


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 <p>9073</p> <p>Accredited to ISO 15189:2012</p>	University Hospitals Dorset NHS Foundation Trust	
	Issue No: 004 Issue date: 01 October 2020	
	Haematology Department Royal Bournemouth Hospital Castle Lane East Bournemouth BH7 7DW	Contact: Nathan Bourne Tel: +44 (0) 300 019 4879 E-Mail: nathan.bourne@uhd.nhs.uk Website: www.uhd.nhs.uk
Testing performed by the Organisation at the locations specified below		

Locations covered by the organisation and their relevant activities

Laboratory locations:

Location details	Activity	Location code
Haematology Department The Royal Bournemouth Hospital Castle Lane East Bournemouth BH7 7DW	Local contact Simon Mclean Tel: +44 (0) 300 019 4796 E-Mail: simon.mclean@rbch.nhs.uk	RBH
	Local contact Mike Trevett Tel: +44 (0) 300 019 4800	
	Local contact Dr Rachel Ibbotson Tel: +44 (0) 300 019 4805 E-Mail: rachel.ibbotson@rbch.nhs.uk	
	Routine Haematology Coagulation	
	Blood Transfusion	
	Flow Cytometry Molecular Pathology	

Site activities performed away from the locations listed above:

Location details	Activity
Main Theatre The Royal Bournemouth Hospital Castle Lane East Bournemouth BH2 7DW	No testing occurs on this site, blood storage only
Issue Fridge Room The Royal Bournemouth Hospital Castle Lane East Bournemouth BH2 7DW	No testing occurs on this site, blood storage only



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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 TISSUE AND FLUIDS	<u>Haematology examinations for the purposes of clinical diagnosis</u>	Following in-house documented procedures and manufacturer's equipment instructions where relevant	
Blood (EDTA)	Full blood counts and automated differential: Haemoglobin (Hb) White Blood Cell Count (WBC) Red Blood Count (RBC) Platelet Count Mean Cell Volume (MCV) Mean Cell Haemoglobin (MCH) Mean Cell Haemoglobin Concentration (MCHC) Neutrophils Lymphocytes Monocytes Eosinophils Basophils Reticulocytes	Siemens Advia 2120i analyser flow cytometry, laser light refraction, Hb colorimetric measurement and light absorption for reticulocytes B-HAE-M-H00040 B-HAE-P-H00074 B-HAE-P-H00175	RBH
Blood (EDTA)	Erythrocyte Sedimentation Rate (ESR)	Alifax test1 analyser – photometrical capillary stopped flow kinetic analysis B-HAE-P-H00270	RBH
Bone marrow	Examination of bone marrow films: in order to identify or exclude Morphological and Cytological abnormalities for the purpose of diagnosis	Manual slide preparation and interpretation. Staining using the Merck Miratsainer II and manual staining (Romanovsky and Perls stain) B-HAE-P-H0003 B-HAE-P-H00026 B-HAE-P-H00273	RBH



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HUMAN TISSUE AND FLUIDS (cont'd)	<u>Haematology examinations for the purposes of clinical diagnosis (cont'd)</u>	Following in-house documented procedures and manufacturer's equipment instructions where relevant	
Blood	Blood Film: Detection of normal and abnormal morphologies and white blood cell differential	Manual slide preparation and interpretation. Staining using the Merck Miratsainer II and manual staining (Romanovsky and Perls stain) B-HAE-P-H00003 B-HAE-P-H00249	RBH
Blood (EDTA)	Rapid diagnostic test for detection of Malarial antigens of: <i>P. falciparum</i> and /or Pan-detection for <i>P. malariae</i> , <i>P. ovale</i> & <i>P. vivax</i>	Manual method using CareStart Malaria RapydTest HRP2/pLDH B-HAE-P-H00269	RBH
Blood (EDTA)	Demonstration of Malaria Parasites	Microscopy & cytochemistry (Thick and thin films stained by Fields stain and Giemsa) B-HAE-P-H00089	RBH
Blood (EDTA)	Glandular fever by detection of IM IgM heterophile antibodies	Biokit Monogen IM (Infectious Mononucleosis) test using one step rapid latex particle agglutination test B-HAE-P-H00005	RBH
Blood	Vitamin B12 Folate Ferritin	Siemens Centaur XP Chemiluminescence immunoassay B-HAE-M-H00030	RBH



