# Schedule of Accreditation

**issued by**

# United Kingdom Accreditation Service

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

**9092**

**Accredited to ISO 15189:2022**

## Synnovis Analytics LLP

**Issue No:** 019 **Issue date:** 04 December 2025


**Department of Haematological Medicine**
**2nd Floor**
**Friars Bridge Court**
**41-43 Blackfriars Road**
**London**
**SE1 8NZ**
**United Kingdom**

**Contact: Nura Ibrahim**
**Tel: +44 (0) 203 299 7685**
**E-Mail: nura.ibrahim@synnovis.co.uk**
**Website: www.synnovis.co.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 |
|---|---|---|---|
| **Address**<br>Department of Haematological Medicine<br>Ground Floor, Bessemer Wing<br>King's College Hospital<br>Denmark Hill<br>London<br>SE5 9RS | **Local contact**<br>Nura Ibrahim (as above) | Haematology<br>Molecular Haematology<br>Haemoglobinopathies<br>Blood Transfusion<br>Coagulation | KCH |
| Blackfriars Hub Laboratory<br>2nd Floor<br>Friars Bridge Court<br>41 Blackfriars Road<br>London<br>SE1 8NZ | Nura Ibrahim (as above) | Blood Sciences Laboratory:<br>Haematology | HUB |
| Pathology Department<br>South Wing, 1st Floor<br>Princess Royal University Hospital<br>Orpington<br>Kent<br>BR6 8ND | Nura Ibrahim (as above) | Blood Sciences Laboratory:<br>Haematology<br>Blood Transfusion<br>Storage & issue of blood & blood products | PRUH |

| | |
|---|---|
| 9092<br>**Accredited to ISO 15189:2022** | **Schedule of Accreditation**<br>**issued by**<br>**United Kingdom Accreditation Service**<br>2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK |
| | **Synnovis Analytics LLP**<br>**Issue No:** 019 **Issue date:** 04 December 2025 |
| **Testing performed by the Organisation at the locations specified below** | |

**Site activities performed away from the locations listed above:**

| Location details | Activity |
|---|---|
| King's College Hospital (Denmark Hill):<br>• Emergency Department<br>• Liver Theatre<br>• Main Theatres<br>• Nightingale Birth Centre (NBC)<br>• Liver Unit ITU (LITU)<br>• Centenary Wing<br>• Harris Birthright (Windsor Walk)<br>• Critical Care Unit<br>• Guthrie Ward (X-ray)<br><br>King's College Hospital (Orpington Site):<br>• Orthopaedic Theatres | Storage & issue of blood & blood products only |

DETAIL OF ACCREDITATION

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used | Location code |
|---|---|---|---|
| HUMAN TISSUES AND FLUIDS (cont'd)<br><br>Amniotic Fluid<br>Chorionic Villus Sample<br>Cultured Amniocytes<br>Dried Blood Spot<br>Foetal Blood<br>Formalin-Fixed Paraffin-Embedded (FFPE) samples<br>Plasma<br>Saliva<br>Serum<br>Whole blood | <u>Molecular haematology examinations for the purpose of clinical diagnosis</u> | In house documented methods incorporating manufacturers' instructions as required<br><br>DNA Extraction, manual methods and automated using:<br><br>QIAsymphony (blood)<br>LP-HAE-PND105<br><br>Qiagen EZ1<br>LP-HAE-PND076 (foetal samples)<br>LP-HAE-PND116 (saliva) | KCH |
| Genomic DNA extracted in house from whole blood (unless stated otherwise for specified tests) or received as primary sample type | | PCR amplification using any of (unless stated otherwise for specified tests):<br>Applied Biosystems Veriti™ Thermal Cycler and:<br>Veriti™ Thermal Cycler User Guide (PN 4375799)<br>Rotor-Gene Q and:<br>Rotor-Gene Q Operator manual 1.7.87<br>Eppendorf Mastercycler Nexus and:<br>Eppendorf Mastercycler Nexus operating manual (2012) | |
| and DNA extracted from<br>Saliva | Thrombophilia genetic analysis:<br><br>Detection of three genetic variants affecting thrombophilia:<br>Factor V Leiden<br>Prothrombin C<br>Methylene Tetrahydrofolate Reductase<br><br>Hereditary Haemochromatosis genetic analysis:<br>Detection of the two common genetic variants in the HFE gene associated with hereditary haemochromatosis:<br>HFE p.C282Y<br>HFE p.H63D | <br><br>RT PCR Allelic discrimination<br>TaqMan assay<br>LP-HAE-PND110<br><br><br><br>RT PCR Allelic discrimination<br>TaqMan assay<br>LP-HAE-PND104 | KCH |

