

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: 002

Issue date: 21 November 2018

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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 (Burtons tyrosine kinase) expression	ISOP8: BTK 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 manufacturers 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 Ptyr 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



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Immunology examination activities for the purposes of clinical diagnosis (cont'd)</u>	
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 manufacturers instructions and in house documentation ISOP22: PHADIA 250



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Immunology examination activities for the purposes of clinical diagnosis (cont'd)</u>	
Serum	<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 manufacturers 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 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 CTLSOP 034 Staining – Post TCR α / β /CD19 Depletion CTL SOP 048
Bone marrow or apheresis	Colony forming unit CFU-GM x 10 ⁴ /kg and BFUE x 10 ⁴ /kg	GM-CFU Colony Assays using CTLSOP 050



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Immunology examination activities for the purposes of clinical diagnosis (cont'd)</u>	
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 manufacturers 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		