


# Schedule of Accreditation

issued by

## United Kingdom Accreditation Service

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

|  |  |   |
|--|--|---|
|  <p><b>Accredited to<br/>ISO 15189:2022</b></p> | <b>University Hospitals Plymouth NHS Trust</b><br><br><b>Issue No: 013 Issue date: 18 November 2025</b>  |   |
|  | <b>Derriford Combined Laboratory</b><br><b>University Hospitals Plymouth NHS Trust</b><br><b>Derriford Hospital</b><br><b>Derriford</b><br><b>Plymouth</b><br><b>Devon</b><br><b>PL6 8DH</b> | <b>Contact: Kate Prior</b><br><b>Tel: +44 (0) 1752 430097</b><br><b>E-Mail: kate.prior3@nhs.net</b><br><b>Website: www.plymouthhospitals.nhs.uk</b> |
| <b>Testing performed at the above address only</b>   |  |   |

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

| Location details   | Activity                                       |
|--|--|
| Derriford Combined Laboratory (Blood Bank)<br>University Hospitals Plymouth NHS Trust<br>Derriford Hospital<br>Derriford<br>Plymouth<br>Devon<br>PL6 8DH | Storage & issue of blood & blood products only |
| Cardiac Theatre<br>University Hospitals Plymouth NHS Trust<br>Derriford Hospital<br>Derriford<br>Plymouth<br>Devon<br>PL6 8DH                            | Storage & issue of blood & blood products only |
| Cardiac Intensive Care<br>University Hospitals Plymouth NHS Trust<br>Derriford Hospital<br>Derriford<br>Plymouth<br>Devon<br>PL6 8DH                     | Storage & issue of blood & blood products only |



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

| Location details   | Activity                                       |
|--|--|
| Maternity Delivery and Theatre<br>University Hospitals Plymouth NHS Trust<br>Derriford Hospital<br>Derriford<br>Plymouth<br>Devon<br>PL6 8DH | Storage & issue of blood & blood products only |
| Theatre Suite (Level 2)<br>University Hospitals Plymouth NHS Trust<br>Derriford Hospital<br>Derriford<br>Plymouth<br>Devon<br>PL6 8DH        | Storage & issue of blood & blood products only |
| Theatre Suite (Level 4)<br>University Hospitals Plymouth NHS Trust<br>Derriford Hospital<br>Derriford<br>Plymouth<br>Devon<br>PL6 8DH        | Storage & issue of blood & blood products only |
| Peninsula NHS Orthopaedic Treatment Centre<br>Brest Road<br>Plymouth<br>PL6 5XP  | Storage & issue of blood & blood products only |
| St. Luke's Hospice<br>Stamford Close<br>Plymouth<br>PL9 9XA  | Storage & issue of blood & blood products only |
| Main Ward<br>Plymouth Hospitals NHS Trust<br>Tavistock Hospital<br>Spring Hill<br>Tavistock<br>PL19 8LD                                      | Storage & issue of blood & blood products only |



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

| <b>Location details</b>  | <b>Activity</b>                                |
|--|--|
| Renal Unit<br>Plymouth Hospitals NHS Trust Renal Unit<br>Plymbridge Road<br>Estover<br>Plymouth<br>PL6 7FL             | Storage & issue of blood & blood products only |
| NHS South Devon and Torbay CCG<br>Main Ward<br>South Hams Hospital<br>Plymouth Road<br>Kingsbridge<br>Devon<br>TQ7 1AT | Storage & issue of blood & blood products only |



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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>Citrated Plasma</p> | <p><u>Coagulation examinations for the purpose of clinical diagnosis and management</u></p> <p>Clotting Tests</p> <p>Prothrombin Time - PT Activated Partial Thromboplastin Time</p> <p>Clauss Fibrinogen</p> <p>INR Internal Normalised Ratio (INR)</p> <p>Lupus Anticoagulant</p> <p>Thrombophilia screening:</p> <p>Free Protein S Activity</p> <p>Protein C Activity</p> <p>Anti Thrombin III</p> <p>Clotting factors:<br/>Factor II<br/>Factor V<br/>Factor VII<br/>Factor VIII<br/>Factor IX<br/>Factor X<br/>Factor XI<br/>Factor XII<br/>Factor XIII</p> <p>Von Willebrand Factor Antigen</p> <p>D-dimer (FDP)</p> <p>Von Willebrand Factor Activity</p> | <p>Procedures documented in manufacturer's equipment manuals in conjunction with in-house procedures as specified below</p> <p>Stago STA-R Max:<br/>Viscosity clot detection method</p> <p>SOP: DC0041, DC37</p> <p>SOP: DC0099</p> <p>Calculated using the patient's PT and reagent ISI Technoclone Ak-calibrant SOP: DC0041</p> <p>Viscosity clot detection method<br/>SOP DC0012</p> <p>Chromogenic detection method</p> <p>SOP: DC0032</p> <p>SOP: DC0028</p> <p>SOP: DC0002</p> <p>Viscosity clot detection<br/>SOP DC0029 and DC0036</p> <p>Immunoturbidimetric method<br/>SOP: DC0027</p> <p>SOP: DC0001</p> <p>SOP: DC0151</p> |