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used | Location code |
|---|---|---|---|
| HUMAN TISSUES AND FLUIDS (cont'd) | Molecular haematology examinations for the purpose of clinical diagnosis (cont'd) | In house documented methods incorporating manufacturers' instructions as required | |
| Genomic DNA extracted in house from whole blood (unless stated otherwise for specified tests) or received as primary sample type (cont'd) | Detection of large deletions and duplications in the HFE gene | Multiplex ligation-dependent probe amplification (MLPA) by PCR using: Eppendorf Mastercycler Nexus or Applied Biosystems Veriti™ Applied Biosystems 3500XL Genetic Analyser LP-HAE-PND117 | KCH |
| | Alpha-1-antitrypsin deficiency genotyping: | | |
| | Detection of two genetic variants in the SERPINA1 gene which are known to cause Alpha-1-antitrypsin deficiency: Z and S mutations | RT PCR machine allelic discrimination TaqMan assay LP-HAE-PND111 | |
| | Gilbert's syndrome genetic analysis: | | |
| | Homozygosity for the 7 repeat allele of the dinucleotide repeat region in the promoter of the UGT1A gene | Applied Biosystems 3500XL Genetic Analyser LP-HAE-PND071 | |
| and DNA extracted from Saliva | Variegate and Acute Intermittent Porphyria genetic analysis: | | KCH |
| | Detection of the most common PPOX gene mutation known to cause Variegate Porphyria: R59W | RT PCR allelic discrimination TaqMan assay using: Rotor-Gene Q LP-HAE-PND122 | |
| | Detection of other single base changes and microlesions in the PPOX gene that cause Variegate Porphyria | Sanger Sequencing using: Applied Biosystems 3500XL Genetic Analyser LP-HAE-PND125 | |
| | Detection of single base changes and microlesions in the HMBS gene that cause Acute Intermittent Porphyria | Sanger Sequencing using: Applied Biosystems 3500XL Genetic Analyser LP-HAE-PND121 | |

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used | Location code |
|---|---|---|---|
| HUMAN TISSUES AND FLUIDS (cont'd)<br><br>Genomic DNA extracted in house from whole blood (unless stated otherwise for specified tests) or received as primary sample type (cont'd) | <u>Molecular haematology examinations for the purpose of clinical diagnosis</u> (cont'd) | In house documented methods incorporating manufacturers' instructions as required | KCH |
| and DNA extracted from CVS | Pyruvate Kinase deficiency genetic analysis: | | |
| | Detection of large deletions and duplications in the PKLR gene | MLPA by PCR using:<br>Eppendorf Mastercycler Nexus or Applied Biosystems Veriti™ Thermal Cycler- Veriti™<br>Applied Biosystems 3500XL Genetic Analyser<br>LP-HAE-PND117 | |
| and DNA extracted from:<br>Saliva<br>Dried Blood Spot<br>Amniotic Fluid<br>CVS<br>Cultured Amniocytes<br>Foetal Blood | Haemoglobin variant genetic analysis: | | KCH |
| | Detect of the most common HBB gene mutation known to cause Sickle cell disease: HbS and the haemoglobin variant: HbC | RT PCR Allelic discrimination TaqMan assay using:<br>Rotor-Gene Q<br>LP-HAE-PND039 | |
| | Confirmation of HbS and HbC variants | Restriction fragment length polymorphism (RFLP) assay by PCR using:<br>Eppendorf Mastercycler Nexus or Applied Biosystems Veriti™ and Agarose gel electrophoresis<br>LP-HAE-PND013 | |
| | Confirmation of the HbS mutation | Sanger Sequencing using:<br>Applied Biosystems 3500XL Genetic Analyser<br>LP-HAE-PND039 | KCH |

