


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 <p>UKAS MEDICAL 9765</p> <p>Accredited to ISO 15189:2012</p>	<h3>National Health Service Blood and Transplant</h3> <p>Issue No: 003 Issue date: 20 May 2021</p>	
	<p>International Blood Group Reference Laboratory 500 North Filton Park Filton Bristol BS34 7QH</p>	<p>Contact: Nicole Thornton Tel: +44 (0) 117 9217586 E-Mail: nicole.thornton@nhsbt.nhs.uk Website: www.nhsbt.nhs.uk</p>
<p>Testing performed at the above address only</p>		

DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
<p>HUMAN TISSUE AND FLUIDS</p> <p>Human Whole Blood (EDTA); Red Cells, Plasma Human Whole Blood (Coagulated); Serum</p>	<p>Red Cell Immunohaematology investigations for the purpose of clinical diagnosis</p> <p>Determination of antibodies directed to all known blood group antigens</p>	<p>Manufacturer's instructions for: Medion Cell washers, ECHOtherm incubators, Diamed and Diacent 12 centrifuges and inverted microscope using in-house procedures: SOP4054 SOP4055</p> <p>Indirect antiglobulin tube method</p> <p>Indirect antiglobulin test Biorad gel card method</p> <p>Direct agglutination 18/37C</p> <p>Elution using the Gamma ElutKit II</p> <p>Enzyme treated and chemically modified cells</p> <p>Inhibition assays</p>



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HUMAN TISSUE AND FLUIDS (cont'd)	<u>Red Cell Immunohaematology investigations for the purpose of clinical diagnosis (cont'd)</u>	Manufacturer's instructions for: Medion Cell washers, ECHOtherm incubators, Diamed and Diacent 12 centrifuges and inverted microscope using in-house procedures: SOP4054 SOP4055
Human Whole Blood (EDTA); Red Cells, Plasma Human Whole Blood (Coagulated); Serum	Confirmation of red cell antigen phenotype: A, B, A1, D, C, c, E, e, C ^w , M, N, S, s, P1, Lu ^a , K, k, Kp ^a , Le ^a , Le ^b , Fy ^a , Fy ^b , Jk ^a , Jk ^b Additional antigens for rare donor confirmatory testing: Kp ^b , Js ^a , Js ^b , Lu ^b , Lu ³ , Fy ³ , U, Jk ³ , Co ^a , Co ^b , Yt ^a , Yt ^b , Vel, Lan, I, i, In ^a , In ^b , H	SOP4086 SOP4054 Indirect antiglobulin tube method Indirect antiglobulin test Bio-Rad gel card method Direct agglutination 18/37C Using RBCs Polyclonal antibodies Monoclonal antibodies Lectins Manual methods listed above using in-house procedures: SOP4086 SOP4054 Using: RBCs Polyclonal antibodies Monoclonal antibodies Lectins Eluates



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<p>HUMAN TISSUE AND FLUIDS (cont'd)</p> <p>Human Whole Blood (EDTA); Red Cells, Plasma Human Whole Blood (Coagulated); Serum</p> <p>Whole blood EDTA, maternal plasma, amniocytes, chorionic villus samples</p> <p>DNA extracted from samples listed above:</p>	<p><u>Red Cell Immunohaematology investigations for the purpose of clinical diagnosis (cont'd)</u></p> <p>Other antigens: Majority of known red blood cell antigens (currently comprises 356 antigens)</p> <p align="center"><u>Molecular</u></p>	<p>Manufacturer's instructions for: Medion Cell washers, ECHOtherm incubators, Diamed and Diacent 12 centrifuges and inverted microscope using in-house procedures: SOP4054 SOP4055</p> <p>Indirect antiglobulin tube method</p> <p>Indirect antiglobulin test Bio-Rad gel card method</p> <p>Direct agglutination 18/37C</p> <p>using: RBCs Polyclonal antibodies Monoclonal antibodies Lectins Eluates</p> <p>Manufacturer's instructions for Qiagen blood DNA mini kit (manual) and QiaSymphony (automated) for extraction of DNA and in-house procedures: SOP4095 SOP4092 SOP4109 SOP5195</p> <p>Nanodrop 2000 Quantification of DNA</p> <p>SOP5276</p>



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<p>HUMAN TISSUE AND FLUIDS (cont'd)</p> <p>DNA isolated from sample types listed above</p>	<p><u>Red Cell Immunohaematology investigations for the purpose of clinical diagnosis (cont'd)</u></p> <p>Detection of red cell antigen phenotype:</p> <p>Blood Group sequencing principally <i>RHD</i> and <i>RHCE</i> genes to identify rare and complex variants</p> <p>Detection of the presence of the <i>RHD*Weak D type 1 and 2</i> alleles</p>	<p>PCR using BioRad C1000 Touch Thermal Cycler and 3500XL Genetic analyser (di-deoxynucleotide chain termination during DNA replication) Seqscape v3</p> <p>Sanger DNA sequencing 3500XL Genetic analyser (di-deoxynucleotide chain termination during DNA replication) Seqscape v3 and in-house procedures:</p> <p>SOP4305, 4306, 4307, 4308</p> <p>Allele specific Multiplex PCR using C1000 Touch Thermal Cycler (BioRad) and in-house procedures:</p> <p>SOP4095, SOP572, SOP5165</p>



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HUMAN TISSUE AND FLUIDS (cont'd)	<u>Red Cell Immunohaematology investigations for the purpose of clinical diagnosis (cont'd)</u>	Manufacturer's instructions for BASIS BioArray Solutions imaging system BioArray AIS400 Beadchip technology (elongation mediated multiplexed analysis of polymorphisms) and C1000 Touch thermal cycler and in-house procedure:
DNA	Determination of red cell antigen type: D, C, c, E, e, V, VS M, N, S, s, U, K, k, Kpa/Kpb, Jsa, Jsb Fya, Fyb, Fyx, Jka, Jkb, Doa, Dob, Hy+/-, Joa, Job Lua, Lub, Dia/b, Coa/b Lw1/Lw2	SOP4214
DNA	Determination of red cell antigen type: C, c, E, e, M, N, S, s, U, K, k, Kpa/Kpb, Jsa, Jsb, Fya, Fyb, Jka, Jkb, Doa, Dob, Lua, Lub ABO	Real time PCR allelic discrimination Quantstudio 12K, and Dx system and in-house procedures. Biomek NXP automation workstation. SOP4098, SOP4984
DNA	D,C, c	Allele-specific PCR / gel electrophoresis PCR using BioRad C1000 Touch Thermal Cycler SOP4097



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HUMAN TISSUE AND FLUIDS (cont'd)	<u>Red Cell Immunohaematology investigations for the purpose of clinical diagnosis (cont'd)</u>	Semi quantitative real time PCR using manufacturer's instructions for Biomek NXP automation workstation, Quantstudio 12K, and Dx system and in-house procedures:
DNA	Determination of fetal blood group genotype:	
DNA derived from maternal plasma	D, C, c, E, K1	SOP4093 SOP4102 SOP4103 SOP4104 SOP4105 SOP4107
DNA	Detection of Y chromosome gene DYS14	Semi quantitative real time PCR using manufacturer's instructions for Quantstudio 12K, and Dx system and in-house procedure: SOP4096
DNA provided by customers	DNA sequence	DNA sequencing using: manufacturer's instructions for Sanger sequencing (dideoxynucleotide chain termination) with Bio-Rad C1000 Thermal cycler and 3500 XL genetic analyser SOP5233
END		