


# Schedule of Accreditation

issued by

## United Kingdom Accreditation Service

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

|  |  |   |
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|  <p><b>UKAS</b><br/>MEDICAL</p> <p>8623</p> <p>Accredited to<br/>ISO 15189:2012</p> | <p><b>Great Ormond Street Hospital for Children NHS Foundation Trust</b></p> <p>Issue No: 004 Issue date: 28 October 2021</p>  |   |
|  | <p>Haematology Department<br/>(Haematology and Blood Transfusion, SIHMDS)</p> <p>Level 1 Camelia Botnar Laboratories</p> <p>Great Ormond Street Hospital<br/>London<br/>WC1N 3JH</p> | <p>Contact: Dr R Liesner</p> <p>Tel: +44 (0) 207 829 7937</p> <p>E-Mail: <a href="mailto:ri.liesner@gosh.nhs.uk">ri.liesner@gosh.nhs.uk</a></p> <p>Website: <a href="http://www.labs.gosh.nhs.uk/">http://www.labs.gosh.nhs.uk/</a></p> |
| <p>Testing performed at the above address only</p>   |  |   |

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

| Location details   | Activity  |
|--|---|
| Blood collection lobby P 1.027<br>Great Ormond Street Hospital<br>London<br>WC1N 3JH         | Blood component storage fridge<br>Platelet incubator / agitator PC900<br>No testing occurs on this site, blood storage only |
| Room B4110, NICU drug room VCB Level 4<br>Great Ormond Street Hospital<br>London<br>WC1N 3JH | Blood issue fridge<br>No testing occurs on this site, blood storage only  |
| Ocean Theatres OBW Level 1<br>Great Ormond Street Hospital<br>London<br>WC1N 3JH             | Blood component storage fridge<br>No testing occurs on this site, blood storage only  |
| Flamingo CICU Level 4 MSB N4100<br>Great Ormond Street Hospital<br>London<br>WC1N 3JH        | Blood component storage fridge<br>No testing occurs on this site, blood storage only  |
| Main Theatres Level 3 MSB N3016<br>Great Ormond Street Hospital<br>London<br>WC1N 3JH        | Blood component storage fridge<br>No testing occurs on this site, blood storage only  |



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DETAIL OF ACCREDITATION

| Materials/Products tested | Type of test/Properties measured/Range of measurement   | Standard specifications/ Equipment/Techniques used  |
|---------------------------|---|---|
| HUMAN TISSUE AND FLUIDS   | <u>Haematology examinations for the purposes of clinical diagnosis</u>  | Following in-house documented procedures and manufacturer's equipment instructions where relevant   |
| Blood (EDTA)              | Full blood counts and automated differential:<br><br>Haemoglobin (Hb)<br>White Blood Cell Count (WBC)<br>Red Blood Count (RBC)<br>Platelet Count<br>Haematocrit<br>Mean Cell Volume (MCV)<br>Mean Cell Haemoglobin (MCH)<br>Mean Cell Haemoglobin Concentration (MCHC)<br>Neutrophils<br>Lymphocytes<br>Monocytes<br>Eosinophils<br>Basophils | Sysmex XE5000<br><br>Fluorescence flow cytometry, electrical impedance, SLS-haemoglobin method, RBC pulse height detection method, sheath flow direct current (DC) detection method and calculated red cell parameters<br><br>HSOP 204 & 204A |
| Blood (EDTA)              | Erythrocyte Sedimentation Rate (ESR)  | HSOP 216 – manual method<br>Sarstedt Microvette CB200<br>Equipment / Westergren method  |
| Bone marrow               | Examination of bone marrow films: in order to identify or exclude Morphological and Cytological abnormalities for the purpose of diagnosis  | Manual slide preparation and interpretation.<br>HSOP 210 Staining of Bone Marrow Slides using the Hematek® Slide stainer<br>HQU 016 Clinical Reporting Policy   |
| Blood                     | Blood Film: Detection of normal and abnormal morphologies and white blood cell differential   | Manual slide preparation and interpretation.<br>HSOP 204B Microscopy  |



