# **Schedule of Accreditation**

issued by

**United Kingdom Accreditation Service** 

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



8067

Accredited to ISO 15189:2012

### **North Bristol NHS Trust**

Issue No:009 Issue date: 07 May 2024

Department of Immunology and Immunogenetics Southmead Hospital Southmead Road Westbury on Trym Bristol BS10 5NB

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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 TISSUE AND FLUIDS Serum unless otherwise specified	Immunology examination activities for the purpose of clinical diagnosis	Manufacturer's instructions for Thermofisher Immunocap 250 analyser (fluorescence solid phase immunoassay) and in-house procedure:
	Detection and quantification of specific IgE to the following allergens: Almond Apple rArah2 Aspergillus fumigatus IgE Banana Birch Blue Mussel Brazil Nut Cashew Nut Cashew Nut Cat Epithelium Cheese, cheddar Cheese, mould Chilli Pepper Chocolate (Cacao) Coconut Codfish Dog Dander Egg White Gluten Grapefruit Guinea Pig Epithelium Hamster Epithelium	IMMALSOP003

#### DETAIL OF ACCREDITATION



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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN TISSUE AND FLUIDS (cont'd) Serum unless otherwise specified	Immunology examination activities for the purpose of clinical diagnosis (cont'd)	Manufacturer's instructions for Thermofisher Immunocap 250 analyser fluorescence solid phase immunoassay and in house
(cont'd)		procedure:
	Detection and quantification of specific IgE to the following allergens: (cont'd)	IMMALSOP003
	Honey Bee Horse Dander House Dust Mite	
	Kiwi Fruit Latex	
	Lemon	
	Milk Mouse Epithelium	
	Oak Orange	
	Ovomucoid Peanut	
	Pecan Nut Penicilloyl G	
	Penicilloyl V Pistachio	
	Potato	
	Rabbit Epithelium Rat Epithelium	
	Salmon Sesame Seed	
	Shrimp (Prawn) Soya Bean	
	Strawberry Sycamore	
	Timothy Grass	
	Tomato Tuna	
	Walnut Wasp	
	Wheat White Bean	
	Fungal Antigen Aspergillus IgG	



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Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
Immunology examination activities for the purpose of clinical diagnosis (cont'd)	Manufacturer's instructions for Thermofisher Immunocap 250 analyser fluorescence solid phase immunoassay and in-house procedure:
Detection and quantification of specific IgE to allergens - mixed antigen panels	IMMALSOP003
Mixed Nuts panel (Peanut, Hazel nut, Brazil nut, Almond, Coconut)	
Mixed Feathers panel (Goose, Chicken, Duck, Turkey)	
Mixed Cage Birds panel (Budgerigar, Parrot, Canary, Parakeet, Finch)	
Mixed Seafood panel (Cod, Shrimp, Blue mussel, Tuna, Salmon)	
Mixed Cereals panel (Wheat, Oat, Maize, Sesame seed, Buckwheat)	
Mixed Foods panel (Egg white, milk, cod, wheat, peanut, soya)	
Mixed Meats panel (Pork, Beef, Chicken and Turkey)	
Mixed Moulds(Penicillium, Cladosporium, Aspergillus, and Alternaria)	
Mixed Weeds (Mugwort, Plaintain, Goosefoot, Golden Rod, and Nettle)	
Detection and quantification of Total IgE	
Mast Cell Tryptase	
	measured/Range of measurement Immunology examination activities for the purpose of clinical diagnosis (cont'd) Detection and quantification of specific IgE to allergens - mixed antigen panels Mixed Nuts panel (Peanut, Hazel nut, Brazil nut, Almond, Coconut) Mixed Feathers panel (Goose, Chicken, Duck, Turkey) Mixed Cage Birds panel (Budgerigar, Parrot, Canary, Parakeet, Finch) Mixed Seafood panel (Cod, Shrimp, Blue mussel, Tuna, Salmon) Mixed Cereals panel (Wheat, Oat, Maize, Sesame seed, Buckwheat) Mixed Foods panel (Egg white, milk, cod, wheat, peanut, soya) Mixed Meats panel (Pork, Beef, Chicken and Turkey) Mixed Moulds(Penicillium, Cladosporium, Aspergillus, and Alternaria) Mixed Weeds (Mugwort, Plaintain, Goosefoot, Golden Rod, and Nettle) Detection and quantification of Total IgE



