

Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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



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Accredited to
ISO 15189:2022

Great Ormond Street Hospital for Children NHS Foundation Trust

Issue No: 009 Issue date: 17 December 2024

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Testing performed by the Organisation at the locations specified below

Locations covered by the organisation and their relevant activities

Laboratory locations:

Location details	Activity	Location code
Department of Immunology Pathology Department Camelia Botnar Laboratories London WC1N 3JH Local contact Dr Kimberly Gilmour +44 (0)20 7829 8835	Immunology	A
Zayed Centre for Research 20 Guilford Street WC1N 1DZ Dr Kimberly Gilmour +44 (0)20 7829 8835	Immunology	B



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DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
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)		Intracellular Flow cytometry using Kit based cell permeabilisation and then analysis using the BD FACS Lyric Flow Cytometers	
	Perforin expression (HLH profile)	ISOP067: Detection of Perforin by FACs	A
	SAP/XIAP (SLAM associated protein)	ISOP024:SAP/XIAP by FACs:	A
	p47 (CGD protein) expression	ISOP021:CGD p47	A
	Dock8	ISOP042: Dock8 by FACS	A
Blood EDTA (unless specified)		Extracellular Flow Cytometry 4,6, and 8 colour using the BD FACS Lyric Flow Cytometers	
	gp91 expression	ISOP059: Detection of gp91 by FACs	A
	Gamma chain expression	ISOP002: Detection of gamma chain	A
	V beta	ISOP18: V Beta Abs	A
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 using the BD FACSCanto II and using the BD FACS Lyric Flow Cytometers and in house documented method ISOP 038: Immunophenotyping	A



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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: Flow Cytometry using 4,6, and 8 colour using the BD FACSCanto II and using the BD FACS Lyric Flow Cytometers and inhouse documented methods	
Blood EDTA	XBMEM (Extended B Cell Memory)	Immunophenotyping ISOP 038	A
Lithium Heparin	CTLA4	CTLA4 and LRBA Assay ISOP 356	A
	<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	
Blood EDTA	Familial Haemophagocytic Lymphohistiocytosis (HLH) proteins)	ISOP351: Granule Release Assay (HLH). Reported as normal, abnormal, absent	A
Blood EDTA	STAT5 tyrosine phosphorylation	ISOP300: STAT5 P _{tyr} by FACs	A
Blood (Lithium Heparin)	CD154 (CD40L)	ISOP002: CD154 Expression	A
Blood (Lithium heparin)	DHR (dihydrorhodamine)	ISOP27: Respiratory Burst Assay Reported as normal, consistent with carrier, abnormal	A
Blood (Lithium heparin)	Neutrophil phagocytosis	ISOP028: Phagocytosis Assay	A
Blood (Lithium heparin)	CD62L L-selectin shedding	ISOP026: L-selectin Shedding assay Reported as normal, abnormal, absent	A
Blood (Lithium heparin)	Th 17 cell evaluation	ISOP355: Th17 assay using CD3, CD4 and CD45RO and using the BD FACS Lyric	A



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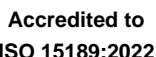
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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Immunology examination activities for the purposes of clinical diagnosis (cont'd)</u>	Manufacturer's instructions for analyser/kit in conjunction with in-house documented methods:	
Serum and plasma (EDTA)	IL-2 IL-4 IL-6 IL-10 TNF IFN-g	Cytokine bead array by flow cytometry IRD SOP 014 Human Th1/Th2 cytokine bead array	A
Blood EDTA	Detection of WASp (Wiskott-Aldrich Syndrome protein)	Flow cytometry ISOP 039 WASp	A
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	A
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	A A A A A A A A



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Immunology 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	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	A
Serum	Mannose binding lectin (MBL)	Manufacturer's instructions for ELISA reader Dynex MRX serial number 1CXD-6066: ISOP 003: MBL by enzyme immunoassay	A
Serum	Soluble CD25	ISOP 29: Measurement of sCD25 by enzyme immunoassay	A
Serum	Functional complement	ISOP 23: Measurement of functional complement pathways	A
Serum	Soluble FAS ligand (sFasL)	ISOP36: Measurement by enzyme immunoassay	A
Haematopoietic progenitor cells - apheresis/haematopoietic progenitor cells—marrow (HPC-A/HPC-M), blood, Peripheral blood mononuclear cells, T cells	CD34/CD3 enumeration TCR α / β and CD19 enumeration post depletion	Monitoring Post Cell Manipulations/Cell Therapy: CD34 and CD3 Enumeration and Viability test using the FACS Canto II and using the BD FACS Lyric Flow Cytometers CTLSOP 034 Staining – Post TCR α / β /CD19 Depletion CTL SOP 048	A, B
Bone marrow or apheresis HPC-Apheresis HPC-M (buffy coat or MNC) CD34-Enriched cells CD34-Depleted cells TCR α / β /CD19 Depleted cells	Colony forming unit CFU-GM x 10 ⁴ /kg and BFUE x 10 ⁴ /kg	GM-CFU Colony Assays using CTLSOP 050	A, B



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Faeces	Quantification of Faecal Calprotectin	DS2 ELISA ISOP44	A
Serum	Tetanus Toxoid IgG antibodies	DS2, ELISA ISOP 52 – Measurement of Tetanus Toxoid Antibodies on the DS2 platform	A
Serum	Rheumatoid factor	BNII nephelometry ISOP 068	A
Serum	Qualitative detection of SARS-CoV-2 IgG antibody First line testing of staff and patients	Vitros 5600 CSOP AO58 using COVID-19 Anti-SARS-CoV-2 IgG Ortho Clinical Diagnostics Assay	
Blood, Lithium Heparin	COVID T Cell Proliferation	Cell proliferation assays using manufacturer's instructions and in-house documented records for: Class II cabinet Cell Harvester Beta Counter Separated Cell Stimulation Assays ISOP 028	A
Serum	Anti-nuclear antibodies Anti-endomysial antibodies	Manufacturer's instructions for Microscope (Zeiss Axioskop 2 serial number 801075) and in house documented methods: ISOP 035: Indirect immunofluorescence	A
Blood (Lithium heparin)	FAS (Apoptosis functional)	Class II Cabinet, 4 colour flow cytometers Apoptosis Function Assay ISOP 30 Reported as normal or abnormal	A
Serum	Measurement of Myeloid Related Protein 8/14 (MRP / serum calprotectin)	Using enzyme immunoassay Manual ELISA (Buhlmann MRP8/14 ELISA kit) ISOP 38	A
EDTA (Plasma)	Soluble C5b-9 complex	Manual ELISA, Plate reader ISOP55 - measurement of Soluble C5b-9s	A



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Immunology examination activities for the purposes of clinical diagnosis</u> (cont'd)	Manufacturer's instructions for analyser/kit in conjunction with in-house documented methods:	A
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	
END			