


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 <p>UKAS MEDICAL 8666</p> <p>Accredited to ISO 15189:2012</p>	<h3>County Durham and Darlington NHS Foundation Trust</h3> <p>Issue No: 010 Issue date: 12 December 2024</p>	
	<p>Blood Sciences Department University Hospital of North Durham Durham County Durham DH1 5TW</p>	<p>Contact: Mrs Rebecca Sedman Tel: +44 (0) 191 333 2116 E-Mail: rebecca.sedman@nhs.net Website: www.cddft.nhs.uk</p>
<p>Testing performed by the Organisation at the locations specified below</p>		

Locations covered by the organisation and their relevant activities

Laboratory locations:

Location details		Activity	Location code
<p>Address Biochemistry Department University Hospital of North Durham North Road Durham County Durham DH1 5TW</p>	<p>Local contact Mrs Hazel Borthwick Joanne Lawson</p>	<p>Clinical Biochemistry</p> <p>Haematology and Blood Transfusion</p> <p>Documented in-house methods to meet the requirements of the Sickle cell and Thalassaemia (SCT) screening programme as defined in the laboratory QA evidence requirements:</p> <ul style="list-style-type: none"> • Review of Family Origin Questionnaire and Full Blood Count screen • Subsequent testing at a laboratory accredited to ISO 15189 for detection of haemoglobin variants via HPLC • Clinical interpretation and reporting 	UHND
<p>Address Biochemistry Department Darlington Memorial Hospital Hollyhurst Road Darlington DL3 6HX</p>	<p>Local contact Dr Laura Bernstone Nicola McKeague</p>	<p>Clinical Biochemistry</p> <p>Immunology</p> <p>Haematology and Blood Transfusion</p>	DMH



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Site activities performed away from the locations listed above:

Location details		Activity
Address Shotley Bridge Hospital Shotley Bridge Consett DH8 0NB	Local Contact Joanne Lawson Tel: +44 (0)191 333 2628 Email: jlawson5@nhs.net	Management of Ward 4 blood fridge
Address Bishop Auckland Hospital Cockton Hill Road DL14 6AD	Local Contact Nicola McKeague Tel: +44 (0)1325 743686 Email nicola.mckeague@nhs.net	Management of laboratory-based blood fridge Specimen reception



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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
HUMAN BODY FLUIDS	<u>Biochemistry examination activities for the purpose of clinical diagnosis</u>	Documented in-house procedures in conjunction with manufacturers instructions for analysis using Siemens Advia 2400 XPT Using supplier methods unless otherwise stated	
Serum	Albumin ALP ALT Ammonia Amylase AST Bile Acids Calcium Carbamazepine Chloride Cholesterol CK Conjugated Bilirubin Creatinine CRP Enzymatic creatinine GGT HDL-cholesterol Iron LDH Lithium Magnesium Paracetamol Phenytoin Phosphate Potassium Salicylate Sodium TCO2 Theophylline Total Bilirubin Total protein Transferrin Triglyceride	LP/PA/CB/CBAU205 LP/PA/CB/CBAU203 LP/PA/CB/CBAU207 LP/PA/CB/CBAU217 LP/PA/CB/CBAU213 LP/PA/CB/CBAU206 Randox kit LP/PA/CB/CBAU243 LP/PA/CB/CBAU209 LP/PA/CB/CBAU235 LP/PA/CB/CBAU225 LP/PA/CB/CBAU212 LP/PA/CB/CBAU211 LP/PA/CB/CBAU227 LP/PA/CB/CBAU221 LP/PA/CB/CBAU226 LP/PA/CB/CBAU242 LP/PA/CB/CBAU208 LP/PA/CB/CBAU238 LP/PA/CB/CBAU229 LP/PA/CB/CBAU231 Thermo Infinity Kit LP/PA/CB/CBAU215 LP/PA/CB/CBAU232 LP/PA/CB/CBAU219 LP/PA/CB/CBAU236 LP/PA/CB/CBAU210 LP/PA/CB/CBAU224 Stanbio kit LP/PA/CB/CBAU218 LP/PA/CB/CBAU223 LP/PA/CB/CBAU222 LP/PA/CB/CBAU237 LP/PA/CB/CBAU202 LP/PA/CB/CBAU204 LP/PA/CB/CBAU233 LP/PA/CB/CBAU216	UHND, DMH UHND, DMH UHND, DMH UHND, DMH UHND, DMH UHND, DMH UHND, DMH DMH UHND, DMH DMH UHND, DMH