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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN TISSUE AND FLUIDS (cont'd)	Immunology examination activities for the purpose of clinical diagnosis (cont'd)	Manufacturer's instructions for Thermofisher Immunocap 250 analyser (ELiA) and in-house
Serum unless otherwise specified (cont'd)	<u> </u>	procedure:
	Detection of antibodies to dsDNA (quantitative)	IMMAISOP028
	Detection of Anti-Transglutaminase (tTG) antibodies	IMMAISOP028
	Detection of Thyroids Stimulating Hormone Receptor Antibodies	IMMAISOP028
		Manufacturer's instructions for Quantalyser stainer and fluorescence microscopy or manual staining assay with fluorescence microscopy and in-house procedure:
	Detection of Anti-neutrophil Cytoplasmic Antibodies (ANCA)	IMMAISOP030 IMMAISOP006 (manual ANCA)
	ANCA titre	IMMAISOP030 IMMAISOP006 (manual ANCA)
	Auto Immune Profile (AIP)	IMMAISOP030
		IMMAISOP005 (manual AIP)
	Detection of Anti-Nuclear Antibodies (Hep2 cells)	IMMAISOP030
	Detection of organ specific autoantibodies Adrenal Islet cell Paraneoplastic Skin IgA/IgG Endomysial Ds DNA using Crithidia	IMMAISOP033 IMMAISOP011 (manual)



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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN TISSUE AND FLUIDS (cont'd) Serum unless otherwise specified	Immunology examination activities for the purpose of clinical diagnosis (cont'd)	Manufacturer's instructions for Dynex DS2 (ELISA) and in-house procedure:
(cont'd)	Detection of Anti Cardiolipin IgG antibodies	IMMAISOP021
	Detection of Anti-Cyclic Citrullinated Peptide (CCP) antibodies	IMMAISOP021
	Detection of Anti PLA2-R antibodies	IMMAISOP027



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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN TISSUE AND FLUIDS (cont'd)	Immunology examination activities for the purpose of clinical diagnosis (cont'd)	Manufacturers instructions for Euroimmun Euroblot analyser (line blot) and manual method and in- house procedure:
Serum unless otherwise specified (cont'd)	Detection of liver antibodies M2 LKM-1 LC-1 and SLA/LP	IMMAISOP035 (automated) IMMAISOP020 (manual)
	Detection of Paraneoplastic autoantibodies	IIMMAISOP035 (automated) IMMAISOP018 (manual)
	Detection of systemic sclerosis antibodies (ScI-70, CENP A, CENP B, RP11, RP155, fibrillarin, NOR90, Th/To, PM- ScI100, PM-ScI75, Ku,)	IIMMAISOP035 (automated) IMMAISOP032 (manual)
	Detection of Myositis antibodies (Mi- 2 alpha, Mi-2 beta, TIF1g, MDA5, NXP2, SAE1, Ku, PM-Scl100, PM-Scl75, Jo-1, SRP, PL-7, PL-12, EJ, OJ, Ro-52)	IIMMAISOP035 (automated) IMMAISOP031(manual)
	Detection of Extractable Nuclear Antigen specificities (ENA) :	IMMAISOP035 (automated) IMMAISOP036 (manual)
	Anti Ro antibody Anti La antibody Anti Sm antibody Anti RNP antibody Anti Scl-70 antibody Anti Jo-1 antibody	
		Manufacturer's instructions for Binding Site Optilite ( turbidimetric assay) and in house procedure:
	Determination of serum proteins: Immunoglobulins (G,M,A) IgG Subclasses C3/C4 C1Inhibitor	IMMICSOP030
	Caeruloplasmin	
	Free Light chains	IMMICSOP030



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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN TISSUE AND FLUIDS (cont'd) Serum unless otherwise specified	Immunology examination activities for the purpose of clinical diagnosis (cont'd)	Manufacturers instructions for Fujirebio Lumipulse (chemiluminescence) analyser and in-house procedure
(cont'd)		
	Detection of Mesothelin antibodies	IMMAISOP034
		Manufacturer's instructions for DYNEX DS2 (ELISA) and in-house procedure:
Faeces	Detection of Faecal Elastase	IMMAISOP021 IMMICSOP019
Faeces	Detection of Faecal Calprotectin	IMMAISOP021 IMMICSOP018 using the Calex extraction device
		Manufacturers instructions for HM JACKarc Integrated Sphere Latex Turbidimetry and in-house procedure
Faeces	Quantitation of faecal haemoglobin	IMMICSOP033



