


# Schedule of Accreditation

issued by

## United Kingdom Accreditation Service

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

|   |  |   |
|---|--|---|
|  <p>Accredited to<br/>ISO 15189:2012</p> | <b>University Hospitals Bristol NHS Foundation Trust</b>   |   |
|   | <b>Issue No: 004    Issue date: 01 August 2017</b>   |   |
|   | <b>Haematology Department</b><br><b>Bristol Royal Infirmary</b><br><b>Marlborough Street</b><br><b>Bristol</b><br><b>BS2 8HW</b> | <b>Contact: Mrs Elizabeth Worsam</b><br><b>Tel: +44 (0) 117 3422575</b><br><b>E-Mail: Elizabeth.worsam@uhbristol.nhs.uk</b><br><b>Website: www.uhbristol.nhs.uk</b> |
| <b>Testing performed at the above address only</b>  |  |   |

### Site activities performed away from the locations listed above:

| Location details  | Activity                            | Location code |
|---|-------------------------------------|---------------|
| Blood issue fridge<br>Bristol Children's Hospital<br>Upper Maudlin Street<br>Bristol<br>BS2 8BJ                             | Storage of blood and blood products | N/A           |
| Blood issue fridge<br>St Michael's Maternity Hospital<br>Southwell Street<br>Bristol<br>BS2 8EG                             | Storage of blood and blood products | N/A           |
| Blood issue fridge<br>South Bristol Community Hospital<br>Hengrove Promenade<br>Bristol<br>BS14 0DE                         | Storage of blood and blood products | N/A           |
| Blood issue fridge<br>Cardiac ICU<br>Bristol Royal Infirmary<br>Upper Maudlin Street<br>Bristol<br>BS2 8BJ                  | Storage of blood and blood products | N/A           |
| Blood issue fridge<br>Blood Transfusion Laboratory<br>Bristol Royal Infirmary<br>Upper Maudlin Street<br>Bristol<br>BS2 8BJ | Storage of blood and blood products | N/A           |
|   |                                     |               |



8227  
Accredited to  
ISO 15189:2012

**Schedule of Accreditation**  
issued by  
**United Kingdom Accreditation Service**  
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

**University Hospitals Bristol NHS Foundation Trust**  
**Issue No: 004 Issue date: 01 August 2017**

Testing performed at main address only

| Location details   | Activity                            | Location code |
|--|-------------------------------------|---------------|
| Blood issue fridge<br>Bristol Haematology and Oncology Centre<br>Upper Maudlin Street<br>Bristol<br>BS2 8BJ      | Storage of blood and blood products | N/A           |
| Blood issue fridge<br>Heygroves Theatre<br>Bristol Royal Infirmary<br>Upper Maudlin Street<br>Bristol<br>BS2 8BJ | Storage of blood and blood products | N/A           |



8227  
Accredited to  
ISO 15189:2012

**Schedule of Accreditation**  
issued by  
**United Kingdom Accreditation Service**  
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

**University Hospitals Bristol NHS Foundation Trust**

**Issue No:** 004 **Issue date:** 01 August 2017

Testing performed at main address only

DETAIL OF ACCREDITATION

| Materials/Products tested | Type of test/Properties measured/Range of measurement   | Standard specifications/ Equipment/Techniques used   |
|---------------------------|---|--|
| HUMAN BODY FLUIDS         | <u>Haematology examinations for the purposes of clinical diagnosis</u>  | In-house documented procedures based on equipment manuals as relevant  |
| Blood                     | Full Blood Count <ul style="list-style-type: none"> <li>• Haemoglobin</li> <li>• White Blood Cell Count</li> <li>• Red Blood Count</li> <li>• Platelet Count</li> <li>• Haematocrit</li> <li>• Mean Cell Volume</li> <li>• Mean Cell Haemoglobin</li> <li>• Mean Cell Haemoglobin Concentration</li> <li>• Neutrophil count</li> <li>• Lymphocyte count</li> <li>• Monocyte count</li> <li>• Eosinophil count</li> <li>• Basophil count</li> <li>• Reticulocyte count</li> <li>• Nucleated Red Cells</li> </ul> | Using Sysmex XN-10 and Sysmex XN-20 by impedance spectrophotometry fluorescent flow cytometry.<br>LP-HAEM-XNDaily<br>LP-HAEM-XNWeekly<br>LP-HAEM-XNQC<br>LP-HAEM-XNFBC<br>LP-HAEM-XNReagent<br>LP-HAEM-XNAlarm |
|                           | Erythrocyte Sedimentation Rate  | 1) Manual technique using DispetteESR system, Westergren method<br>LP-HAEM-ESR<br>LI-HAEM-ESR<br><br>2) Diesse Vescube, Westergren method<br>LP-HAEM-ESRVescube  |
| Blood                     | G6PDH quantitative assay  | Using the Trinity Biotech G6PD Assay kit and Cecil Spectrophotometer.<br>LP-HAEM-G6PD, LI-HAEM-G6PDH   |
| Blood                     | Peripheral Blood Film Assessment  | Using Sysmex SP10 for automatic blood smear and stain<br>Sysmex SP10 for staining (after manual smear)<br>Examined by light microscopy<br>LP-HAEM-ManualFilm<br>LP-HAEM-SP-10                                  |



