Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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



8198

Accredited to ISO 15189:2022

Northern Ireland Blood Transfusion Service (Special Agency)

Issue No:006 Issue date: 20 May 2025

Belfast City Hospital Complex

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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 BODY FLUIDS | Blood Transfusion investigations to assist in clinicalinvestigations diagnosis. | Documented manufacturer's instructions in conjunction with documented in- house procedures by the following methods: | |
| Blood | Blood Group determination (ABO and RhD) Including the presence of A subgroups. | Manual tube agglutination using test tubes: SOP-AN002, AN003, AN005, AN013, AN047 Manual tube agglutination using test tubes: SOP- BG009, BG010, BG083 Manual BioRad column gel card technology: SOP – BG073, BG083, BG012, BG097 Automated using Galileo NEO analyser (Microtitre plate based platform: Haemagglutination and modified coombs techniques-Weak Rh D detection): SOP- DT079, DT086 | |
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| HUMAN BODY FLUIDS Cont'd | Blood Transfusion investigations to assist in clinicalinvestigations diagnosis (cont'd) | 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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| HUMAN BODY FLUIDS Cont'd | Blood Transfusion investigations to assist in clinicalinvestigations diagnosis (cont'd) | Documented manufacturer's instructions in conjunction with documented in- house procedures by the following methods: |
| Blood | Compatibility testing of patients' plasma with donor cells | Crossmatching using manual tube techniques: SOP - BG013, BG020, BG045, BG046, BG054, BG070, BG083, BG086, BG088, BG108, BG118, BG120 |
| | | Crossmatching using manual BioRad column gel card technology: SOP;'s BG043, BG073, BG083, BG086, BG097 |
| Blood | Direct Antiglobulin Test (DAT) | Manual BioRad column gel card technology: SOP's: BG043, BG073, BG083,BG086 BG097 |
| | | Manual Tube technology: SOP - BG014, BG043, BG083, BG090, AN012 |
| | | Automated immunohaematology testing using BioRad IH-500 analyser (column agglutination technology) and IH-Com software. SOP – BG043, BG118, BG119, BG120, BG121, BG097 |
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| HUMAN BODY FLUIDS Cont'd | Blood Transfusion investigations to assist in clinicalinvestigations diagnosis (cont'd) | Documented manufacturer's instructions in conjunction with documented in- house procedures by the following methods: |
| Blood | Detection and identification of unexpected antibodies, investigation of non-specific antibodies and removal of 'nuisance' antibodies to detect underlying clinically significant antibodies: • High Titre Low Avidity (HTLA) antibodies | 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 |
| | Antibodies Antibodies to low frequency antigens Antibodies to high frequency antigens Cold reactive antibodies Warm autoagglutinins Therapeutic monoclonal antibodies | Manual BioRad column gel card technology: SOP - BG043, BG073, BG083, BG107, BG097 |
| | | Automated immunohaematology testing using BioRad IH-500 analyser (column agglutination technology) and IH-Com software. SOP – BG118, BG119, BG120, BG121, BG097, BG043 |
| 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 | Rh Phenotyping: • C ^w , C, c , E, e | Manual tube technique: SOP- AN008, BG010 BG011, BG043, BG044, BG083 |
| | | Manual BioRad column gel card technology: SOP- BG043, BG044, BG073, BG083, BG097 |
| | | Automated using the BioRad IH-500 analyser (column gel technology) SOP – BG043, BG097, BG118, BG119, BG120, BG121 |

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| HUMAN BODY FLUIDS Cont'd | Blood Transfusion investigations to assist in clinicalinvestigations diagnosis cont'd | Documented manufacturer's instructions in conjunction with documented in- house procedures by the following methods: |
| Blood | Extended Red Cell Phenotyping: 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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| HUMAN BODY FLUIDS Cont'd | Blood Transfusion investigations to assist in clinical investigations diagnosis cont'd | Documented manufacturer's instructions in conjunction with documented in- house procedures by the following methods: |
| Blood | Human Platelet Antigen (HPA) typing | Use of NanoDrop Spectrophotometer for Estimation of DNA concentration and purity SOP- BG110 |
| Blood | Microbial serology for: HIV Antibody/Antigen HBsAg Antigen Syphilis Antibody Rubella antibody | 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 |
| END | | |

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