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HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry examination activities for the purpose of clinical diagnosis</u> (cont'd)	Documented in-house procedures in conjunction with manufacturers instructions for analysis using Siemens Advia 2400 XPT Using supplier methods unless otherwise stated	
Serum	Urate Urea	LP/PA/CB/CBAU214 LP/PA/CB/CBAU220	UHND, DMH UHND, DMH
Plasma (Fluoride Oxalate)	Glucose Lactate	LP/PA/CB/CBAU239 LP/PA/CB/CBAU230	UHND, DMH UHND, DMH
Urine	Calcium Chloride Creatinine Magnesium Microalbumin Phosphate Potassium Protein Sodium Urea Uric Acid	LP/PA/CB/CBAU209 LP/PA/CB/CBAU225 LP/PA/CB/CBAU221 LP/PA/CB/CBAU232 LP/PA/CB/CBAU241 LP/PA/CB/CBAU210 LP/PA/CB/CBAU224 LP/PA/CB/CBAU34 LP/PA/CB/CBAU223 LP/PA/CB/CBAU220 LP/PA/CB/CBAU214	UHND, DMH UHND, DMH UHND, DMH UHND, DMH UHND, DMH UHND, DMH UHND, DMH UHND, DMH UHND, DMH UHND, DMH UHND, DMH UHND
CSF	Glucose Lactate Protein	LP/PA/CB/CBAU239 LP/PA/CB/CBAU230 LP/PA/CB/CBAU234	UHND, DMH UHND, DMH UHND, DMH



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HUMAN BODY FLUIDS (cont'd)	<u>Immunoassay examination activities for the purpose of clinical diagnosis</u>	Documented in-house procedures in conjunction with manufacturers instructions for analysis using Siemens Advia Centaur XPT	
Serum	Cortisol Digoxin ELF assays (hyaluronic acid & TMP1) Ferritin Folate FSH FT3 FT4 Gentamicin hCG (Total) LH Macroprolactin Screen NtproBNP Oestradiol P3NP Procalcitonin Progesterone Prolactin PSA Sodium Valproate SHBG Testosterone THIH(high sensitivity troponin) TSH Vitamin B12 Anti-thyroid peroxidase antibody (a-TPO)	LP/PA/CB/CBIA012 LP/PA/CB/CBIA013 LP/PA/CB/CBIA045 LP/PA/CB/CBIA025 LP/PA/CB/CBIA026 LP/PA/CB/CBIA006 LP/PA/CB/CBIA004 LP/PA/CB/CBIA003 LP/PA/CB/CBIA032 LP/PA/CB/CBIA015 LP/PA/CB/CBIA007 Inc Polyethylene glycol pre-treatment LP/PA/CB/CBIA020 LP/PA/CB/CBIA41 LP/PA/CB/CBIA014 LP/PA/CB/CBIA034 LP/PA/CB/CBIA040 LP/PA/CB/CBIA008 LP/PA/CB/CBIA005 LP/PA/CB/CBIA009 LP/DM/CB/CBIA035 LP/ND/CB/CBIA038 LP/PA/CB/CBIA011 LP/PA/CB/CBIA036 LP/PA/CB/CBIA002 LP/PA/CB/CBIA027 LP/PA/CB/CBIA021	UHND, DMH UHND, DMH DMH UHND, DMH UHND, DMH DMH UHND, DMH UHND, DMH UHND, DMH UHND, DMH DMH DMH UHND, DMH DMH DMH DMH UHND, DMH DMH DMH UHND, DMH UHND, DMH UHND, DMH UHND
Plasma (EDTA)	PTH	LP/ND/CB/CBIA024	UHND