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HUMAN TISSUE AND FLUIDS (cont'd)	<u>Haematology examinations for the purposes of clinical diagnosis (cont'd)</u>	Following in-house documented procedures and manufacturer's equipment instructions where relevant	
Plasma	Coagulation screen: Prothrombin time INR Activated partial thromboplastin time and ratio Clauss fibrinogen D-Dimer Thrombin time Reptilase time Direct oral anticoagulant assays	Werfen ACL TOP700 light transmission for turbidometric measurement and chromogenic assay B-HAE-M-H00020 B-HAE-M-H00021 B-HAE-M-H00026	RBH
Plasma	Factors II, V, VII, VIII, VIII(Ag), IX, X, XI, XII, XIII and Bethesda Assay for Factor inhibitors	Werfen ACL TOP700 light transmission for turbidometric measurement and chromogenic assay B-HAE-M-H00024	RBH
Plasma	Anti Thrombin (Functional)	Werfen ACL TOP700 Chromogenic assay B-HAE-M-H00023	RBH
Plasma	Protein C Activity	Werfen ACL TOP700 Chromogenic assay B-HAE-M-H00023	RBH
Plasma	Protein S Activity	Werfen ACL TOP700 Chromogenic assay B-HAE-M-H00023	RBH
Plasma	Free Protein S Functional Protein S	Werfen ACL TOP700 Turbidometric measurement of immuno induced agglutination B-HAE-M-H00023	RBH
Plasma	Lupus test – DRVVT, KCT and Silica Clotting Time	Werfen ACL TOP700 light transmission for turbidometric measurement B-HAE-M-H00022	RBH



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HUMAN TISSUE AND FLUIDS (cont'd)	<u>Haematology examinations for the purposes of clinical diagnosis (cont'd)</u>	Following in-house documented procedures and manufacturer's equipment instructions where relevant	
Plasma	Plasminogen and Plasmin Inhibitor	Werfen ACL TOP700 Chromogenic assay B-HAE-M-H00023	RBH
Plasma	Activated Protein C Resistance (APCr)	Werfen ACL TOP700 light transmission for turbidometric measurement B-HAE-M-H00023	RBH
Plasma	Von Willebrand antigen, activity	Werfen ACL TOP700 Latex particle enhanced Immunoturbidimetric assay B-HAE-M-H00024	RBH
Plasma	Von Willebrand Ristocetin CoFactor activity	Werfen ACL TOP700 Latex particle enhanced Immunoturbidimetric assay B-HAE-M-H00024	RBH
Plasma	Platelet function (PFA)	PAP 8E aggregometer Platelet aggregation using agonists measured by optical transmission B-HAE-M-H00025	RBH
Plasma	Thrombocytopenia screen – detection of antibodies to platelet factor 4 and heparin	Bio-Rad Heparin/PF4 Antibody test Particle Gel Immuno Assay B-HAE-P-H00537	RBH
Plasma	Thromboelastograph Measurement of clot viscoelasticity	Haemascope TEG5000 analyser Thromboelastography B-HAE-P-H00566	RBH



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HUMAN TISSUE AND FLUIDS (cont'd)	<u>Blood transfusion examinations</u>	Documented in-house procedures based on manufacturer's instructions	RBH
Whole blood (EDTA)	Blood group by detection and identification of antigens – A B O and AB groups Rh groups: Rh D Positive, Rh D Negative	Automated method using Bio-Rad IH-1000 analyser and Diamed gel cards from Bio-Rad B-TRA-P-T00069 B-TRA-P-T00070 B-TRA-P-T00082 B-TRA-P-T00083 B-TRA-P-T00084	RBH
Whole blood (EDTA)	Blood group by detection and identification of antigens – A B O and AB groups Rh groups: Rh D Positive, Rh D Negative	Manual methods using tube method SOP B-TRA-P-T00048	RBH
Whole blood (EDTA)	Antibody screening Detection of antibodies to the following antigens – C ^w , C, c, D, E, e K, k, Kp ^a , Kp ^b Jk ^a , Jk ^b Fy ^a , Fy ^b Lu ^a , Lu ^b M, N, S, s Le ^a , Le ^b P1	Automated method using Bio-Rad IH-1000 analyser and Diamed gel cards from Bio-Rad B-TRA-P-T00069 B-TRA-P-T00070 B-TRA-P-T00082 B-TRA-P-T00083 B-TRA-P-T00084	RBH
Whole blood (EDTA)	Antibody identification using cells containing the following antigens: C ^w , C, c, D, E, e K, k, Kp ^a , Kp ^b Jk ^a , Jk ^b Fy ^a , Fy ^b Lu ^a , Lu ^b M, N, S, s Le ^a , Le ^b P1	Automated method using Bio-Rad IH-1000 analyser and Diamed gel cards from Bio-Rad B-TRA-P-T00051 B-TRA-P-T00059	RBH



