


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 Accredited to ISO 15189:2012	University Hospitals of Derby and Burton NHS Foundation Trust- trading as 'Derbyshire Pathology'	
	Issue No: 002 Issue date: 01 June 2020	
	Blood Sciences Department Chesterfield Royal Hospital Calow Chesterfield S44 5BL	Contact: Christine Ainger Tel: +44 (0)1246 512242 E-Mail: chris.ainger@nhs.net
Testing performed at the above address only		

Site activities performed away from the locations listed above:

Location details	Activity
Blood issue fridge W9G9163 Theatre Phase 1 Main Theatres	Blood storage & issue only Fridge managed by Blood transfusion
Blood Issue Fridge W9F8652 Theatres Phase 2 Obs & Gynae theatres	Blood storage & issue only Fridge managed by Blood Transfusion
Blood Product Issue fridge Trinity Ward	Anti-D Immunoglobulin storage and issue Fridge managed by Blood Transfusion
Blood component issue fridge NGS Macmillan Unit	Red blood cells and platelet storage and issue Fridge managed by Blood Transfusion
Ward areas, The Den, Antenatal Clinic, Suite 9, NGS Macmillan Unit	Phlebotomy
OPD/ward areas, Chesterfield Royal Hospital	Sweat collection



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DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS	<u>Biochemistry examination activities for the purposes of clinical diagnosis:</u>	Documented in house methods and manufacturers' instructions for
Serum (unless otherwise stated)	Quantitative determination of:	Roche Cobas c702 Module: Immunoturbidometric
Serum & Plasma	Alpha 1 antitrypsin Phenobarbitone Complement C3 & C4 Caeruloplasmin CRP IgA IgG IgM Haptoglobin Phenytoin Theophylline Albumin	CRHRMO-LP-RMO059 CRHRMO-LP-RMO030 CRHSPE-LP-SPE033 CRHRMO-LP-RMO058 CRHRMO-LP-RMO014 CRHSPE-LP-SPE027
Urine	Quantitative determination of:	CRHSPE-LP-SPE034 CRHRMO-LP-RMO031 CRHRMO-LP-RMO036 CRHRMO-LP-RMO028
Serum, Plasma	Albumin	Roche Cobas c702 Module: Spectrophotometry CRHRMO-LP-RMO001
Serum, Plasma	Alkaline Phosphatase	CRHRMO-LP-RMO002
Serum, Plasma	Alanine Transferase	CRHRMO-LP-RMO003
Serum, Plasma, Urine	Amylase	CRHRMO-LP-RMO005
Serum, Plasma	Aspartate transferase	CRHRMO-LP-RMO006
Serum, Plasma	Bicarbonate	CRHRMO-LP-RMO007
Serum, Plasma	Bilirubin Total	CRHRMO-LP-RMO008
Serum, Plasma	Creatinine (enzyme assay)	CRHRMO-LP-RMO013
Urine	Creatinine (Jaffe assay)	CRHRMO-LP-RMO013
CSF, Urine, Serum & Plasma	Total Protein	CRHRMO-LP-RMO037 CRHRMO-LP-RMO038
Serum, Plasma, Urine	Calcium	CRHRMO-LP-RMO009
Serum, Plasma	Direct Bilirubin	CRHRMO-LP-RMO017
Serum, Plasma	Total Cholesterol	CRHRMO-LP-RMO011
Serum, Plasma	Creatine Kinase	CRHRMO-LP-RMO012
Serum, Plasma, CSF	Glucose	CRHRMO-LP-RMO015 CRHRMO-LP-RMO020
Plasma, CSF	Lactate	CRHRMO-LP-RMO24
Serum, Plasma	Triglycerides	CRHRMO-LP-RMO038
Serum, Plasma	GGT	CRHRMO-LP-RMO018
Serum, Plasma	Iron	CRHRMO-LP-RMO022
Serum, Plasma, CSF	Lactate dehydrogenase	CRHRMO-LP-RMO025
Serum, Plasma	Magnesium	CRHRMO-LP-RMO027
Plasma	Ammonia	CRHRMO-LP-RMO004



