


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 10259 Accredited to ISO 15189:2012	Birmingham Women's and Children's NHS Foundation Trust	
	Issue No: 003 Issue date: 07 August 2020	
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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
Address	Local contact		
Address Haematology Department Birmingham Women's Hospital Mindelsohn Way Edgbaston Birmingham B15 2TG	Local contact Ms Julie Cooper	Haematology Coagulation Transfusion	A
Address Biochemistry Department Birmingham Women's Hospital Mindelsohn Way Edgbaston Birmingham B15 2TG	Local contact Dr Sarah Heap	Biochemistry - FASP	B



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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 BODY FLUIDS			
EDTA Plasma / Red Blood Cells. Neonatal EDTA Red Blood Cells	<p><u>Blood Transfusion examinations to assist in clinical investigations</u></p> <p>Blood Group by detection and identification of antigens: A Rh D Positive AB Rh D Positive B Rh D Positive O Rh D Positive A Rh D Negative AB Rh D Negative B RhD Negative O Rh D Negative</p>	<p>Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:</p> <p>IBG Immucor NEO Iris Analyser SOP1527: ABO/D group, antibody screen and DAT using the NEO Iris analyser</p> <p>IBG Immucor ECHO Lumena Analyser SOP1565: ABO/ D group antibody screen and DAT using the ECHO Lumena analyser</p> <p>Manual test using Grifols DG Therm incubator and DG Spin centrifuge using Grifols DG Gel ABO/Rh (2D) + Kell card and Grifols DG Gel Newborn Card SOP40: Manual methods for ABO/D Group Antibody Screen and DAT</p>	A
EDTA Plasma	<p>Antibody Screen by detection of antibodies to</p> <ul style="list-style-type: none"> - Rh (C, D, E, c, e Cw); - Kell (K k Kpa Kpb Jsa Jsb); - Duffy (Fya Fyb); - Kidd (Jka Jkb); - P1; - MNS (M N S s); - Lutheran (Lua and Lub) - Lea and Leb 	<p>IBG Immucor NEO Iris Analyser SOP1527: ABO/D group, antibody screen and DAT using the NEO Iris analyser</p> <p>IBG Immucor ECHO Lumena Analyser SOP1565: ABO/ D group antibody screen and DAT using the ECHO Lumena analyser</p>	A



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HUMAN BODY FLUIDS	<u>Blood Transfusion examinations to assist in clinical investigations</u>	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:	
EDTA Plasma	Antibody Screen by detection of antibodies to <ul style="list-style-type: none"> - Rh (C, D, E,c, e Cw); - Kell (K k Kpa Kpb Jsa Jsb); - Duffy (Fya Fyb); - Kidd (Jka Jkb); - P1; - MNS (M N S s); - Lutheran (Lua and Lub) - Lea and Leb 	Indirect Antiglobulin Test: column agglutination technology using Grifols DG Gel Coombs card and Serascan 4 red cells. SOP40: Manual methods for ABO/D Group Antibody Screen and DAT Manual: Indirect Antiglobulin Test using NHSBT 4 Cell rr r'r and r'r cells, Indirect Antiglobulin test using DG Coombs card and Column Agglutination Technology SOP 1410: 4 Cell D negative Antibody Screen	A



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HUMAN BODY FLUIDS (cont'd)	<u>Blood Transfusion examinations to assist in clinical investigations</u> (cont'd)	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:	
EDTA Plasma	Identification of antibodies to: <ul style="list-style-type: none"> - Rh (C, D, E, c, e Cw); - Kell (K k Kpa Kpb Jsa Jsb); - Duffy (Fya Fyb); - Kidd (Jka Jkb); - P1; - MNS (M N S s); - Lutheran (Lua and Lub) - Lea and Leb 	IBG Immucor NEO Iris Analyser SOP 41: Antibody Identification by automated and manual Techniques IBG Immucor ECHO Lumena Analyser SOP 41: Antibody Identification by automated and manual techniques Manual Indirect Antiglobulin Test: column agglutination technology using Grifols DG Gel Coombs card and Identisera DIANA red cell panel. SOP 41: Antibody Identification by automated and manual techniques Manual Direct agglutination on DG Neutral card and Enzyme IAT on DG Coombs card with Grifols Identisera DIANA P Papainised antibody identification cells using column agglutination technology SOP 41: Antibody Identification by automated and Manual Techniques	A
EDTA Plasma	Compatibility testing of patients' plasma with donor cells	Manual test using Grifols DG Therm incubator and DG Spin Centrifuge SOP 28: Compatibility Testing Using Grifols System	A



