


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 <p>UKAS MEDICAL 8227</p> <p>Accredited to ISO 15189:2012</p>	<p>University Hospitals Bristol and Weston NHS Foundation Trust</p> <p>Issue No: 008 Issue date: 30 June 2020</p>	
	<p>Haematology Department Bristol Royal Infirmary Marlborough Street Bristol BS2 8HW</p>	<p>Contact: Mrs Elizabeth Worsam Tel: +44 (0) 117 3422575 E-Mail: Elizabeth.worsam@uhbw.nhs.uk Website: www.uhbnhs.uk</p>
<p>Testing performed at the above address only</p>		

Site activities performed away from the locations listed above:

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

Issue No: 008 Issue date: 30 June 2020

Testing performed at main address only

Location details	Activity	Location code
Blood issue fridge Bristol Haematology and Oncology Centre Upper Maudlin Street Bristol BS2 8BJ	Storage of blood and blood products	N/A
Blood issue fridge Heygroves Theatre Bristol Royal Infirmary Upper Maudlin Street Bristol 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 and Weston NHS Foundation Trust

Issue No: 008 Issue date: 30 June 2020

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"> • Haemoglobin • White Blood Cell Count • Red Blood Count • Platelet Count • Haematocrit • Mean Cell Volume • Mean Cell Haemoglobin • Mean Cell Haemoglobin Concentration • Neutrophil count • Lymphocyte count • Monocyte count • Eosinophil count • Basophil count • Reticulocyte count • Nucleated Red Cells 	Using Sysmex XN-10 and Sysmex XN-20 by impedance spectrophotometry fluorescent flow cytometry. LP-HAEM-XNDaily LP-HAEM-XNWeekly LP-HAEM-XNQC LP-HAEM-XNFBC LP-HAEM-XNReagent LP-HAEM-XNAlarm
	Erythrocyte Sedimentation Rate	1) Manual technique using DispetteESR system, Westergren method LP-HAEM-ESR LI-HAEM-ESR 2) Diesse Vescube, Westergren method LP-HAEM-ESRVescube
Blood	G6PDH quantitative assay	Using the Trinity Biotech G6PD Assay kit and Cecil Spectrophotometer. LP-HAEM-G6PD, LI-HAEM-G6PDH
Blood	Peripheral Blood Film Assessment	Using Sysmex SP10 for automatic blood smear and stain Sysmex SP10 for staining (after manual smear) Examined by light microscopy LP-HAEM-ManualFilm 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 and Weston NHS Foundation Trust

Issue No: 008 Issue date: 30 June 2020

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</u> (cont'd)	In-house documented procedures based on equipment manuals as relevant (cont'd)
Blood	Malaria screen for P. falciparum P. vivax P. ovale P. malariae P. knowlesi	Using Giemsa/Fields Staining for thick and thin smears and manual microscope LP-HAEM-MALFILMS, LP-HAEM-MALFILMEX
Blood	Rapid Screen Malaria pLDH and HRP2 antigens	Malaria Antigen test using Care Start RapydTest LP-HAEM-CSMALRDT
Blood	Haemoglobinopathy HbA2 HbF Abnormal Hb	Using Biorad HPLC Variant 2 LP-HAEM-HREPORTING 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>	
	APTT PT Fibrinogen INR Low Molecular Weight Heparin Unfractionated Heparin Thrombin Clotting Time	Using Sysmex CS2500 analyser, coagulation and chromogenic methods using SOPs LP-COAG-Xa LP-COAG-CS2500
	D-Dimer	LP-COAG-D-Dimer
	Thrombophilia testing	Using Sysmex CS2500 analyser, coagulation, chromogenic, immunoassay and aggregation assays. LP-COAG-CS2500
	<ul style="list-style-type: none"> • Antithrombin • Protein C • Free protein S • Activated protein C resistance • Lupus Anticoagulant Assay 	} LP-COAG-Thrombo LP-COAG-LUPUS



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 and Weston NHS Foundation Trust
Issue No: 008 **Issue date:** 30 June 2020

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 AND TISSUES (cont'd)</p> <p>Bone Marrow aspirate Peripheral Blood Cerebrospinal fluids Effusions/other fluids Tissues and fine needle aspirates</p>	<p><u>Specialist Integrated Haematological Malignancies Diagnostics Services (SIHMDS) investigations for the purposes of clinical diagnosis</u></p> <p>Immunophenotyping of the following markers/antigens to diagnose and monitor the following disorders:</p> <p>Acute Leukaemia Mastocytosis Myelodysplastic/myeloproliferative neoplasms Mature Lymphoid Disorders B cell and T cell Lymphoproliferative Disorders Lymphoma Myeloma/Plasma cell neoplasms</p> <p>CD15 CD16 CD19 CD20 CD22 CD23 CD24 CD25 CD26 CD30 CD33 CD34 CD36 CD41 CD42 CD43 CD45 CD49d CD56 CD57 CD58 CD59 CD61 CD64 CD71 CD79a CD79b CD81</p>	<p>In-house documented procedures based on equipment manuals as relevant</p> <p>Becton Dickinson FACS Canto 10 and LSR Fortessa laser flow cytometry and: SOP LP-FLOW-CANTO and LP-FLOW-FORTESSA. LP-FLOW-Acquisition LP-FLOW-IS LP-FLOW-ACUTE LP-FLOW-MDS LP-FLOW-BLPD LP-FLOW-TLPD LP-FLOW-Plasma Cell LP-FLOW-CSF LP-FLOW-Non-Haem LP-Flow-Nuclear</p>



