


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 UKAS MEDICAL 8917 Accredited to ISO 15189:2012	Torbay & South Devon NHS Foundation Trust	
	Issue No: 004 Issue date: 09 June 2021	
	Department of Haematology & Blood Transfusion Levels 3 & 5 Torbay Hospital Lowe's Bridge Torquay TQ2 7AA United Kingdom	Contact: Nikki Harwood Tel: +44 (0) 01803-655261 Email: Nikki.harwood@nhs.net Website: http://www.torbayandsouthdevon.nhs.uk/
Testing performed by the Organisation at the locations specified below		

Site activities performed away from the locations listed above:

Location details	Activity
Community Hospital Blood Fridge – Brixham Brixham Hospital Greenswood Road Brixham Devon TQ5 9HW	Blood storage only Fridge managed by laboratory
Community Hospital Blood Fridge –Dawlish Dawlish Hospital Barton Terrace Dawlish Devon EX7 9DH	Blood storage only Fridge managed by laboratory
Community Hospital Blood Fridge -Newton Abbot Newton Abbot Hospital Jetty Marsh Road Newton Abbot Devon TQ12 4PT	Blood storage only Fridge managed by laboratory
Community Hospital Blood Fridge –Totnes Totnes Hospital Coronation Road Totnes Devon TQ8 5GH	Blood storage only Fridge managed by laboratory



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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 Venous Blood; red cells	<p><u>Blood Transfusion examinations to assist in clinical investigations</u></p> <p>Blood Grouping by antigen detection:</p> <ul style="list-style-type: none"> • A,B, AB and O groups • Rh (D) groups, <p>Additional red cell antigens determine as required Rh blood group system C^w, C, c, D, E, e Kell blood group system: K, Kp^a, Kidd blood group system: Jk^a, Jk^b, Duffy blood group system: Fy^a, Fy^b, MNS blood group system: M, N, S, s Lewis blood group system: Le^a,Le^b,</p>	<p>Procedures documented in relevant equipment manuals and in house documented procedures by the following methods</p> <p>Automated Blood grouping Analysers Immucor NEO IRIS</p> <p>SOPs: LP TRA NEO 001 Sample processing using the NEO Blood grouping Analyser LP TRA NEO 002 Maintenance and Processing Quality Control Samples using the NEO IRIS Blood Grouping Analyser Manual blood grouping procedures using DiaMed equipment and Bio-Rad ID-cards</p> <p>SOPs: LP TRA EQP 002 Maintenance and Use of the DiaMed ID-Centrifuge 12S II LP TRA EQP 003 Maintenance and use of the DiaMed ID-incubator 37SI LP TRA SER 003 Manual ABO/Rh Typing LP TRA SER 005 Rh Genotyping LP TRS SER 006 Cord Blood (Baby Group) Testing-Manual technique LP TRS SER 009 A1Typing LP TRA SER 010 Red Cell antigen typing LP TRA SER 023 Manual Baby ABO/Rh typing</p>



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HUMAN BODY FLUIDS (cont'd)	<u>Blood Transfusion examinations to assist in clinical investigations</u> (cont'd)	Procedures documented in relevant equipment manuals and in house documented procedures by the following methods
Venous Blood; plasma	Detection of the following Antibodies: Rhesus blood group antibodies: anti-C ^w , anti-C, anti-c, anti-D, anti-E, anti-e, Kell system blood group antibodies: anti-K, anti-k, anti-Kp ^a Kidd blood group antibodies: anti-Jk ^a , anti-Jk ^b Duffy blood group antibodies: anti-Fy ^a , anti-Fy ^b Lutheran blood group antibodies: anti-Lu ^a MNS blood group antibodies: anti-M, anti-N, anti-S, anti-s Lewis blood group antibodies: anti-Le ^a , anti-Le ^b P blood group antibodies: anti-P ₁	Automated antibody screening and Identification on Immucor NEO blood grouping Analysers LP TRA NEO 001 Sample processing using the NEO Blood grouping Analyser Manual antibody screening and identification procedures using Bio-Rad ID-cards. Manual blood grouping procedures using DiaMed equipment and Bio-Rad ID-cards using procedure: LP TRA SER 002 LP TRA SER 004 LP TRA SER 020 LP TRA SER 022
Venous Whole Blood	Kleihauer for foetal/maternal bleed estimation reported as ml foetal red cells in maternal circulation	SOP LP TRA SER 007 Transplacental Haemorrhage Estimation (kleihauer) and Anti-D Immunoglobulin using Immucor Kleihauer kit LP TRA SER 009 Apt Test
Venous Whole Blood	DAT – Using monospecific AHG	Manual technique using BioRad ID-cards
Venous whole Blood	Compatibility Testing of patients plasma with donor red cells	Compatibility Testing (ABO Rh, Antibody Screen. IAT X-Match) SOP LPTRA SER 011 Compatibility Testing (Paediatric Crossmatch) SOP LP TRA SER 012 Electronic Issue of Red cells SOP LP TRA SER 025



