


# Schedule of Accreditation

issued by

## United Kingdom Accreditation Service

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

 <p><b>UKAS</b> MEDICAL 8826</p> <p>Accredited to ISO 15189:2012</p>	<h3>Synnovis Analytics LLP</h3> <p><b>Issue No:</b> 012    <b>Issue date:</b> 03 September 2024</p>	
	<p><b>Department of Blood Science</b>  <b>Royal Brompton Hospital</b>  <b>Sydney Street</b>  <b>London</b>  <b>SW3 6NP</b>  <b>United Kingdom</b></p>	<p><b>Contact: Janet Okafor</b>  <b>Tel: +44 (0)207 351 8418</b>  <b>E-Mail: janet.okafor@nhs.net</b>  <b>Website: www.synnovis.co.uk</b></p>
<p><b>Testing performed by the Organisation at the locations specified below</b></p>		

### Locations covered by the organisation and their relevant activities

#### Laboratory locations:

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



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



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HUMAN BODY FLUIDS (cont'd)	<u>Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)</u>	Documented in house methods and manufacturer's instructions for	
	<u>General Chemistry / Toxicology/ Therapeutic drug monitoring:</u> Quantitative determination of:	Analysis using the following Beckman analysers based on measurement by turbidometry, colourimetry, ion-sensitive electrode, immunoassay and SOP. <b>SOPCB1170</b> - Beckman AU680 ISE, spectrophotometric and immunoassays at <b>RBH and HH</b> <b>SOPCB1157</b> - Beckman AU480, ISE, spectrophotometric and immunoassays at <b>HH</b>	
Serum	Total CO <sub>2</sub> (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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	<u>General Chemistry / Toxicology/ Therapeutic drug monitoring:</u> Quantitative determination of:	Analysis using the following Beckman analysers based on measurement by turbidometry, colourimetry, ion-sensitive electrode, immunoassay and SOP. <b>SOPCB1170</b> - Beckman AU680 ISE, spectrophotometric and immunoassays at <b>RBH and HH</b> <b>SOPCB1157</b> - Beckman AU480, ISE, spectrophotometric and immunoassays at <b>HH</b>	
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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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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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	HH
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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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)	<u>Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)</u>  General Chemistry: Quantitative determination of:	Documented in house methods and manufacturer's instructions for  Analysis using the following Beckman analysers based on measurement by turbidometry, colourimetry, ion-sensitive electrode, immunoassay and SOP. <b>SOPCB1170</b> - Beckman AU680 ISE, spectrophotometric and immunoassays at <b>RBH and HH</b> <b>SOPCB1157</b> - Beckman AU480, ISE, spectrophotometric and immunoassays at <b>HH</b>	
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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	<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. <b>SOPCB1170</b> - Beckman AU680 ISE, spectrophotometric and immunoassays at <b>RBH and HH</b> <b>SOPCB1157</b> - Beckman AU480, ISE, spectrophotometric and immunoassays at <b>HH</b>	
Serum	Transferrin	Immunoturbidimetric SOPCB1170 (RBH)-AU680 SOPCB1157(HH)-AU480	RBH HH
Serum	Apolipoprotein A1	Immunoturbidimetric SOPCB1114(HH)-AU480	HH
Serum	Apolipoprotein B	Immunoturbidimetric SOPCB1114(HH)-AU480	HH
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)	<u>Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)</u>	Documented in-house procedures in conjunction with manufacturer's instructions	
Sweat	<u>Chromatography / Electrophoresis / other</u> 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)	<u>Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)</u>	Documented in-house procedures in conjunction with manufacturer's instructions	
Serum	<u>Immunochemistry</u> Quantitative determination of:  CK-MB (mass)	Immunoassay using Beckman Access2 SOPCB1177 (HH)	HH
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)	<u>Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)</u>	<u>Biochemistry examination activities for the purpose of clinical diagnosis</u>	
EDTA Plasma	<u>Immunochemistry</u> Quantitative determination of:  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)	<u>Biochemistry examination activities for the purpose of clinical diagnosis (cont'd)</u>	<u>Biochemistry examination activities for the purpose of clinical diagnosis</u>	
Serum	<u>Immunochemistry</u> Quantitative determination of:  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:	<u>Haematology examination activities for the purposes of clinical diagnosis</u>	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.  SOPHA00494	RBH HH
Whole blood	Nucleated RBCs and Reticulocyte Count	Beckman Coulter DxH 800 using New Methylene Blue stain –  SOPHA00494	RBH
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)  SOPHA00503 Preparation & staining of blood films  SOPHA00474 Microscope use & maintenance.	RBH HH
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  SOPHA00484	RBH



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HUMAN BODY FLUIDS as specified below: (cont'd)	<u>Haematology examination activities for the purposes of 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)  SOPHA00016	RBH HH
Blood	Sickle Cell Screen	ClinTech Sickle Test kit detecting relative insolubility of HbS in buffer containing reducing agent  SOPHA00219	RBH HH
Plasma	Plasma Free Haemoglobin	HemoCue plasma/low Hb photometer using conversion of haemoglobin to azidemethaemoglobin followed by absorbance measurement  SOPHA00271	RBH HH
Blood	Infectious mononucleosis screen	Clearview IM rapid diagnostic test kit One step immunoassay for detection of IgM heterophile antibody  SOPHA00237	RBH



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HUMAN BODY FLUIDS as specified below: (cont'd)	<u>Haematology examination activities for the purposes of 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) SOPHA00040 D-dimer assay SOPHA00115 HIT screening Assay on the TOP500 SOPHA00533: Further investigation of HIT positive samples (ELISA method) RBH SOPHA00092 Anti-Xa assay SOPHA00137 Antithrombin assay SOPHA00037 PT mix SOPHA00104 APTT 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 activities for the purposes of clinical diagnosis</u> (cont'd)	In house documented procedures based on equipment manuals and standard methods as specified below:	RBH
Plasma (citrated)	<u>Specialist Coagulation tests:</u> 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) SOPHA00042 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))	



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**Synnovis Analytics LLP**

**Issue No: 012 Issue date: 03 September 2024**

**Testing performed by the Organisation at the locations specified**

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)	<u>Blood Transfusion examination activities for the purposes of clinical diagnosis</u>	In house documented procedures based on equipment manuals and standard methods as specified below:	
Blood	<u>Automated Blood Grouping</u> A, B, O and AB groups Rh groups, antigens: 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 specific and mono specific (anti-IgG and anti-C3d) cards	RBH HH
Blood	<u>Manual Blood Group/Phenotype</u> A, B, O and AB groups Rh groups, antigens: 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	<u>Blood Transfusion examination activities for the purposes of clinical diagnosis</u> (cont'd)  Red Cell Antibody Identification: Indirect antiglobulin test (IAT) panel Enzyme panel	In house documented procedures based on equipment manuals and standard methods as specified below:  Manual method using Diamed micro column cards ( RBH, HH)  SOPHA00172	RBH HH (manual only)
END			