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| <p>HUMAN BODY FLUIDS (cont'd)</p> <p>Citrated plasma</p> <p>Serum (unless otherwise specified)</p> | <p><u>Coagulation examinations for the purpose of clinical diagnosis and management</u> (cont'd)</p> <p>Anti-Xa Assay for Anticoagulant Control</p> <ul style="list-style-type: none"> <li>- LMW Heparin</li> <li>- Fondaparinux</li> <li>- Rivaroxban</li> <li>- Apixaban</li> </ul> <p>Thrombin Time</p> <p>Reptilase Time</p> <p>Platelet Function Studies</p> <ul style="list-style-type: none"> <li>- PFA-100</li> <li>- Platelet Aggregation</li> </ul> <p><u>Immunology examinations for the purpose of clinical diagnosis</u></p> <p>Investigation of auto immunity</p> <p>IgG Anti-Cardiolipin antibodies<br/>IgM Anti-Cardiolipin antibodies</p> <p>Anti Double stranded DNA Antibodies</p> <p>Anti Tissue Transglutaminase antibodies</p> <p>Anti Glomerular Basement Membrane (GMB) antibodies</p> <p>Anti Mitochondrial 2 (M2) Antibodies</p> <p>Anti TSH Receptor Autoantibodies</p> <p>Extractable Nuclear Antigen (ENA) Screen</p> | <p>Procedures documented in manufacturer's equipment manuals in conjunction with in-house procedures as specified below</p> <p>Chromogenic detection method SOP: DC0098</p> <p>Viscosity clot detection method SOP: DC0034</p> <p>Viscosity clot detection method SOP: DC0097</p> <p>PFA-100 analyser SOP: DC0048<br/>PAP-8E aggregometer SOP: DC0045</p> <p>Phadia UniCap 250 SOP UNI250/007</p> <p>DS2 analyser ELISA SOP: ELI/027 and ELI/013</p> <p>SOP: ELI/004</p> |



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| <p>HUMAN BODY FLUIDS (cont'd)</p> <p>Serum (unless otherwise specified) (cont'd)</p> | <p><u>Immunology examinations for the purpose of clinical diagnosis</u> (cont'd)</p> <p>Extractable Nuclear Antigens;</p> <p>Anti - nRNP/Sm<br/>Anti - Sm<br/>Anti - SSA/Ro<br/>Anti - Ro- 52<br/>Anti - SS- B/La<br/>Anti - SCL70<br/>Anti - PM-Sci<br/>Anti - Jo1<br/>Anti - CENBPB<br/>Anti - PCNA<br/>Anti - Nucleosomes<br/>Anti - Hhistone<br/>Anti - Ribosomal P</p> <p>Anti Myeloperoxidase (MPO) antibodies</p> <p>Anti Proteinase 3 (PR3) antibodies</p> <p>Investigation of Auto Immune Disease:</p> <p>Anti-Nuclear Antibodies</p> <p>Anti-Neutrophil Cytoplasmic Antibodies</p> <p>Cytoplasmic ANCA<br/>Perinuclear ANCA</p> | <p>Procedures documented in manufacturer's equipment manuals in conjunction with in-house procedures as specified below</p> <p>EuroImm Profile 3. Euroline method<br/>Immunoblot<br/>Immunofluorescence microscopy<br/>SOP AUT/004</p> <p>Phadia250<br/>UNI250 007</p> <p>Phadia250<br/>UNI250 007</p> <p>Indirect immunofluorescence microscopy using HEp-2 slides. QL3000 automated method AUT/005, manual method AUT/006</p> <p>Indirect immunofluorescence microscopy using ethanol fixed neutrophils. QL3000 automated method AUT/005, manual method AUT/006</p> |





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| <p>HUMAN BODY FLUIDS (cont'd)</p> <p>Peripheral Blood (EDTA)<br/>Bone marrow Aspirate<br/>CSF<br/>Fine needle Aspirate<br/>Pleural Fluid</p> | <p><u>Immunology/ Histochemistry examinations for the purpose of clinical diagnosis</u></p> <p>Haematological malignancy investigations using abnormal intracellular and extracellular marker expression for:</p> <p>Acute Leukaemia Panel:<br/>CD2, CD34, CD7, CD34, HLA-DR, CD33, CD13, CD20, CD117, CD19, CD10, CD14</p> <p>Chronic Leukaemia / Lymphoma panel:<br/>CD5, CD19, CD22, CD23, CD3, FMC7, Kappa, Lambda, CD25, CD4, CD10, CD103, CD38, CD20</p> | <p>Procedures documented in manufacturer's equipment manuals in conjunction with in-house procedures as specified below</p> <p>Becton Dickinson FACSLyric flow cytometer fluorescent labelled monoclonal antibody panels, acquired via laser using hydrodynamic focussing</p> <p>SOP: IMMHI/013, IMMHI/043, IMMHI/002B, IMMHI/003B</p> <p>SOP: IMMHI/040, IMMHI/046, IMMHI/050, IMMHI/030, IMMHI/001</p> |



