Schedule of Accreditation

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Accredited to ISO 15189:2022

Great Ormond Street Hospital for Children NHS Foundation Trust

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Testing performed at the above address only

Site activities performed away from the locations listed above:

Location details	Activity
Blood collection lobby P 1.027 Great Ormond Street Hospital London WC1N 3JH	Blood component storage fridge Platelet incubator / agitator PC900 No testing occurs on this site, blood storage only
Flamingo CICU Level 4 MSB N4100 Great Ormond Street Hospital London WC1N 3JH	Blood component storage fridge No testing occurs on this site, blood storage only
Main Theatres Level 3 MSB N3016 Great Ormond Street Hospital London WC1N 3JH	Blood component storage fridge No testing occurs on this site, blood storage only

DETAIL OF ACCREDITATION

Materials/Products Tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN TISSUE AND FLUIDS	Haematology examinations for the purposes of clinical diagnosis	Following in-house documented procedures and manufacturer's equipment instructions where relevant
Whole Blood (EDTA)	Full blood counts and automated differential: Haemoglobin (Hb) White Blood Cell Count (WBC) Red Blood Count (RBC) Platelet Count Haematocrit Mean Cell Volume (MCV) Mean Cell Haemoglobin (MCH) Mean Cell Haemoglobin Concentration (MCHC) Red Cell Distribution Width (RDW) Neutrophils Lymphocytes Monocytes Eosinophils Basophils NRBC Reticulocytes	Sysmex XN2000 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 HSOP 204A & HSOP 208
CSF/Body fluid/peritoneal, pleural and bronchial lavage	White Cell Count, Red Cell Count and White Cell Differential	Automated Method: XN-2000, HSOP 207 and 214
Whole Blood (EDTA)	Erythrocyte Sedimentation Rate (ESR)	P4 Westergren Kits manufactured by Aquisel HSOP 216 – manual method Manual ESR Aquisel tubes Equipment / Westergren method
Bone marrow	Staining and 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. HSOP 210 Staining of Bone Marrow Slides using the Hematek® Slide stainer HQU 016 Clinical Reporting Policy

Materials/Products Tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN TISSUE AND FLUIDS (cont'd)	Haematology examinations for the purposes of clinical diagnosis (cont'd)	Following in-house documented procedures and manufacturer's equipment instructions where relevant
Whole Blood (EDTA)	Staining and examination of peripheral Blood Film: Detection of normal and abnormal morphologies and white blood cell differential	Blood film preparation and examination by light microscopy HSOP 210, HSOP 211, FSOP 470.
Whole blood (EDTA)	Malarial Parasite Antigen for pLDH (plasmodium Lactate Dehydrogenase). Detects Plasmodium +/-Falciparum (HRP_2)	CareStartTM Malaria Rapydtest (RDT). immunochromatogenic membrane assay HSOP 213
Whole Blood (EDTA)	Sickle Solubility test for presence of sickle haemoglobin (HbS)	Using SickleDex Sickle Solubiltiy Kit Manual Method – Relative insolubility HSOP 220 Sickle Solubility Test
Whole Blood (EDTA)	Glandular fever by detection of IM IgM heterophile antibodies	Clearview IM (Infectious Mononucleosis) test using HSOP 221 Chromatographic immunoassay
CSF	White Cell Count, Red Cell Count	HSOP 214 – chamber count, Shandon Cytospin & microscopy
Whole blood (EDTA)	Glucose-6-Phosphate (G6PD) quantitation	Pointe Scientific Kit Cecil Spectrophotometer, Enzymecolorimetric method HSOP 264

Materials/Products Tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN TISSUE AND FLUIDS (cont'd)	Biochemistry examination activities for the purpose of clinical diagnosis	Following in-house documented procedures and manufacturer's equipment instructions where relevant
Plasma (EDTA)	Quantitation of Methotrexate	ARK™ Immunoassay using HSOP 218 and manufacturers' instructions for Vitros 7600
Plasma (Citrate) unless otherwise specified	Haematology examinations for the purposes of clinical diagnosis	In house documented procedures based on standard methods and incorporating Sysmex CN3000 analyser manufacturers' instructions as relevant: for all tests below unless otherwise stated
	Coagulation screen: Prothrombin Time, APTT, Thrombin Time, Fibrinogen, Mixing tests,	Photometric end-point clot detection HSOP 109
	D Dimers	Latex Immunoassay HSOP 109
	Factors II, V, VII, VIII, IX, X, XI, XII	One Stage assay using multi dilution analysis HSOP 120
	Factor VIII Factor XIII	Chromogenic assay HSOP 120
	Antithrombin Antigen	Immunoturbidimetric Assay, HSOP 148
	Protein C Activity	Chromogenic assay HSOP 148
	Free Protein S Antigen	Latex Immunoassay HSOP 148
	Lupus Anticoagulant Screen by DRVVT	DRVVT HSOP 137
	Plasminogen	Chromogenic assay HSOP 133
	Activated Protein C Resistance (APCr)	Clotting assay HSOP 148
	Antithrombin Activity	CN3000 Chromogenic Assay, HSOP 148