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| HUMAN TISSUE AND FLUIDS (cont'd)      | <u>Haematology examinations for the purposes of clinical diagnosis (cont'd)</u> | Following in-house documented procedures and manufacturer's equipment instructions where relevant        |
| Blood (EDTA)                          | Demonstration of Malaria Parasites  | HSOP 213B – microscopy & cytochemistry (Thick and thin films stained by Fields stain and Giemsa)         |
| Blood (EDTA)                          | Sickle Solubility test for presence of sickle haemoglobin (HbS)                 | Using TCS Biosciences Screening Test for Haemoglobin S and in house procedure HSOP 220 Solubility method |
| Blood (EDTA)                          | Glandular fever by detection of IM IgM heterophile antibodies                   | Clearview IM (Infectious Mononucleosis) test using HSOP 221 Chromatographic immunoassay                  |
| CSF                                   | Cell counts   | HSOP 214 – chamber count, Shandon Cytospin & microscopy  |
| Whole blood                           | Glucose-6-Phosphate Dehydrogenase (G6PD) screen                                 | Trinity Biotech G-6-PD Screening Test Kit using HSOP 263, semi-quantitative fluorescent blood spot test  |
| Whole blood (EDTA or Lithium Heparin) | G6PD quantitation   | Assay using Trinity Biotech Kit and Cecil Spectrophotometer (colorimetric method) using HSOP 264         |



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| HUMAN TISSUE AND FLUIDS (cont'd) | <u>Haematology examinations for the purposes of clinical diagnosis (cont'd)</u>                                     | Following in-house documented procedures and manufacturer's equipment instructions where relevant   |
|                                  | <u>Biochemistry examination activities for the purpose of clinical diagnosis</u>                                    | Following in-house documented procedures and manufacturer's equipment instructions where relevant   |
| Plasma                           | Quantitation of Methotrexate  | Alpha Laboratories Method Immunoassay using HSOP 218 and manufacturers' instructions for Vitros 5600  |
|                                  | <u>Haematology examinations for the purposes of clinical diagnosis</u>  | In house documented procedures based on standard methods and incorporating Sysmex CS2000 manufacturers' instructions as relevant: for all tests below unless otherwise stated |
| Plasma                           | <b>Coagulation screen:</b><br>Prothrombin Time, APTT, Thrombin Time, Fibrinogen, Mixing tests, Protamine correction | HSOP 109  |
| Plasma                           | D Dimers  | HSOP 115<br>Immunoassay   |
| Plasma                           | Factors 2, 5, 7, 10, 8, 9, 11, 12 and Refacto Factor 8  | HSOP 120<br>Clotting assays   |
| Plasma                           | Factor 8  | HSOP 123<br>Chromogenic assay   |



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| HUMAN TISSUE AND FLUIDS (cont'd) | <u>Haematology examinations for the purposes of clinical diagnosis (cont'd)</u> | In house documented procedures based on standard methods and incorporating Sysmex CS2000 manufacturers' instructions as relevant: for all tests below unless otherwise stated |
| Plasma                           | Factor 13   | HSOP 122<br>Chromogenic assay   |
| Plasma                           | Anti Thrombin (Functional)  | HSOP 139<br>Chromogenic assay   |
| Plasma                           | Anti Thrombin (Antigen)   | HSOP 160<br>Immunoassay   |
| Plasma                           | Protein C   | HSOP 141<br>Chromogenic assay   |
| Plasma                           | Protein S   | HSOP 145<br>Immunoassay   |
| Plasma                           | Lupus test - DRVVT  | HSOP 137<br>Clotting assay  |
| Plasma                           | Plasminogen   | HSOP 146<br>Chromogenic assay   |
| Plasma                           | Activated Protein C Resistance (APCr)   | HSOP 148<br>Clotting assay  |
| Plasma                           | Heparin Anti Xa activity  | HSOP 131<br>Chromogenic assay   |
| Plasma                           | Factor 8 inhibitor  | HSOP 127<br>Clotting assay  |
| Plasma                           | Alpha 2 antiplasmin   | HSOP 133<br>Chromogenic assay   |
| Plasma                           | Hepzyme APTT  | HSOP 157<br>Absorption  |



