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
Royal Brompton Hospital Sydney Street London SW3 6NP	Local contact Biochemistry Nelesh Morjaria n.morjaria@rbht.nhs.uk Haematology and Blood Transfusion Steve Owen Tel: +44 (0)330 128 8407	Clinical Biochemistry Haematology Coagulation Blood Transfusion Blood Transfusion Issue Fridges located within laboratory, Adult ICU, theatres and paediatric ICU Issue of Blood and Blood Products	RBH
Pathology Building Harefield Hospital Hill End Road Harefield UB9 6JH	Local contact Krishna Putta k.putta@rbht.nhs.uk Haematology and Blood Transfusion Steve Owen Tel: +44 (0)330 128 8407	Clinical Biochemistry Haematology Coagulation Blood Transfusion Blood Transfusion Issue Fridges located within laboratory and ITU/ theatres Issue of Blood and Blood Products	НН
Immunosuppression Monitoring Service Laboratory Heart Science Centre Harefield Hospital	Local contact Suzanne Diamond s.diamond@rbht.nhs.uk	Immunosuppression monitoring only	HHIMS

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	Synnovis Analytics LLP	
8826 Accredited to ISO 15189:2012	Issue No: 012 Issue date: 02 April 2025	
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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)	Biochemistry examination activities for the purpose of clinical diagnosis	Documented in house methods and manufacturer's instructions for	
	<u>General Chemistry /</u> <u>Toxicology/ Therapeutic drug</u> <u>monitoring</u> : Quantitative determination of:	Analysis using the following Beckman analysers based on measurement by turbidometry, colourimetry, ion-sensitive electrode, immunoassay and SOP. SOPCB1170- Beckman AU680 ISE, spectrophotometric and immunoassays at RBH and HH SOPCB1157 - Beckman AU480, ISE, spectrophotometric and immunoassays at HH	
Serum, urine	Sodium	ISE SOPCB1170 (RBH)-AU680 SOPCB1157(HH)-AU480	RBH HH
Serum, urine	Potassium	ISE SOPCB1170 (RBH)-AU680 SOPCB1157(HH)-AU480	RBH HH
Serum, urine	Urea	Kinetic reaction with rate monitoring SOPCB1170 (RBH)-AU680 SOPCB1157(HH)-AU480	RBH HH
Serum, urine	Creatinine	Kinetic reaction with fixed point monitoring SOPCB1170 (RBH)-AU680 SOPCB1157(HH)-AU480	RBH HH
Serum	Estimated GFR	Calculated parameter from creatinine using MDRD SOPCB1170 (RBH)-AU680 SOPCB1157(HH)-AU480	RBH HH
Serum, CSF	Glucose	End point reaction SOPCB1170 (RBH)-AU680	RBH

DETAIL OF ACCREDITATION

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HUMAN BODY FLUIDS (cont'd)	Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)	Documented in house methods and manufacturer's instructions for	
	<u>General Chemistry /</u> <u>Toxicology/ Therapeutic drug</u> <u>monitoring</u> : Quantitative determination of: (cont'd)	Analysis using the following Beckman analysers based on measurement by turbidometry, colourimetry, ion-sensitive electrode, immunoassay and SOP. SOPCB1170- Beckman AU680 ISE, spectrophotometric and immunoassays at RBH and HH SOPCB1157 - Beckman AU480, ISE, spectrophotometric and immunoassays at HH	
Serum	Total CO ₂ (bicarbonate)	Enzymatic reaction with fixed point monitoring SOPCB1170 (RBH)-AU680 SOPCB1157(HH)-AU480	RBH HH
Serum	Chloride	ISE SOPCB1170 (RBH)-AU680 SOPCB1157(HH)-AU480	RBH HH
Serum	Total bilirubin	End point reaction SOPCB1170 (RBH)-AU680 SOPCB1157(HH)-AU480	RBH HH
Serum	Direct bilirubin	End point reaction SOPCB1170 (RBH)-AU680	RBH
Serum	ALP	Rate reaction SOPCB1170 (RBH)-AU680 SOPCB1157(HH)-AU480	RBH HH
Serum	GGT	Rate reaction SOPCB1170 (RBH)-AU680 SOPCB1157(HH)-AU480	RBH HH
Serum	ALT	Rate reaction SOPCB1170 (RBH)-AU680 SOPCB1157(HH)-AU480	RBH HH

