

Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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



8917

Accredited to
ISO 15189:2012

Torbay and South Devon NHS Foundation Trust

Issue No: 008

Issue date: 23 December 2024

Department of Haematology &
Blood Transfusion

Level 3 Torbay Hospital

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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 –Dawlish Dawlish Hospital Barton Terrace Dawlish Devon EX7 9DH | Blood storage Fridge managed by laboratory |
| Community Hospital Blood Fridge -Newton Abbot Newton Abbot Hospital Jetty Marsh Road Newton Abbot Devon TQ12 4PT | Blood storage Fridge managed by laboratory |
| Community Hospital Blood Fridge –Totnes Totnes Hospital Coronation Road Totnes Devon TQ8 5GH | Blood storage Fridge managed by laboratory |
| Department of Haematology & Blood Transfusion Level 3 Torbay Hospital Lowe's Bridge Torquay TQ2 7AA | Blood storage |
| Level 5 Torbay Hospital Lowe's Bridge Torquay TQ2 7AA | Blood storage 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 | <u>Blood Transfusion examinations to assist in clinical investigations</u> | Procedures documented in relevant equipment manuals and in house documented procedures by the following methods |
| Venous Blood; red cells | Blood Grouping by antigen detection: A,B, AB and O groups Rh (D) groups | Automated Blood grouping Analysers Immucor NEO IRIS LP TRA1 LP TRA2 |
| 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 TRA1 LP TRA6 Manual abo/Rh D typing cards using BioRad cards LP TRA5 Manual antibody screening using Bio-Rad ID cards LP TRA4 LP TRA6 LP TRA21 |
| Venous Whole Blood | Kleihauer for foetal/maternal bleed estimation reported as ml foetal red cells in maternal circulation | Transplacental haemorrhage estimation (Kleihauer) and Anti-D immunoglobulin using Guest Medical Kleihauer kit LP TRA9 |



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| HUMAN BODY FLUIDS (cont'd) | <u>Blood Transfusion examinations to assist in clinical investigations (cont'd)</u> | Procedures documented in relevant equipment manuals and in house documented procedures by the following methods |
| Venous Whole Blood | DAT – Using monospecific AHG | Manual technique using Bio-Rad LISS/Coombs cards and DC screening II cards LP TRA3 |
| Venous Whole Blood | Compatibility Testing of patients plasma with donor red cells | Compatibility Testing (ABO Rh, Antibody Screen IAT X-Match) LP TRA13 Compatibility Testing (Paediatric Crossmatch) LP TRA14 Electronic Issue of Red cells LP TRA26 |
| HUMAN BODY FLUIDS (cont'd) | <u>Haematological examinations to assist in clinical diagnosis and disease maintenance</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 | Rapid Latex particle agglutination test supplied by Monogen LP HAE63 |
| Venous whole blood: EDTA | Full Blood Count to include: Haemoglobin Red cell Platelet counts Haematocrit Differential white cell count and reticulocytes MCV MCH MCHC WBC | Horiba Yumizen 1500/2500 automated analyser using flow cytometry, cytochemistry, impedance, absorbance, optical cytometry and fluoro-flow cytometry LP HAE2 LP HAE3 |
| Venous whole blood: EDTA | Blood Film reporting of normal and abnormal morphologies including WBC Diff | Manual Microscopy LP HAE68 |



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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 : Citrate | ESR | Modified Westergren method LP HAE22 |
| Venous whole blood: EDTA | Detection & speciation (thin & thick films) of malaria parasites: Plasmodium falciparum Plasmodium malariae Plasmodium ovale Plasmodium vivax Plasmodium knowlsei | Preparation of thick and thin films, manual May Grunwald-Giemsa staining and light microscopy LP HAE35 LP HAE36 |
| Bone Marrow and Urine | Detection of normal and abnormal morphologies | Manual microscopy and staining LP HAE80 LP HAE21 LP HAE67 Ironstain (haemosiderin) Documented in-house methods to meet the requirements of the Sickle Cell and Thalassemia screening programme as defined in the NHS Sickle Cell and thalassemia screening: Laboratory QA evidence requirements. |
| Venous whole blood: EDTA | Thalassaemia screening to include quantification of Haemoglobin S, A2 and F | Sickle cell and thalassaemia screening using Capillarys 3 Tera LP HAE90 |
| Venous whole blood: EDTA | Hb electrophoresis for detection / confirmation of Hb variants | Sebia Hydrasys 2 - agarose gel electrophoresis LP HAE9 |
| Venous whole blood: EDTA | Detection of HbS (Sickle Solubility Screen | Sickledex (Streck) LP HAE26 |



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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 Blood Citrate (plasma) | <u>Diagnostic Haemostasis</u> Haemostasis and thrombosis examinations for the purpose of clinical diagnosis Prothrombin time (INR) Activated Partial Thromboplastin Time Fibrinogen estimation Factor Assays D Dimer Clotting Screen) (including PT, APTT, INR) D-Dimer vWF screen Anti-thrombin Thrombophilia screen Protein C Protein S Factor's 8,9,7,2,5,12,11,10 Von Willebrand Factor Activity (RiCof) | STAGO STaR Max coagulation analyser LP HAE17 Routine coag / D-Dimer LP HAE38 Factor assays LP HAE45 Antithrombin LP HAE44 Protein C LP HAE46 Free Protein S LP HAE41 DRVV LP HAE37 VWF |
| Venous Blood SST (serum) | Anti-cardiolipin antibodies | Werfen Bioflash analyser using Inova Quantaflash chemiluminescence immunoassay antocardioplin and anti-B2 glycoprotein IgG and IgM kits LP HAE55 LP HAE89 |
| Venous Blood SST (serum) | Anti-TTG antibodies | Werfen Bioflash analyser using Inova Quantaflash TTG IgA kits LP HAE28 |
| Venous Blood SST (serum) | Detection of intrinsic factor antibodies | Quantalite intrinsic factor ELISA assay on DS2 LP HAE18 |
| END | | |