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| HUMAN TISSUE AND FLUIDS (cont'd) | <u>Haematology examinations for the purposes of clinical diagnosis (cont'd)</u>   | Following in-house documented procedures and manufacturer's equipment instructions where relevant |
| Plasma                           | Von Willebrand antigen, activity & Collagen Binding   | HSOP 158 - MultiSkan plate reader (ELISA)   |
| Plasma                           | Von Willebrand antigen, activity  | HSOP 128 Immunoassay  |
| Plasma                           | Platelet function (PFA)   | HSOP 134 - PFA 100  |
| Plasma                           | Platelet aggregation  | HSOP 135 – Helena aggram  |
| Serum/plasma                     | Anti Cardiolipin  | HSOP 169 – Multiskan Ascent (ELISA)   |
|                                  | <u>Blood transfusion examinations</u>   | Documented in-house procedures based on manufacturer's instructions                               |
| Whole blood (EDTA)               | Blood grouping by antigen screening: <ul style="list-style-type: none"> <li>• ABO/D blood groups</li> <li>• Antibody screening</li> </ul> | Automated method using HSOP 331, 331C<br>Bio-Rad IH-500   |
| Whole blood (EDTA)               | Antibody Identification for the following antigens:<br>D,C,E,c,e,Cw,K,k,Kpa,Kpb,Fya,Fyb, Jka,Jkb,Lea,Leb,P1,M,N,S,s,Lua,                  | Automated identification of red cell antibodies<br>HSOP 306<br>Bio-Rad IH-500                     |
| Whole blood (EDTA)               | Blood grouping by antigen screening: <ul style="list-style-type: none"> <li>• ABO/D blood groups</li> <li>• Antibody screening</li> </ul> | Manual method using Diamed ID Gel cards<br>HSOP 305   |



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| HUMAN TISSUE AND FLUIDS (cont'd) | <u>Blood transfusion examinations (cont'd)</u>  | Documented in-house procedures based on manufacturer's instructions              |
| Whole blood (EDTA)               | Antibody screening and identification using cells containing the following antigens:<br>D,C,E,c,e,Cw,K,k,Kpa,Kpb,Fya,Fyb, Jka,Jkb,Lea,Leb,P1,M,N,S,s, Lua | Manual method using Diamed ID Gel cards<br>HSOP 306                              |
| Whole blood (EDTA)               | Direct Antiglobulin Test (DAT)  | Automated method using Bio-Rad IH-500 and HSOP319                                |
| Whole blood (EDTA)               | Direct Antiglobulin Test (DAT)  | Manual method Diamed Gel cards using HSOP319                                     |
| Whole blood (EDTA)               | Compatibility Testing:<br>Serological Crossmatch - serological compatibility testing between donor red cell antigens and patient plasma                   | Diamed Gel cards using HSOP307   |
| Whole blood (EDTA)               | Red cell phenotyping for the following antigens:<br>C,E,c,e,Cw,K,k,Kpa,Kpb, Fya,Fyb,M,N,S,s   | Manual using Diamed cards and automated method using Bio-Rad IH-500 and HSOP 308 |
| Whole blood (EDTA)               | Isohaemagglutinins<br>Anti-A IgM immunoglobulin<br>Anti-B IgM immunoglobulin  | Cold agglutination titration using HSOP 312                                      |



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| <p>HUMAN TISSUE AND FLUIDS (cont'd)</p> <p>Bone Marrow / Peripheral Blood / Unstained slides</p> <p>Blood EDTA, Bone marrow (EDTA or ACD)</p> <p>RNA derived from Blood/ Bone Marrow</p> | <p><u>Molecular testing examinations for the purposes of clinical diagnosis</u></p> | <p>Following in-house documented procedures and manufacturer's equipment instructions where relevant</p> <p>DNA extraction for downstream applications/assays using:</p> <p>QIAamp extraction mini blood DNA extraction kit and in house procedure HSOP 499<br/>NanoDrop One UV-Vis Spectrophotometer</p> <p>Cell sorting for downstream applications/assays using:</p> <p>Magnetic bead cell sorting technology following manufacturers' instructions for Cell Fractionation using the AutoMACS Pro and using in-house standard operating procedures HSOP 461.</p> <p>Reverse transcription using commercially available kit (Superscript III), thermal cyclers and in-house standard operating procedures;<br/>FSOP 013,FSOP 007</p> <p>Analysis of products for QC purposes on agarose Gel using Gel tank and power pack and in house procedure HSOP 646</p> |





