


# Schedule of Accreditation

issued by

## United Kingdom Accreditation Service

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

|   |  |   |
|---|--|---|
|  <p><b>UKAS</b><br/>MEDICAL<br/>9765</p> <p>Accredited to<br/>ISO 15189:2012</p> | <h3>NHS Blood Transplant</h3> <p><b>Issue No:</b> 004    <b>Issue date:</b> 22 December 2023</p>                           |   |
|   | <p><b>International Blood Group Reference Laboratory</b><br/>500 North Filton Park<br/>Filton<br/>Bristol<br/>BS34 7QH</p> | <p><b>Contact:</b> Nicole Thornton<br/><b>Tel:</b> +44 (0) 117 9217586<br/><b>E-Mail:</b> nicole.thornton@nhsbt.nhs.uk<br/><b>Website:</b> www.nhsbt.nhs.uk</p> |
| <p><b>Testing performed at the above address only</b></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<br/>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:<br/>SOP4054<br/>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:  |
| Human Whole Blood (EDTA); Red Cells, Plasma<br>Human Whole Blood (Coagulated); Serum | Confirmation of red cell antigen phenotype:<br><br>A, B, A1, D, C, c, E, e, C <sup>w</sup> , M, N, S, s, P1, Lu <sup>a</sup> , K, k, Kp <sup>a</sup> , Le <sup>a</sup> , Le <sup>b</sup> , Fy <sup>a</sup> , Fy <sup>b</sup> , Jk <sup>a</sup> , Jk <sup>b</sup><br><br>Additional antigens for rare donor confirmatory testing:<br><br>Kp <sup>b</sup> , Js <sup>a</sup> , Js <sup>b</sup><br>Lu <sup>b</sup> , Lu3<br>Fy3<br>U<br>Jk3<br>Co <sup>a</sup> , Co <sup>b</sup><br>Yt <sup>a</sup> , Yt <sup>b</sup><br>Vel<br>Lan<br>I, i<br>In <sup>a</sup> , In <sup>b</sup><br>H | SOP4054<br>SOP4055<br><br>SOP4086<br>SOP4054<br><br>Indirect antiglobulin tube method<br><br>Indirect antiglobulin test Bio-Rad gel card method<br><br>Direct agglutination 18/37C<br><br>Using RBCs<br>Polyclonal antibodies<br>Monoclonal antibodies<br>Lectins<br><br>Manual methods listed above using in-house procedures:<br>SOP4086<br>SOP4054<br><br>Using:<br>RBCs<br>Polyclonal antibodies<br>Monoclonal antibodies<br>Lectins<br>Eluates |



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| <p>HUMAN TISSUE AND FLUIDS (cont'd)</p> <p>Human Whole Blood (EDTA); Red Cells, Plasma<br/>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>]</p> | <p><u>Red Cell Immunohaematology investigations for the purpose of clinical diagnosis (cont'd)</u></p> <p>Other antigens:<br/>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:<br/>SOP4054<br/>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:<br/>RBCs<br/>Polyclonal antibodies<br/>Monoclonal antibodies<br/>Lectins<br/>Eluates</p> <p>Manufacturer's instructions for Qiagen blood DNA mini kit (manual) and QiaSymphony (automated) for extraction of DNA and in-house procedures:<br/>SOP4095<br/>SOP4092<br/>SOP5195<br/>SOP5813<br/>SOP5276</p> <p>Nanodrop 2000<br/>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)<br/>Seqscape v3</p> <p>Sanger DNA sequencing 3500XL Genetic analyser (di-deoxynucleotide chain termination during DNA replication)<br/>Seqscape v3<br/>and in-house procedures:</p> <p>SOP4305, 4306, 4307, 4308</p> <p>Allele specific Multiplex PCR using C1000 Touch Thermal Cycler (BioRad)<br/>and in-house procedures:</p> <p>SOP4095, , SOP5165, SOP5276</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> |   |
| 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<br><br>SOP5233 |
| END                              |   |   |