


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 <p>UKAS MEDICAL 8198</p> <p>Accredited to ISO 15189:2012</p>	<h3>Northern Ireland Blood Transfusion Service (Special Agency)</h3> <p>Issue No:005 Issue date: 09 November 2024</p>	
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<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 BODY FLUIDS</p> <p>Blood</p>	<p><u>Blood Transfusion investigations to assist in clinical investigations diagnosis.</u></p> <p>Blood Group determination (ABO and RhD) Including the presence of A subgroups.</p>	<p>Documented manufacturer's instructions in conjunction with documented in- house procedures by the following methods:</p> <p>Manual tube agglutination using test tubes: SOP-AN002, AN003, AN005, AN013, AN047</p> <p>Manual tube agglutination using test tubes: SOP- BG009, BG010, BG083</p> <p>Manual BioRad column gel card technology: SOP – BG073, BG083, BG012, BG097</p> <p>Automated using Galileo NEO analyser (Microtitre plate based platform: Haemagglutination and modified coombs techniques-Weak Rh D detection): SOP- DT079, DT086</p>



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HUMAN BODY FLUIDS Cont'd	<u>Blood Transfusion investigations to assist in clinical investigations diagnosis (cont'd)</u>	Documented manufacturer's instructions in conjunction with documented in-house procedures by the following methods:
Blood	Blood Group determination cont'd	Automated immunohaematology testing using BioRad IH-500 analyser (column agglutination technology) and IH-Com software. SOP – BG118, BG119, BG120, BG121, BG097, BG043
Blood	Antibody Screen by detection of red cell antibodies: Rh –C,D,E,c,e, C ^w Kell –K, k, Kp ^a Duffy –Fy ^a , Fy ^b MNSs- M, N, S, s Kidd –JK ^a , Jk ^b	Automated antibody screening: Galileo NEO Capture R™ technology SOP-DT079
Blood	Identification of red cell antibodies: Rh: Anti – C, D, E, c, e, C ^w Kell: Anti – K, k, Kp ^a Duffy: Anti – Fy ^a , Fy ^b MNS-s: Anti–M, N, S, s Kidd –JK ^a , Jk ^b Lewis: Anti-Le ^a , Le ^b P: Anti-P ₁ Lutheran: Anti-Lu ^a , Lu ^b	Manual tube IAT techniques using test tubes: SOP- BG019, BG002, BG005, BG030, BG036, BG053, BG056, BG076, BG081, BG083, BG086, BG108, BG043 SOP AN002, AN003, AN009 Manual BioRad column gel card technology and in-house procedures SOP – BG073, BG083, BG097, BG043 Automated immunohaematology testing using BioRad IH-500 analyser (column agglutination technology) and IH-Com software. SOP – BG118, BG119, BG120, BG121, BG097, BG086, BG043



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<p>HUMAN BODY FLUIDS Cont'd</p> <p>Blood</p> <p>Blood</p>	<p><u>Blood Transfusion investigations to assist in clinical investigations diagnosis (cont'd)</u></p> <p>Compatibility testing of patients' plasma with donor cells</p> <p>Direct Antiglobulin Test (DAT)</p>	<p>Documented manufacturer's instructions in conjunction with documented in- house procedures by the following methods:</p> <p>Crossmatching using manual tube techniques: SOP - BG013, BG020, BG045, BG046, BG054, BG070, BG083, BG086, BG088, BG108, BG118, BG120</p> <p>Crossmatching using manual BioRad column gel card technology: SOP's: BG043, BG073, BG083, BG086, BG097</p> <p>Manual BioRad column gel card technology: SOP's: BG043, BG073, BG083, BG086, BG097</p> <p>Manual Tube technology: SOP - BG014, BG043, BG083, BG090, AN012</p> <p>Automated immunohaematology testing using BioRad IH-500 analyser (column agglutination technology) and IH-Com software. SOP – BG043, BG118, BG119, BG120, BG121, BG097</p>