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| HUMAN BODY FLUIDS (cont'd)   | <u>Immunology/ Histochemistry examinations for the purpose of clinical diagnosis</u> (cont'd)   | Procedures documented in manufacturer's equipment manuals in conjunction with in-house procedures as specified below   |
| Peripheral Blood (EDTA)<br>Bone marrow Aspirate<br>CSF<br>Fine needle Aspirate<br>Pleural Fluid (cont'd) | Haematological malignancy investigations using abnormal intracellular and extracellular marker expression for: (cont'd)<br><br>Lymphocyte Subset Analysis: TSET, CD19, CD56, CD3, CD4, CD8, CD4/CD8 Ratio<br><br>T Cell profile: CD4%, CD3, CD4, CD8, CD4/CD8 Ratio<br><br>PID: Primary Immunodeficiency B Cell Phenotyping (BSET) CD38, CD19, CD21, CD27, IgM, IgG | Becton Dickinson FACSLyric flow cytometer fluorescent labelled Monoclonal antibody panels, acquired via laser using hydrodynamic focussing<br><br>SOP: IMMHI/001 IMMHI/30<br><br>SOP IMMHI/001 IMMHI/030<br><br>SOP; IMMHI/047 IMMHI/013 |
| Peripheral Blood EDTA  | PNH (Paroxysmal Nocturnal Haematuria) Screening CD59, CD15, CD33  | Alexa 488 SOP: IMMHI/041<br><br>Becton Dickinson Fascanto II flow Cytometer:<br>MA Hydro dynamic focusing<br>SOP IMMHI/044 IMMHI/013   |
| Bone Marrow  | Myeloma Immunophenotyping: CD38, CD138, CD19+, CD56+  |  |
| Peripheral Blood EDTA  | Hereditary Spherocytosis screening  | Flow fluorescent expression EMA binding to RBC membrane.<br>SOP: IMMHI/024   |
| Peripheral Blood (Lithium Heparin)   | Neutrophil Function   | Oxidative burst measured by Flow Cytometry.<br>SOP: IMMHI/015  |
| Serum  | Protein electrophoresis<br>Alpha-1 globulins<br>Alpha-2 globulins<br>Beta globulins<br>Gamma globulins  | Helena V8 capillary zone electrophoretic separation<br>SOP: PROT/027, PROT/025   |



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| HUMAN BODY FLUIDS (cont'd) | <u>Immunology/ Histochemistry examinations for the purpose of clinical diagnosis</u> (cont'd)   | Procedures documented in manufacturer's equipment manuals in conjunction with in-house procedures as specified below   |
| Serum                      | Paraprotein Identification  | Immunofixation by gel electrophoresis<br>SOP: PROT/022   |
| Urine                      | Bence Jones Protein<br><br>Urine immunofixation of GAM Kappa / Lambda   | Gel based Electrophoresis protein separation SAS-3 and SAS-4 systems and Immuno fixation<br>SOP: PROT/023, SOP: PROT/024   |
| Serum                      | Serum Free Light Chains:<br>Kappa / Lambda ratio<br>Serum free Kappa<br>Serum free Lambda   | The Binding Site – Optilite<br>PROT 029  |
| Serum                      | IgG Sub- classes:<br>IgG1 subclass<br>IgG2 subclass<br>IgG4 subclass  | The Binding Site – Optilite<br>PROT 029  |
| Paired Serum and CSF       | IgG Oligoclonal Bands   | Electrophoretic separation of protein by isoelectric point.<br>Agarose gel pH gradient using Helena SAS-MX<br>SOP: PROT/026  |
| Whole Blood                | Cryoglobulins   | Gel based Electrophoresis protein separation Helena SAS-3 and SAS-4 systems Immunofixation<br>SOP: PROT/ 016<br><br>ThermoFisher Phadia UniCap 250 Sandwich Immunoassay measuring high total binding capacity: |
| Serum                      | Total IgE<br><br>Specific IgE antibodies:<br>c1 Penicillin G<br>c3 Penicillin V<br>c6 Amoxycilloxyl<br>d1 D.pteronysinus<br>e1 Cat dander | UNICAP/003<br><br>UNICAP/004   |









