Schedule of Accreditation

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Accredited to ISO 15189:2012

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
Room B4110, NICU drug room VCB Level 4 Great Ormond Street Hospital London WC1N 3JH	Blood issue fridge No testing occurs on this site, blood storage only
Ocean Theatres OBW Level 1 Great Ormond Street Hospital London WC1N 3JH	Blood component storage fridge 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	<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: 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) Neutrophils Lymphocytes Monocytes Eosinophils Basophils	Sysmex XE5000 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 204 & 204A
Blood (EDTA)	Erythrocyte Sedimentation Rate (ESR)	HSOP 216 – manual method Sarstedt Microvette CB200 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. HSOP 210 Staining of Bone Marrow Slides using the Hematek® Slide stainer HQU 016 Clinical Reporting Policy
Blood	Blood Film: Detection of normal and abnormal morphologies and white blood cell differential	Manual slide preparation and interpretation. HSOP 204B Microscopy

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
Blood (EDTA)	Rapid diagnostic test for detection of Malarial antigens of: P. *falciparum and /or* Pan-detection for P. *malariae*, P. *ovale* & P. *vivax*	HSOP 213A – manual method using CareStart Malaria RapydTest HRP2/pLDH
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)	Haemoglobinopathy: Quantitation of HbA2 Quantitation of HbF Quantitation of HbS	HPLC using Bio-Rad D10 and HSOP 269
Blood (EDTA)	Haemoglobin A1C (HbA1C) quantification	HPLC using Bio-Rad D10 and HSOP 269
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

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 or Lithium Heparin)	G6PD quantitation	Assay using Trinity Biotech Kit and Cecil Spectrophotometer (colorimetric method) using HSOP 264
	Biochemistry examination activities for the purpose of clinical diagnosis	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
	Haematology examinations for the purposes of clinical diagnosis	In house documented procedures based on standard methods and incorporating Sysmex CS2000 manufacturers' instructions as relevant: for all tests below unless otherwise stated
Plasma	**Coagulation screen:** Prothrombin Time, APTT, Thrombin Time, Fibrinogen, Mixing tests, Protamine correction	HSOP 109
Plasma	D Dimers	HSOP 115 Immunoassay
Plasma	Factors 2, 5, 7, 10, 8, 9, 11, 12 and Refacto Factor 8	HSOP 120 Clotting assays
Plasma	Factor 8	HSOP 123 Chromogenic assay

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)	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 Chromogenic assay
Plasma	Anti Thrombin (Functional)	HSOP 139 Chromogenic assay
Plasma	Anti Thrombin (Antigen)	HSOP 160 Immunoassay
Plasma	Protein C	HSOP 141 Chromogenic assay
Plasma	Protein S	HSOP 145 Immunoassay
Plasma	Lupus test - DRVVT	HSOP 137 Clotting assay
Plasma	Plasminogen	HSOP 146 Chromogenic assay
Plasma	Activated Protein C Resistance (APCr)	HSOP 148 Clotting assay
Plasma	Heparin Anti Xa activity	HSOP 131 Chromogenic assay
Plasma	Factor 8 inhibitor	HSOP 127 Clotting assay
Plasma	Alpha 2 antiplasmin	HSOP 133 Chromogenic assay
Plasma	Hepzyme APTT	HSOP 157 Absorption

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>	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: • ABO/D blood groups • Antibody screening	Automated method using HSOP 331, 331C Diamed Gelstation
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 Diamed Gelstation
Whole blood (EDTA)	Blood grouping by antigen screening: • ABO/D blood groups • Antibody screening	Manual method using Diamed ID Gel cards HSOP 305

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
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 Diamed GelStation 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,k,Kpa,Kpb, Fya,Fyb,M,N,S,s	Manual using Diamed cards and automated method using Diamed Gelstation 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)	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 using in-house standard operating procedures HSOP 461.
RNA derived from Blood/ Bone Marrow		Reverse transcription using commercially available kit (Superscript III), thermal cyclers and in-house standard operating procedures; FSOP 013,FSOP 007 Analysis of products for QC purposes on agarose Gel using Gel tank and power pack and in house procedure HSOP 646

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
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 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).	Quantitative real time PCR (RQ-PCR) using: In house B/T-cell screening primer mix plate, Qiagen Hot Star Taq DNA Polymerase, Qiagen dNTPs CBS Scientific Gel Rig BigDye3 Terminator sequencing kit, AB3130 Genetic Analyser Chromas sequencing software. TaqMan Universal PCR mastermix, Qiagen Quantitech Probe PCR mastermix, TaqMan 7500 Fast PCR system ALL MRD screening and Heteroduplex analysis HSOP 492, Electrophoresis and Isolation of ALL MRD Screening PCR Product HSOP 493, ALL MRD Sequencing Analysis HSOP 494, ALL MRD Analysis of Junctional Regions HSOP 495, 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.

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 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). RNA extraction using commercial kit (Qiagen) and following manufacturers' instruction and in-house standard operating procedure HSOP 412. Reverse transcription for cDNA synthesis using commercial kit (Invitrogen) and in-house standard operating procedures FSOP 013, RT-PCR using HSOP 467 Fragment analysis HSOP 468 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).

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) 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 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.
	Immunophenotyping examinations for the purposes of clinical diagnosis	Using manufacturers instructions for Becton Dickinson FACSCanto II 3 laser 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)	Immunophenotyping examinations for the purposes of clinical diagnosis (cont'd)	Using manufacturers instructions for Becton Dickinson FACSCanto II 3 laser 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 and documented in house procedures
Blood	Platelet activation markers PAC-1 expression P-selecting expression	FSOP484, FSOP489, HSOP490 and HSOP491
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 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

END