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HUMAN BODY FLUIDS (cont'd)	Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)	Documented in house methods and manufacturer's instructions for	
	<u>General Chemistry /</u> <u>Toxicology/ Therapeutic drug</u> <u>monitoring:</u> Quantitative determination of: (cont'd)	Analysis using the following Beckman analysers based on measurement by turbidometry, colourimetry, ion-sensitive electrode, immunoassay and SOP. SOPCB1170- Beckman AU680 ISE, spectrophotometric and immunoassays at RBH and HH SOPCB1157 - Beckman AU480, ISE, spectrophotometric and immunoassays at HH	
Serum	AST	Rate reaction SOPCB1170 (RBH)-AU680	RBH
Serum	Total protein	End point reaction SOPCB1170 (RBH)-AU680 SOPCB1157(HH)-AU480	RBH HH
CSF, urine	Protein	End point reaction SOPCB1170 (RBH)-AU680	RBH
Serum	Albumin	End point reaction SOPCB1170 (RBH)-AU680 SOPCB1157(HH)-AU480	RBH HH
Urine	Albumin	Turbidimetric SOPCB1170 (RBH)-AU680 SOPCB1157(HH)-AU480	RBH HH
Serum	Creatine kinase	Rate reaction SOPCB1170 (RBH)-AU680 SOPCB1157(HH)-AU480	RBH HH
Serum, urine	Calcium	End point reaction SOPCB1170 (RBH)-AU680 SOPCB1157(HH)-AU480	RBH HH

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HUMAN BODY FLUIDS (cont'd)	Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)	Documented in house methods and manufacturer's instructions for	
	<u>General Chemistry /</u> <u>Toxicology/ Therapeutic drug</u> <u>monitoring:</u> Quantitative determination of: (cont'd)	Analysis using the following Beckman analysers based on measurement by turbidometry, colourimetry, ion-sensitive electrode, immunoassay and SOP. SOPCB1170- Beckman AU680 ISE, spectrophotometric and immunoassays at RBH and HH SOPCB1157 - Beckman AU480, ISE, spectrophotometric and immunoassays at HH	
Plasma	Ammonia	Rate reaction SOPCB1158 (RBH)	RBH
Serum	Inorganic phosphate	End point reaction SOPCB1170 (RBH)-AU680 SOPCB1157(HH)-AU480	RBH HH
Serum	Magnesium	End point reaction SOPCB1170 (RBH)-AU680 SOPCB1157(HH)-AU480	RBH HH
Serum	Amylase	Rate reaction SOPCB1170 (RBH)-AU680 SOPCB1157(HH)-AU480	RBH HH
Serum	CRP	Latex particle immunoturbidimetric SOPCB1170 (RBH)-AU680 SOPCB1157(HH)-AU480	RBH HH
Serum	Cholesterol	End point reaction SOPCB1170 (RBH)-AU680 SOPCB1157(HH)-AU480	RBH HH
Serum	HDL Cholesterol	End point reaction SOPCB1170 (RBH)-AU680 SOPCB1157(HH)-AU480	RBH HH

