# **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 Rapid Response Laboratory (UCLH) 60 Whitfield Street London W1T 4EU	Local contact Julie Dilling	Biochemistry Haematology Haemostasis Blood Transfusion	A
Diabetic Clinic Satellite Laboratory First Floor – Podium Diabetic Clinic K University College London Hospital 235 Euston Road London NW1 2BU	Julie Dilling	Biochemistry	В
Intra-operative PTH Satellite Laboratory Operating Theatres University College London Hospital 235 Euston Road London NW1 2BU	Julie Dilling	Biochemistry	С
OSCAR Clinic Satellite Laboratory Foetal and Maternal Assessment Unit Elizabeth Garrett Anderson Unit University College London Hospital 235 Euston Road London NW1 2BU	Julie Dilling	Biochemistry	D
Satellite Laboratory Accident & Emergency Department University College London Hospital 235 Euston Road London NW1 2BU	Julie Dilling	Haematology Virology	E

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Location details		Activity	Location code
Near Patient Testing Laboratory Macmillan Cancer Centre University College London Hospital Huntley Street London WC1E 6AG	Julie Dilling	Haematology	F

### Site activities performed away from the locations listed above:

Location details		Activity
Blood Issue Fridge Accident & Emergency Department University College London Hospital 235 Euston Road London NW1 2BU	Julie Dilling	Blood issue fridge for storage of blood products only; no testing occurs at this site
Blood Issue Fridge Tower Floor, Level 16 University College London Hospital 235 Euston Road London NW1 2BU	Julie Dilling	Blood issue fridge for storage of blood products only; no testing occurs at this site
Blood Issue Fridge Podium Level 3 University College London Hospital 235 Euston Road London NW1 2BU	Julie Dilling	Blood issue fridge for storage of blood products only; no testing occurs at this site
Blood Issue Fridge Operating Theatres University College London Hospital 235 Euston Road London NW1 2BU	Julie Dilling	Blood issue fridge for storage of blood products only; no testing occurs at this site

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Location details		Activity
Blood Issue Fridge Elizabeth Garrett Anderson Unit University College London Hospital 235 Euston Road London NW1 2BU	Julie Dilling	Blood issue fridge for storage of blood products only; no testing occurs at this site
Blood Issue Fridge Macmillan Cancer Centre University College London Hospital Huntley Street London WC1E 6AG	Julie Dilling	Blood issue fridge for storage of blood products only; no testing occurs at this site
Blood Issue Fridge National Hospital for Neurology & Neurosurgery Queen Square London WC1N 3BG	Julie Dilling	Blood issue fridge for storage of blood products only; no testing occurs at this site
Blood Issue Fridge University College London Hospital at Westmoreland Street 16-18 Westmoreland Street London W1G 8PH	Julie Dilling	Blood issue fridge for storage of blood products only; no testing occurs at this site
Blood Issue Fridge University College London Hospital at Grafton Way 1 Grafton Way London WC1E 6AS	Julie Dilling	Blood issue fridge for storage of blood products only; no testing occurs at this site

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS	General Biochemistry		
	Biochemical examination activities for the purposes of clinical diagnosis. Quantitation of:	In house documented procedures based on equipment manuals and standard methods as specified:	
Serum / Plasma (unless otherwise stated)		Ion Sensitive Electrode module using Roche Cobas 8000 system SOP BIO-MP1-8	A
Urine also	Sodium		
Urine also	Potassium		
Urine also	Chloride	Immunoassay using Roche Cobas e602 module	A
	Cortisol	SOP BIO-MP1-8	
	Digoxin		
	Free Triiodothyronine		
	Free Thyroxine 4		
	Total Human Chorionic Gonadotrophin		
	Progesterone		
	Thyroid Stimulating Hormone		
	Troponin T	Photometry using Roche Cobas c702 module	A
Urine also	Albumin	SOP BIO-MP1-8	
Urine also	Amylase		
	Alkaline Phosphatase		
	Alanine Transaminase		

