

# Schedule of Accreditation

issued by

## United Kingdom Accreditation Service

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



8634

Accredited to  
ISO 15189:2012

### Great Ormond Street Hospital for Children NHS Foundation Trust

Issue No: 004 Issue date: 13 June 2022

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Testing performed at the above address only

#### DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS AND TISSUES (unless specified)	<u>Immunophenotyping examination activities for the purposes of clinical diagnosis</u>	Manufacturer's instructions for analyser/kit in conjunction with in house documented methods:
Blood EDTA (unless specified)	Perforin expression (HLH profile)	Intracellular Flow cytometry using Kit based cell permeabilisation and then analysis on BD FACS Canto II Flow Cytometers ISOP067: Detection of Perforin by FACs
	SAP/XIAP (SLAM associated protein)	ISOP024: SAP/XIAP by FACs:
	p47 (CGD protein) expression	ISOP021: CGD p47
	BTK (Burtions tyrosine kinase) expression	ISOP8: BTK by FACS
	Dock8	ISOP042: Dock8 by FACS
Blood EDTA (unless specified)	gp91 expression	Extracellular Flow Cytometry 4,6, and 8 colour BD FACSCanto II Flow Cytometers ISOP059: Detection of gp91 by FACs
	Gamma chain expression	ISOP002: Detection of gamma chain
	V beta	ISOP18: V Beta Abs



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Immunophenotyping examination activities for the purposes of clinical diagnosis (cont'd)</u>	Manufacturer's instructions for analyser/kit in conjunction with in house documented methods:
Blood EDTA	LSS (TBNK) VSS MEM CD25 ACT TCT THYE NP MHC1 BSS CD14	Extracellular Flow Cytometry Panels using manufacturer's instructions for 4, 6, 8 colour BD FACSCanto II Flow Cytometers and in house documented method ISOP 038: Immunophenotyping
	<u>Immunology examination activities for the purposes of clinical diagnosis</u>	Cell Stimulations and Flow Cytometry using 4,6, and 8 colour BD FACSCanto II Flow Cytometers and incubators/water bath
	Familial Haemophagocytic Lymphohistiocytosis (HLH) proteins)	ISOP351: Granule Release Assay (HLH). Reported as normal, abnormal, absent
	STAT5 tyrosine phosphorylation	ISOP300: STAT5 P <sub>tyr</sub> by FACs
	CD154 (CD40L)	ISOP002: CD154 Expression
Blood (Lithium heparin)	DHR (dihydrorhodamine)	ISOP27: Respiratory Burst Assay Reported as normal, consistent with carrier, abnormal
	Neutrophil phagocytosis	ISOP028: Phagocytosis Assay
	CD62L L-selectin shedding	ISOP026: L-selectin Shedding assay Reported as normal, abnormal, absent
Blood (Lithium heparin)	Th 17 cell evaluation	ISOP355: Th17 assay using CD3, CD4 and CD45RO



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Immunology examination activities for the purposes of clinical diagnosis</u> (cont'd)	
Serum and plasma (EDTA)	IL-2 IL-4 IL-6 IL-10 TNF IFN-g	Cytokine bead array by flow cytometry IRD SOP 014 Human Th1/Th2 cytokine bead array
Blood EDTA	Detection of WASp ( Wiskott-Aldrich Syndrome protein)	Flow cytometry ISOP 039 WASp
Blood EDTA	WASp (Wiskott-Aldrich protein) CGD (Chronic Granulomatous Disease)	Cell lysates/Immunoblot/imaging using Gel electrophoresis equipment, semi-dry transfer, Imaging system ISOP045: Storing cell pellets/making lysates ISOP295: Immunoblot ISOP256: Immunoblot Imaging
Serum	Quantitative detection of:  IgE dsDNA antibodies ENA (Extractable Nuclear Antigens) GBM antibodies PR3 antibodies MPO antibodies Thyroid antibodies (TPO) TTG antibodies (IgA)	Automated ELISA using manufacturer's instructions and in house documentation ISOP22: PHADIA 250