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used | Location code |
|---|---|---|---|
| HUMAN TISSUES AND FLUIDS (cont'd)<br><br>Genomic DNA extracted in house from whole blood (unless stated otherwise for specified tests) or received as primary sample type (cont'd)<br><br>and DNA extracted from:<br>Saliva | <u>Molecular haematology examinations for the purpose of clinical diagnosis</u> (cont'd)<br><br>Detection of large deletions and duplications in the HBB, HBA1 and HBA2 genes<br><br>Thalassaemia syndromes genetic analysis: | In house documented methods incorporating manufacturers' instructions as required<br><br>MLPA by PCR and:<br>Applied Biosystems 3500XL Genetic Analyser<br>LP-HAE-PND117 | KCH |
| Dried blood spots<br>Amniotic fluid<br>CVS<br>Cultured amniocytes<br>Fetal blood | Detection of common deletions in the HBA1 and HBA2 genes known to cause Alpha Thalassaemia | Gap PCR using:<br>Eppendorf Mastercycler Nexus or Applied Biosystems Veriti™ Thermal Cycler and Agarose gel electrophoresis<br>LP-HAE-PND052 | |
| | Detection of single base changes and microlesions in the HBB, HBA1 and HBA2 genes that cause Thalassaemia syndromes | Sanger Sequencing using:<br>Applied Biosystems 3500XL Genetic Analyser<br>LP-HAE-PND118 | |
| | Detection of large deletions and duplications in the alpha globin loci on chromosome 16 and the beta globin loci on chromosome 11 | MLPA by PCR using:<br>Eppendorf Mastercycler Nexus or Applied Biosystems Veriti™ Thermal Cycler<br>Applied Biosystems 3500XL Genetic Analyser<br>LP-HAE-PND117 | |

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used | Location code |
|---|---|---|---|
| HUMAN TISSUES AND FLUIDS (cont'd) | Molecular haematology examinations for the purpose of clinical diagnosis (cont'd) | In house documented methods incorporating manufacturers' instructions as required | KCH |
| Genomic DNA extracted in house from whole blood (unless stated otherwise for specified tests) or received as primary sample type (cont'd) | Hereditary persistence of fetal haemoglobin (HPFH) genetic analysis: | | |
| and DNA extracted from:<br>Whole blood<br>Saliva<br>Dried Blood Spot | Detection of the most common deletional forms of HPFH caused by large deletions in the beta globin loci | MLPA by PCR using:<br>Eppendorf Mastercycler Nexus or Applied Biosystems Veriti™ Thermal Cycler<br>Applied Biosystems 3500XL Genetic Analyser<br>LP-HAE-PND072 | |
| | Confirmation of the deletional forms of HPFH | Gap PCR Eppendorf Mastercycler Nexus or Applied Biosystems Veriti™ Thermal Cycler and Agarose gel electrophoresis<br>LP-HAE-PND072 | |
| | Detection of single base changes and microlesions in the promoter regions of the A gamma (HBG1) and the G gamma (HBG2) globin genes to that cause non-deletional HPFH | Sanger Sequencing using:<br>Applied Biosystems 3500XL Genetic Analyser<br>LP-HAE-PND118 | |
| and DNA extracted from:<br>Whole blood<br>Amniotic Fluid<br>CVS<br>Cultured Amniocytes<br>Dried Blood Spot<br>Fetal Blood<br>Formalin-Fixed Paraffin-Embedded (FFPE) samples<br>Plasma<br>Serum | Maternal cell contamination:<br>Analysis of repeat length of 16 microsatellite markers | ABI AmpFLSTR kit multiplexed PCR reaction. Products analysed using Applied Biosystems 3500XL Genetic Analyser<br>LP-HAE-PND067 | KCH |