## DETAIL OF ACCREDITATION

	Schedule of Accreditation	
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UKAS MEDICAL	HSL (Analytics) LLP	
10204 Accredited to	Issue No: 016 Issue date: 25 April 2025	
ISO 15189:2022		
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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd)	General Biochemistry (cont'd)		
	Biochemical examination activities for the purposes of clinical diagnosis. (cont'd) Quantitation of:	In house documented procedures based on equipment manuals and standard methods as specified: (cont'd)	
Serum / Plasma (unless otherwise stated) (cont'd)		Photometry using Roche Cobas c702 module SOP BIO-MP1-8 BIO-MP1-7 BIO-MP1-37	A
	Amikacin		
	Ammonia		
	Aspartate Aminotransferase		
	Bicarbonate		
	Bilirubin (conjugated)		
	Bilirubin (total)		
Urine also	Calcium		
	Carbamazepine		
	Cholesterol (total)		
	Cholesterol (HDL)		
	Creatine kinase		
Urine and Serum	Creatinine (Enzymatic)		
	C Reactive Protein (CRP)		
	Ethanol		
	Ferritin	Roche ECLIA Ferritin assay	А
	Gamma Glutamyl Transferase		
	1		1

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS	General Biochemistry (cont'd)		
(cont'd)	Biochemical examination activities for the purposes of clinical diagnosis. (cont'd) Quantitation of:	In house documented procedures based on equipment manuals and standard methods as specified: (cont'd)	
Serum / Plasma (unless otherwise stated) (cont'd)	Gentamicin	Photometry using Roche Cobas c702 module SOP BIO-MP1-8	A
CSF also	Glucose		
	Iron		
CSF also	Lactate		
	Lactate Dehydrogenase		
	Lithium		
Urine also	Magnesium		
	Methotrexate	SOP BIO-60RR-1	
Urine only	Microalbumin		
	Paracetamol		
	Phenobarbitone		
	Phenytoin		
Urine also	Phosphate		
Urine & CSF also	Protein (total)		
	Salicylate		
	Theophylline		
	Triglycerides		
Urine also	Urate		
Urine also	Urea		

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
	<u>General Biochemistry</u> (cont'd)		
(cont'd)	Biochemical examination activities for the purposes of clinical diagnosis. (cont'd) Quantitation of:	In house documented procedures based on equipment manuals and standard methods as specified: (cont'd)	
Serum / Plasma (unless otherwise stated) (cont'd)	Unsaturated Iron Binding Capacity	Photometry using Roche Cobas c702 module SOP Bio-MP1-8	A
	Valproate		
	Vancomycin		
Serum & urine	Osmolality	Freezing point depression using Osmo 1 Osmometer SOP BIO-60RR-2	A
EDTA Blood	HbA1c	Ion-exchange high performance liquid chromatography using TOSOH G8 SOP POCT-60RR-3	В
Plasma	Intra-operative of Parathyroid Hormone	Immunoassay using Future Diagnostics STAT-IO-I-PTH kit SOP POCT-60RR-2	С
		Documented in-house methods to meet the requirements of the Fetal Anomaly Screening Programme (FASP) as defined in the laboratory QA evidence requirements	
Serum	Free Beta-Human chorionic gonadotrophin (hCG)	Immunofluorometric assay using Perkin Elmer Delfia Xpress SOP FASP-POCT-60RR-4 &	D
	Pregnancy Associated Plasma Protein-A (PAPP-A)	FASP-60RR-1	
Urine and Serum	Creatinine Clearance	By calculation in Middleware LIMS	А
Calculation	eGFR	By calculation in Middleware LIMS	А

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd)	Haematology		
	Haematological examination activities for the purposes of clinical diagnosis.	In house documented procedures based on equipment manuals and standard methods as specified:	
EDTA Blood	Full Blood Count:	Measurement principles as described using Sysmex XN10, XN20, SP50 and TS10 modules on XN9000 system HAE-60RR-54 HAE-60RR-50	A
		Measurement principles as described using Sysmex XS-1000 SOP HAE-60RR-51	E
		Measurement principles as described using Sysmex XN-1000 SOP HAE-60RR-54	F
	White blood cells, neutrophils, lymphocytes, eosinophils, monocytes, basophils, nucleated red blood cells, reticulocytes	by fluorescence flow cytometry	
	Red blood cells, platelets	by impedance	
	Haemoglobin	by SLS photometry	
	Haematocrit	by cumulative pulse measurement	
Peripheral Blood	Blood film assessment & cell differential	Staining with May Grunwald & Giemsa stain manually or using RAL Staining Machine followed by microscopy SOP HAE-60RR-24	A
EDTA Blood	Erythrocyte sedimentation rate	Automated using Starrsed Interrliner (automated) HAE-60RR-10	A