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HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry examination activities for the purpose of clinical diagnosis</u>	Documented in-house procedures in conjunction with manufacturers instructions for analysis using Siemens Advia Centaur XPT	
Serum/plasma/urine	Anion Gap	By calculation	UHND, DMH
Serum/Plasma	Globulin	By calculation	UHND, DMH
Serum	Adjusted Calcium	By calculation	UHND, DMH
Urine	eGFR	By calculation	UHND, DMH
Serum	Cholesterol:HDL ratio	By calculation	UHND, DMH
Serum	LDL Cholesterol	By calculation	UHND, DMH
Serum/plasma	Protein:Creatinine ratio	By calculation	UHND, DMH
24 hr Urine	Creatinine Clearance	By calculation	UHND, DMH
Serum/plasma	Microalbumin:Creatinine ratio	By calculation	UHND, DMH
Serum	Free androgen index	By calculation	UHND, DMH
Serum	Transferrin Saturation	By calculation	UHND, DMH
Urine	Urine urate:creatinine ratio	By calculation	UHND
Serum/plasma	Acute Kidney Injury, derived from creatinine	By calculation	UHND, DMH
Serum	ELF Score	By calculation	DMH
Serum/Urine	Osmolality	Vitech 3320 Osmometer (freezing point depression) SOP LP/PA/CB/CBSP034	UHND, DMH
Serum	Vitamin D	Elecsys Vitamin D total III assay-Roche COBAS e411 LP/PA/CB/IA035	DMH
Faeces	Faecal Calprotectin	Extraction using Buhlmann Assay LP/PA/CBAU244	UHND, DMH
	Faecal Calprotectin	Testing using PETIA method on Advia XPT analyser LP/PA/CBAU244	DMH
Whole blood	HbA1c	Menarini HA9210 HPLC with specific reference to LP/PA/CB/CBSP006	UHND, DMH
CSF	Xanthochromia	Uvikon spectrophotometry with reference to LP/PA/CB/CBSP028	UHND



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HUMAN BODY FLUIDS (cont'd)	<u>Immunology examination activities for the purpose of clinical diagnosis</u>	Documented in-house procedures in conjunction with manufacturers instructions for analysis	
Serum		Siemens Advia XPT using immunoturbidimetric measurement principle:	DMH
	Immunoglobulin A	LP/PA/CB/CBAU245	
	Immunoglobulin G	LP/PA/CB/CBAU246	
	Immunoglobulin M	LP/PA/CB/CBAU247	
	Rheumatoid factor	LP/PA/CB/CBAU249	
	B2M	LP/PA/CB/CBAU250	
	Serum electrophoresis	Agarose gel electrophoresis using Hydrasys II automated gel electrophoresis by Sebia SOP LP/PA/IM/SOP10	DMH
	Serum Immunofixation		
	Serum Free Light Chains	Turbidimetry on Optilite Freelite kappa Free kit LK016.OPT Optilite Freelite lambda Free kit LK018. OPT SOP LP/PA/IM/SOP037	DMH



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HUMAN BODY FLUIDS (cont'd)	<u>Blood Transfusion examination activities for the purpose of clinical diagnosis</u>	Manufacturer's instructions and documented In-house methods using:	
Whole Blood: EDTA samples	Blood Grouping <ul style="list-style-type: none"> A B O Rhesus D status 	Automated Bio-Rad IH1000 blood transfusion analysers SOP: LP/PA/TR 9 Manual methods using DiaMed-ID Micro Typing system LP/PA/TR16	UHND, DMH
Whole Blood: EDTA samples	Antibody Screening Antibodies of the following systems: <ul style="list-style-type: none"> Rh- C,D,E,c,e, Kell- K,k, Duffy- Fya, Fyb MNSs- M,N,S,s Kidd- Jka, Jkb	Automated Bio-Rad IH1000 blood transfusion analysers SOP: LP/PA/TR 9 Manual methods using DiaMed-ID Micro Typing system LP/PA/TR16	UHND, DMH
	Antibody Screening Antibodies of the following systems: <ul style="list-style-type: none"> Rh- Cw Kell- Kpa Lutheran- Lua, Lewis- Lea, Leb P- P1	Automated Bio-Rad IH1000 blood transfusion analysers SOP: LP/PA/TR 9 Manual methods using DiaMed-ID Micro Typing system LP/PA/TR16	UHND, DMH
Whole Blood: EDTA samples	Antigen phenotyping C, c, E, e, K, Fya, Fyb, Jka, Jkb, M, N, S, s	Manual methods using DiaMed-ID Micro Typing system LP/PA/TR57	DMH