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used | Location code |
|---|---|---|---|
| HUMAN TISSUES AND FLUIDS (cont'd) | Molecular haematology examinations for the purpose of clinical diagnosis (cont'd) | In house documented methods incorporating manufacturers' instructions as required | |
| Genomic DNA extracted in house from whole blood (unless stated otherwise for specified tests) or received as primary sample type (cont'd) | Red blood cell disorders and mutations:<br>Membranopathy<br>Red Cell Enzyme<br>Haemoglobinopathies<br>Congenital Erythrocytosis<br>Diamond-Blackfan Anaeimia<br>Bone Marrow Failure<br>Thrombocytopenia<br>Neutropenia<br>Porphyria<br>Siderblastic Anaemia<br>Iron Regulation<br>HLH<br>Lymphedema<br>Single Genes (HP, Serpina1, UGTA1)<br>Sex Chromosome Markers | Beckman Coulter Biomek i7 robot to construct sequencing libraries followed by hybridisation to probe targets and amplification.<br>Tapestation 4150<br>Amplified library sequenced by Next Generation Sequencing (NGS) on Illumina MiSeq.<br>Data analysed using a NIPY pipeline<br>LP-HAE-PND132 | KCH |
| | Validation of variants from NGS | Sanger Sequencing using:<br>Applied Biosystems 3500XL Genetic Analyser<br>LP-HAE-PND131 | KCH |

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used | Location code |
|---|---|---|---|
| HUMAN BODY FLUIDS (cont'd) | Haematology examinations for the purpose of clinical diagnosis | In house documented methods incorporating manufacturers' instructions as required | |
| Blood | Full Blood Count (FBC):<br>White cell count WBC<br>Red cell count RBC<br>Haemoglobin HGB<br>Haematocrit (HCT)<br>MCV<br>MCH<br>MCHC<br>RDW-CV<br>Platelet count (PLT)<br>MPV<br>#Neutrophils<br>#Lymphocytes<br>#Monocytes<br>#Eosinophils<br>#Basophils<br>#NRBC<br>Metamylelocyte count<br>Mylelocyte count<br>Promyelocyte count<br>Blasts count<br>Blast Flag<br>Fragments Flag<br>Immature Granulocyte Flag<br>Platelet Clump Flag<br>Atypical Lymphocyte Flag | Sysmex XN-9100 series – XN10<br>Optical Analysis (Flow Cytometry)<br>LP-BS-HA001<br>LP-BS-HA005<br>LP-BS-HA008<br>BSL-HUB-HAEM-SOP1<br>BSL-HUB-HAEM-SOP6 | KCH<br>HUB |
| Whole Blood | Full Blood Count (FBC) Analysis:<br>Total red cell count<br>Haemoglobin<br>Mean cell volume<br>Mean cell haemoglobin<br>Mean cell haemoglobin concentration<br>Haematocrit<br>Red cell distribution width<br>Total white cell count<br>Absolute neutrophil count<br>Absolute lymphocyte count<br>Absolute monocyte count<br>Absolute eosinophil count<br>Absolute basophil count<br>Platelet count<br>Mean platelet volume | Sysmex XN10 & XN20<br>Fluorescence Flow Cytometry<br>BH-AP-040 | PRUH |

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used | Location code |
|---|---|---|---|
| HUMAN BODY FLUIDS (cont'd) | Haematology examinations for the purpose of clinical diagnosis (cont'd) | In house documented methods incorporating manufacturers' instructions as required | |
| Blood | Reticulocytes:<br>Retic absolute<br>Retic Percentage<br>LFR<br>MFR<br>HFR<br>Retic RBC<br>IRF<br>%HYPO<br>Ret-He | Sysmex XN-9100 series – XN10<br>Optical Analysis (Flow Cytometry)<br>LP-BS-HA001<br>LP-BS-HA005<br>BSL-HUB-HAEM-SOP1<br>BSL-HUB-HAEM-SOP6 | KCH<br>HUB |
| Whole Blood | Reticulocytes | Sysmex XN10 & XN20<br>Fluorescence Flow Cytometry<br>BH-AP-040 | PRUH |
| Blood | Citrate platelet count | Sysmex XN-9100 series – XN10<br>Optical Analysis (Flow cytometry)<br>BSL-HUB-HAEM-SOP1<br>BSL-HUB-HAEM-SOP6 | HUB |
| Whole Blood | Nucleated Red Cell Count | Sysmex XN10 & XN20<br>Fluorescence Flow Cytometry<br>BH-AP-040 | PRUH |