8227  
Accredited to  
ISO 15189:2012

**Schedule of Accreditation**  
issued by  
**United Kingdom Accreditation Service**  
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

**University Hospitals Bristol NHS Foundation Trust**

**Issue No: 004 Issue date: 01 August 2017**

Testing performed at main address only

| Materials/Products tested  | Type of test/Properties measured/Range of measurement  | Standard specifications/ Equipment/Techniques used   |
|----------------------------|--|--|
| HUMAN BODY FLUIDS (cont'd) | <u>Haematology examinations for the purposes of clinical diagnosis (cont'd)</u>  | In-house documented procedures based on equipment manuals as relevant (cont'd)   |
| Blood                      | Malaria screen for<br>P. falciparum<br>P. vivax<br>P. ovale<br>P. malariae<br>P. knowlesi  | Using Giemsa/Fields Staining for thick and thin smears and manual microscope<br>LP-HAEM-MALFILMS, LP-HAEM-MALFILMEX  |
| Blood                      | Rapid Screen Malaria pLDH and HRP2 antigens  | Malaria Antigen test using Care Start RapydTest<br>LP-HAEM-CSMALRDT  |
| Blood                      | Haemoglobinopathy<br>HbA2<br>HbF<br>Abnormal Hb  | Using Biorad HPLC Variant 2<br>LP-HAEM-HREPORTING<br>LP-HAEM-BIORADQC&SMPLS  |
| Blood                      | Sickle solubility test for presence of sickle haemoglobin (HbS)  | Streck Sickledex using SOP LP-HAEM-SICKLEDEX   |
| Blood                      | HbA1c quantification   | Menarini Hb9210 by HPLC using LP-HAEM-HBA  |
| Blood Plasma               | <u>Coagulation examinations for the purpose of clinical diagnosis</u><br><br>APTT<br>PT<br>Fibrinogen<br>INR<br>Low Molecular Weight Heparin<br>Unfractionated Heparin<br>Thrombin Clotting Time<br><br>D-Dimer<br><br>Thrombophilia testing<br><br><ul style="list-style-type: none"> <li>• Antithrombin</li> <li>• Protein C</li> <li>• Free protein S</li> <li>• Activated protein C resistance</li> <li>• Lupus Anticoagulant Assay</li> </ul> | Using Sysmex CS2100i, coagulation and chromogenic methods using SOPs<br>LP-COAG-Xa<br><br>LP-COAG-D-Dimer<br><br>Using Sysmex CS2100i, coagulation, chromogenic, immunoassay and aggregation assays.<br><br><ul style="list-style-type: none"> <li>} LP-COAG-Thrombo</li> <li>LP-COAG-LUPUS</li> </ul> |



8227  
Accredited to  
ISO 15189:2012

**Schedule of Accreditation**  
issued by  
**United Kingdom Accreditation Service**  
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