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HUMAN BODY FLUIDS (cont'd)	Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)	Documented in house methods and manufacturer's instructions for	
	<u>General Chemistry /</u> <u>Toxicology/ Therapeutic drug</u> <u>monitoring:</u> Quantitative determination of: (cont'd)	Analysis using the following Beckman analysers based on measurement by turbidometry, colourimetry, ion-sensitive electrode, immunoassay and SOP. SOPCB1170- Beckman AU680 ISE, spectrophotometric and immunoassays at RBH and HH SOPCB1157 - Beckman AU480, ISE, spectrophotometric and immunoassays at HH	
Serum	Triglycerides	End point reaction SOPCB1170 (RBH)-AU680 SOPCB1157(HH)-AU480	RBH HH
Serum	LDL Cholesterol	Calculated parameter from total cholesterol, HDL cholesterol and triglyceride SOPCB1170 (AU680 - RBH&HH)	RBH HH
Serum	Lipoprotein (a)	Immunoturbidimetric SOPCB1157(HH)- AU480	НН
Serum	Urate	End point reaction SOPCB1170 (RBH)-AU680 SOPCB1157(HH)-AU480	RBH HH
Serum	ACE	Enzymatic FAPGG SOPCB1170 (RBH)-AU680 SOPCB1157(HH)-AU480	RBH
Serum	Lactate dehydrogenase	Rate Reaction SOPCB1170 (RBH)-AU680 SOPCB1157(HH)-AU480	RBH HH
Serum	Digoxin	Latex- enhanced immunoinhibition SOPCB1170 (RBH)-AU680	RBH

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HUMAN BODY FLUIDS (cont'd)	Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)	Documented in house methods and manufacturer's instructions for	
	<u>General Chemistry /</u> <u>Toxicology/ Therapeutic drug</u> <u>monitoring:</u> Quantitative determination of: (cont'd)	Analysis using the following Beckman analysers based on measurement by turbidometry, colourimetry, ion-sensitive electrode, immunoassay and SOP. SOPCB1170- Beckman AU680 ISE, spectrophotometric and immunoassays at RBH and HH SOPCB1157 - Beckman AU480, ISE, spectrophotometric and immunoassays at HH	
Serum	Theophylline	Homogeneous enzyme immunoassay – rate monitored SOPCB1170 (RBH)-AU680	RBH
Serum	Amikacin	Homogeneous enzyme immunoassay – rate monitored SOPCB1170 (RBH)-AU680	RBH
Serum	Gentamicin	Homogeneous enzyme immunoassay – rate monitored SOPCB1170 (RBH)-AU680	RBH
Serum	Tobramycin	Homogeneous enzyme immunoassay – rate monitored SOPCB1170 (RBH)-AU680	RBH
Serum	Vancomycin	Homogeneous enzyme immunoassay – rate monitored SOPCB1170 (RBH)-AU680	RBH

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HUMAN BODY FLUIDS (cont'd)	Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)	Documented in house methods and manufacturer's instructions for	
	<u>General Chemistry</u> : Quantitative determination of:	Analysis using the following Beckman analysers based on measurement by turbidometry, colourimetry, ion-sensitive electrode, immunoassay and SOP. SOPCB1170 - Beckman AU680 ISE, spectrophotometric and immunoassays at RBH and HH SOPCB1157 - Beckman AU480, ISE, spectrophotometric and immunoassays at HH	
Serum	Immunoglobulin G	Immunoturbidimetric SOPCB1170 (RBH)-AU680	RBH
Serum	Immunoglobulin A	Immunoturbidimetric SOPCB1170 (RBH)-AU680	RBH
Serum	Immunoglobulin M	Immunoturbidimetric SOPCB1170 (RBH)-AU680	RBH
Serum	Complement C3	Immunoturbidimetric SOPCB1170 (RBH)-AU680	RBH
Serum	Complement C4	Immunoturbidimetric SOPCB1170 (RBH)-AU680	RBH
Serum	Alpha-1-Antitrypsin	Immunoturbidimetric SOPCB1170 (RBH)-AU680	RBH
Serum	Haptoglobin	Immunoturbidimetric SOPCB1170 (RBH)-AU680	RBH
Serum	Iron	End point reaction SOPCB1170 (RBH)-AU680 SOPCB1157(HH)-AU480	RBH HH
Serum	TIBC	Calculated parameter SOPCB1177 (rbh&hh)- AU680	RBH HH