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used | Location code |
|---|---|---|---|
| HUMAN BODY FLUIDS (cont'd) | Haematology examinations for the purpose of clinical diagnosis (cont'd) | In house documented methods incorporating manufacturers' instructions as required | |
| Blood | Detection and speciation of Malaria parasites:<br>*Plasmodium falciparum,*<br>*P. vivax,*<br>*P. ovale,*<br>*P. malariae,*<br>*P. knowlesi,* t<br>trypanosomes,<br>microfilariae,<br>*Leishmania* spp. | Wright-Giemsa & Giemsa R66 staining followed by Light Microscopy<br>LP-BS-ML008,<br>LP-BS-ML009 | KCH |
| Whole Blood (Blood Film) | Detection & presumptive speciation of Malaria & non-malaria parasites, including:<br>*P. falciparum, P. vivax, P. ovale, P. malariae, P. knowlesi*<br><br>% Parasitaemia for *P. falciparum* & *P. knowlesi* | Thick and thin film Giemsa (pH7.2) staining<br>BH-AP-002<br><br>Nikon Eclipse 80i<br>Olympus BX43<br>Microscopy<br>BH-AP-10<br>BH-AP-30 | PRUH |
| | *P. falciparum*-specific HRPII antigen<br>Pan-malarial antigen of:<br>*P. falciparum,*<br>*P. vivax,*<br>*P. ovale,*<br>*P. malariae* | BINAX NOW ICT<br>Immunochromatographic assay<br>LP-BS-ML009 | KCH |
| Whole Blood | Detection of Malaria antigens:<br>*Plasmodium falciparum* HRP2 &<br>*P. falciparum, P. vivax, P. ovale, P. malariae* Pan LDH | CareUS<br>Immunochromogenic method<br>BH-AP-002 | PRUH |
| Blood (Thin blood films) | Detection of *Plasmodium* spp. | Pathway Diagnostics Quantitative Buffy Coat (QBC) kit & Fluorescence microscopy<br>LP-BS-ML009 | KCH |
| Blood | Morphological analysis & differential cell count | Light Microscopy<br>LP-BS-ML007,<br>LP-BS-ML018 | KCH |

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used | Location code |
|---|---|---|---|
| HUMAN BODY FLUIDS (cont'd) | Haematology examinations for the purpose of clinical diagnosis (cont'd) | In house documented methods incorporating manufacturers' instructions as required | |
| Blood | Erythrocyte Sedimentation Rate (ESR) | Sysmex Starrsed Interrliner XN FRL Westergren method<br>LP-BS-HA002 | KCH |
| | | Sysmex Starrsed Interliner XN9100<br>BSL-HUB-HAEM-SOP6 | HUB |
| Whole Blood | Erythrocyte Sedimentation Rate (ESR) | StaRRsed Autocompact<br>Red cell sedimentation<br>BH-AP-011 | PRUH |
| Blood | Infectious Mononucleosis screen:<br>Detection of the heterophile antibody | Accusay Mono Solid-phase immunoassay<br>and:<br>LP-BS-ML003 | KCH |
| Plasma | Prothrombin/ INR*<br>Activated partial thromboplastin time/APTT*<br>Clauss Fibrinogen*<br>Thrombin Time /TT* | Sysmex CN6500 (tests marked with * for urgent workflow)<br>LP-BS-HT0013<br>Sysmex CS-5100<br>Clotting method<br>LP-BS-HT001<br>LP-BS-HT003<br>LP-BS-HT004 | KCH |
| Whole Blood | Clauss Fibrinogen | Sysmex CS-2500<br>Spectrophotometry<br>BH-CP-002 | PRUH |
| Plasma | Prothrombin time/PT<br>Activated partial thromboplastin time/APTT<br>APTT ratio<br>Fibrinogen<br>D-Dimer<br>INR<br>INR and APTT 50/50 correction<br>Reptilase time | Sysmex CN6000<br>BSL-ALL-HT-SOP1 | HUB |