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Materials/Products tested	Type of test/Properties	Standard specifications/
	measured/Range of measurement	Equipment/Techniques used
HUMAN TISSUE AND FLUIDS (cont'd)	Immunology examination activities for the purpose of clinical diagnosis (cont'd)	Manufacturer's instructions for SEBIA CAPILLARYS 3 TERA(capillary electrophoresis) and
Serum unless otherwise specified (cont'd)		in-house procedure:
	Detection of serum monoclonal proteins	IMMICSOP014
		Manufacturer's instructions for SEBIA HYDRASYS (gel electrophoresis and immunofixation) and in-house procedure:
	Identification of serum monoclonal proteins	Serum Immunofixation Electrophoresis IMMICSOP006
Urine	Detection of urine monoclonal proteins	Urine Immunofixation Electrophoresis (IFE) IMMICSOP021/IMMICSOP012
Serum, Body fluids	Detection of Asialotransferrin	IMMICSOP023
	Alpha 1 antitrypsin phenotype	IMMICSOP027
	C3 nephritic factor	IMMICSOP004
Whole Blood (EDTA)	C3 degradation products	IMMICSOP004
Serum	Cryoglobulins	Serum Immunofixation Electrophoresis (IFE) IMMICSOP005



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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN TISSUE AND FLUIDS (cont'd)	Immunophenotyping examination activities for the purpose of clinical diagnosis	Manufacturer's instructions for Becton Dickinson Facs Lyric (flow cytometry) and in-house procedure:
Whole Blood (EDTA), Bone Marrow, Lymph Node, Body Fluids	Leukaemia/lymphoma type	IMMIPSOP007 GP/PPP/0017
	CD1a CD2 CD3 CD44 CD5 CD7 CD8 CD10 CD11c CD11b CD13 CD14 CD15 CD19 CD20 CD22 CD23 CD25 CD26 CD30 CD33 CD34 CD34 CD36 CD38 CD41a CD41a CD42b CD45 CD45 CD45 CD45 CD45 CD45 CD45 CD45	IMMIPSOP008 IMMIPSOP029 IMMIPSOP043 IMMIPSOP044



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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN TISSUE AND FLUIDS (cont'd)	Immunophenotyping examination activities for the purpose of clinical diagnosis (cont'd)	Manufacturer's instructions for Becton Dickinson Facs Lyric(flow cytometry) and in-house procedure:
Whole Blood (EDTA), Bone Marrow, Lymph Node, Body Fluids (cont'd)	Leukaemia/lymphoma type (cont'd)	IMMIPSOP007 GP/PPP/0017
	cTdt cIgM	IMMIPSOP008 IMMIPSOP012
	cCD3 DR	IMMIPSOP029 IMMIPSOP043
	GlycoA Kappa	IMMIPSOP044 IMMIPSOP046
	Lamda	
Whole Blood (EDTA), Bone Marrow, Lymph Node, Body Fluids	Detection of malignant plasma cells CD19 CD27 CD38 CD45 CD56 CD81 CD117	IMMIPSOP009 IMMIPSOP007
	CD138	GP/PPP/0017 IMMIPSOP008 IMMIPSOP012 IMMIPSOP029 IMMIPSOP043 IMMIPSOP044
		IMMIPSOP046



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HUMAN TISSUE AND FLUIDS (cont'd)	Immunophenotyping examination activities for the purpose of clinical diagnosis (cont'd)	Manufacturer's instructions for Becton Dickinson Facs Lyric(flow cytometry) and in-house procedure:
Whole Blood (EDTA), Bone Marrow, Lymph Node, Body Fluids	Detection of Minimal Residual Disease (AML, ALL, CLL) CD1a CD2 CD3 CD4CD5 CD7 CD8 CD10 CD13 CD15 CD16 CD19 CD20 CD22 CD33 CD34 CD38 CD45 CD45 CD48 CD56 CD58 CD66c CD73 CD79b CD81 CD99 CD117 CD123 CD304 NG2 Dr cCD3	IMMIPSOP021 IMMIPSOP007 GP/PPP/0017 IMMIPSOP012 IMMIPSOP043 IMMIPSOP044 IMMIPSOP046