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| HUMAN BODY FLUIDS (cont'd) | <u>Immunology/ Histochemistry examinations for the purpose of clinical diagnosis</u> (cont'd)  | Procedures documented in manufacturer's equipment manuals in conjunction with in-house procedures as specified below  |
| Serum (cont'd)             | Chlorhexidine (C8)<br>Alpha-gal (o215)<br>Horse fly (i204)<br>Pea (f12)<br>Cow dander (e4)<br>Lupin pollen (w207)<br>Lupin Seed (f335)<br>Scallop (f338)<br>Alternaria alternate (m6)<br>rAra h 2 Peanut (f423)<br>rAra h 8 PR-10 (f352)<br>rAra h 9 LTP (f427)<br>rCor a 1 PR-10 ((f428)<br>nCor a 9, Hazel nut (f440)<br>rApi m 1 Phospholipase A2, Honeybee (i208)<br>rVes v 1 Phospholipase A1, Common wasp (i211)<br>rVes v 5 Common wasp (i209)<br>rMal d 1 PR-10, Apple (f434)<br>rMal d 3 LTP, Apple (f435)<br>rPru p 3 LTP, Peach (f420)<br>nGal d 1, Ovomuroid ((f233)<br>nGal d 2, Ovalbumin (f232)<br>rBet v 1 PR-10, Birch (t215) | Thermofisher Phadia UniCap 250 Sandwich Immunoassay measuring high total binding capacity:<br><br>UNICAP/004  |
| Serum                      | Mast Cell Tryptase   | UNICAP250/008   |
| Peripheral Blood EDTA      | HLA Typing of Deceased Donors<br>HLA-A, -B, -C<br>DRB1<br>DRB3/4/5 -DQA1<br>DQB1<br>DPB1<br>DPA1   | RT-PCR using LinkSeq kits, QuantStudio & SureTyper software.<br>SOP HANDIMOL051 &<br>SOP HANDIMOL052<br><br>LinkSeq - Backup method Luminex PCR-SSP (Bead array technology)<br>SOP: HANDILUM002 |



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| HUMAN BODY FLUIDS (cont'd)                                      | <u>Immunology/ Histochemistry examinations for the purpose of clinical diagnosis</u> (cont'd)  | Procedures documented in manufacturer's equipment manuals in conjunction with in-house procedures as specified below:  |
| Peripheral blood EDTA Spleen or lymph nodes for deceased donors | HLA typing of patients, donors (living & deceased), and disease association studies<br><br>HLA -A, -B, -C<br>DRB1<br>DRB3/4/5<br>-DQB1 | One Lambda Luminex PCR-SSO (Bead array technology)<br>SOP: HANDILUM002   |
| Peripheral blood EDTA   | HLA B27 typing for disease Associations  | PCR-SSP run on thermal cyclers Applied Biosystems 9700, Applied Biosystems Veriti & Techne TC412 with electrophoresis BioRad ATTO mini-PAGE (in-house primers)<br>SOP: HANDIMOL032<br>SOP: HANDIMOL018                           |
| Peripheral blood EDTA   | HLA typing for other disease associations:<br><br>Coeliac (DQB1)<br>Birdshot chorioretinopathy (HLA A)<br>Behcet's (HLA B)             | PCR-SSO (Bead array technology), One Lambda Luminex with analysis by HLA Fusion<br>SOP: HANDILUM 002<br>SOP: HANDILUM 026<br>SOP: HANDILUM 032   |
| Peripheral blood EDTA   | HLA B*57:01 typing for Abacavir reactivity   | PCR-SSP run on thermal cyclers Applied Biosystems 9700, Applied Biosystems Veriti & Techne TC412 with gel electrophoresis – BioRad ATTO mini-PAGE (in-house primers)<br>SOP: HANDIMOL019<br>SOP: HANDIMOL026<br>SOP: HANDIMOL032 |



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| HUMAN BODY FLUIDS (cont'd)   | <u>Immunology/ Histochemistry examinations for the purpose of clinical diagnosis</u> (cont'd)   | Procedures documented in manufacturer's equipment manuals in conjunction with in-house procedures as specified below:   |
| Peripheral blood EDTA  | Virtual cross matching for deceased donor kidneys and living donor kidneys  | PCR-SSP run on thermal cyclers Applied Biosystems 9700, Applied Biosystems Veriti & Techne TC412 with gel electrophoresis BioRad ATTO mini-PAGE (in-house primers)<br>SOP: HANDICALL016 |
| Serum  | HLA antibody screening to all common and well defined (CWD) HLA class I and II antigens (pos/neg)   | Bead array technology;<br>One Lambda Luminex with analysis by HLA Fusion<br>SOP: HANDILUM005<br>SOP: HANDILUM011<br>SOP: HANDIFLOW007<br>SOP: HANDIFLOW018<br>SOP: HANDIFLOW037         |
| Serum  | HLA antibody identification to all common and well defined (CWD) HLA class I and II antigens  | Bead array technology;<br>One Lambda Luminex with analysis by HLA Fusion<br>SOP: HANDILUM008<br>SOP: HANDIFLOW018<br>SOP: HANDIFLOW037<br>SOP: HANDIMOL024                              |
| Serum sample(s) from Recipient. EDTA (living) or spleen cadaveric) samples | Flow cytometric crossmatching for transplant<br><br>Identifies HLA specific IgG antibodies on T and B cells which are an increased risk to transplant | 3 colour flow cytometry using BD Flow Cytometer (in-house method)<br><br>SOP: HANDICALL006<br>SOP: HANDIFLOW006<br>SOP: HANDIFLOW007<br>SOP: HANDIMOL024<br>SOP: TT/CALL/008            |