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| <p>HUMAN TISSUE AND FLUIDS (cont'd)</p> <p>DNA from Bone Marrow / Peripheral Blood / Unstained slides</p> | <p><u>Molecular testing examinations for the purposes of clinical diagnosis (cont'd)</u></p> <p>Minimal Residual Disease analysis as defined by (number of cells displaying clonal rearrangement previously identified at diagnosis) on patient follow-up samples.</p> <p>Range of Measurement: 10 – 0.0001% (within maximum range of 1 – 5 logs).</p> | <p>Following in-house documented procedures and manufacturer's equipment instructions where relevant</p> <p>Next Generation Sequencing using Illumina MiSeq Sequencer (Life Technologies) following in-house SOPs</p> <p>MRD NGS Stage 1 PCR for Diagnostic Samples (HSOP 793)</p> <p>MRD NGS Stage 2 PCR for Diagnostic Samples (HSOP 794)</p> <p>MRD NGS Pronex Bead Size Selection (HSOP 795)</p> <p>MRD NGS Qubit Quantification (HSOP 796)</p> <p>MRD NGS Tapestation Use (HSOP 797)</p> <p>MRD NGS Normalisation and Pooling (HSOP 801)</p> <p>MRD NGS Loading and Running the Miseq (HSOP 799)</p> <p>MRD NGS Vidjil Analysis (HSOP 800)</p> |



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| HUMAN TISSUE AND FLUIDS (cont'd) | <u>Molecular testing examinations for the purposes of clinical diagnosis (cont'd)</u> | Following in-house documented procedures and manufacturer's equipment instructions where relevant   |
| DNA                              | Chimerism genotyping  | Using G-storm 4 thermal cycler, 3500xl Genetic Analyser and commercial kit (Promega) for STR analysis, HSOP 460, 463 and FSOP 491.  |
| Sorted cells from blood (EDTA)   | Quantification of T cell receptor diversity   | T cell receptor spectratyping using Magnetic bead cell sorting of T cells using HSOP 461 and HSOP 466 (Spectratyping Guidelines).<br><br>RNA extraction using commercial kit (Qiagen) and following manufacturers' instruction and in-house standard operating procedure HSOP 412.<br><br>Reverse transcription for cDNA synthesis using commercial kit (Invitrogen) and in-house standard operating procedures FSOP 013, RT-PCR using HSOP 467<br>Fragment analysis HSOP 468<br><br>AutoMACS Pro (MiltenyiBiotec), SuperScript™ First-Strand Synthesis System for RT-PCR (Invitrogen), QiagenHot Star Taq DNA Polymerase, G Storm 4 PCR machine, 3500xl Genetic Analyser (FSOP 491). |



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| <p>HUMAN TISSUE AND FLUIDS (cont'd)</p> <p>TCRE DNA from cells sorted from blood (EDTA)</p> <p>Extracted DNA</p> | <p><u>Molecular testing examinations for the purposes of clinical diagnosis (cont'd)</u></p> <p>Thymic T-cell recovery</p> <p>Adenosine Deaminase Deficient (ADA) Severe Combined Immunodeficiency (SCID) Mutation Analysis</p> | <p>Following in-house documented procedures and manufacturer's equipment instructions where relevant</p> <p>Detection of T cell receptor excision circle using:</p> <p>Taqman Universal PCR Mastermix and the Taqman 7500 Fast PCR System (Life Technologies)</p> <p>Quantitative real-time PCR using manufacturers' instructions and HSOP 482 TRECs part 2 - qPCR and HSOP 483 TRECs part 3</p> <p>G Storm 4 or Veriti PCR machine. 3500xl Genetic Analyser. DNA extraction using commercial kit (Qiagen) HSOP 499. PCR using Qiagen Hot Star Taq DNA Polymerase with HSOP 735 and HFM743. PCR product clean-up using commercial enzymatic method (ExoStar, GE Healthcare) and HSOP 736. Cycle Sanger sequencing using commercial method (Big Dye 3, Life Technologies) and HSOP 737</p> |