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS (cont'd)	Haematology (cont'd)		
	Haematological examination activities for the purposes of clinical diagnosis (cont'd)	In house documented procedures based on equipment manuals and standard methods as specified:	
Plasma	Coagulation: Prothrombin Time International Normalised ratio Activated Partial Thromboplastin Time (APTT) APTT ratio Fibrinogen-Clauss D-Dimer	Light absorption using Sysmex CS5100 SOPs HAE-60RR-24, COAG-RF1- 112, COAG-F1-113, COAG-RF1- 114	A
Whole Blood	Detection of Sickle Cell Abnormal Haemoglobin	Helena Sickle Solubility Screen kit SOP HAE-60RR-13	A
Serum / plasma	Detection of Infectious Mononucleosis Heterophile Antibody	Immunoassay using Biokit Monogen kit SOP HAE-60RR-14	A
	Special Coagulation		
Plasma	Antithrombin III Activity	Chromogenic assay using Sysmex CS2500 SOP COAG-60R-28	A
Plasma	Anti-Xa	Chromogenic assay using Sysmex CS2500 SOP COAG-60RR-2	A
Plasma	Dilute Russell Viper Venom Time (DRVVT)	Clotting assay using Sysmex CS2500 SOP COAG-60RR-18	A
Plasma	Intrinsic and Extrinsic Factor Assays: Detection of: Factor II Factor V Factor VII Factor VIII Factor IX Factor X Factor XI Factor XII	Clotting assay using Sysmex CS2500 SOP COAG-60RR-9	A

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HUMAN BODY FLUIDS	Special Coagulation (cont'd)		
(cont'd)	Haematological examination activities for the purposes of clinical diagnosis (cont'd)	In house documented procedures based on equipment manuals and standard methods as specified	
Plasma	Factor 13	Chromogenic assay using Sysmex CS2500 SOP COAG-60RR-8	A
Plasma / Serum	Heparin / Platelet Factor 4 Induced Antibodies	Manual ELISA using Asserachrom kit (Diagnostica Stago) SOP COAG-60RR-11	
Plasma	Detection of:	Sysmex CS2500 and the following measurement principles: SOP COAG-60RR-28	A
	Protein C Activity Protein S Antigen Protein S Activity	by chromogenic assay by immunoturbidimetric assay by clotting based assay	
Plasma	Taipan Venom Time	Clotting assay using Sysmex CS2500 SOP COAG-60RR-1	A
Plasma	Von Willibrand Factor Antigen and Activity	Immunoturbidimetric assay using Sysmex CS2500 SOP COAG-60RR-10	A
Plasma / Serum	ADAMTS-13 Activity	Immunoassay and FRET method using Flurostar Omega SOP COAG-60RR-3	A
Plasma / Serum	ADAMTS-13 Antibody	Manual ELISA using in-house method SOP COAG-60RR-13	A
Citrated Plasma / Serum	ADAMTS-13 Activity	Ceveron S100 using FRET technology SOP COAG-60RR-33	A
Plasma	Viscosity	Capillary oscillation using Benson Viscometer SOP COAG-60RR-27	A

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HUMAN BODY FLUIDS (cont'd)	Special Coagulation (cont'd)		
	Haematological examination activities for the purposes of clinical diagnosis (cont'd)	In house documented procedures based on equipment manuals and standard methods as specified	
Serum / Plasma	Anti-cardiolipin antibodies Beta-2-glycoprotein antibodies	Chemiluminescent immunoassay using Werfen Bioflash SOP COAG-60RR-16	A
Citrated blood	Collagen/Epinephrine closure time (seconds)	Whole blood shear using Siemens PFA-200 COAG-60RR-25	A
	Collagen/ADP closure time (seconds)		
	Inhibition of P2Y12 receptor for ADP		
Citrated blood	Platelet Aggregation	By light transmission aggregometry using BioData PAP8E SOP COAG-60RR-22	A