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HUMAN BODY FLUIDS (cont'd)	Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)	Documented in house methods and manufacturer's instructions for	
	<u>General Chemistry</u> : Quantitative determination of: (cont'd)	Analysis using the following Beckman analysers based on measurement by turbidometry, colourimetry, ion-sensitive electrode, immunoassay and SOP. SOPCB1170 - Beckman AU680 ISE, spectrophotometric and immunoassays at RBH and HH SOPCB1157 - Beckman AU480, ISE, spectrophotometric and immunoassays at HH	
Serum	Transferrin	Immunoturbidimetric SOPCB1170 (RBH)-AU680 SOPCB1157(HH)-AU480	RBH HH
Serum	Apolipoprotein A1	Immunoturbidimetric SOPCB1114(HH)-AU480	НН
Serum	Apolipoprotein B	Immunoturbidimetric SOPCB1114(HH)-AU480	НН
Serum	Vitamin A	SOPCB1012- RBH using the Beckman Coulter system gold HPLC	RBH
Serum	Vitamin E	SOPCB1012- RBH using the Beckman Coulter system gold HPLC	RBH
Plasma and urine	Catecholamines	Kontron Instruments HPLC system with electrochemical detector SOPCB1073 (urine) SOPCB1074 (plasma)	RBH

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HUMAN BODY FLUIDS (cont'd)	Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)	Documented in-house procedures in conjunction with manufacturer's instructions	
	<u>Chromatography /</u> Electrophoresis / other		
Sweat	Chloride	Sherwood 962S chloride analyser using titrimetric method using silver nitrate reagent SOPCB1067	RBH
Whole blood	Glycated Hb	Ion exchange HPLC using Biorad D10 Haemoglobin A1c analyser SOPCB1013 (RBH) SOPCB0203(HH)	RBH HH
Serum, urine	Osmolality	Freezing point depression using Advanced Micro-osmometer model 3300 -SOPCB1153 (HH) model 3320 - SOPCB1008 (RBH)	RBH HH

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HUMAN BODY FLUIDS (cont'd)	Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)	Documented in-house procedures in conjunction with manufacturer's instructions	
	Immunochemistry Quantitative determination of:		
Serum	CK-MB (mass)	Immunoassay using Beckman Access2 SOPCB1177 (HH)	нн
Serum	Free T4	Immunoassay using Beckman Access2 SOPCB1066 (RBH) SOPCB1114(HH)	RBH HH
Serum	TSH	Immunoassay using Beckman Access2 SOPCB1066 (RBH) SOPCB1114(HH)	RBH HH
Serum	Troponin I	Immunoassay using Beckman Access2 SOPCB1066 (RBH) SOPCB1114(HH)	RBH HH
Serum	Cortisol	Immunoassay using Beckman Access2 SOPCB1066 (RBH)	RBH

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HUMAN BODY FLUIDS (cont'd)	Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)	Biochemistry examination activities for the purpose of clinical diagnosis	
	Immunochemistry Quantitative determination of: (cont'd)		
EDTA Plasma	BNP	Immunoassay using Beckman Access2 SOPCB1066 (RBH) SOPCB1114(HH)	RBH HH
Serum	PSA	Immunoassay using Beckman Access2 SOPCB1066 (RBH)	RBH
Serum	BHCG	Immunoassay using Beckman Access2 SOPCB1066 (RBH)	RBH
Serum	Total IgE	Immunoassay using Beckman Access2 SOPCB1066 (RBH)	RBH
Serum	Insulin	Immunoassay using Beckman Access2 SOPCB1066 (RBH)	RBH
Serum	fT3	Immunoassay using Beckman Access2 SOPCB1066 (RBH)	RBH
Serum	Ferritin	Immunoassay using Beckman Access2 SOPCB1066 (RBH) SOPCB1114(HH)	
Serum	Vitamin B12	Immunoassay using Beckman Access2 SOPCB1066 (RBH) SOPCB1114(HH)	RBH HH

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HUMAN BODY FLUIDS (cont'd)	Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)	Biochemistry examination activities for the purpose of clinical diagnosis	
	Immunochemistry Quantitative determination of: (cont'd)		
Serum	Folate	Immunoassay using Beckman Access2 SOPCB1066 (RBH) SOPCB1114(HH)	RBH HH
EDTA Whole Blood	Ciclosporin Tacrolimus Sirolimus Everolimus	2D TurboFlow™ Prelude HPLC with TSQ Quantum Endura MS/MS detection or Transcend II HPLC with TSQ Quantum Discovery MS/MS detection SOPCB1186	HHIMS