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<p>HUMAN BODY FLUIDS AND TISSUES (cont'd)</p> <p>Serum</p>	<p><u>Immunology examination activities for the purposes of clinical diagnosis (cont'd)</u></p> <p>Detection and quantification of specific IgE to the following allergens:</p> <p>ALMOND F20            ASPERGILLUS M3            BANANA F92            BEEF F27            BIRCH TREE T3            WHITE BEAN PHASEOLUS VULGARIS F15            MUTTON OVIS SPP. F88            ALTERNARIA ALTERNATA M6            CASHEW NUT F202            CAT DANDER E1            CHICKEN F83            COD F3            COWS MILK F2            DOG DANDER E5            EGG WHITE F1            HAZELNUT F17            HOUSE DUST MITE D1            KIWI F84            LATEX K82            MIXED FOOD FX5            MIXED GRASS GX1            MIXED MOULD MX2            MIXED NUT FX1            MIXED TREE TX1            PEANUT F13            PECAN F201            PEN V C2            PISTACHIO F203            SESAME F10            SHRIMP F24            SOYA F14            WHEAT F4</p>	<p>Automated ELISA using manufacturer's instructions and in house documentation            ISOP22: PHADIA 250</p>



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Immunology examination activities for the purposes of clinical diagnosis (cont'd)</u>	
Blood EDTA	NBT	Cell stimulation and cell visualisation using ISOP 036: Nitroblue tetrazolium test Reported as normal, consistent with carrier, or consistent with a diagnosis of CGD
Serum	Mannose binding lectin (MBL)	Manufacturer's instructions for ELISA reader Dynex MRX serial number 1CXD-6066: ISOP 003: MBL by enzyme immunoassay
Serum	Soluble CD25	ISOP 29: Measurement of sCD25 by enzyme immunoassay
Serum	Functional complement	ISOP 23: Measurement of functional complement pathways
Serum	Soluble FAS ligand (sFasL)	ISOP36: Measurement by enzyme immunoassay
Haematopoietic progenitor cells - apheresis/haematopoietic progenitor cells—marrow (HPC-A/HPC-M), blood, Peripheral blood mononuclear cells, T cells	CD34/CD3 enumeration TCR $\alpha/\beta$ and CD19 enumeration post depletion	Monitoring Post Cell Manipulations/Cell Therapy: CD34 and CD3 Enumeration and Viability test using the FACS Canto II CTLSOP 034  Staining – Post TCR $\alpha/\beta$ /CD19 Depletion CTL SOP 048
Bone marrow or apheresis	Colony forming unit CFU-GM x 10 <sup>4</sup> /kg and BFUE x 10 <sup>4</sup> /kg	GM-CFU Colony Assays using CTLSOP 050
Faeces	Quantification of Faecal Calprotectin	DS2 ELISA ISOP44
Serum	Rheumatoid factor	BNII nephelometry ISOP 068



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Immunology examination activities for the purposes of clinical diagnosis</u> (cont'd)	
Serum	Qualitative detection of SARS-CoV-2 IgG antibody Fist line testing of staff and patients  Confirmatory testing	Vitros 5600 CSOP AO58 using COVID-19 Anti-SARS-CoV-2 IgG Ortho Clinical Diagnostics Assay  DS2 Enzyme immunoassay ELISA ISOP45
Serum	Anti-nuclear antibodies Anti-endomysial antibodies Anti-gastric parietal cell antibodies Anti-smooth muscle antibodies Anti-mitochondrial antibodies Anti-LKM antibodies Anti-reticulin 1 antibodies	Manufacturer's instructions for Microscope (Zeiss Axioskop 2 serial number 801075) and in house documented methods: ISOP 035: Indirect immunofluorescence
Blood (Lithium heparin)	FAS (Apoptosis functional)	Class II Cabinet, 4 colour flow cytometers Apoptosis Function Assay ISOP 30 Reported as normal or abnormal
Serum	Measurement of Myeloid Related Protein 8/14 (MRP / serum calprotectin)	Using enzyme immunoassay Manual ELISA (Buhlmann MRP8/14 ELISA kit) ISOP 38
Blood (Lithium heparin)	PHA stimulation (whole blood and separated cell) CD3 stimulation Candida stimulation	Cell proliferation assays using manufacturer's instructions and in house documented methods for Class II Cabinet Cell harvester Beta counter ISOP 028: Separated cell stimulations ISOP 281: Whole blood cell stimulations Reported as normal, impaired, absent



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END		