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used | Location code |
|---|---|---|---|
| HUMAN BODY FLUIDS (cont'd) | Haematology examinations for the purpose of clinical diagnosis (cont'd) | In house documented methods incorporating manufacturers' instructions as required | |
| Whole Blood | Clotting Screen:<br>Prothrombin Time (PT)<br>Activated Partial Thromboplastin Time (APTT) | Sysmex CS-2500<br>Spectrophotometry<br>Correction studies (where required)<br>BH-CP-002 | PRUH |
| Plasma | Factor Assays:<br>FII<br>FV<br>FVII<br>FVIII<br>FIX<br>FX<br>FXI<br>FXII | Sysmex CN6500<br>LP-BS-HT0013<br>Sysmex CS-5100<br>Clotting method<br>LP-BS-HT001<br>LP-BS-HT003<br>LP-BS-HT004 | KCH |
| Plasma | LA Screen (DRVVT)<br>Activated Protein C Resistance | Sysmex CS-5100<br><br>Clotting method<br>LP-BS-HT005<br>LP-BS-HT006 | KCH |
| Plasma | DDimer<br>VWF Antigen<br>Free Protein S Antigen | Sysmex CN6500 (tests marked with * for urgent workflow)<br>LP-BS-HT0013<br>Sysmex CS-5100<br>Latex bead Immunoturbidimetric Assay<br>LP-BS-HT003<br>LP-BS-HT006<br>LP-BS-HT008 | KCH |
| Whole Blood | D-dimer | Sysmex CS-2500<br>Spectrophotometry<br>BH-CP-002 | PRUH |
| Plasma | Anti-Xa:<br>Rivaroxaban<br>Apixaban<br>Edoxaban<br>Dabigataran<br>Antithrombin Activity<br>Protein C Activity | Sysmex CS-5100<br>Chromogenic method<br>LP-BS-HT007<br>LP-BS-HT005 | KCH |

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used | Location code |
|---|---|---|---|
| HUMAN BODY FLUIDS (cont'd) | Haematology examinations for the purpose of clinical diagnosis (cont'd) | In house documented methods incorporating manufacturers' instructions as required | |
| Blood | Haemoglobin H bodies identification | Supra-vital staining with brilliant Cresyl blue and microscopic examination LP-HAE-RC-HB009 | KCH |
| Blood | Haemoglobin S and Haemoglobin F quantification | Bio-Rad Variant II HPLC analyser LP-HAE-RC-HB003 | KCH |
| Blood | Investigation for Hereditary Spherocytosis | EMA dye binding to red blood cells and flow cytometry analysis on Becton Dickinson FACS Canto II LP-HAE-RC-NEH-007 | KCH |
| Bone marrow | Morphological analysis | May-Grunwald and Giemsa staining followed by microscopy LP-HAE-IM1005 | |
| Whole Blood (Blood Film) | Red Cell morphology<br>White Cell morphology<br>Platelet morphology<br>White Cell Differential | RAL Stainer<br>Methylene Blue and May-Grünwald stains<br>Methanol Free, Chromatic Detection<br>BH-AP-039<br><br>Nikon Eclipse 80i<br>Olympus BX43<br>Microscopy<br>BH-AP-10<br>BH-AP-30 | PRUH |