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HUMAN BODY FLUIDS as specified below:	Haematology examination activities for the purposes of clinical diagnosis	In house documented procedures based on equipment manuals and standard methods as specified below:	
Whole Blood	Blood Full Blood Count (PCV, MCV, Hb, RBC, WBC, Hct, MCV, MCH, MCHC, RDW Platelets, Neutrophils, lymphocytes, monocytes, Eosinophils, Basophils and Nucleated RBCs)	Beckman Coulter DxH 800 analysers using impedance principle for cell counting and sizing; volume, conductivity and light scatter (VCSn) for differential leucocyte count and measurement of absorbance of stable pigment for haemoglobin concentration.	RBH HH
		SOPHA00494	
Whole blood	Nucleated RBCs and Reticulocyte Count	Beckman Coulter DxH 800 using New Methylene Blue stain –	RBH
		SOPHA00494	
Blood film prepared from whole blood specimen	Blood Film Examination for Assessment for cell typing and morphology including white blood cell differential for enumeration of cell types.	DxH Slidemaker/Stainer (RBH) Shandon Varistain 12 (HH)	RBH HH
		SOPHA00503 Preparation & staining of blood films	
		SOPHA00474 Microscope use & maintenance.	
Urine	Iron stain for Urine hemosiderin in the diagnosing of intravascular haemolysis.	Manual light microscopy of urine smears using manual Iron (Perl's stain) SOPHA00330	RBH
Whole Blood	ESR - Erythrocyte Sedimentation Rate	Sarstedt Sediplus S2000 Automated ESR analyser. Uses light detection and changes in absorbance between the plasma/red cell interface	RBH
		SOPHA00484	

	Schedule of Accreditation issued by United Kingdom Accreditation Service 2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK
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HUMAN BODY FLUIDS as specified below: (cont'd)	<u>Haematology examination</u> <u>activities for the purposes of</u> <u>clinical diagnosis</u> (cont'd)	In house documented procedures based on equipment manuals and standard methods as specified below:	
Blood	Detection of variant haemoglobins HbA2, HbF & HbS quantitation	Biorad D-10 haemoglobin testing system using high performance liquid chromatography (HPLC)	RBH HH
		SOPHA00016	
Blood	Sickle Cell Screen	ClinTech Sickle Test kit detecting relative insolubility of HbS in buffer containing reducing agent	RBH HH
		SOPHA00219	
Plasma	Plasma Free Haemoglobin	HemoCue plasma/low Hb photometer using conversion of haemoglobin to azidemethaemoglobin followed by absorbance measurement	RBH HH
		SOPHA00271	
Blood	Infectious mononucleosis screen	Clearview IM rapid diagnostic test kit One step immunoassay for detection of IgM heterophile antibody	RBH
		SOPHA00237	

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HUMAN BODY FLUIDS as specified below: (cont'd)	<u>Haematology examination</u> <u>activities for the purposes of</u> <u>clinical diagnosis</u> (cont'd)	In house documented procedures based on equipment manuals and standard methods as specified below:	
Plasma (citrated)	<u>General Coagulation tests:</u> Prothrombin time (PT) and International Normalised Ratio (INR) Activated partial thromboplastin time (APTT) Fibrinogen assay Thrombin time (TT) D-dimer assay Heparin-induced thrombocytopenia (HIT) test Anti-Xa assay Antithrombin assay PT mix APTT mix	Instrumentation Laboratory Werfen ACL TOP 500 coagulometers. Measurement principles include turbidometric clot endpoint detection, chromogenic assays and immunoturbidometric assays. SOPHA00429 Routine use of ACL TOP 500 SOPHA00037 Prothrombin time (PT) and International Normalised Ration (INR) SOPHA00104 Activated partial thromboplastin time (APTT) SOPHA00296 Fibrinogen assay SOPHA00106 Thrombin time (TT) SOPHA00106 Thrombin time (TT) SOPHA00115 HIT screening Assay on the TOP500 SOPHA00533: Further investigation of HIT positive samples (ELISA method) RBH SOPHA00137 Antithrombin assay SOPHA00137 PT mix SOPHA00137 PT mix	RBH HH
Plasma (citrated)	HIT-Heparin Induced thrombocytopenia Von Willebrand collagen binding	Enzyme linked immunosorbent assays using TECAN Infinite F200Pro Plate Reader SOPHA00533 Further investigation of HIT positive samples (ELISA method) SOPHA00113 von Willebrand assays	RBH

