Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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



8464

Accredited to ISO 15189:2012

Oxford University Hospitals NHS Foundation Trust

Issue No: 010 Issue date: 05 September 2024

Department of Laboratory

. Haematology

Level 4 John Radcliffe University

Hospital

Headley Way

Headington

Oxford

OX3 9DU

Contact: Andrew Platt Tel: +44 (0)1865 (8)57663

E-Mail: andrew.platt@ouh.nhs.uk

Website: www.ouh.nhs.uk

Testing performed by the Organisation at the locations specified below

Locations covered by the organisation and their relevant activities

Laboratory locations:

| Location details | | Activity | Location code |
|---|--|---|---------------|
| Level 4 John Radcliffe University Hospital Headley Way Headington Oxford OX3 9DU | Local contact: Mr Andrew Platt (01865 857663) | Routine haematology Routine Coagulation Blood Grouping and antibody screen Blood & blood product issue Immunophenotyping by flow analysis Haemoglobinopathy analysis | JRH |
| Horton Hospital Oxford Road Banbury OX16 9AL | Haematology: Mrs Ranvir Thiara (01865 857663) Blood Transfusion: Miss J Staves (01865 220334) | Routine haematology Routine Coagulation Blood Grouping and antibody screen Blood & blood product issue | нн |
| Churchill Hospital Laboratory Medicine Old Road Headington Oxford OX3 7LE | Mr P Baker (01865 857096) | Routine FBC analysis Routine Coagulation Blood & blood product issue | CHLM |
| Oxford Haemophilia and Thrombosis Centre Nuffield Orthopaedic Centre, Windmill Road, Headington Oxford OX3 7HE | Mr P Baker (01865 857096) | Routine Coagulation Factor Assay analysis Haemostatic investigations Thrombophilia investigations | ОНТС |

Assessment Manager: SG Page 1 of 17



United Kingdom Accreditation Service 2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

Oxford University Hospitals NHS Foundation Trust

Issue No: 010 Issue date: 05 September 2024

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Site activities performed away from the locations listed above:

| Location details | Activity |
|--|---|
| Churchill Hospital Porters Lodge Old Road Headington Oxford OX3 7LE | Blood storage & issue Fridge managed by Haematology |
| Delivery Suite John Radcliffe Hospital Headley Way Oxford OX3 9DU | Blood storage & issue only Fridge managed by Haematology |
| West Wing Theatres Level 1 John Radcliffe Hospital Headley Way Oxford OX3 9DU | Blood storage & issue only Fridge managed by Haematology |
| John Radcliffe Theatres John Radcliffe Hospital Headley Way Oxford OX3 9DU | Blood storage & issue only Fridge managed by Haematology |
| Cardio Thoracic Critical Care John Radcliffe Hospital Headley Way Oxford OX3 9DU | Blood storage & issue only Fridge managed by Haematology |
| Churchill Theatres Level 1 Old Road Headington Oxford OX3 7LE | Blood storage & issue only Fridge managed by Haematology |

Assessment Manager: SG Page 2 of 17



Schedule of Accreditation issued by

United Kingdom Accreditation Service 2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

Oxford University Hospitals NHS Foundation Trust

Issue No: 010 Issue date: 05 September 2024

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| Location details | Activity |
|--|---|
| Day Treatment Unit Level 1 Churchill Hospital Old Road Headington Oxford OX3 7LE | Blood storage & issue only Fridge managed by Haematology |
| Haematology Ward Level 1 Churchill Hospital Old Road Headington Oxford OX3 7LE | Blood storage & issue only Fridge managed by Haematology |
| Theatres Nuffield Orthopaedic Centre Windmill Road Headington Oxford OX3 7HE | Blood storage & issue only Fridge managed by Haematology |
| The Foscote Hospital 2 Foscote Rise Banbury OX16 9XP | Blood storage & issue only Fridge monitored by Haematology |
| Treatment Centre Oxford Road, Banbury OX16 7FG | Blood storage & issue only Fridge monitored by Haematology |

Assessment Manager: SG Page 3 of 17



United Kingdom Accreditation Service 2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