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| HUMAN TISSUE AND FLUIDS (cont'd) | <u>Molecular testing examinations for the purposes of clinical diagnosis (cont'd)</u>  | Following in-house documented procedures and manufacturer's equipment instructions where relevant   |
| Extracted DNA                    | Mutation detection for Factor V Leiden and Prothrombin Variant   | Thrombotic Mutation Detection Assay by Taqman Q-PCR. HSOP444<br><br>TaqMan ® Fast Universal PCR Master Mix (2X) (No AmpErase UNG), TaqMan 7500 Fast PCR system. |
| Blood                            | <u>Immunophenotyping examinations for the purposes of clinical diagnosis</u><br><br>Platelet Glycoproteins<br>Quantification of surface expression of platelet glycoproteins GpIb, GpIIb/IIIa and GpIIIa | Using manufacturers instructions for Becton Dickinson FACSCanto II 3 laser flow cytometer and in house procedures<br><br>HSOP427, FSOP489, HSOP490 and HSOP491  |
| Blood<br>Bone marrow             | Quantification of Paroxysmal Nocturnal Haemoglobinuria (PNH) clone   | HSOP488, FSOP489, HSOP490 and HSOP491   |



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| HUMAN TISSUE AND FLUIDS (cont'd)   | <u>Immunophenotyping examinations for the purposes of clinical diagnosis (cont'd)</u>  | Using manufacturers instructions for Becton Dickinson FACSCanto II 3 laser flow cytometer and documented in house procedures |
| Blood<br>Bone marrow<br>Pleural fluid<br>Ascitic fluid<br>Pericardial fluid<br>Cerebro-spinal fluid<br>Biopsies<br>Other fluids and tissues as indicated | Full Bone marrow / blood characterization <ul style="list-style-type: none"> <li>Extended Myeloid immunophenotyping</li> <li>Lymphoid phenotyping</li> <li>Lymphoma phenotyping</li> <li>B-cell maturation phenotyping</li> <li>T-cell phenotyping</li> <li>Erythroid phenotyping</li> </ul> Myelodysplastic / Myeloproliferative phenotyping:<br>CD19, CD2, CD34, CD10, CD13, CD45, CD20, CD16, CD7, CD4, CD5, CD117, CD33, HLADR, sCD3, CD8, CD79b, CD38, CD86, CD44, NG2, CD24, CD22, CD41a, CD42b, CD61, CD11b, CD15, CD14, CD64, CD71, GlyA, CD133, CD56<br><br>Others as indicated:<br>Kappa, Lambda, CD1a, Smlg, TCRalpha/beta, TCR gamma/delta, CD123, CD21, PD1 | HSOP413, HSOP414A, HSOP414B, HSOP415, HSOP416, HSOP419, HSOP420, HSOP421, FSOP481, FSOP489, HSOP490 and HSOP491              |
| Blood<br>Bone marrow   | CD66abce expression  | FSOP485, FSOP489, HSOP490 and HSOP491  |
| Blood<br>Bone marrow<br>Cerebro-spinal fluid   | NG2 expression   | HSOP416, FSOP489, HSOP490 and HSOP491  |



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| Blood  | Platelet activation markers<br>PAC-1 expression<br>P-selecting expression  | FSOP484, FSOP489, HSOP490 and HSOP491  |
| Blood<br>Bone marrow<br>Pleural fluid<br>Ascitic fluid<br>Pericardial fluid<br>Cerebro-spinal fluid<br>Biopsies<br>Other fluids and tissues as indicated | Intracellular Marker Expression<br><br>CD79a<br>CyCD3<br>MPO<br>TDT  | HSOP418, FSOP489, HSOP490 and HSOP491  |
| Blood<br>Bone marrow<br>Cerebro-spinal fluid<br>Other if indicated   | Quantification of Minimal Residual Disease (MRD) in Myeloid and Lymphoid Leukaemia - detected levels of a leukaemia associated immunophenotype | FSOP483, HSOP484, FSOP489, HSOP490 and HSOP491   |
| Blood  | Red cell membrane defects by calculating the EMA ratio   | Becton Dickinson FACSCanto II 3 laser flow cytometer and Eosin-5-Maleimide (E5M) Dye binding fluorescence Assay              |
| Biopsy<br>Resection tissue<br>Bone Marrow  | Neuroblastoma Panel – by detecting non haematopoietic population that meet NBL phenotype criteria  | FSOP492 ,FSOP489, HSOP490 and HSOP491  |
| END  |  |  |