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| HUMAN BODY FLUIDS (cont'd)  | <u>Blood Transfusion examinations to assist in clinical investigations</u>   | Procedures documented in manufacturers equipment manuals in conjunction with documented procedures as specified below:                            |
| Whole blood EDTA            | Blood group determination<br>By detection and<br>Identification of red cell<br>Antigens:<br>A Rh D Positive<br>AB Rh D Positive<br>B Rh Positive<br>O Rh Positive<br>A Rh Negative<br>AB Rh Negative<br>B Rh Negative<br>O Rh Negative   | BIO RAD Monoclonal antibody column agglutination technology, automated using the Immucor NEO blood grouping analyser<br>SOP: BB111 and:           |
| Whole Blood EDTA/ Red cells | Red cell atypical antibody Screening for the detection of:<br>Rhesus system antibodies:<br>Anti Cw, anti C, anti c, Anti D<br>anti E, anti e.<br>Kell system antibodies:<br>anti K, anti k, anti Kpa, anti Kpb.<br>Kidd system antibodies:<br>anti Jka, anti Jkb.<br>Duffy system antibodies:<br>anti Fya, anti Fyb.<br>Lutheran system antibodies:<br>Lua, Lub.<br>MNS system antibodies:<br>anti M, anti N, anti s.<br>Lewis system antibodies:<br>anti Lea, anti Leb.<br>P system: anti P | Using phenotyped red cell screening cells on automated Immunocor NEO blood group Analyser SOP: BB111  |
| Whole Blood EDTA            | Direct Antiglobulin Test (DAT)   | BIO RAD column agglutination technology, using automated using the Immucor NEO blood grouping analyser SOP: BB016                                 |
| Whole blood EDTA            | Manual ABO and Rh Blood Grouping and Atypical Antibody screening:  | Manual techniques using BIO RAD Column agglutination technology and tube methods, using monoclonal antibodies and phenotyped red cells SOP: BB102 |



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| HUMAN BODY FLUIDS (cont'd) | <u>Blood Transfusion examinations to assist in clinical investigations</u> (cont'd)               | Procedures documented in manufacturers equipment manuals in conjunction with documented procedures as specified below:                                    |
| Plasma EDTA                | Automated or Manual Atypical Investigation and identification by Indirect Antiglobulin Test (IAT) | Automated Capture R technology using the Immucor NEO blood grouping analysers.<br>Manual using IAT BIO-RAD Column agglutination technology.<br>SOP: BB062 |
| Plasma EDTA                | Antibody titration  | Automated techniques using the Immunocor NEO blood grouping analysers<br>SOP: BB090   |
| Red Cells                  | Antibody Elution  | Manual techniques using BIO RAD Column agglutination technology and tube methods<br>SOP: BB103  |
| Red Cells                  | Red Cell Phenotyping  | Manual techniques using BIO RAD Column technology using monoclonal antibodies.<br>SOP: BB23   |
| Red Cells                  | Feto Maternal Haemorrhage Quantitative method   | Red Cell Automated Flow Cytometry - BD FACSLyric<br>SOP: BB058  |
| Plasma                     | Manual Crossmatch of Red Cell units for transfusion   | Manual techniques using tube and BIO RAD column technology.<br>SOP: BB010   |
| Blood                      | Foeto materal haemorrhage screnning   | Kleihauer test - Staining kit from Clin-Tech<br>BB030   |
| Blood                      | Extended Rh D Typing  | BioRad kit of 6 D clones<br>BB068   |



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| HUMAN BODY FLUIDS (cont'd)             | <u>Biochemical examinations for the purpose of clinical diagnosis</u> | Abbott Architect c16000 analyser<br>SOP: ARC 001<br>SOPs: ARC 010 to ARC 019 inclusive and method sheets |
| Serum Plasma (unless otherwise stated) | Acetaminophen   | Enzymatic/Colorimetric   |
|  | Alkaline Phosphatase  | Para-Nitrophenyl Phosphate   |
|  | Albumin   | Dye binding Bromocresol green  |
|  | ALT   | NADH (without P-5'-P)  |
| Including urine                        | Amylase   | CNPG3 Substrate  |
| EDTA Plasma                            | Ammonia   | Glutamate Dehydrogenase  |
| Urine                                  | Amphetamine   | Enzyme Immunoassay (EMIT)  |
|  | Alpha 1 Antitrypsin   | Immunoturbidimetric  |
|  | AST   | NADH (without P-5'-P)  |
|  | Bilirubin (total)   | Diazonium Salt   |
| Urine                                  | Benzodiazepine  | Enzyme Immunoassay (EMIT)  |
|  | Bicarbonate (CO <sub>2</sub> )  | PEP carboxylase  |
| Including Urine                        | Calcium   | Arsenazo III Dye   |
|  | Calcium (Adjusted)  | Calculated: Calcium+(0.017 x (43-<br>albumin)  |
|  | Cholesterol   | Enzymatic  |
| Serum Plasma                           | Cholesterol HDL ratio (CHDLR)   | Calculated = Cholesterol / HDL   |
| Including Plasma Urine                 | Chloride  | Indirect Ion Selective electrode   |
| Urine                                  | Cocaine   | Enzyme Immunoassay (EMIT)  |
|  | Carbamazepine   | Particle-enhanced turbidimetric inhibition immunoassay (PETINIA)   |
|  | C3  | Immunoturbidimetric  |