Oxford University Hospitals NHS Foundation Trust

Issue No: 010 Issue date: 05 September 2024

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DETAIL OF ACCREDITATION

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|---------------------------|--|--|------------------|
| HUMAN BODY FLUIDS | Blood Transfusion examinations to assist in clinical investigations | Procedures documented in manufacturer's equipment manuals in conjunction with documented inhouse procedures by the following methods: | |
| Blood Plasma | Blood Group by detection and identification of antigens: A Rh D Positive AB Rh D Positive B Rh D Positive O Rh D Positive A Rh Negative AB Rh D Negative B RhD Negative | Automated using Werfen/Immunocor Neo Iris analyser (JRH) SOP HJ 2559 SOP HJ 2560 SOP HJ 2561 SOP HJ 2562 SOP HJ 2563 Automated using Werfen/Immunocor Echo analyser (HH) | JRH |
| Blood | O Rh D Negative Including the presence of A2 antigens Antibody Screen by | Haem SOP 677 Haem SOP 678 Haem SOP 679 Automated using Werfen/Immunocor | JRH |
| Plasma | detection of antibodies to: Rh -C,D,E,c,e, Cw Kell -K, K, Kpa Duffy -Fya, Fyb MNSs- M, N, S, s Kidd -JKa, Jkb Lutheran -Lua P-P1 Anti-Chido/Rogers | Neo Iris analyser SOP HJ 2559 SOP HJ 2560 SOP HJ 2561 SOP HJ 2562 SOP HJ 2563 | |
| Blood Plasma | Antibody Screen by detection of antibodies to: Rh –C,D,E,c,e, Cw Kell –K, K, Kpa Duffy –Fya, Fyb MNSs- M, N, S, s Kidd –JKa, Jkb | Automated using Werfen/Immunocor Echo analyser Haem SOP 677 Haem SOP 678 Haem SOP 679 | HH |

Assessment Manager: SG Page 4 of 17



Schedule of Accreditation issued by

United Kingdom Accreditation Service 2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

Oxford University Hospitals NHS Foundation Trust

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| HUMAN BODY FLUIDS (cont'd) | Blood Transfusion examinations to assist in clinical investigations (cont'd) | Procedures documented in manufacturer's equipment manuals in conjunction with documented inhouse procedures by the following methods: | |
| Blood Plasma | Blood Group by detection and identification of antigens: Rh –C,D,E,c,e, Cw Kell –K, K, Kpa Duffy –Fya, Fyb MNSs- M, N, S, s Kidd –JKa, Jkb P–P1 Anti-Chido/Rogers | Spin agglutination using BioRad/Diamed Column gel technology HJ 2513 (JRH) Haem SOP 462 (HH) | JRH HH |
| Plasma | Antibody Screen by detection of antibodies to: Rh -C,D,E,c,e, Cw Kell -K, K, Kpa Duffy -Fya, Fyb MNSs- M, N, S, s Kidd -JKa, Jkb | Manual BioRad/Diamed Column gel IAT technology HJ 2551 | JRH HH |
| Blood Plasma | Compatibility testing of patients plasma with donor cells | Cross matching using BioRad/Diamed Column gel IAT technology HJ 2531 (JRH) HH 2639 (HH) | JRH HH |
| Blood | Direct Antiglobulin Test (DAT) | BioRad/Diamed Column gel IAT technology HJ 2590 | JRH HH |
| Blood Plasma | ABO titrations | Werfen/Immunocor Neo Iris analyser and microtitre plate analysis Haem SOP 439 | JRH |

Assessment Manager: SG Page 5 of 17



United Kingdom Accreditation Service 2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

Oxford University Hospitals NHS Foundation Trust

Issue No: 010 Issue date: 05 September 2024

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| HUMAN BODY FLUIDS (cont'd) | Blood Transfusion examinations to assist in clinical investigations (cont'd) | Procedures documented in manufacturer's equipment manuals in conjunction with documented inhouse procedures by the following methods: | |
| Blood Plasma | Antibody investigation by detection, identification and quantification of: Rh –C,D,E,c,e, Cw Kell –K, K, Kpa Duffy –Fya, Fyb MNSs- M, N, S, s Kidd –JKa, Jkb | BioRad/Diamed Column gel IAT technology HJ 2603 HJ 2597 HJ 2609 HJ 2604 HJ 2737 HJ 2605 HJ 2594 HJ 2576 HJ 2516 for including elution's, auto and cross absorptions | JRH HH |
| Blood | Foetal Maternal Haemorrhage | Clin Tech Shepard kits Kleihauer Acid Elution Technique HJ 2569 | JRH |
| | Haematological examinations for the purpose of clinical diagnosis | Procedures documented in manufacturer's equipment manuals in conjunction with documented inhouse procedures by the following methods: | |
| Blood | Erythrocyte Sedimentation Rate (ESR) | Automated Starrsed analysers, modified Westergren method | |
| | | Haem SOP 905 ESR Flex and Auto Compact | JRH HH |
| | | Modified Westergren method (manual) H 543 | JRH HH |
| Plasma | Plasma Viscosity | Benson Viscometers, capillary sheer stress measurements Haem SOP 110 | JRH |