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<p>HUMAN BODY FLUIDS (cont'd)</p> <p>Whole Blood: EDTA samples (cont'd)</p>	<p><u>Blood Transfusion examination activities for the purpose of clinical diagnosis</u> (cont'd)</p> <p>Antigen phenotyping (cont'd)</p> <p>C, c, E, e, K, Fya, Fyb, Jka, Jkb, M, N, S, s, Lea, Leb, P1, Kpa, Lua, Cw</p>	<p>Manufacturer's instructions and documented In-house methods using:</p> <p>Manual methods using DiaMed-ID Micro Typing system</p> <p>LP/PA/TR57</p>	UHND
	<p>c, C, e ,E, and K</p>	<p>Manual methods using DiaMed-ID Micro Typing system and DiaClon Rh-subgroups + K cards</p> <p>LP/PA/TR57</p>	UHND, DMH
	<ul style="list-style-type: none"> • Diaclon Anti-Jka/Jkb, • Diaclon Anti-M/N, • Diaclon Anti-Fya/Fyb & ID Anti-Fya/Fyb test serum for phenotyping Fya, Fyb antigens, • Diaclon Anti-S/s & ID Anti-S/s test serum, • Biorad Seraclone Anti-s (MNS4) antisera, • Biorad Seraclone Anti-Fya (FY1) antisera, <p>Biorad Seraclone Anti-Fyb (FY2) antisera</p>	<p>Manual methods using DiaMed-ID Micro Typing system</p> <p>LP/PA/TR57</p>	UHND, DMH
	<ul style="list-style-type: none"> • Diaclon Anti-Lea/Leb, • Biorad Seraclone Anti-Kpa (KEL3) antisera, • Biorad Seraclone Anti-Lua (LU1) antisera, <p>Biorad Seraclone Anti-Cw (RH8) antisera</p>	<p>Manual methods using DiaMed-ID Micro Typing system</p> <p>LP/PA/TR57</p>	UHND
<p>Whole Blood: EDTA samples</p>	<p>Kleihauer test for estimation of foeto-maternal haemorrhage</p>	<p>Clin Tech Shepherds Stain kit and Eosin stain SOP: LPPATR3</p>	UHND, DMH



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HUMAN BODY FLUIDS (cont'd)	<u>Blood Transfusion examination activities for the purpose of clinical diagnosis</u> (cont'd)	Manufacturer's instructions and documented In-house methods using:	
Whole Blood: EDTA samples	Direct anti-globulin test, monospecific and polyspecific	SOP LPPATR 9 Manual methods using DiaMed-ID Micro Typing system	
Whole Blood: EDTA samples	Crossmatch	SOP LPPATR51 SOP LPPATR58	
Plasma (sodium citrate)	<u>Coagulation examination activities for the purpose of clinical diagnosis</u> Blood Coagulation	Manufacturer's instructions and documented In-house methods using: ACL TOP 550 CTS	
	<ul style="list-style-type: none"> • PT • APTT • Clauss-Fibrinogen • Actin FS 	Optical clot detection Key SOPs LP/PA/HA/CO3 LP/PA/HA/CO2 LP/PA/HA/CO3	UHND, DMH
	<ul style="list-style-type: none"> • Activated Protein C Resistance • Antithrombin • Free Protein S • Heparin monitoring • Lupus anticoagulant • Protein C Chromogenic • Reptilase Clotting Time • Thrombin Time Blood • Thrombophilia Screen Blood • Factor VIIIc 	LP/PA/HA/CO3 LP/PA/HA/CO2 LP/PA/HA/CO7 LP/PA/HA/CO6 LP/PA/HA/CO9 LP/PA/HA/CO11 LP/PA/HA/CO8 LP/PA/HA/CO5 LP/PA/HA/CO22 LP/PA/HA/CO10	UHND