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| HUMAN BODY FLUIDS (cont'd)                      | <u>Biochemical examinations for the purpose of clinical diagnosis</u> (cont'd) | Abbott Architect c16000 analyser<br>SOP: ARC 001<br>SOPs: ARC 010 to ARC 019 inclusive and method sheets |
| Serum Plasma (unless otherwise stated) (cont'd) | C4   | Immunoturbidimetric  |
| Including Urine                                 | Creatinine   | Kinetic Alkaline Picrate (jaffe reaction)  |
|   | Creatine Kinase (CK)   | NAC (N-acetyl-L-cysteine)  |
|   | C Reactive Protein (CRP)   | Immunoturbidimetric  |
|   | eGFR   | Calculated: EGFR EPI Calculation applied   |
| Including Urine                                 | Ethanol  | Alcohol dehydrogenase  |
|   | Gentamicin   | Particle enhanced turbidimetric inhibition immunoassay (PETINIA)   |
|   | Globulin   | Calculated = Total Protein - Albumin   |
| Including CSF                                   | Glucose  | Hexokinase/G-6- PDH  |
|   | GGT  | L-Gamma-glutamyl-3-carboxy-4-nitroanilide substrate  |
|   | HDL Cholesterol  | Homogenous accelerator selective detergent   |
|   | Haptoglobin  | Immunoturbidimetric  |
|   | IgA  | Immunoturbidimetric  |
|   | IgG  | Immunoturbidimetric  |
|   | IgM  | Immunoturbidimetric  |
|   | Iron   | Ferene   |
| Plasma  | Lactate  | Oxidation of lactate to pyruvate   |



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| HUMAN BODY FLUIDS (cont'd)                      | <u>Biochemical examinations for the purpose of clinical diagnosis</u> (cont'd) | Abbott Architect c16000 analyser<br>SOP: ARC 001<br>SOPs: ARC 010 to ARC 019 inclusive and method sheets |
| Serum Plasma (unless otherwise stated) (cont'd) | LDH Lactate Dehydrogenase  | IFCC lactase to pyruvate (NADH)  |
|   | LDL  | Calculated: Cholesterol -(Trig / 2.21) + HDL   |
|   | Lipase   | Quinone Dye  |
|   | Lithium  | Colorimetric   |
| Including Urine                                 | Magnesium  | Arsenazo   |
| Urine   | Methadone  | Enzyme Immunoassay (EMIT)  |
| Urine   | Micro Albumin  | Immunoturbidimetric  |
| Urine   | Micro Albumin Creatinine ratio (MCR)   | Calculated: = microalbumin / creatinine  |
| Urine   | Opiate   | Enzyme Immunoassay (EMIT)  |
|   | Non-HDL Cholesterol (NHDL)   | Calculated: = Cholesterol - HDL  |
|   | Phenobarbitone   | Particle- enhanced turbidimetric inhibition Immunoassay (PETINIA)  |
|   | Phenytoin  | Enzyme Immunoassay   |
| Including Urine                                 | Phosphate  | Phosphomolybdate   |
| Including Urine                                 | Potassium  | Indirect Ion Selective electrode   |
| Urine   | Protein Creatinine ratio (PCR)   | Calculated = (Urine protein / Urine creatinine) x 100  |
|   | Rheumatoid Factor  | Immunoturbidimetric  |
|   | Salicylate   | Enzymatic/colorimetric   |
| Including Urine                                 | Sodium   | Indirect Ion Selective electrode   |
|   | Theophylline   | Enzyme Immunoassay   |
| Urine   | TH5Q2 (Cannabis)   | Enzyme Immunoassay (EMIT)  |