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HUMAN BODY FLUIDS Cont'd	<u>Blood Transfusion investigations to assist in clinical investigations diagnosis (cont'd)</u>	Documented manufacturer's instructions in conjunction with documented in- house procedures by the following methods:
Blood	<p>Detection and identification of unexpected antibodies, investigation of non-specific antibodies and removal of 'nuisance' antibodies to detect underlying clinically significant antibodies:</p> <ul style="list-style-type: none"> • High Titre Low Avidity (HTLA) antibodies • Antibodies to low frequency antigens • Antibodies to high frequency antigens • Cold reactive antibodies • Warm autoagglutinins • Therapeutic monoclonal antibodies 	<p>Manual tube techniques: SOP – AN022 SOP - BG001, BG002, BG005, BG014, BG018, BG019, BG030, BG036, BG037, BG043, BG047, BG053, BG058, BG061, BG063, BG072, BG083, BG085, BG091, BG108</p> <p>Manual BioRad column gel card technology: SOP - BG043, BG073, BG083, BG107, BG097</p> <p>Automated immunohaematology testing using BioRad IH-500 analyser (column agglutination technology) and IH-Com software. SOP – BG118, BG119, BG120, BG121, BG097, BG043</p>
Blood	Serological investigation of transfusion reactions to determine reaction to transfused donor red cells	Manual tube techniques: SOP - BG015, BG022, BG043, BG083
Blood	Antibody titration	Manual tube AHG technique SOP-AN024
	Titration of anti-A and /or anti-B for solid organ transplant patients	Automated BioRad column gel technology and in-house procedures: SOP - BG043, BG083, BG100, BG097
Blood	<p>Rh Phenotyping:</p> <ul style="list-style-type: none"> • C^w, C, c, E, e 	<p>Manual tube technique: SOP-AN008, BG010, BG011, BG043, BG044, BG083</p> <p>Manual BioRad column gel card technology: SOP- BG043, BG044, BG073, BG083, BG097</p> <p>Automated using the BioRad IH-500 analyser (column gel technology) SOP – BG043, BG097, BG118, BG119, BG120, BG121</p>



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HUMAN BODY FLUIDS Cont'd	<u>Blood Transfusion investigations to assist in clinical investigations diagnosis cont'd</u>	Documented manufacturer's instructions in conjunction with documented in- house procedures by the following methods:
Blood	Extended Red Cell Phenotyping: <ul style="list-style-type: none"> • K, k, Kpa, Kpb • Jka, Jkb • Fya, Fyb, • M, N, S, s • Lua, Lub • Lea, Leb • P1 	Manual tube technique: SOP-AN008, AN009, BG013, BG043, BG083 Manual BioRad column gel card technology and in-house procedures SOP – BG043, BG073, BG083, BG097, BG122
Blood	Detection and identification of Rh D Variant	Manual BioRad column gel card technology: SOP – BG043, BG012, BG083, BG097 Automated: Galileo NEO Weak D assay SOP- DT079
Blood	Detection of platelet antibodies	Capture P solid phase system, PakPlus (ELISA) test: SOP- BG039, BG043, BG069, BG076, BG111, BG112, BG116, BG117



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<p>HUMAN BODY FLUIDS Cont'd</p> <p>Blood</p> <p>Blood</p>	<p><u>Blood Transfusion investigations to assist in clinical investigations diagnosis cont'd</u></p> <p>Human Platelet Antigen (HPA) typing</p> <p>Microbial serology for: HIV Antibody/Antigen HBsAg Antigen Syphilis Antibody Rubella antibody</p>	<p>Documented manufacturer's instructions in conjunction with documented in- house procedures by the following methods:</p> <p>Use of NanoDrop Spectrophotometer for Estimation of DNA concentration and purity SOP-BG110</p> <p>Automated Immuoassay on Architect i2000SR: SOP HE126 Operation and Maintenance of Architect i2000SR SOP HE131 Screening of Antenatal Patient Samples HE103 Identifying Preparing and Disposal of Patient Samples Received for Mandatory Marker Screening HE128 Use of Abbott AMS Interface for Reporting Architect Results and Upload to Pulse and DSS</p>
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