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HUMAN BODY FLUIDS (cont'd)	Blood Transfusion		
	General examination activities for the purposes of clinical diagnosis:	In house documented procedures in conjunction with equipment manuals and standard methods as specified below:	
EDTA Blood	Blood group: A Rh D positive A Rh D negative O Rh D positive O Rh D negative B Rh D positive	Automated using Ortho Vision Max Analyser SOP BTF-RFRR-60 SOP BTF-RFRR-38 Manual using Ortho Cassettes	A
	B Rh D negative AB Rh D positive AB Rh D negative	SOP BTF-RFRR-52 SOP BTF-RFRR-38	
EDTA Blood	Red Cell Antigen phenotyping Rh: C, E, c, e, Kell: K Extended red cell phenotyping for Fya, Fyb, Lea, Leb, M,N,S,s, Jka, Jkb, Cw	Automated using Ortho Vision Max Analyser SOP BTF-RFRR-60	A
		Manual using Ortho Cassettes SOP BTF-RFRR-51	A

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HUMAN BODY FLUIDS (cont'd)	Blood Transfusion (cont'd) General examination activities for the purposes of clinical diagnosis:	In house documented procedures in conjunction with equipment manuals and standard methods as				
EDTA Blood	Compatibility testing of patient's plasma with donor cells	specified below: Serological crossmatch using Manual Tube IAT, Immediate Spin and Cassette method and electronic issue of blood. SOP BTF-RFRR-40 & 41	A			
EDTA	Detection of Foetal Haemoglobin and cells	Manual method using Guest Medical Kleihauer test. SOP BTF-RFRR-27	A			
EDTA Blood	Antibody detection and identification: Rh: D, C, E, c, e, C <sup>W</sup> Kell: K, k, kp <sup>a</sup> , kp <sup>b</sup> , Js <sup>a</sup> , Js <sup>b</sup> Duffy: Fy <sup>a</sup> , Fy <sup>b</sup>	Automated using Ortho Vision Max Analyser SOP BTF-RFRR-60 SOP BTF-RFRR-38	A			
	Kidd: Jk <sup>a</sup> , Jk <sup>b</sup> Lewis: Le <sup>a</sup> , Le <sup>b</sup> P: P <sub>1</sub> MNS: M, N, S, s Luth: Lu <sup>a</sup> , Lu <sup>b</sup> Xg: Xg <sup>a</sup>	Manual Antiobody screen and identification using IAT and Enzyme panels and with Ortho cassettes. SOP BTF-RFRR-47 SOP BTF-RFRR-38	A			
EDTA Blood	Direct Antiglobulin test (including newborn)	Automated using Ortho Vision Max Analyser SOP BTF-RFRR-60	A			
		Manual method using Ortho cassettes and tube method. SOP BTF-RFRR-26	A			

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HUMAN BODY FLUIDS (cont'd)	<u>Virology</u> Examination activities for the purpose of clinical diagnosis				
Nasopharyngeal or combined nose / throat swabs in viral transport media	Detection of SARS CoV-2 virus RNA (COVID-19) specific gene sequences: E, N2	Polymerase chain reaction using Cepheid GeneXpert and Xpert Xpress SARS-CoV-2 kit SOP PCR2-MP5-49	Α, Ε		
Nasopharyngeal or combined nose / throat swabs in viral transport media	Detection and differentiation of RNA from SARS-CoV-2, Influenza A, Influenza B and/or respiratory syncytial virus (RSV) testing	Polymerase chain reaction using Cepheid GeneXpert analyser and Xpert Xpress CoV-2/Flu-RSV Plus kits. SOP PCR2-MP5-49	A, E		
Serum / plasma	Qualitative determination of HIV-1 p24 antigen and antibodies to HIV-1, including group O, and HIV-2	ROCHE ECLIA HIV combi PT assay	A		
END					