Assessment Manager: SG Page 6 of 17



United Kingdom Accreditation Service 2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

Oxford University Hospitals NHS Foundation Trust

Issue No: 010 Issue date: 05 September 2024

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| HUMAN BODY FLUIDS (cont'd) | Haematological examinations for the purpose of clinical diagnosis (cont'd) | Procedures documented in manufacturer's equipment manuals in conjunction with documented inhouse procedures by the following methods: | |
| Blood | Full Blood Count (FBC) analysis of the following parameters: WBC RBC HGB HCT MCV MCH MCHC RDW-CV PLT NEUT LYMPH MONO EOS BASO Nucleated red blood cell (NRBC) count Reticulocyte count | Sysmex XN automated analysers, differential laser light scatter Haem SOP 879 | JRH CHLM HH |
| Plasma Serum | Glandular Fever Screen | Biokit Monogen commercial kit, latex micro particle immunoassay H 559 | JRH HH |
| Blood | G6PD | Commercial (Pointe Scientific) kit, functional enzyme colourimetric assay G6PD SOP: H 541 | НН |

Assessment Manager: SG Page 7 of 17



Schedule of Accreditation issued by

United Kingdom Accreditation Service 2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

Oxford University Hospitals NHS Foundation Trust

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| HUMAN BODY FLUIDS (cont'd) | Haematological examinations for the purpose of clinical diagnosis (cont'd) | Procedures documented in manufacturer's equipment manuals in conjunction with documented inhouse procedures by the following methods: | |
| Blood | Malarial antigens of: Plasmodium falciparum and pan-detection for: Plasmodium malariae, Plasmodium ovale & Plasmodium vivax | CareStart commercial kit H 3010 | JRH HH |
| | Haemostasis and thrombosis examinations for the purpose of clinical diagnosis | Procedures documented in manufacturer's equipment manuals in conjunction with documented inhouse procedures by the following methods: | |
| Plasma | Routine Coagulation testing for: | Sysmex CS5100 automated analysers, optical end-point detection and in-house procedures: | JRH HH |
| | Prothrombin Time (PT) Activated Partial Thromboplastin Time (APTT) | Haem SOP 808 Haem SOP 809 | CHLM |
| | Fibrinogen (Clauss) Thrombin Time (TT) | Haem SOP 855 Haem SOP 830 H 1016 | |
| | | Sysmex CN6000/6500 automated analysers, optical end-point detection and in-house procedures: | |
| | Routine Coagulation testing for: | | NOC |
| | Prothrombin Time (PT) Activated Partial Thromboplastin Time (APTT) Fibrinogen (Clauss) Thrombin Time (TT) | Haem SOP 808 Haem SOP 809 Haem SOP 855 Haem SOP 830 H 1016 | |
| | | | |

Assessment Manager: SG Page 8 of 17



United Kingdom Accreditation Service 2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