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HUMAN TISSUE AND FLUIDS (cont'd)	<u>Blood transfusion examinations (cont'd)</u>	Documented in-house procedures based on manufacturer's instructions	
Whole blood (EDTA)	Antibody identification using cells containing the following antigens: C ^w , C, c, D, E, e K, k, Kp ^a , Kp ^b Jk ^a , Jk ^b Fy ^a , Fy ^b Lu ^a , Lu ^b M, N, S, s Le ^a , Le ^b P1	Manual methods using Diamed gel cards from Bio-Rad B-TRA-P-T00051 B-TRA-P-T00059	RBH
Whole blood (EDTA)	Serological compatibility testing between donor red cell antigens and patient plasma including manual group and antibody screen and blood selection	Manual process B-TRA-P-T00002 B-TRA-P-T00003 B-TRA-P-T00005 B-TRA-P-T00009 B-TRA-P-T00010 B-TRA-P-T00048	RBH
Whole blood (EDTA)	Direct Antiglobulin Test (DAT)	Automated method using Bio-Rad IH-1000 analyser and Diamed gel cards from Bio-Rad B-TRA-T00049 B-TRA-T00069	RBH
Whole blood (EDTA)	Direct Antiglobulin Test (DAT)	Manual methods using Diamed gel cards from Bio-Rad B-TRA-P-T00049	RBH
Whole blood (EDTA)	Red cell phenotyping for the following antigens: C ^w , C, c, D, E, e K, k, Kp ^a , Kp ^b Jk ^a , Jk ^b Fy ^a , Fy ^b Lu ^a , Lu ^b M, N, S, s Le ^a , Le ^b P1 A ₁	Manual methods using Diamed gel cards from Bio-Rad B-TRA-P-T00055 B-TRA-P-T00063 B-TRA-P-T00068	RBH



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HUMAN TISSUE AND FLUIDS (cont'd)	<u>Blood transfusion examinations (cont'd)</u>	Documented in-house procedures based on manufacturer's instructions	
Whole blood (EDTA)	Feto-Maternal Haemorrhage Estimation (FMH)	Manual Kleihauer using commercial kit SOP B-TRA-P-T00053	RBH
Whole blood (EDTA)	Cord blood group determination	Manual methods using Diamed gel cards from Bio-Rad B-TRA-P-T00052	RBH
Whole blood (EDTA)	Cord blood group determination	Automated process using Biorad IH1000 analyser and Diamed gel cards from Bio-Rad B-TRA-P-T00069 B-TRA-P-T00052	RBH
	<u>Molecular testing for the purpose of clinical diagnosis</u>	Following in-house documented procedures and manufacturer's equipment instructions where relevant	
Blood/serum	Mutation detection for Factor V Leiden and Prothrombin Variant	Cepheid GeneXpert DNA Extraction, amplification and detection in one cartridge B-HAE-M-H00023	RBH
Bone Marrow / Peripheral Blood / FFPE		DNA extraction for downstream applications/assays using: Qiagen EZ1 DNA extraction platform Qiagen DNA extraction by column (manual)	RBH



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HUMAN TISSUE AND FLUIDS (cont'd)	<u>Molecular testing for the purpose of clinical diagnosis</u>	Following in-house documented procedures and manufacturer's equipment instructions where relevant	
DNA	EGFR mutation detection	Qiagen RGQ real-time PCR machine (mutations screened: exon 19 deletions, L858R, L861Q, G719X, S768I, exon 20 insertions, and the resistance mutation T790M) B-MOL-P-NAT001 B-MOL-P-NAT002 B-MOL-P-NAT016	RBH
DNA	Detection of <ul style="list-style-type: none"> • KRAS mutation • NRAS mutation 	Life technologies 9700 PCR machine and Qiagen PyroMark Q24 system KRAS - PCR and pyrosequencing (codons 12, 13, 61 & 146) NRAS - PCR and pyrosequencing (codons 12, 13 & 61) B-MOL-P-NAT001 B-MOL-P-NAT011	RBH



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HUMAN TISSUE AND FLUIDS (cont'd)	<u>Immunophenotyping examinations for the purposes of clinical diagnosis</u>	Using manufacturers instructions for Becton Dickinson FACSCanto II 3 laser flow cytometer and in house procedures	
Blood, bone marrow, CSF, pleural fluid, Fine Needle Aspirates, lymphoid tissues (e.g. Lymph node/spleen) or other tissues or fluids.	Leukaemia and Lymphoma Immunophenotyping using the following markers for the purpose of Haematological Diagnosis and monitoring: CD2, CD3, CD4, CD5, CD7, CD8, CD10, CD11b, CD11c, CD13, CD14, CD15, CD16, CD19, CD20, CD22, CD23, CD25, CD26, CD27, CD30, CD33, CD34, CD36, CD38, CD43, CD45, CD49d, CD52, CD56, CD57, CD64, CD71, CD79b, CD81, CD85k, CD103, CD117, CD123, CD138, CD163, CD200, CD235a, CD300e, Kappa, Lambda, TCR $\alpha\beta$, TCR $\gamma\delta$, HLA-DR, FMC7, TDT, MPO, NG2, IGG	Multicolour Flow Cytometry using relevant panels acquired and analysed using BD Flow Cytometer and software as per B-MOL-P-FLW003 B-MOL-P-FLW008 B-MOL-P-FLW023	RBH
EDTA Blood	CD34 viable absolute count enumeration CD34, CD45, 7-AAD, BD Trucount	BD Flow Cytometer and FACS Clinical software as per B-MOL-P-FLW034	RBH
EDTA Blood	CD4 Immune monitoring/absolute count enumeration (CD3, CD4, CD8, CD45, BD Trucount).	BD Flow Cytometer and FACS Clinical software Sample preparation by BD SPA III as per B-MOL-P-FLW006	RBH
END			