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HUMAN BODY FLUIDS (cont'd)	<u>Coagulation examination activities for the purpose of clinical diagnosis</u> (cont'd)	Manufacturer's instructions and documented In-house methods using:	
Plasma (sodium citrate)	Blood Coagulation	ACL TOP 550 CTS	UHND, DMH
	INR	Optical clot detection SOP LP/PA/HA/CO26	
	D-Dimer	Latex enhanced immunoassay using Werfen D-Dimer HS500 kit SOP LP/PA/HA/CO32	
	Anti Xa Assay	LP/PA/HA/CO3	UHND, DMH
	Derived fibrinogen	Algorithm on ACL TOP 550 CTS SOP LP/PA/HA/CO1	UHND, DMH
	<u>Haematology examination activities for the purpose of clinical diagnosis</u>	Manufacturer's instructions and documented In-house methods using:	
Whole Blood (EDTA)	Screening test for Glucose 6 phosphate dehydrogenase deficiency	Trinity Biotech kit, visual qualitative fluorescence SOP LP/PA/HA37	UHND
Urine	Identification of urinary haemosiderin	Manual iron stain SOP LP/PA/HA60	UHND
Bone marrow aspirate slides	Reporting of normal and abnormal morphologies	Manual MGG stain Automated stain using SP10 Manual iron stain SOP LP/PA/HA60 LP/PA/HA/59 LP/PA/HA/63	UHND, DMH UHND, DMH



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HUMAN BODY FLUIDS (cont'd)	<u>Haematology examination activities for the purpose of clinical diagnosis</u> (cont'd)	Manufacturer's instructions and documented In-house methods using:	
Whole blood, Plasma (citrate or EDTA), Serum.	Detection of infectious mononucleosis heterophile antibodies	Clearview IM II test chromatographic immunoassay kit SOP LP/P/HA/4	UHND, DMH
Whole blood (EDTA)	Identification of normal and abnormal morphologies including WBC differential count	Sysmex SP10 Manual MGG Manual microscopy Key SOPs LP/PA/HA7 LP/PA/HA21 LP/PA/HA61	UHND, DMH. UHND UHND, DMH
Whole Blood EDTA	Malaria screening for: P. falciparum P. vivax P. ovale P. malariae	Thick and thin films Fields stain and manual microscopy Binax Now immunochromatographic test Key SOPs LP/PA/HA/13 LP/PA/HA1	UHND, DMH
Whole blood EDTA	ESR	Vitech Interliner Key SOPs LP/PA/HA17 LP/PA/HA22	UHND, DMH
	ESR	Manual method – Westergreen tube method on half hour tikme with 1-hour conversion algorithm, on board	UHND



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HUMAN BODY FLUIDS (cont'd)	<u>Haematology examination activities for the purpose of clinical diagnosis</u> (cont'd)	Manufacturer's instructions and documented In-house methods using:	
Serum	Measurement of: Anticardiolipin IgG/IgM antibodies	Launch Diagnostics Dynex DS2 analyser (ELISA) LP/PA/HA129	UHND
	Intrinsic Factor Antibodies	LP/PA/HA130	UHND
Whole blood (EDTA)	Full Blood count: <ul style="list-style-type: none"> • Haemoglobin • Platelets • Red Blood Cells • Haematocrit • MCV • MCH • MCHC • Red cell distribution width • White Cell Differential • Neutrophils • Lymphocytes • Monocytes • Eosinophils • Basophils 	Sysmex XN9000 Key SOPs LP/PA/HA5 LP/PA/HA14	UHND, DMH
Whole blood (EDTA)	Reticulocytes	Sysmex XN9000 Key SOPs LP/PA/HA45 LP/PA/HA67	UHND, DMH
Whole Blood (EDTA)	Detection of haemoglobin S (Hb-S),	Clintech Solubility test kit SOP LP/PA/HA19	UHND
END			