sternberg cells, granulocytes and granulocyte precursors, monocytes, a subset of tissue macrophages, and activated T-lymphocytes	CD15	
	B-cells	CD20	
	Follicular dendritic cell meshwork	CD21	
	Follicular dendritic cell meshwork	CD23	
	T-cells	CD3	
	Reed-Sternberg cells, anaplastic large cell lymphomas.	CD30	
	Endothelial cells	CD31	
	Endothelial cells	CD34	
	T-helper cells	CD4	
	Lymphocytes	CD45	
	T-cells	CD5	
	Natural killer cells, neuroendocrine glands, neural tissue	CD56	
	Macrophages and some myeloid elements	CD68	
	B-cells	CD79a	



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	T-cytotoxic cells	CD8	
	Gastrointestinal epithelium	CDX2	
	Adenocarcinomas from the lung, colon, stomach, esophagus, pancreas, gallbadder, urachus, salivary gland, ovary, and endocervix	CEA (monoclonal)	
	Endocrine cells, tumors of neuroendocrine origin	Chromogranin A	
	Epithelial Cells	CK AE1/AE3	
	Epithelial Cells	CK CAM 5.2	
	Epithelial Cells	CK MNF116	
	Epithelial Cells	CK14	
	Epithelial Cells	CK19	
	Epithelial Cells	CK20	
	Epithelial Cells	CK5/6	
	Epithelial Cells	CK7	
	Cytomegalovirus	Cytomegalovirus	
	Proliferating cells, mantle cell lymphoma	Cyclin D1	
	Myocytic cells, muscle cells	Desmin	
	Cajal cells, gastrointestinal stromal tumour	DOG-1	
	Epithelial tissue	E-CAD	
	Glandular epithelia	EMA	
	Estrogen Receptor	ER	
	Endothelial cells	ERG	



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	Breast carcinoma and urothelial carcinoma	GATA-3	
	Helicobacter Pylori	Helicobacter Pylori	
	c-erbB-2 oncoprotein	HER-2	
	Human herpesvirus 8 (Kaposi sarcoma-associated herpes virus)	HHV8 (KSHV)	
	Melanocytes, melanoma	HMB45	
	Clonal restriction of B cell and plasma cell populations	Kappa	
	Proliferating cells	Ki-67 (MIB-1)	
	Clonal restriction of B cell and plasma cell populations	Lambda	
	Melanocytes, melanoma	Melan-A	
	Mismatch repair protein deficiency	MLH1	
	Mismatch repair protein deficiency	MSH2	
	Mismatch repair protein deficiency	MSH6	
	B-cell lymphomas	MUM-1	
	Gonadal and extra-gonadal seminomas, dysgerminomas and embryonal carcinomas	OCT-4	
	Surrogate marker for HPV	p16	
	Basal cells	p40	
	Malignant cells of the colon, bladder, ovary, breast and mesothelium.	p53	
	Basal cells	p63	



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	B-cells	PAX-5	
	Ovarian serous carcinoma, clear cell renal cell carcinoma, and papillary thyroid carcinoma	PAX-8	
	Mismatch repair protein deficiency	PMS2	
	Lymphatic endothelium	Podoplanin (D2-40)	
	Progesterone Receptor	PR	
	Prostate specific antigen	PSA	
	Glial cells of the central and peripheral nervous system, melanocytes, chondrocytes, and adipocytes	S100	
	Smooth muscle cells, myofibroblasts and myoepithelial cells	SMA	
	Smooth muscle cells, myoepithelial cells	SMMHC (Myosin)	
	Melanocytes, melanoma	SOX-10	
	Endocrine cells, tumors of neuroendocrine origin	Synaptophysin	
	Thyroid and lung tumours	TTF-1	
	Fibroblasts, smooth muscle cells and lymphoid cells	Vimentin	
	Wilms' tumor 1 protein	WT-1	
	Anaplastic lymphomas	ALK-1 (lymphoma)	
	Nuclear accumulation of Beta-Catenin protein protein.	Beta-Catenin	