**University Hospitals Bristol NHS Foundation Trust**

**Issue No:** 004 **Issue date:** 01 August 2017

Testing performed at main address only

| Materials/Products tested  | Type of test/Properties measured/Range of measurement  | Standard specifications/ Equipment/Techniques used  |
|--|--|---|
| HUMAN BODY FLUIDS AND TISSUES (cont'd)   | <u>Coagulation examinations for the purpose of clinical diagnosis</u> (cont'd)                     | In-house documented procedures based on equipment manuals as relevant (cont'd)  |
|  | Von Willebrand Factor Antigen  | LP-COAG-VWAG<br>LP-COAG-RICOF   |
|  | Ristocetin Factor and CoFactor Assays: II; V; VII; VIII; IX; X; XI and XII XIII                    | LP-COAG-Factor Assays<br>LP-COAG-Factor XIII  |
| Platelet rich plasma   | Platelet aggregation studies detecting platelet aggregation reported as percentage aggregation     | Using PAP-8E aggregometer and light transmission aggregometry<br>LP-COAG-Platelet Aggregation   |
|  | <u>Haematology examinations for the purposes of clinical diagnosis</u>                             | In-house documented procedures based on equipment manuals as relevant   |
| Bone Marrow aspirate<br>Peripheral Blood<br>Cerebrospinal fluids<br>Effusions/other fluids<br>Tissues and fine needle aspirates as defined below | Immunophenotyping  | Becton Dickinson LSR Fortessa flow cytometer using SOP LP-FLOW-CANTO and LP-FLOW-FORTESSA.<br>Measurements using monoclonal antibodies and other fluorescent labels and Laser flow cytometry  |
| Blood  | CD34 enumeration   | LP-FLOW-CD34  |
| Blood  | Measurement of Platelet glycoprotein   | LP-FLOW-PLATELET GP   |
| HUMAN BODY FLUIDS  | <u>Haematology Molecular examinations</u><br><u>Genetic studies for detection of gene mutation</u> | Polymerase chain reactions, and where applicable, sequencing of RNA and DNA products.   |
| Blood and bone marrow<br>Blood<br>Blood  | JAK2 V617F<br>Factor 5 Leiden<br>Prothrombin gene mutation   | Extraction by Promega Maxwell followed by real-time PCR and melting curve analysis using a LightCycler 1.5 Thermocycler using SOPs: LP-MOL-Maxbld and LP-MOL-LJAK2, LP-MOL-LFVL or LP-MOL-LPT.  |
| Bone marrow and blood<br>Blood<br>Formalin fixed paraffin embedded tissues (FFPE)  | FLT3, NPM1<br>IgV <sub>H</sub> mutation status   | Extraction by Promega Maxwell followed by PCR using a Biometra, Peqlab or BIOER Thermocycler and gel electrophoresis using the Agilent TapeStation using SOPs:LP-MOL-Maxbld and LP-MOL-FLT3, LP-MOL-NPM1, LP-MOL-IGV or LP-MOL-gist followed by LP-MOL-TapeStation and LP-MOL-seq if applicable |



8227  
Accredited to  
ISO 15189:2012

**Schedule of Accreditation**  
issued by  
**United Kingdom Accreditation Service**  
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

**University Hospitals Bristol NHS Foundation Trust**

**Issue No: 004 Issue date: 01 August 2017**

Testing performed at main address only

| Materials/Products tested     | Type of test/Properties measured/Range of measurement                            | Standard specifications/ Equipment/Techniques used   |
|-------------------------------|--|--|
| HUMAN BODY FLUIDS (cont'd)    | <u>Haematology Molecular examinations for the purposes of clinical diagnosis</u> | In-house documented procedures based on equipment manuals as relevant (cont'd)   |
| Bone marrow or blood          | Quantitative BCRABL  | Manual RNA extraction using the 5Prime RNA extraction kit followed by cDNA generation using the Biometra Thermocycler followed by Real-time quantitative PCR using a LightCycler 1.5 using SOP LP-MOL-BCQ  |
| Blood, bone marrow or FFPE    | TCR and IgH Clonality  | Extraction by Promega Maxwell followed by PCR using a Biometra, Peqlab or BIOER Thermocycler and gel electrophoresis using the Agilent Tapestation, using SOPs LP-MOL-IGH or LP-MOL TCRgclonality  |
| HUMAN BODY FLUIDS AND TISSUES | <u>Haematology examinations for the purposes of clinical diagnosis</u>           | In-house documented procedures based on equipment manuals as relevant (cont'd)   |
|                               | Detection of (8;21), t(15;17), Inv (16)  | Manual RNA extraction using the 5Prime RNA extraction kit followed by cDNA generation using the Biometra Thermocycler followed by nested PCR using a Biometra, Peqlab or BIOER Thermocycler and gel electrophoresis using the Agilent Tapestation, using SOPs: LP-MOL-RNA extract, LP-MOL-RTPCRmann and LP-MOL-NESTEDAML |



8227  
Accredited to  
ISO 15189:2012

**Schedule of Accreditation**  
issued by  
**United Kingdom Accreditation Service**  
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