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 and Weston NHS Foundation Trust

Issue No: 008 Issue date: 30 June 2020

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 AND TISSUES (cont'd)</p> <p>Bone Marrow aspirate Peripheral Blood Cerebrospinal fluids Effusions/other fluids Tissues and fine needle aspirates</p>	<p><u>Specialist Integrated Haematological Malignancies Diagnostics Services (SIHMDS) investigations for the purposes of clinical diagnosis</u></p> <p>Immunophenotyping of the following markers/antigens to diagnose and monitor the following disorders:</p> <p>Acute Leukaemia Mastocytosis Myelodysplastic/myeloproliferative neoplasms Mature Lymphoid Disorders B cell and T cell Lymphoproliferative Disorders Lymphoma Myeloma/Plasma cell neoplasms</p> <p>CD99 CD103 CD117 CD123 CD138 CD200 CD203c CD303 MPO Kappa Lambda TdT IgM NG-2 TCRab TCRgd GPA</p>	<p>In-house documented procedures based on equipment manuals as relevant</p> <p>Becton Dickinson FACS Canto 10 and LSR Fortessa laser flow cytometry and: SOP LP-FLOW-CANTO and LP-FLOW-FORTESSA. LP-FLOW-Acquisition LP-FLOW-IS LP-FLOW-ACUTE LP-FLOW-MDS LP-FLOW-BLPD LP-FLOW-TLPD LP-FLOW-Plasma Cell LP-FLOW-CSF LP-FLOW-Non-Haem LP-Flow-Nuclear</p>



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 and Weston NHS Foundation Trust
Issue No: 008 **Issue date:** 30 June 2020

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>Specialist Integrated Haematological Malignancies Diagnostics Services (SIHMDS) investigations for the purposes of clinical diagnosis</u>	In-house documented procedures based on equipment manuals as relevant
Peripheral Blood	Immunophenotyping of the following markers/antigens to diagnose and monitor the following disorders Paroxysmal Nocturnal Haemoglobinuria FLAER GPA CD59 CD24 CD14 CD16 CD45 CD64	BD FACS Canto 10 Flow Cytometer BD LSR Fortessa Flow Cytometer and LP-FLOW-CANTO LP-FLOW-Fortessa LP-FLOW-Acquisition LP-FLOW-PNH
Blood	CD34+ stem cell absolute count Using the following antisera: CD34 CD45	BD FACS Canto Flow Cytometer BD LSR Fortessa Flow Cytometer and LP-FLOW-CANTO LP-FLOW-Fortessa LP-FLOW-Acquisition LP-FLOW-CD34
Blood	Measurement of Platelet glycoprotein CD41 CD42a CD61 CD36 CD45	Becton Dickinson FACS Canto 10 and LSR Fortessa laser flow cytometry and: SOP LP-FLOW-CANTO and LP-FLOW-FORTESSA. LP-FLOW-Acquisition LP-FLOW-PLATELET GP



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 and Weston NHS Foundation Trust
Issue No: 008 Issue date: 30 June 2020

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>Blood Transfusion investigations for the purposes of clinical diagnosis</u>	In-house documented procedures based on equipment manuals as relevant
Blood	Cross match	Manual column agglutination in Bio RadID cards LP-BTR-COMPATIBILITY LP-BTR-GROUPCONF LP-BTR-MANGROUP LP-BTR-RBCISSUE LP-BTR-EISSUE
Blood	Blood Groups Antibody panels Antigens of the following systems: Rh – C,D,E,c,e, Cw Kell – K, K, Kpa Duffy –Fya, Fyb MNSs M, N, S, s Kidd – JKa, Jkb Lutheran – Lua Lewis – Lea, Leb P – P1	Bio Rad IH1000 column agglutination LP-BTR-IH1000 LP-BTR-ABP LP-BTR-GELSTATION LP-BTR-ANTENATAL 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 Rhesus and K phenotyping Rh – C, D, E, c, e Kell - K	Manual technique Using Bio Rad Cards LP-BTR-RhKPHENO
Blood	Direct antiglobulin test for detection of antibody bound red cells	Using the Tube Technique and Cell Washer LP-BTR-DCT



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 and Weston NHS Foundation Trust

Issue No: 008 Issue date: 30 June 2020

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) Serum	<p><u>Immunology examinations for the purpose of clinical diagnosis</u></p> <p>Detection of:</p> <ul style="list-style-type: none"> • Anti-PR3 autoantibodies • Anti-MPO autoantibodies • Intrinsic Factor antibodies <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 Anti-nuclear Ab (ANA) Anti smooth muscle Ab Anti gastric parietal cell Ab Anti mitochondrial Ab Anti liver/kidney microsomal Ab</p>	<p>In-house documented procedures based on equipment manuals as relevant In-house documented procedures based on equipment manuals as relevant</p> <p>Using DS2 automated ELISA processor and reader with the following kits</p> <p>Quanta Lite by Inova Diagnostics using SOP LP-IMM-PR3, SOP LP-IMM-MPO and LP-IMM-Intrinsic Factor</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>Manual assay using Biokit kit and 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 LP-IMM-HP2 LP-IMM-AIP LP-IMM-AIP LP-IMM-AIP LP-IMM-AIP</p>
END		