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HUMAN BODY FLUIDS (cont'd)	<u>Haematological examinations to assist in clinical diagnosis and disease management</u>	Procedures documented in relevant equipment manuals and in house documented procedures by the following methods
Venous whole blood: EDTA	Glandular fever/Infectious Mononucleosis screen (qualitative) – detection of Epstein-Barr Virus (EBV) antibodies	SOPs: LP HAE MAN 006 SOPs: LP HAE ELI 001
Venous whole blood: EDTA	Full Blood Count to include: <ul style="list-style-type: none"> • Haemoglobin • Red cell and platelet counts • Haematocrit • Differential white cell count and reticulocytes • MCV • MCH • MCHC 	ABX Pentra automated analyser using Flow cytometry, Cytochemistry, impedance, absorbance, optical cytometry and fluoro-flowcytometry and SOP's LP HAE ABX 001-Use of ABX pentra DX 120; LP HAE MAN 039-manual film report; LP HAE ABX 004-Criteria for making blood films Horiba Pentra C60+ FBC analyser Horiba Yumizen 1500/2500 SPS FBC analysers LP HAE MAN 034 LP HAE YUM 001 LP HAE YUM 002
Venous whole blood: EDTA	Blood Film reporting of normal and abnormal morphologies including WBC Diff	Manual Microscopy using SOPs: LP HAE MAN 039-Manual film report; LP HAE ABX 004-Criteria for making blood films
Venous whole blood: EDTA	Detection & speciation (thin & thick films) of malaria parasites: Plasmodium falciparum Plasmodium malariae Plasmodium ovale Plasmodium vivax Malarial antigens of: Plasmodium falciparum and pan-detection for: Plasmodium malariae, Plasmodium ovale & Plasmodium vivax	Manual Microscopy using SOPs: Preparation of thick and thin films, manual May Grunwald-Giemsa staining and light microscopy LP HAE MAN 001-Malaria thick film; LP HAE MAN 002-Malaria thin film; LP HAE MAN 039-Manual film report
		CareStart commercial kit LP HAE MAN 003; LP HAE MAN 039-Manual film report



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HUMAN BODY FLUIDS (cont'd)	<u>Haematological examinations to assist in clinical diagnosis and disease maintenance</u> (cont'd)	Procedures documented in relevant equipment manuals and in house documented procedures by the following methods
Venous whole blood :EDTA	ESR	Westergren method SOP: LP HAE MAN 042
Venous whole blood :EDTA	Plasma Viscosity for detection and monitoring of inflammation	Benson Viscometer – plasma viscometry SOP: LP HAE BEN 001
Bone Marrow	Detection of Normal and abnormal morphologies	Manual Microscopy using procedures: LP HAE GEN 006-Assisting with collection of bone marrow samples & preparation of slides; LP HAE GEN 007-Staining, filing & disposal of bone marrow slides; LP HAE MLA 001-Ironstain (haemosiderin) for bone marrow; LP HAE GEN 017 Bone marrow reporting Staining of blood films and Bone Marrow using Sudan Black stain LP HAE MLA 001-Ironstain (hemosiderin) for bone marrow
Venous whole blood :EDTA	Detection of Intrinsic Factor Antibodies	Quantalite intrinsic factor ELISA assay SOP: LP HAE ELI 002
Venous whole blood :EDTA	Thalassaemia Screening to include Quantification of Haemoglobin S,A2 and F	Documented in-house methods to meet the requirements of the SCT screening programme as defined in the July 2018 ' NHS sickle cell and thalassaemia screening programme: laboratory quality assurance evidence requirements' HPLC TOSOH G8 Analyser using SOPs: LP HAE AHB 002- Operating TOSOH G8 HPLC analyser
	Hb Electrophoresis for detection of Hb Variants	Sebia system - agarose gel electrophoresis SOP: LP HAE AHB 003
	Detection of HbS (Sickle Solubility Screen)	LP HAE AHB 009- Sickle cell screen



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HUMAN BODY FLUIDS (cont'd)	<u>Diagnostic Haemostasis</u>	Procedures documented in manufacturer's equipment manuals in conjunction with in-house procedures by the following methods
Venous Blood	Haemostasis and thrombosis examinations for the purpose of clinical diagnosis Prothrombin time (INR) Activated Partial Thromboplastin Time Fibrinogen estimation D Dimer Clotting Screen) (including PT, APTT, INR) D-Dimer vWF screen Anti-thrombin Factor 8 inhibitors Phospholipid antibody screen Thrombophilia screen Protein C Protein S Factor's 8,9,7,2,5,12,11,10	Automated testing using LP HAE STA 001-Routine coagulation on STAGO STaR Max coagulation analyser LP HAE STA 004-Factor assays;
	Anti-cardiolipin antibodies	ELISA/DS2 analyser LP HAE ELI 001 Werfen Bioflash analyser using Inova Quantaflash Anticardiolipin IgG and IgM kits
	Anti-TTG antibodies	Werfen Bioflash analyser using Inova Quantaflash TTG IgA kits
Urine	Detection of Urinary haemosiderin	Using LP HAE MLA 001-Iron stain for Bone marrow & urine
END		