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Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
Immunophenotyping examination activities for the purpose of clinical diagnosis (cont'd)	Manufacturer's instructions for Becton Dickinson Facs Lyric(flow cytometry) and in-house procedure:
Immunodeficiency screen CD3 CD4 CD8 CD19 CD45 CD56/16	IMMIPSOP045 IMMIPSOP036
Rituximab monitoring CD19	IMMIPSOP036 IMMIPSOP045
Quantification of memory B cells IgD IgM CD19 CD27	IMMIPSOP027 IMMIPSOP007 IMMIPSOP012 IMMIPSOP043 IMMIPSOP044
Quantification of dual negative CD4/CD8 cells CD3 CD4 CD8 TCR (alpha/beta)	IMMIPSOP028 IMMIPSOP007 IMMIPSOP012 IMMIPSOP043 IMMIPSOP044
Quantification of T cell subsets CD3 CD4 CD8 CD45	IMMIPSOP015 IMMIPSOP045
Identification of PNH clones FLAER CD14 CD15 CD45 CD55 CD59 GlycoA	IMMIPSOP010 IMMIPSOP007 GP/PPP/0017 IMMIPSOP012 IMMIPSOP043 IMMIPSOP044
	measured/Range of measurement Immunophenotyping examination activities for the purpose of clinical diagnosis (cont'd) Immunodeficiency screen CD3 CD4 CD8 CD19 CD45 CD56/16 Rituximab monitoring CD19 Quantification of memory B cells IgD IgM CD19 CD27 Quantification of dual negative CD4/CD8 cells CD3 CD4 CD8 TCR (alpha/beta) Quantification of T cell subsets CD3 CD4 CD8 CD45 Identification of PNH clones FLAER CD14 CD15 CD45 CD55 CD59



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HUMAN TISSUE AND FLUIDS (cont'd)	Immunophenotyping examination activities for the purpose of clinical diagnosis (cont'd)	Manufacturer's instructions for Becton Dickinson Facs Lyric(flow cytometry)and in-house procedure:
	Functional Assays	
Whole Blood (Heparin)	Neutrophil function- Adhesion molecules	IMMIPSOP012
		IMMIPSOP043 IMMIPSOP044 IMMIPSOP048
Whole Blood (Heparin)	Lymphocyte function tests	IMMIPSOP011
Whole Blood (Heparin)	CD40 Ligand	IMMIPSOP011
		Manufacturer's instructions for DYNEX DS2 (ELISA) and QUANTIFERON assay and in- house procedure:
Whole Blood (Test specific samples vials)	Tb interferon gamma release assay	IMMIPSOP041



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Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN TISSUE AND FLUIDS (cont'd)	Histocompatibility and Immunogenetics examination activities for the purpose of clinical	
Serum unless otherwise specified (cont'd)	diagnosis	
Whole Blood (EDTA or Citrate), Lymph Node, Spleen		Extraction of DNA. using Promega Maxwell RSC automated extraction platform in-house procedure:
		TTTYPSOP046
DNA. extracted from sample types listed above	PCR HLA tying HLA class I/II HLA- A, B, C, DRB1, DRB3/4/5, DQB1, DQA1, DPB1 and DPA1	Manufacturer's instructions for ProflexPCR and Luminex LX100 PCR-SSO assay and Lifecodes kit and in-house procedures:
	HLA B57/B*57:01	TTTYPSOP 048 TTTYPSOP049
	HLA B27 Ankylosing Spondylitis	11112502049
	HLA B51 (5) Behcets Syndrome	
	HLA DR15(2), DQ6(DQB1*06:02) Narcolepsy	
	HLA A29 Birdshot Retinopathy	
	HLA-DQ2 and HLA DQ8 Coeliac disease	
DNA. extracted from sample types listed above	PCR HLA typing HLA class I/II HLA- A, B, C, DRB1, DRB3/4/5, DQB1, DQA1, DPB1 and DPA1	Manufacturer's instructions for Roche Lightcycler 480 II RT-PCR and CareDX QType assay and in- house procedure TTTYPSOP050



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HUMAN TISSUE AND FLUIDS (cont'd)	Histocompatibility and Immunogenetics examination	Manufacturer's instructions for Luminex 200 (multiplex bead assay with fluorescence detection) and in-	
Serum unless otherwise specified (cont'd)	activities for the purpose of clinical diagnosis (cont'd)	house procedure:One Lambda kits	
Serum	HLA antibody screen	TTSCRSOP005 TTSCRSOP006	
Serum	HLA antibody identification (Class I and Class II single antigen beads)	TTSCRSOP005	
Serum	HLA antibody identification (Class I and Class II single antigen beads)	TTSCRSOP006	
Serum	HLA incompatibility transplantation (Class I and Class II single antigen beads)	TTSCRSOP016	
		Manufacturer's instructions for Becton Dickinson Facs Lyric (flow cytometry) and in-house procedure:	
Whole Blood (EDTA or Citrate), Lymph node, Spleen	Flow cytometry Crossmatch	TTRENSOP008 TTRENSOP017	
Whole Blood (EDTA)	Monitoring of Desensitization to ABO incompatible Donor	Manual In house procedure: (Manual titration) TTRENSOP016	
END			