Materials/Products Tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
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 CN3000 analyser manufacturers' instructions as relevant: for all tests below unless otherwise stated
Plasma (Citrate) unless otherwise specified	Heparin Anti Xa activity	Photometric end-point clot detection HSOP 109
	Inhibitor Assays - FVIII, FIX	Clotting assay, Bethesda Assay HSOP 127
	Alpha 2 antiplasmin	Chromogenic assay HSOP 133
	Von Willebrand Factor Collagen Binding Assay (vW:CBA)	Manual Method ELISA read on MultiSkan plate reader HSOP 158
	Von Willebrand Factor antigen, (vW:Ag), Von Willebrand Factor Activity (vW:GpIbM)	Latex assay HSOP 128
Whole Blood (Citrate)	Platelet function (PFA)	Platelet Function Analysis Via Shear Flow Volume for Collagen/Epinephrine and Collagen/ADP HSOP 134

Materials/Products Tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN TISSUE AND FLUIDS (cont'd)	Blood transfusion examinations	Documented in-house procedures based on manufacturer's instructions
Whole blood (EDTA)	Blood grouping by antigen screening: • ABO/D blood groups • Antibody screening	Automated method using HSOP 331, 331C Bio-Rad IH-500
Whole blood (EDTA)	Antibody Identification for the following antigens: 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 HSOP 306 Bio-Rad IH-500
Whole blood (EDTA)	Blood grouping by antigen screening: • ABO/D blood groups • Antibody screening	Manual method using Diamed ID Gel cards HSOP 305
Whole blood (EDTA)	Antibody screening and identification using cells containing the following antigens: 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 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: 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: C,E,c,e,Cw,K,	Manual using Diamed cards and automated method using Bio-Rad IH-500 and HSOP 308
Whole blood (EDTA)	Isohaemagglutinins Anti-A IgM immunoglobulin Anti-B IgM immunoglobulin	Cold agglutination titration using HSOP 312

Materials/Products Tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN TISSUE AND FLUIDS (cont'd)	Blood transfusion examinations (cont'd)	Documented in-house procedures based on manufacturer's instructions
Plasma (EDTA blood)	Semiquantitative detection of Total ABO Isohaemagglutinins (IgG/IgM)	Titration performed manually or by automated method using the IH-500 HSOP 312
	Molecular testing examinations for the purposes of clinical diagnosis	Following in-house documented procedures and manufacturer's equipment instructions where relevant
Bone Marrow / Peripheral Blood / Unstained slides		DNA extraction for downstream applications/assays using: QIAamp extraction mini blood DNA extraction kit and in house procedure HSOP 499 NanoDrop One UV-Vis Spectrophotometer
Blood EDTA, Bone marrow (EDTA or ACD)		Cell sorting for downstream applications/assays using: Magnetic bead cell sorting technology following manufacturers' instructions for Cell Fractionation using the AutoMACS Pro and MultiMACS X using in-house standard operating procedures HSOP 461. Lymphoprep Ficoll cell sorting process using in-house standard operating procedure HSOP 407
RNA derived from Blood/ Bone Marrow		Reverse transcription using commercially available kit (GoScript), thermal cyclers and in-house standard operating procedures; HSOP 499, HSOP 780 Analysis of products for QC purposes using Albumin control gene HSOP 500

Materials/Products Tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN TISSUE AND FLUIDS (cont'd)	Molecular testing examinations for the purposes of clinical diagnosis (cont'd)	Following in-house documented procedures and manufacturer's equipment instructions where relevant
DNA from Bone Marrow/Peripheral Blood	Kymriah Chimeric Antigen Receptor (CAR T)	Quantitative measurement using digital droplet PCR (ddPCR). Range of Measurement: 0 – 100%. Using Bio-Rad QX200 Auto Droplet Generator Plate Sealer (Bio-Rad) Bio-Rad C1000 Touch Thermal Cycler Bio-Rad QX200 Plate Reader and SOP ASOP 117
DNA from Bone Marrow / Peripheral Blood / Unstained slides	Minimal Residual Disease analysis as defined by (number of cells displaying clonal rearrangement previously identified at diagnosis) on patient follow-up samples. Range of Measurement: 10 – 0.0001% (within maximum range of 1 – 5 logs).	Next Generation Sequencing using Illumina MiSeq Sequencer (Life Technologies) following in-house SOPs MRD NGS Library preparation HSOP 805 ALL MRD Selection of Targets, Design and Ordering of ASO primers HSOP 496, ALL MRD Control Gene Analysis HSOP 500, ALL MRD Measurement by RQ-PCR HSOP 501. ALL MRD Measurement by RQ-PCR for ALLtogether trial (A2G)