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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
	T-cells	CD2	
	T-cells	CD7	
	Megakaryocytes	CD61	
	Dermatofibroma	Factor XIIIa	
	Astrocytes, Schwann cells, satellite cells, enteric glial cells	GFAP	
	Plasma cells	IgG4	
	Sex cord stromal tumors and adrenal cortical tumors	Inhibin, alpha	
	neutrophil granulocytes and monocytes	Myeloperoxidase	
	neurons of the central and peripheral nervous system	Neurofilament Protein (NFP)	
	lung adenocarcinoma	Napsin A	
	lymphoblastic lymphomas	TdT	



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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		Preparation of slides for staining Documented in-house procedures in conjunction with manufacturer's instructions using: Hologic Thinprep 5000 benchtop processor SOP CS1 SOP CS2 SOP CP1	STEP



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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	
Unstained slides prepared from above		<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
	<u>Serological examination activities for the purposes of clinical diagnosis</u>	In house documented procedures (listed) in conjunction with manufacturer's instructions for equipment as specified	
	<u>Molecular detection for the purposes of clinical diagnosis</u>	In house documented procedures (listed) in conjunction with manufacturer's instructions for equipment as specified	



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HUMAN BODY TISSUE	<u>Haematological examination activities for the purposes of clinical diagnosis</u>	In house documented procedures (listed) in conjunction with manufacturer's instructions for equipment as specified	CAVE
Blood	<u>Cell Morphology</u>	Manual staining and microscopy using SOP HAE002	CAVE
Blood	<u>ESR</u>	Manual method using Greiner Vacuette and SOP HAE003	CAVE
Blood	<u>FBC</u>	Siemens Advia 560 using Impedance, light scatter and light absorbance measurements SOP HAE001	CAVE
Plasma	<u>CBC</u> <u>Differential WCC</u> <u>HGB</u> <u>PT</u> <u>INR</u> <u>APTT</u> <u>FIB</u> <u>LUPUS SCREEN</u> <u>50/50 APTT mixing studies</u> <u>DRVV screen</u> <u>DRVV confirmation</u>	Stago STAR Max using oscillation and SOP HAE016	CAVE



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<p>HUMAN BODY TISSUE</p> <p>Serum unless otherwise indicated</p> <p>Plasma</p>	<p><u>Biochemical examination activities for the purposes of clinical diagnosis</u></p> <p><u>Albumin</u> <u>Amylase</u> <u>Total Bilirubin</u> <u>Calcium</u> <u>Adjusted Calcium</u> <u>CK</u> <u>Bicarbonate</u> <u>GGT</u> <u>ALT</u> <u>AST</u> <u>Glucose</u> <u>Direct HDL</u> <u>TIBC</u> <u>Iron</u> <u>LDH</u> <u>Magnesium</u> <u>Inorganic Phosphorus</u> <u>Transferrin</u> <u>Urea</u> <u>IgA</u> <u>IgG</u> <u>IgM</u> <u>Total Cholesterol</u> <u>Creatinine (enzymatic)</u> <u>Total Protein</u> <u>Triglyceride</u> <u>Calculated LDL</u> <u>Uric Acid/ Urate</u> <u>HS CRP</u></p>	<p>In house documented procedures (listed) in conjunction with manufacturer's instructions for equipment as specified</p> <p>Siemens Atellica using Photometry SOPBIO001</p>	CAVE



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Serum	<u>Ferritin</u> <u>Folate</u> <u>FT4</u> <u>TSH</u> <u>Troponin I HS</u> <u>Vitamin B12</u> <u>Vitamin D</u> <u>NT Pro BNP</u> <u>FT3</u> <u>FSH</u> <u>LH</u> <u>Progesterone</u> <u>Testosterone</u> <u>Oestradiol</u> <u>Prolactin</u> <u>HCG</u> <u>E2</u> <u>PSA</u> <u>SHBG</u> <u>aTPO</u> <u>CA125</u> <u>CA19-9</u> <u>CEA</u>	Siemens Atellica using chemiluminescent immunoassay SOPBIO001	CAVE
Serum	<u>Sodium</u> <u>Potassium</u> <u>Chloride</u>	Siemens Atellica using Indirect ISE SOPBIO001	CAVE
END			