Oxford University Hospitals NHS Foundation Trust

Issue No: 010 Issue date: 05 September 2024

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| HUMAN BODY FLUIDS (cont'd) | Haemostasis and thrombosis examinations for the purpose of clinical diagnosis (cont'd) | Procedures documented in manufacturer's equipment manuals in conjunction with documented inhouse procedures by the following methods: | |
| | | Sysmex CN6000/6500 automated analysers, optical end-point detection and in-house procedures: | |
| Plasma | Anti-Ila (Dabigatran) | Haem SOP 1045 | NOC |
| Plasma | Reptilase | Haem SOP 943 | NOC |
| Plasma | Echis Time | Haem SOP 847 | NOC |
| Plasma | High Molecular Weight Kininogen (HMWK) | Haem SOP 953 | NOC |
| Plasma | Factor Assay analysis: FII FV FVII FVIII FX FX FXI FXII | Haem SOP 817 Haem SOP 818 Haem SOP 819 Haem SOP 834 Haem SOP 835 Haem SOP 820 Haem SOP 836 Haem SOP 837 | NOC |
| Plasma | Factor Acquired Inhibitor Screen FVIII FIX | HC 1222 HC 1225 | NOC |
| Plasma | Factor Inhibitor (Bethesda) analysis | Modified Nijmegen HC 1224 | NOC |
| Plasma | Acquired Thrombophilia (Lupus) Screen (DRVVT screen / confirm, Actin FSL) | Haem SOP 1046 | NOC |
| Plasma | Factor assay analysis FVIII FXIII | Sysmex CN6000/6500 automated analysers, chromogenic assay and in-house procedures: Haem SOP 590 Haem SOP 839 | NOC |

Assessment Manager: SG Page 9 of 17



United Kingdom Accreditation Service 2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

Oxford University Hospitals NHS Foundation Trust

Issue No: 010 Issue date: 05 September 2024

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| HUMAN BODY FLUIDS (cont'd) | Haemostasis and thrombosis examinations for the purpose of clinical diagnosis (cont'd) | Procedures documented in manufacturer's equipment manuals in conjunction with documented inhouse procedures by the following methods: | |
| | | Sysmex CN6000/6500 automated analysers, chromogenic assay and in-house procedures: | |
| Plasma | Inherited Thrombophilia | | NOC |
| | Screen: Protein C AT | Haem SOP2604 | |
| | Al | Haem SOP 1019 | |
| | Free Protein S | Haem SOP 1022 | NOC |
| Plasma | Fibrinolysis Screen: Plasminogen Alpha-2 Anti plasmin | Haem SOP 949 Haem SOP 838 | NOC |
| | | Sysmex CS5100 automated analysers, chromogenic assay and in-house procedures | |
| Plasma | Anti-Xa | Haem SOP 919 | JRH |
| | | Sysmex CS5100 automated analysers, latex optical end-point detection and in-house procedures: | |
| Plasma | D-Dimer | Haem SOP 864 | JRH CHLM HH |
| | | Sysmex CN6000/6500 automated analysers, latex optical end-point detection and in-house procedures: | |
| Plasma | vWD analysis (Antigen) | HC 1286 | NOC |
| Plasma | vWD analysis (Activity) | HC SOP 591 | NOC |
| | | | |

Assessment Manager: SG Page 10 of 17



United Kingdom Accreditation Service 2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

Oxford University Hospitals NHS Foundation Trust

Issue No: 010 Issue date: 05 September 2024

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| HUMAN BODY FLUIDS (cont'd) | Haemostasis and thrombosis examinations for the purpose of clinical diagnosis (cont'd) | Procedures documented in manufacturer's equipment manuals in conjunction with documented inhouse procedures by the following methods: | |
| Plasma | Ristocetin Co-Factor (RiCOF) | Sysmex CN6000/6500 automated analysers, platelet aggregation HC 1285 | NOC |
| Plasma | vWD Type 2N analysis | Asserachrom vwf:FVIIIB manual ELISA HC 1231 | NOC |
| Plasma | Collagen Binding Assay (CBA) | AcuStar coagulation analyser; Haem SOP 2084 IL AcuStar- Collagen Binding Activity Haem SOP 2082 IL AcuStar- Overview and maintenance | NOC |
| Blood | Heparin Induced Thrombocytopenia Screen (HIT) | AcuStar coagulation analyser; Haem SOP 2085 IL AcuStar -HIT IgG (PF4) Haem SOP 2082 IL AcuStar- Overview and maintenance | NOC |
| Blood | Platelet aggregation | Light transmission aggregometry AggRam and procedures HC 1335, HC 1264 & HC 1334 | NOC |

Assessment Manager: SG Page 11 of 17



Schedule of Accreditation issued by

United Kingdom Accreditation Service 2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