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HUMAN BODY FLUIDS as specified below: (cont'd)	<u>Haematology examination</u> <u>activities for the purposes of</u> <u>clinical diagnosis</u> (cont'd)	In house documented procedures based on equipment manuals and standard methods as specified below:	
Plasma (citrated)	Specialist Coagulation tests: Protein C Free protein S DRVT (lupus anticoagulant) APCR vWf antigen vWf functional assay (Ristocetin cofactor) Plasminogen assay Factor assays: II, V, VII, VIII, IX, X, XI, XII Anti-Factor Xa Assay for Direct Xa Inhibitors	Instrumentation Laboratory Werfen ACL TOP 500 coagulometers. Measurement principles include turbidometric clot endpoint detection, chromogenic assays and immunoturbidometric assays. SOPHA00429 Routine use of ACLTOP 500 coagulometer SOPHA00111 Protein C SOPHA00112 Free protein S SOPHA00122 DRVT (lupus anticoagulant) SOPHA0042 APCR SOPHA00113 vWf antigen SOPHA00113 vWf functional assay (Ristocetin cofactor) SOPHA00229 Plasminogen assay SOPHA00129 (Factor Assays APTT) SOPHA00130 (Factor Assays PT) SOPHA00536 (Apixaban and Rivaroxaban assays) SOPHA00537 (Direct Thrombin Inhibitor assay (Dabigatran)	RBH

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HUMAN BODY FLUIDS as specified below: (cont'd)	Blood Transfusion examination activities for the purposes of clinical diagnosis	In house documented procedures based on equipment manuals and standard methods as specified below:	
Blood	Automated Blood Grouping A, B, O and AB groups Rh groups, anitigens-;C, c, D, E, e, Kell blood group system, antigens: K Kidd blood group system, antigens: Jka Duffy blood group system, antigens: Fya MNS blood group system, antigens: S	BioRad iH500 using Diamed micro column cards SOP HA000538	RBH HH
Blood	Red Cell Antibody detection	using Diamed micro column cards and 3 cell panel	RBH HH
Blood	Direct antiglobulin test (DAT)	Poly specifc and mono specific (anti-IgG and anti-C3d)cards	RBH HH
Blood	Manual Blood Group/Phenotype A, B, O and AB groups Rh groups, anitigens-;C, c, D, E, e, Kell blood group system, antigens: K Kidd blood group system, antigens: Jka Duffy blood group system, antigens: Fya MNS blood group system, antigens: S	Manual method using Diamed micro column cards (as back-up to automated method) SOPHA00176	RBH HH
Blood	Direct antiglobulin test (DAT) If positive, further tests against anti-IgG and anti-C3d	Screening test using polyspecific reagent- Manual method using Diamed micro column cards SOPHA00527	RBH HH

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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 as specified below: (cont'd)	Blood Transfusion examination activities for the purposes of clinical diagnosis (cont'd)	In house documented procedures based on equipment manuals and standard methods as specified below:	
Blood	Red Cell Antibody Identification: Indirect antiglobulin test (IAT) panel Enzyme panel	Manual method using Diamed micro column cards (RBH, HH) SOPHA00172	RBH HH (manual only)
Blood	/Crossmatching Indirect antiglobulin test (IAT) crossmatch Immediate spin crossmatch Emergency issue Saline 37 degree centigrade crossmatch (RBH only)	IAT crossmatch carried out by manual method using Diamed microcolumn cards. Immediate spin crossmatch carried out by manual direct agglutin technique. SOPHA00164 Emergency issue (RBH) SOPHA00128 Crossmatching & red cell issue (HH) SOPHA00380 Emergency issue (HH) SOPHA00164 cross-site procedure	RBH HH
END			