**University Hospitals Bristol NHS Foundation Trust**

**Issue No:** 004    **Issue date:** 01 August 2017

Testing performed at main address only

| Materials/Products tested              | Type of test/Properties measured/Range of measurement   | Standard specifications/ Equipment/Techniques used   |
|--|---|--|
| HUMAN BODY FLUIDS AND TISSUES (cont'd) | <u>Haematology examinations for the purposes of clinical diagnosis (cont'd)</u>   | In-house documented procedures based on equipment manuals as relevant (cont'd)   |
|  | <u>Blood Transfusion</u>  |  |
| Blood                                  | Cross match   | Manual column agglutination in Diamed ID cards<br>LP-BTR-COMPATIBILITY<br>LP-BTR-GROUPCONF<br>LP-BTR-MANGROUP<br>LP-BTR-RBCISSUE<br>LP-BTR-EISSUE  |
| Blood                                  | Blood Groups  |  |
|  | Antibody panels<br>Antigens of the following systems:<br>Rh – C, D, E, c, e, Cw<br>Kell – K, K, Kpa<br>Duffy – Fya, Fyb<br>MNSs M, N, S, s<br>Kidd – JKa, Jkb<br>Lutheran – Lua<br>Lewis – Lea, Leb<br>P – P1 | Using Diamed H100 and Gel-station, column agglutination<br>LP-BTR-IH1000<br>LP-BTR-ABP<br>LP-BTR-GELSTATION<br>LP-BTR-ANTENATAL<br>LP-BTR-MANGROUP |
| Blood                                  | Measurement of foetal Hb in maternal blood for FMH determination  | SOP LP-BTR-KLE using the Kleihauer technique with acid elution and the Clin-Tech Shepard's stain kit.  |
| Blood                                  | Phenotyping<br>Rhesus and K phenotyping<br>Rh – C, D, E, c, e<br>Kell - K   | Manual technique Using Diamed Cards<br>LP-BTR-RhKPHENO   |
| Blood                                  | Direct antiglobulin test for detection of antibody bound red cells  | Using the Tube Technique and Cell Washer<br>LP-BTR-DCT   |
| Serum                                  | <u>Immunology examinations for the purpose of clinical diagnosis</u>  | In-house documented procedures based on equipment manuals as relevant  |
|  | Detection of:   | Using DS2 automated ELISA processor and reader with the following kits   |
|  | <ul style="list-style-type: none"> <li>• Anti-PR3 autoantibodies</li> <li>• Anti-MPO autoantibodies</li> <li>• Intrinsic Factor antibodies</li> </ul>   | Quanta Lite by Inova Diagnostics using SOP LP-IMM-PR3, SOP LP-IMM-MPO and LP-IMM-Intrinsic Factor  |



8227  
Accredited to  
ISO 15189:2012

**Schedule of Accreditation**  
issued by  
**United Kingdom Accreditation Service**  
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

**University Hospitals Bristol NHS Foundation Trust**

**Issue No: 004 Issue date: 01 August 2017**

Testing performed at main address only

| Materials/Products tested                      | Type of test/Properties measured/Range of measurement   | Standard specifications/ Equipment/Techniques used   |
|--|---|--|
| <p>HUMAN BODY FLUIDS</p> <p>Serum (cont'd)</p> | <p><u>Blood Transfusion</u> (cont'd)</p> <p><u>Immunology examinations for the purpose of clinical diagnosis</u> (cont'd)</p> <p>Detection of Cardiolipin antibody</p> <p>Detection of DNA antibody</p> <p>Detection of Anti CCP antibody</p> <p>Extractable Nuclear Antigen (ENA) screening test and ENA antibody confirmation</p> <p>Detection of heterophile antibodies to Infectious mononucleosis (Glandular fever) (Paul Burnell)</p> <p>Detection of Rheumatoid factor - screening test</p> <p>Autoimmune testing</p> <p>ANCA</p> <p>Anti-nuclear Ab (ANA)</p> <p>Anti smooth muscle Ab</p> <p>Anti gastric parietal cell Ab</p> <p>Anti mitochondrial Ab</p> <p>Anti liver/kidney microsomal Ab</p> | <p>Documented in-house procedures based on equipment manuals as relevant</p> <p>In-house documented procedures based on equipment manuals as relevant</p> <p>Organtec kit using SOP LP-IMM-ACA</p> <p>Diastat kit using SOP LP-IMM-DNA</p> <p>Inova kit using SOP LP-IMM-CCP</p> <p>Ogantec kit using SOPs LP-IMM-ENA and LP-IMM-ENT</p> <p>Monogen kit using SOP LP-IMM-SHA</p> <p>Biokit kit using SOP LP-IMM-RAL</p> <p>Automated film preparation using an ASP processor (SOP LP-IMM-ASP-1200) followed by staining with FITC reagent and fluorescent microscopy using the following SOPs</p> <p>LP-IMM-ANCA</p> <p>LP-IMM-HP2</p> <p>LP-IMM-AIP</p> <p>LP-IMM-AIP</p> <p>LP-IMM-AIP</p> <p>LP-IMM-AIP</p> |

END