Materials/Products Tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN TISSUE AND FLUIDS (cont'd)	Molecular testing examinations for the purposes of clinical diagnosis (cont'd)	Following in-house documented procedures and manufacturer's equipment instructions where relevant
DNA	Chimerism genotyping	Using G-storm 4 and Proflex thermal cyclers, 3500xl Genetic Analyser and PowerPlex Fusion commercial kit (Promega) for STR analysis, HSOP 460, HSOP 790, HSOP 791 and FSOP 49
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). RNA extraction using commercial kit (Qiagen) and following manufacturers' instruction and in-house standard operating procedure HSOP 499. Reverse transcription for cDNA synthesis using commercial kit (Invitrogen) and in-house standard operating procedures HSOP 780 RT-PCR using HSOP 467 Fragment analysis HSOP 468 AutoMACS Pro (MiltenyiBiotec), GorScript™ First-Strand Synthesis System for RT-PCR (Promega), QiagenHot Star Taq DNA Polymerase, G Storm 4 PCR machine and ProFlex machines, 3500xl Genetic Analyser (FSOP 491).

Materials/Products Tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN TISSUE AND FLUIDS (cont'd)	Molecular testing examinations for the purposes of clinical diagnosis (cont'd)	Following in-house documented procedures and manufacturer's equipment instructions where relevant
TCRE DNA from cells sorted from blood (EDTA)	Thymic T-cell recovery	Detection of T cell receptor excision circle using: Taqman Universal PCR Mastermix and the Taqman 7500 Fast PCR System (Life Technologies) or QuantStudio realtime instrument. Quantitative real-time PCR using manufacturers' instructions and HSOP 482 TRECs part 2 - qPCR and HSOP 483 TRECs part 3
Extracted DNA	Adenosine Deaminase Deficient (ADA) Severe Combined Immunodeficiency (SCID) Mutation Analysis	G Storm 4, ProFlex 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

Materials/Products Tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN TISSUE AND FLUIDS (cont'd)	Molecular testing examinations for the purposes of clinical diagnosis (cont'd)	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 TaqMan ® Fast Universal PCR Master Mix (2X) (No AmpErsae UNG), TaqMan 7500 Fast PCR system or QuantStudio realtime instrument
	Immunophenotyping examinations for the purposes of clinical diagnosis	Using manufacturers instructions for Becton Dickinson FACSCanto II 3 laser flow cytometer or BD Fortessa flow cytometer and in house procedures
Blood	Platelet Glycoproteins Quantification of surface expression of platelet glycoproteins GpIb, GpIIb/IIIa and GpIIIa	HSOP427, FSOP489, HSOP490 and HSOP491
Blood Bone marrow	Quantification of Paroxysmal Nocturnal Haemoglobinuria (PNH) clone	HSOP488, FSOP489, HSOP490 and HSOP491

Materials/Products Tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
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 or BD Fortessa flow cytometer and documented in house procedures
Blood Bone marrow Pleural fluid Ascitic fluid Pericardial fluid Cerebro-spinal fluid Biopsies Other fluids and tissues as indicated	Full Bone marrow / blood characterization • Extended Myeloid immunophenotyping • Lymphoid phenotyping • Lymphoma phenotyping • B-cell maturation phenotyping • T-cell phenotyping • Erythroid phenotyping Myelodysplastic / Myeloproliferative phenotyping: 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 Others as indicated: Kappa, Lambda, CD1a, SmIg, TCRalpha/beta, TCR gamma/delta, CD123, CD21, PD1	HSOP413, HSOP414A, HSOP414B, HSOP415, HSOP416, HSOP419, HSOP420, HSOP421, FSOP481, FSOP489, HSOP490 and HSOP491
Blood Bone marrow	CD66abce expression	FSOP485, FSOP489, HSOP490 and HSOP491
Blood Bone marrow Cerebro-spinal fluid	NG2 expression	HSOP416 ,FSOP489, HSOP490 and HSOP491

Materials/Products Tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN TISSUE AND FLUIDS (cont'd)	Immunophenotyping examinations for the purposes of clinical diagnosis (cont'd)	Using manufacturers instructions for Becton Dickinson FACSCanto II 3 laser flow cytometer or BD Fortessa flow cytometer and documented in house procedures
Blood Bone marrow Pleural fluid Ascitic fluid Pericardial fluid Cerebro-spinal fluid Biopsies Other fluids and tissues as indicated	Intracellular Marker Expression CD79a CyCD3 MPO TDT	HSOP418, FSOP489, HSOP490 and HSOP491
Blood Bone marrow Cerebro-spinal fluid 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 or BD Fortessa flow cytometer and Eosin-5-Maleimide (E5M) Dye binding fluorescence Assay
Biopsy Resection tissue Bone Marrow	Neuroblastoma Panel – by detecting non haematopoietic population that meet NBL phenotype criteria	FSOP492 ,FSOP489, HSOP490 and HSOP491
Bone marrow Blood	B-Cell Precursor Acute Lymphoblastic Leukaemia (BCP-ALL) Flow MRD quantification using the CYT-BCP B-Cell Precursor Panel for patients enrolled on the All2gether trial	8 Colour BD FACS Canto II x 2 (S/N V96300806 and R33896202743) BCP-ALL MRD7 Cytognos Kits FSOP 524 ALL2gether Trial Flow MRD Quantification
END		