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HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry examination activities for the purposes of clinical diagnosis:</u> (cont'd)	Documented in house methods and manufacturers' instructions for
	Quantitative determination of: (cont'd)	Roche Cobas c702 Module: Spectrophotometry
Serum, Plasma	Paracetamol	CRHRMO-LP-RMO029
Serum, Plasma	Phosphate	CRHRMO-LP-RMO032
Serum	Salicylate	CRHRMO-LP-RMO034
Serum, Plasma	Transferrin	CRHRMO-LP-RMO043
Serum, Plasma, Urine	Urate	CRHRMO-LP-RMO040
Serum, Plasma, Urine	Urea	CRHRMO-LP-RMO039
	Quantitative determination of:	Roche Cobas e801 Module: Using Chemiluminescence Immunoassay:
Serum, Plasma	Vitamin B12	CRHSPE-LP-SPE017
Serum	Pro BNP	CRHSPE-LP-SPE025
Serum, Plasma	CA 125	CRHSPE-LP-SPE021
Serum, Plasma	CEA	CRHSPE-LP-SPE022
Serum, Plasma	Cortisol	CRHSPE-LP-SPE014
Serum	Digoxin	CRHSPE-LP-SPE016
Serum, Plasma	Ferritin	CRHSPE-LP-SPE018
Serum, Plasma	FSH	CRHSPE-LP-SPE008
Serum, Plasma	Free thyroxine (FT4)	CRHSPE-LP-SPE005
Serum, Plasma	Free tri-iodothyronine	CRHSPE-LP-SPE006
Serum, Plasma	HCG	CRHSPE-LP-SPE024
Serum, Plasma	LH	CRHSPE-LP-SPE007
Serum	Oestradiol	CRHSPE-LP-SPE009
Plasma	Parathyroid hormone	CRHSPE-LP-SPE015
Serum	Progesterone	CRHSPE-LP-SPE013
Serum	Prolactin/Macroprolactin	CRHSPE-LP-SPE010
Serum, Plasma	Total PSA	CRHSPE-LP-SPE012
Serum, Plasma	Folate	CRHSPE-LP-SPE019
Serum	SHBG	CRHRMO-LP-RMO63
Serum	Testosterone	CRHSPE-LP-SPE011
Serum, Plasma	Thyroid peroxisomal antibody	CRHSPE-LP-SPE023
Serum, Plasma	TSH	CRHSPE-LP-SPE004
Serum, Plasma	Troponin T	CRHSPE-LP-SPE020
Serum	Vitamin D	CRHSPE-LP-SPE052
Serum	Lithium	CRHRMO-LP-RMO64
	Quantitative determination of:	Roche Cobas c702 Module: Microparticle agglutination
Serum	Carbamazepine	CRHRMO-LP-RMO010



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HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry examination activities for the purposes of clinical diagnosis:</u> (cont'd)	Documented in house methods and manufacturers' instructions for
Serum, Plasma, Urine	Quantitative determination of: (cont'd)	Roche Cobas c702 Module : Using Indirect ISE:
	Sodium Potassium Chloride	CRHRMO-LP-RMO033 CRHRMO-LP-RMO035 CRHRMO-LP-RMO068
Serum, Plasma	Quantitative determination of: HDL Cholesterol	Roche Cobas c702 Module: Enzymatic Colorimetric analysis CRHRMO-LP-RMO021
Serum Serum Serum	Quantitative determination of: Gentamicin Vancomycin Valproate	Roche Cobas c702 Module: Enzyme immunoassay CRHRMO-LP-RMO019 CRHRMO-LP-RMO062 CRHRMO-LP-RMO041
Urine	Urine drugs of abuse screen to include: Barbiturates Amphetamine Benzodiazepine Buprenorphine Cocaine Methamphetamine Methadone Phencyclidine THC Cannabis Tricyclic antidepressants Opiates	Abbott/Alere Dipstix analysis by chromatographic assay: CRHRMO-LP-RMO044
Blood	Blood Gas Analysis to include: pH Base Excess pCO2 pO2 Bicarbonate	Werfen GEM 4000, using Potentiometric, Clark electrode, Optical Measurements CRHCHE-LP-RCH032



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HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry examination activities for the purposes of clinical diagnosis:</u> (cont'd)	Documented in house methods and manufacturers' instructions for
Blood	Blood Gas Analysis to include: (cont'd)	Werfen GEM 4000, using Potentiometric, Clark electrode, Optical Measurements
	Methaemoglobin Carboxyhaemoglobin O2 Saturation	CRHCHE-LP-RCH032
Serum, Plasma, Urine	Osmolality	Advanced Instruments Osmometer using freezing point depression: CRHCHE-LP-RCH029
	Quantitative determination of:	Northstar Spectrophotometer: Using Spectrophotometry:
CSF	Xanthochromia	CRHSPE-LP-SPE043
		Hydrasys using hydra gel and electrophoresis
Serum Urine	Cryoglobulins Bence Jones Proteins	CRHSPE-LP-SPE035 CRHSPE-LP-SPE032
	Paraproteins Quantification:	Sebia Hydrasys 2 Scan using hydra gel and electrophoresis and immunofixation Sebia Capillarys 2 using capillary zone electrophoresis:
Serum/Urine	IgG IgA IgM Kappa Lambda	CRHSPE-LP-SPE030/031
		Menarini- HPLC:
Blood	HbA1C	CRHSPE-LP-SPE039



