Schedule of Accreditation

United Kingdom Accreditation Service

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



9765

Accredited to ISO 15189:2012

BS34 7QH

NHS Blood and Transplant

Issue date: 12 June 2025 **Issue No:** 005

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Website: www.nhsbt.nhs.uk **Bristol**

Testing performed at the above address only

DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN TISSUE AND FLUIDS	Red Cell Immunohaematology investigations for the purpose of clinical diagnosis	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	Determination of antibodies directed to all known blood group antigens	Indirect antiglobulin tube method Indirect antiglobulin test Biorad gel card method
		Direct agglutination 18/37C
		Elution using the Gamma ElutKit II
		Enzyme treated and chemically modified cells
		Inhibition assays

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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN TISSUE AND FLUIDS (cont'd)	Red Cell Immunohaematology investigations for the purpose of clinical diagnosis (cont'd)	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:	SOP4086 SOP4054
	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	Indirect antiglobulin tube method Indirect antiglobulin test Bio-Rad gel card method Direct agglutination 18/37C
		Using RBCs Polyclonal antibodies Monoclonal antibodies Lectins
	Additional antigens for rare donor confirmatory testing:	Manual methods listed above using in-house procedures: SOP4086 SOP4054
	Kpb, Jsa, Jsb Lub, Lu3 Fy3 U Jk3 Coa, Cob Yta, Ytb Vel Lan I, i Ina, Inb H	Using: RBCs Polyclonal antibodies Monoclonal antibodies Lectins Eluates

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HUMAN TISSUE AND FLUIDS (cont'd)	Red Cell Immunohaematology investigations for the purpose of clinical diagnosis (cont'd)	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	Other antigens: Majority of known red blood cell antigens (currently comprises 356 antigens)	Indirect antiglobulin tube method Indirect antiglobulin test Bio-Rad gel card method
	<u>Molecular</u>	Direct agglutination 18/37C using: RBCs Polyclonal antibodies Monoclonal antibodies Lectins Eluates Manufacturer's instructions for Qiagen blood DNA mini kit (manual) and QiaSymphony (automated) for extraction of DNA and in-house procedures:
Whole blood EDTA, maternal plasma, amniocytes, chorionic villus samples		SOP4095 SOP4092 SOP5195 SOP5813 SOP5276
DNA extracted from samples listed above:		Nanodrop 2000 Quantification of DNA SOP5276
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HUMAN TISSUE AND FLUIDS (cont'd)	Red Cell Immunohaematology investigations for the purpose of clinical diagnosis (cont'd)	
DNA isolated from sample types listed above	Detection of red cell antigen phenotype:	PCR using BioRad C1000 Touch Thermal Cycler and 3500XL Genetic analyser (di- deoxynucleotide chain termination during DNA replication) Seqscape v3
	Blood Group sequencing principally <i>RHD</i> and <i>RHCE</i> genes to identify rare and complex variants	Sanger DNA sequencing 3500XL Genetic analyser (di-deoxynucleotide chain termination during DNA replication) Seqscape v3 and in-house procedures:
		SOP4305, 4306, 4307, 4308
	Detection of the presence of the RHD*Weak D type 1 and 2 alleles	Allele specific Multiplex PCR using C1000 Touch Thermal Cycler (BioRad) and in-house procedures:
		SOP4095, , SOP5165, SOP5276

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HUMAN TISSUE AND FLUIDS (cont'd)	Red Cell Immunohaematology investigations for the purpose of clinical diagnosis (cont'd)		
		DNA sequencing using: manufacturer's instructions for Sanger sequencing (dideoxynucleotide chain termination) with Bio-Rad C1000 Thermal cycler and 3500 XL genetic analyser	
DNA provided by customers	DNA sequence	SOP5233	
END			

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