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used | Location code |
|---|---|---|---|
| HUMAN BODY FLUIDS (cont'd) | Blood transfusion examinations for the purpose of clinical diagnosis | In house documented methods incorporating manufacturers' instructions as required | |
| Blood | ABO / RhD Blood Group antigens:<br>A, B & D | Automated using:<br>Biorad Banjo ID reader<br>Biorad IH1000<br>Biorad IH500<br>LP-HAE-BT2-001, BT-3-A | KCH |
| Blood | Antibody Screen for:<br>D, C, Cw, E, c, e, K, Fya, Fyb, Jka, Jkb, S, s, Lea, Leb, M,N & Lua | Automated using:<br>Biorad Banjo ID reader<br>Biorad IH1000<br>Biorad IH500<br>LP-HAE-BT2-001, BT3-A | KCH |
| Blood (Red cells, Plasma) | ABO / RhD typing by detection & identification of antigens:<br>A Rh D Positive<br>AB Rh D Positive<br>B Rh D Positive<br>O Rh D Positive<br>A Rh D Negative<br>AB Rh D Negative<br>B Rh D Negative<br>O Rh D Negative | Automated using: CAT<br>BioRad IH500 & IH1000<br>BT-PP-041<br><br>Manual using: CAT<br>BioRad ABO and reverse grouping cards and A1 & B reagent cells<br>BT-PP-032 | PRUH |
| Blood (Plasma) | Antibody screen for detection of antibodies:<br>Rh – C, D, E, c, e, Cw<br>K, k, Kpa<br>Fya, Fyb<br>M, N, S, s<br>Jka, Jkb<br>Lea, Leb<br>Lua<br>P, P1 | Automated using: CAT<br>BioRad IH500 & IH1000<br>SOP??<br>BSL-KDP-BT-SOP5<br>Manual using: CAT<br>BioRad IAT technology, anti-IgG IAT gel cards and BioRad 3 cell antibody screening reagent cells<br>BT-PP-002 | PRUH |
| Blood (Plasma) | Antibody Identification of antibodies:<br>Rh – C, D, E, c, e, Cw<br>K, Kpa<br>Fya, Fyb<br>M, N, S, s<br>Jka, Jkb<br>Lea, Leb<br>Lua<br>P1 | Automated using: CAT<br>BioRad IH500 & IH1000<br>BT-PP-041<br><br>Manual using: CAT<br>BioRad IAT technology, anti-IgG IAT gel cards<br>BT-PP-002 | PRUH |

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used | Location code |
|---|---|---|---|
| HUMAN BODY FLUIDS (cont'd) | Blood transfusion examinations for the purpose of clinical diagnosis (cont'd) | In house documented methods incorporating manufacturers' instructions as required | |
| Blood | DAT (polyspecific, monospecific) | Automated using:<br>Biorad Banjo ID reader<br>Biorad IH1000<br>Biorad IH500<br>LP-HAE-BT2-001, BT2-05, BT3-D | KCH |
| Blood (Red cells) | Direct Antiglobulin Testing (DAT) | Automated using: CAT<br>BioRad IH500 & IH1000<br>BT-PP-041<br><br>Manual using: CAT<br>BioRad polyspecific & monospecific IgG and CD3d DAT cards<br>BT-PP-033 | PRUH |
| Blood | RHK phenotype antigens:<br>D,C,c, E, e, K | Automated using:<br>Biorad Banjo ID reader<br>Biorad IH1000<br>Biorad IH500<br>LP-HAE-BT2-001, BT2-003 | KCH |
| Blood (Red cells) | Rh/K phenotyping of antigens:<br>C, c, E, e, K | Automated using: CAT<br>BioRad IH500 & IH1000<br>BT-PP-041<br><br>Manual using: CAT<br>BioRad Rh/K antigen typing cards<br>BT-PP-006 | PRUH |
| Blood | Non-RHK phenotype antigens:<br>Jka, Jkb, Lea, Leb, S, s, M/N, Fya, Fyb | Automated (except Fya/Fyb) using:<br>Biorad Banjo ID reader<br>Biorad IH500, ID- Incubator 37 SI, ID-Centrifuge 12 S, DiaCent-12<br>LP-HAE-BT2-003, BT3-008 | KCH |
| Blood | Non-RHK phenotype antigens:<br>Fya, Fyb (Biorad automated IH500) | Biorad column agglutination technique<br>Biorad Banjo ID reader<br>LP-HAE-BT2-019-Automated Sample processing using IH-500<br>LP-HAE-BT2-003 Automated and Manual Cell Typing | KCH |