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HUMAN BODY FLUIDS (cont'd)	<p><u>Biochemistry examination activities for the purposes of clinical diagnosis:</u> (cont'd)</p> <p>Calculated Tests to include:</p>	<p>Documented in house methods and manufacturers' instructions for</p> <p>Tests calculated from output of various methodologies from Roche Cobas Systems:</p>
Blood and Urine	<p>eGFR Adjusted Calcium 24 hr Urine Anionic gap</p>	<p>DOC47</p>
Blood and Urine	<p>Amylase/Creatinine clearance ratio Calcium excretion index Calcium creatinine ratio LDL Creatinine clearance Free androgen index FIB4 Non HDL- Cholesterol Transferrin Saturation Urine protein: Creatinine Globulins AKI</p>	<p>CRHCHE-LP-RCH048</p>
Whole Blood	<p><u>Blood Transfusion examinations to assist in clinical investigations</u></p> <p>Blood Group by detection and identification of antigens:</p> <p>A D Positive A D Negative AB D Positive AB D Negative B D Positive B D Negative O Positive O Negative</p>	<p>Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:</p> <p>Automated BioRad analysers, IH1000 and ID Gelstation, ABO/D forward and reverse grouping, Manual using Tubes and Biorad cards, screening on IgG cards by Gel column agglutination and centrifugation</p> <p>CRHBLB-LP-BLB018 IH1000 CRHBLB-LP-BLB003 Manual Biorad cards/tubes</p>



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HUMAN BODY FLUIDS (cont'd)	<p><u>Blood Transfusion examinations to assist in clinical investigations</u></p> <p>Antibody Screen by detection of antibodies to:</p> <p>Rh which includes anti-C, D, E, c, e, C^w, K, k, Kp^a, Kp^b, Fy^a, Fy^b, Jk^a, Jk^b, Le^a, Le^b, S, s, M, N, P₁, Lu^a, Lu^b, X^{ga}</p> <p>Red Cell antibody identification:</p> <p>anti-C, D, E, c, e, C^w, K, Kp^a, Fy^a, Fy^b, Jk^a, Jk^b, Le^a, Le^b, S, s, M, N, P₁, Lu^a, Anti-A1</p> <p>Antibody Screen by detection of antibodies to:</p> <p>Rh which includes anti-C, D, E, C^w, Kp^a, Jk^a, Jk^b, Le^a, Le^b, S, s, M, N, A1, Lu^a</p>	<p>Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:</p> <p>Automated BioRad analysers, IH1000 BSC-BB-SOP-138 BSC-BB-SOP-136</p> <p>BSC-BB-SOP-106</p> <p>Manual using Tubes and Biorad cards, screening on IgG cards by Gel column agglutination and centrifugation</p> <p>BSC-BB-SOP-138 BSC-BB-SOP-136</p>
Plasma		



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HUMAN BODY FLUIDS (cont'd)	<u>Blood Transfusion examinations to assist in clinical investigations</u>	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:
	Red Cell antibody identification:	Manual using Tubes /Biorad cards, screening on IgG cards by Gel column agglutination and centrifugation
	anti-C, D, E, c, e, Kell (K1)	BSC-BB-SOP-138 BSC-BB-SOP-136
Red Cells	Direct Antiglobulin Test (DAT)	DAT card using LISS/Monospecific IgG gel column technology and centrifugation BSC-BB-SOP-147
Maternal whole blood	Detection of fetal cells in maternal whole blood	Manual microscopy using Kleihauer Betke staining for foetal cells BSC-BB-SOP-28 using LISS/Monospecific IgG gel column technology and centrifugation
Donor Blood/Patient plasma	Compatibility testing of patients plasma with donor cells	CRHBLB-LP-BLB023



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HUMAN BODY FLUIDS (cont'd)	<u>Haematological examinations for the purpose of clinical diagnosis</u> (cont'd)	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:
Blood	Quantitative determination of: Full Blood counts and automated differential to include: WBC RBC HGB Platelet count MCV MCH MCHC NEUT LYMPH MONO EOS BASO Nucleated red blood cell (NRBC) count Reticulocyte count	Sysmex XN10 and XN 20 Fluorescence flow cytometry, electrical impedance BSC-HAEM-SOP-1 BSC-HAEM-SOP-6
Plasma	Routine Coagulation testing for: Prothrombin Time (PT) INR Activated Partial Thromboplastin Time (APTT) Fibrinogen	Sysmex CS 2100i automated clotting assays, light transmission BSC-COAG-SOP-1, SOP-5
Plasma	D Dimer	Biomerieux, automated immunoassay, ELISA and immunofluorescence: BSC-COAG-SOP-3
Blood	ESR	Starred compact ESR machine, Westergren sedimentation. BSC-HAEM-SOP-3



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HUMAN BODY FLUIDS (cont'd)	<u>Haematological examinations for the purpose of clinical diagnosis</u> (cont'd)	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:
Blood	Red cell, white cell and platelet morphology and white cell differential	Manual preparation of slide or Sysmex SP-10 (May-Grunwald and Giemsa) Hematek 3000- Modified Wrights stain BSC-HAEM-SOP-6, 7, 20 Monogen Manual assay with latex reagent
Plasma	IM Heterophile antibody	BSC-HEAM-SOP-21 Menarini HPLC
Blood	Haemoglobinopathy analysis by detection of haemoglobin variants: Hb A Hb A2 Hb F Hb S Hb C Hb D Hb E Hb O Barts Leopore	BSC-HAEM-SOP026, 27



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Blood	Presence or absence of plasmodium species	Preparation of films, staining by Hematak 3000 machine using Romanowsky stain and light microscopy BSC-HAEM-SOP-20 BSC-HAEM-SOP-22
Blood	HbS	TCS sickle-Check kit, Using Turbidity BSC-HAEM-SOP-24
END		