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HUMAN BODY FLUIDS (cont'd)	<u>Blood Transfusion examinations to assist in clinical investigations</u> (cont'd)	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:	
EDTA Red Cells	Direct Antiglobulin Test (DAT): Detection of antibodies adsorbed on the red cell membrane	IBG Immucor NEO Iris Analyser SOP1527: ABO/ D group antibody screen and DAT using NEO Iris Analyser. IBG Immucor ECHO Lumena Analyser SOP 1565: ABO/ D group antibody screen and DAT using ECHO Lumena Analyser. Manual Indirect Antiglobulin test on DG Coombs card or DAT columns on DG Gel Newborn card. SOP40: Manual methods for ABO/D Group Antibody Screen and DAT	A
EDTA Red Cells	Antigen Phenotyping: - Rh and K C E c e K	IBG Immucor NEO Iris Analyser SOP 1279: Red Cell Phenotyping IBG Immucor ECHO Lumena Analyser SOP 1279: Red Cell Phenotyping	A
EDTA Whole Blood	Kleihauer test for estimation of foeto-maternal haemorrhage: Qualitative screen for the presence of foetal cells. Quantitative assessment of volume by calculation from cell count.	Microscopic analysis of blood film. Manual staining using Guest Fetal Red cell detection kit SOP 24: The Kleihauer Test	A



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HUMAN BODY FLUIDS (cont'd)	<u>Haematology examinations to assist in clinical investigations</u>	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods:	
Blood	Full Blood Count (FBC) analysis of the following parameters: WBC RBC HGB HCT MCV MCH MCHC RDW-CV PLT NEUT LYMPH MONO EOS BASO	Horiba ABX Pentra Nexus DX analyser SOP: 1001 FBC analysis on Pentra DX Nexus Horiba ABX Pentra P60C+ analyser f SOP: H101 FBC on Pentra 60C+	A
Blood	Reticulocyte count	Horiba ABX Pentra Nexus DX analyser SOP: 62 - Reticulocytes	A
Blood	Glucose 6 Phosphate Dehydrogenase (G6PD) screen	Commercial kit - Trinity Biotech G6PDH Deficiency SOP: 59 G6PD screening test	A
Blood	Reporting of normal and abnormal morphologies Nucleated red blood cell (NRBC) count	Hematek stain machine, Hematek commercial stain pack SOP: 64 Blood film preparation, examination and reporting	A



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HUMAN BODY FLUIDS (cont'd)	<u>Haematology examinations to assist in clinical investigations</u>	Procedures documented in manufacturer's equipment manuals in conjunction with documented in-house procedures by the following methods: 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	
Blood	Detection of haemoglobin S (Hb-S)	Commercial kit Microgen Bioproducts S-Test Kit SOP: 83 - Sickle Solubility Test	A
Blood	Haemoglobinopathy screening for: - α and β thalassemia and abnormal haemoglobins - Determination of HbA ₂ , HbF and HbS levels.	SEBIA Capillars 2 Flex Piercing analyser SOP: 79A Capillary Iso-electric focusing (CIEF) on Sebia Capillars2 Flex piercing	A
Citrated plasma	<u>Coagulation examination activities for the purpose of clinical diagnosis</u> - PT, INR - APTT Fibrinogen	Werfen ACL TOP 350 SOP: 85 Routine use of TOP 500	A
	Lupus anticoagulant screen and confirmation	Werfen ACL TOP 350 SOP: 82 Lupus anticoagulant screening on TOP 500	A
	LMWH Anti Xa assay	Werfen ACL TOP 350 SOP: 87 LMW Heparin anti Xa assay on TOP 500	A



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HUMAN BODY FLUIDS (cont'd)	Biochemistry examination activities for the purpose of clinical diagnosis	Documented -in-house methods to meet the requirements of the FASP screening programme as defined in the April 2019 'FASP screening: laboratory QA evidence requirements'	B
Serum	Alpha-fetoprotein (AFP)	Roche cobas e601 electrochemiluminescence immunoassay: Clinical Chemistry 3188	
	Free B human Chorionic Gonadotrophin (B-hCG)	Clinical Chemistry 54662	B
	Pregnancy Associated Plasma Protein A (PAPP-A)	Clinical Chemistry 54661	
	Total human Chorionic Gonadotrophin (hCG+B)	Clinical Chemistry 3180	
	Inhibin A	Beckman Access 2 electrochemiluminescence immunoassay: Clinical Chemistry 54663	
	unconjugated Oestriol (uE3)	Chem/MsuE3AD	
END			