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used | Location code |
|---|---|---|---|
| HUMAN BODY FLUIDS (cont'd) | Blood transfusion examinations for the purpose of clinical diagnosis (cont'd) | In house documented methods incorporating manufacturers' instructions as required | |
| Blood | Antibody Titres of:<br>Anti-A<br>Anti-B | Manual using:<br>Biorad Banjo ID reader<br>BioRad cards/gels, ID-Centrifuge 12, ID-Incubator 37I<br>LP-HAE-BT5-033 | KCH |
| Blood | Foetal maternal haemorrhage | Kleihauer acid elution test using Microscopy<br>LP-HAE-BT3-J | KCH |
| Blood (Red cells) | Foetal Maternal Haemorrhage | Kleihauer Acid Elution & microscopy<br>BT-PP-005 | PRUH |
| Blood | Antibody identification of:<br>D, C, Cw, E, c, e, K, Fya, Fyb, Jka, Jkb, S, s, Lea, Leb, M, N & Lua | Automated or manual using:<br>Biorad Banjo ID reader<br>Biorad IH500, ID-Incubator 37 SI, ID-Centrifuge 12 S<br>LP-HAE-BT2-002, BT3-B | KCH |
| Blood | Baby ABO / RhD Blood Group antigens:<br>A, B, AB & D | Automated using:<br>Biorad Banjo ID reader<br>Biorad IH1000<br>Biorad IH500<br>LP-HAE-BT3-A, BT2-001 | KCH |
| Blood | ABO / RhD Blood Group antigens: A, B & D | Manual using:<br>BioRad cards/gels, Biorad Banjo ID reader<br>DiaCent 12 Centrifuge<br>LP-HAE-BT4-008 | KCH |
| Blood | DAT (polyspecific, monospecific) | Manual using:<br>Biorad Banjo ID reader<br>Biorad column agglutination technique<br>LP-HAE-BT2-05 | KCH |
| Blood | Antibody Screen for: D, C, Cw, E, c, e, K, Fya, Fyb, Jka, Jkb, S, s, Lea, Leb, M,N & Lua (manual) | Manual using:<br>Biorad Banjo ID reader<br>Biorad column agglutination technique<br>LP-HAE-BT3-A | KCH |
| Blood | Non-RHK phenotype antigens:<br>Jka, Jkb, Lea, Leb, S, s, M/N, Fya, Fyb (manual) | Manual using:<br>Biorad Banjo ID reader<br>Biorad column agglutination technique<br>LP-HAE-BT2-003 | KCH |

| Materials/Products tested | Type of test/Properties measured/Range of measurement | Standard specifications/ Equipment/Techniques used | Location code |
|---|---|---|---|
| HUMAN BODY FLUIDS (cont'd) | Blood transfusion examinations for the purpose of clinical diagnosis (cont'd) | In house documented methods incorporating manufacturers' instructions as required | |
| Blood | RHK phenotype antigens: D,C,c, E, e, K (manual) | Manual using:<br>Biorad Banjo ID reader<br>Biorad column agglutination technique<br>LP-HAE-BT2-003 | KCH |
| Blood | Antibody Titres of: Anti-A, Anti-B (Biorad automated IH500) | Biorad column agglutination technique<br>Biorad Banjo ID reader<br>LP-HAE-BT2-019-Automated Sample processing using IH-500<br>LP-HAE-BT5-033 Titration Of ABO Antibodies | KCH |
| Blood | Baby ABO / RhD Blood Group antigens: A, B, AB & D (manual) | Manual using:<br>Biorad Banjo ID reader<br>Biorad column agglutination technique<br>LP-HAE-BT3-A | KCH |
| Blood | Compatibility testing of patient plasma with donor cells (Manual) | Manual using:<br>Biorad Banjo ID reader<br>Biorad column agglutination technique<br>LP-HAE-BT4-004 | KCH |
| Blood | Compatibility testing of patient plasma with donor cells (Automated) | Biorad automated IH1000 & IH500<br>Biorad column agglutination technique<br>Biorad Banjo ID reader<br>LP-HAE-BT2-019-Automated Sample processing using IH-500<br>LP-HAE-BT4-004 Serological (Full) Crossmatching/Compatibility Testing | KCH |
| Blood (Red cells, Plasma) | Compatibility testing (Crossmatch) | Manual using: CAT<br>BioRad Anti-IgG IAT gel cards<br>BT-PP-003 | PRUH |
| Blood (Red cells, Plasma) | Compatibility testing (Crossmatch) | Automated using: CAT<br>BioRad IH500 & IH1000<br>SOP??BSL-KDP-BT-SOP5 | PRUH |
| END | | | |