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| HUMAN BODY FLUIDS (cont'd)                      | <u>Biochemical examinations for the purpose of clinical diagnosis</u> (cont'd)  | Abbott Architect c16000 analyser<br>SOP: ARC 001<br>SOPs: ARC 010 to ARC 019 inclusive and method sheets |
| Serum Plasma (unless otherwise stated) (cont'd) | Tobramycin  | Particle-enhanced Turbidimetric Immunoassay (PETINIA)  |
|   | Total Protein (Biuret)  | Biuret/Immunoturbidimetric   |
|   | Transferrin   | Immunoturbidimetric  |
|   | Transferrin saturation % TRF  | Calculated = Iron x 3.98 / Transferrin   |
|   | Triglyceride  | Glycerol Phosphate Oxidase   |
|   | Unconjugated Bilirubin (UCBIL)  | Calculated: = T. Bilirubin – Conj. Bilirubin   |
|   | Including Urine   | Urate  |
| Including Urine                                 | Urea  | Urease   |
| Urine   | Urine Calcium Creatinine ratio (UCCR)   | Calculated = urine calcium / urine creatinine  |
| Urine and CSF                                   | Total Protein   | Benezethonium chloride   |
| Urine   | Urine 24 hour (Calcium, creatinine, urate, protein, microalbumin, magnesium, sodium, potassium, chloride, phosphate, urea). | Calculated = Analyte x (urine volume /1000)  |
|   | Valporate   | Homogeneous microparticle – enhanced turbimetric immunoassay   |
|   | Vancomycin  | Particle-enhanced Turbidimetric Immunoassay (PETINIA)  |
|   | Wako Direct Bilirubin L Type  | Vanadate oxidation   |



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| <p>HUMAN BODY FLUIDS (cont'd)</p> <p>Serum Plasma (unless otherwise stated) (cont'd)</p> | <p><u>Biochemical examinations for the purpose of clinical diagnosis</u> (cont'd)</p> <p>Anti - Thyroid Peroxidase</p> <p>AFP (Alpha Fetoprotein)</p> <p>bHCG</p> <p>NT-Pro BNP - (Brain Natriuretic Peptide)</p> <p>B12 (Vitamin)</p> <p>CA-125</p> <p>CA –19-9</p> <p>CEA</p> <p>Cortisol</p> <p>Digoxin</p> <p>Oestradiol</p> <p>Ferritin</p> <p>FSH (Follicle Stimulating Hormone)</p> <p>Folate</p> <p>Free T3</p> <p>Free T4</p> <p>LH (Luteinising Hormone)</p> <p>Methotrexate</p> <p>Prolactin (Macroprolactin)</p> <p>Progesterone</p> <p>PTH (Parathyroid Hormone)</p> <p>PSA (Total Prostate Specific Antigen)</p> | <p>Architect i2000: Abbott<br/>Chemiluminescent Microparticle Immuno Assay (CMIA)<br/>SOP: ARC 003 + Insert on board</p> |



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| <p>HUMAN BODY FLUIDS (cont'd)</p> <p>Serum Plasma (unless otherwise stated) (cont'd)</p> <p>Whole blood</p> <p>Serum</p> <p>Urine</p> <p>Urine</p> | <p><u>Biochemical examinations for the purpose of clinical diagnosis</u> (cont'd)</p> <p>SHBG (Sex Hormone Binding Globulin)</p> <p>Testosterone</p> <p>hsTroponin I</p> <p>TSH (Thyroid Stimulating Hormone)</p> <p>Total Vitamin D</p> <p>Free Androgen Index (FAI)</p> <p>Therapeutic Drug monitoring</p> <p>Ciclosporin<br/>Tacrolimus<br/>Sirolimus</p> <p>Vitamin A, Vitamin E</p> <p>Metanephrines:<br/>Metadrenaline<br/>Normetadrenaline<br/>3-Methoxytyramine</p> <p>5HIAA (5 hydroxyindole acetic acid)</p> | <p>Architect i2000: Abbott<br/>Chemiluminescent Microparticle Immuno Assay (CMIA)<br/>SOP: ARC 003 + Insert on board</p> <p>Calculated: = (Testosterone/SHBG) x 100</p> <p>LCMS WatersAcquity<br/>TDD method for measurement of immunosuppressant drugs<br/>SOP: CSI 107</p> <p>Agilent tech 1260:<br/>HPLC with UV Detection</p> <p>SOP: CSI 111</p> <p>SOP: CSI 114</p> <p>SOP: CSI 133</p> |



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| HUMAN BODY FLUIDS (cont'd) | <u>Biochemical examinations for the purpose of clinical diagnosis</u> (cont'd)       | Procedures documented in manufacturers equipment manuals in conjunction with documented procedures as specified below: |
| Serum                      | AMH (Anti Mullerin Hormone)<br>Growth Hormone<br>Thyroglobulin<br>Anti Thyroglobulin | Access2. Beckman<br>Chemiluminescent Microparticle Immunoassay<br>SOP: CSI137  |
| Urine                      | Drugs of Abuse:<br>Opiate Identification including Buprenorphine<br>Tramadol         | LC-MS,<br>Isotope dilution LC tandem mass spectrometry<br>SOP: CSI 109   |
| Faeces                     | Calprotectin   | Phadia 250 assay SOP: CSI 095<br>Fluorezyme immunoassay (EiLA)   |
| Sweat                      | Chloride   | EliTECH ChloroChek Chloridometer<br>SOP: CSI 097   |
| Urine Fluid                | pH measurement   | Jenway 3510 pH meter<br>Potentiometry SOP: CSI 135   |
| CSF                        | Bilirubin  | Northstar Scientific Uvikon<br>Spectrophotometry<br>SOP: CSI 094   |
| CSF                        | Oxyhaemoglobin   |  |