Oxford University Hospitals NHS Foundation Trust

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| HUMAN BODY FLUIDS (cont'd) | Morphology and immunophenotyping examinations for the purpose of clinical diagnosis | Procedures documented in manufacturer's equipment manuals in conjunction with documented inhouse procedures by the following methods: | |
| Blood Bone marrow | Blood / bone marrow film analysis | May Grunwald-Giemsa staining Manual H 542, HJ 3020 or automated using Sysmex SP-10 (JRH/HH) Haem SOP 895 HJ 3021 Routine Staining of Blood Films and Bone Marrows-Shandon staining machine Varistain 24-4 (JRH) | JRH HH |
| | | Manual light microscopy HJ 3004 (blood) HJ 3006 (blood) HJ 3012 (bone marrow) HJ 3013 (bone marrow) HC2309 (bone marrow) | JRH HH |
| Blood Bone marrow | Blood / bone marrow film analysis | Automated blood film analysis using Sysmex Digital morphology analyser, light microscopy Haem 33913 HJ3400 HJ3401 Haem SOP 900 | JRH |
| Blood Bone Marrow Urine | Iron deposits | Light microscopy following Perl's Prussian Blue iron staining using commercial (TCS Biosciences) Kit HJ 3103 | JRH |
| Blood | Detection & speciation (thin films) of malaria parasites: | Preparation of thick and thin films, manual May Grunwald-Giemsa staining and light microscopy HJ 3009 H555 | JRH HH |
| | Plasmodium falciparum Plasmodium malariae Plasmodium ovale Plasmodium vivax | | |

Assessment Manager: SG Page 12 of 17



Schedule of Accreditation issued by

United Kingdom Accreditation Service 2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

Oxford University Hospitals NHS Foundation Trust

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| HUMAN BODY FLUIDS (cont'd) | Morphology and immunophenotyping examinations for the purpose of clinical diagnosis (cont'd) | Procedures documented in manufacturer's equipment manuals in conjunction with documented inhouse procedures by the following methods: | |
| Blood Bone Marrow | Acute Leukaemia antigen detection and quantification. Panel to include: CD-45 CD-7 CD-33 CD-10 CD-19 CD-34 CD-15 CD-117 HLA-DR CD-13 CD-14 CD-64 CD-41 CD-38 CD-11c Glycophorin-A CD-56 NG2 CD-9 CD-20 lgM CD-25 CD-1a CD-4 | BC Navios , flow cytometry Haem SOP 1899 Haem SOP 1902 Haem SOP 1920 Haem SOP 330 HJ 3340 | JRH |

Assessment Manager: SG Page 13 of 17



United Kingdom Accreditation Service 2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

Oxford University Hospitals NHS Foundation Trust

Issue No: 010 Issue date: 05 September 2024

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| HUMAN BODY FLUIDS (cont'd) | Morphology and immunophenotyping examinations for the purpose of clinical diagnosis (cont'd) | Procedures documented in manufacturer's equipment manuals in conjunction with documented inhouse procedures by the following methods: | |
| Blood Bone Marrow | Chronic Leukaemia antigen detection and quantification. Panel to include: CD-8 CD-2 CD-57 sCD-3 CD-16 + 56 Cyt MPO Cyt CD-79a Cyt TdT Cyt Lysozyme Cyt CD-3 Cyt IgM CD-25 IgG1 PE IgG1 FITC CD-19 CD-20 CD-22 CD-23 FMC-7 CD-79b CD-79a sKappa sLambda CD-5 CD-4 CD-8 CD-45 CD-38 CD-200 sIgM CD-10 | BC Navios , flow cytometry Haem SOP 1899 Haem SOP 1901 Haem SOP 1920 Haem SOP 330 HJ 3340 | JRH |
| Blood | Minimal Residual Disease (MRD) ALL Flow panel | BC Navios analyser, flow cytometry , SOPs used Haem SOP 2643 Haem Doc 2612 | JRH |

Assessment Manager: SG Page 14 of 17



United Kingdom Accreditation Service 2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

Oxford University Hospitals NHS Foundation Trust

Issue No: 010 Issue date: 05 September 2024

Testing performed by the Organisation at the locations specified

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| HUMAN BODY FLUIDS (cont'd) | Morphology and immunophenotyping examinations for the purpose of clinical diagnosis (cont'd) CD-103 CD-25 CD-11c CD-2 CD-3 CD-7 CD-57 CD-16 + 56 TCR-a/b TCR-g/d CD-56 CD-138 Cyt Kappa Cyt Lambda | Procedures documented in manufacturer's equipment manuals in conjunction with documented inhouse procedures by the following methods: | |
| Blood | Paroxsymal nocturnal haemoglobinuria (PNH) clone antigen detection and quantification. Panel to include: | BC Navios analyser, flow cytometry Haem SOP 1899 Haem SOP 1898 – Red cell assay Haem SOP 1900 – White cell assay Haem SOP 1901 Haem SOP 1902 Haem SOP 1920 | JRH |
| | CD-24 Flaer CD-14 CD-45 CD-15 CD-33 CD-59 Glyophorin A | | |
| Blood, Bone Marrow | Minimal residual disease (MRD) detection in AML | BC Navios analyser, flow cytometry Haem SOP 2567 Haem SOP 2568 | JRH |