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| HUMAN BODY FLUIDS (cont'd)<br><br>Serum/plasma<br><br>Urine<br><br>Serum & Urine<br><br>Whole Blood<br><br>Blood (EDTA plasma)<br><br>Blood (EDTA plasma) | <u>Biochemical examinations for the purpose of clinical diagnosis</u> (cont'd)<br><br>Copper and Zinc<br>Selenium<br>Cobalt and Chromium<br>Copper<br><br>Serum and Urine Osmolality<br><br>HbA1c<br><br>Therapeutic Drug monitoring<br><br>Cyclosporin<br>Tacrolimus<br><br>Plasma metanephrines (including metanephrine, normetanephrine and 3-methoxytyramine) | Procedures documented in manufacturers equipment manuals in conjunction with documented procedures as specified below:<br><br>Agilent ICP-MS 7800<br>CSI140<br>CSI142<br>CSI143<br>CSI141<br><br><b>Advanced Instruments Osmo1 and Osmo Pro ARC020</b><br><br><b>Sebia Tera 3 and Octa AC#08</b><br><br>Waters Xevo micro-S LCMS<br>SOP: CSI 107<br><br>Waters Xevo micro-S LCMS<br>CSI144 |



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| <p>HUMAN BODY FLUIDS (cont'd)</p> <p>Whole blood EDTA (unless otherwise specified)</p> <p>Plasma EDTA</p> <p>Whole blood ETDA</p> <p>Whole blood ETDA</p> <p>CSF Fluid</p> | <p><u>Haematology examinations for the purpose of clinical diagnosis</u></p> <p>Peripheral blood film preparation and stain</p> <p>Reviewing blood films - morphology examination and differential</p> <p>Glandular Fever screen (Infectious Mononucleosis screen)</p> <p>G6PD deficiency screening</p> <p>Detection of HRP2 and pLDH antigens for the identification of Malaria parasites</p> <p>Detection and Identification of Malaria parasite species by Microscopy of stained preparations<br/><i>Plasmodium falciparum</i><br/><i>Plasmodium malariae</i><br/><i>Plasmodium ovale</i><br/><i>Plasmodium vivax</i><br/><i>Plasmodium knowlesi</i></p> <p>Fluid Cytospin cell morphology</p> <p>Plasma Viscosity</p> | <p>Manual film preparation<br/>Abbott Alinity HS Slide maker and Stainer (SMS)<br/>(May Grunwald Giemsa stain)<br/>SOP DH00141</p> <p>Nikon Eclipse. Light Microscopy<br/>SOP DH0137<br/>Manual examination by Microscopy<br/>SOP DH0011</p> <p>Manual Monogen method<br/>Agglutination: SOP DH0018</p> <p>Trinity BioTech G6PD Deficiency kit<br/>fluorescence under UV<br/>SOP DH0012</p> <p>Carestart. Malaria HRP2 pLDH<br/>Combo test DH0021 and DH0112</p> <p>Preparation and staining of Thick and Thin Films, Giemsa stain<br/>SOP: DH0021</p> <p>Aerospray Haematology Pro Light<br/>Microscopy<br/>SOP DH0101, DH0110 and<br/>DH0011</p> <p>Benson Viscometer Viscosity<br/>SOP DH0014</p> |



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| HUMAN BODY FLUIDS (cont'd) | <u>Haematology examinations for the purpose of clinical diagnosis</u> (cont'd)   | Procedures documented in manufacturers equipment manuals in conjunction with documented procedures as specified below:   |
| Urine                      | Hemosiderin  | Manual slide preparation, stain and examination by light microscopy<br>SOP DH00118   |
| Blood                      | Sickle cell and thalassaemia (haemoglobinopathy) screening - HbA2, HbF, HbS levels and screening for variant haemoglobins. | Documented in-house methods to meet the requirements of the Sickle Cell and Thalassaemia Screening programme as defined in the laboratory QA evidence requirements<br><br>Capillary electrophoresis using Sebia Capillarys 3 Octa<br>DH00156 |
| Whole blood ETDA           | Identification of Haemoglobin Variants HbS, HbC, HbD, HbE  | Haemoglobin Electrophoresis using Helena Vitresi SAS-3 and SAS-4   |
| Blood                      | Sickle cell solubility screen  | Clin-Tech sickle test<br>DH0036  |
| END                        |  |  |