Assessment Manager: SG Page 15 of 17



ISO 15189:2012

Schedule of Accreditation issued by

United Kingdom Accreditation Service 2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

Oxford University Hospitals NHS Foundation Trust

Issue No: 010 Issue date: 05 September 2024

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| Haemoglobinopathy examinations for the purpose of clinical diagnosis | Procedures documented in manufacturer's equipment manuals in conjunction with documented inhouse procedures by the following methods: | |
| | Documented in-house methods to meet the requirements of the NHS Newborn Blood Spot Screening, Programme as defined in the July 2018 Newborn (Blood Spot) and antenatal; Sickle Cell and Thalassaemia Screening: laboratory QA evidence requirements' | |
| Adult Haemoglobinopathy analysis (including Antenatal) by detection of haemoglobin variants: Hb A Hb A2 Hb F Hb S Hb C Hb D Punjab Hb E | BioRad Variant II analyser, HPLC HC 2029 HC 2006 HC 2039 HC 2030 | JRH |
| Neonatal Haemoglobinopathy analysis by detection of haemoglobin variants: Hb A Hb F Hb S Hb C Hb D Punjab Hb E | Revvity/Perkin Elmer DBS Puncher and BioRad Variant NBS, HPLC HC 2026 HC 2027 HC 2028 BIO-J-LP-ScrePunOp | JRH |
| | measured/Range of measurement Haemoglobinopathy examinations for the purpose of clinical diagnosis Adult Haemoglobinopathy analysis (including Antenatal) by detection of haemoglobin variants: Hb A Hb A2 Hb F Hb S Hb C Hb D Punjab Hb E Neonatal Haemoglobinopathy analysis by detection of haemoglobin variants: Hb A Hb F Hb S Hb C Hb D Punjab | measured/Range of measurement Haemoglobinopathy examinations for the purpose of clinical diagnosis Procedures documented in manufacturer's equipment manuals in conjunction with documented inhouse procedures by the following methods: Documented in-house methods to meet the requirements of the NHS Newborn Blood Spot Screening, Programme as defined in the July 2018 Newborn (Blood Spot) and antenatal; Sickle Cell and Thalassaemia Screening: laboratory QA evidence requirements' Adult Haemoglobinopathy analysis (including Antenatal) by detection of haemoglobin variants: Hb A Hb A 2 Hb F Hb S Hb C Hb D Punjab Hb E Neonatal Haemoglobinopathy analysis by detection of haemoglobin variants: Revvity/Perkin Elmer DBS Puncher and BioRad Variant NBS, HPLC HC 2026 HC 2027 HC 2028 BIO-J-LP-ScrePunOp |

Assessment Manager: SG Page 16 of 17



United Kingdom Accreditation Service 2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

Oxford University Hospitals NHS Foundation Trust

Issue No: 010 Issue date: 05 September 2024

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| HUMAN BODY FLUIDS (cont'd) | Haemoglobinopathy examinations for the purpose of clinical diagnosis (cont'd) | Procedures documented in manufacturer's equipment manuals in conjunction with documented inhouse procedures by the following methods: Documented in-house methods to meet the requirements of the NHS Newborn Blood Spot Screening, Programme as defined in the July 2018 Newborn (Blood Spot) and antenatal; Sickle Cell and Thalassaemia Screening: laboratory QA evidence requirements' | |
| Blood Dried Blood Spots | 2 nd Line Haemoglobinopathy analysis by detection of haemoglobin variants: Hb A Hb A2 Hb F Hb S Hb C Hb D Punjab Hb E | Revvity/Perkin Elmer (MigeleTM tank)), iso-electric focussing method HC 2005 | JRH |
| Blood | Sickle cell solubility | Streck Sickledex modified Itano commercial kit H 1509 | JRH HH |
| END | | | |

Assessment Manager: SG Page 17 of 17