


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 <p>UKAS MEDICAL</p> <p>8696</p> <p>Accredited to ISO 15189:2012</p>	<p>University Hospital Southampton NHS Foundation Trust</p> <p>Issue No: 008 Issue date: 09 January 2025</p>	
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<p><u>Testing performed at the above address only</u></p>		

DETAIL OF ACCREDITATION

<u>Materials/Products tested</u>	<u>Type of test/Properties measured/Range of measurement</u>	<u>Standard specifications/ Equipment/Techniques used</u>
<p>HUMAN BODY FLUIDS</p> <p>Serum unless otherwise specified</p>	<p>Immunology examination activities for the purposes of clinical diagnosis</p> <p>Autoimmunity & Allergy</p> <p>Detection and quantification of specific IgE to:</p> <p>Almond Amoxicilloyl Ampicilloyl Animal mix - Cat dander, Horse dander, Cow dander, Dog dander Aspergillus fumigatus Avocado Banana Barley Brazil nut Cacao Caged bird mix - Budgerigar feathers, Canary bird feathers, Parakeet feathers, Parrot feathers, Finch feathers Cashew nut Cat dander Cefaclor Cereal mix - Wheat, Oat, Maize, Sesame seed, Buckwheat Cheese, cheddar type Chicken Chickpea Chlorhexidine Coconut Cod fish Common silver birch Common wasp (Yellow jacket)</p>	<p>In house documented procedures based on equipment manuals and standard methods as specified.</p> <p>Thermofisher Immunocap 250 analyser (fluorescence solid phase immunoassay) SOP IMCHEM 2.1</p>



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<p>HUMAN BODY FLUIDS (cont'd)</p> <p>Serum unless otherwise specified</p>	<p>Immunology examination activities (cont'd)</p> <p>Autoimmunity & Allergy (cont'd)</p> <p>Detection and quantification of specific IgE to (cont'd):</p> <p>Dog dander Egg Egg white Egg yolk Ethylene oxide Feather mix - Goose feathers, Chicken feathers, Duck feathers, Turkey feathers Fish mix - Fish, Shrimp, Blue mussel, Tuna, Salmon Gal-alpha-1,3-Gal thyroglobulin Bovine Gelatin bovine General food mix - Egg white, Milk, Fish, Wheat, Peanut, Soybean Gluten Grass mix - Dactylis glomerata, Festuca elatior, Lolium perenne, Phleum pratense, Poa pratensis Hazel nut Honey bee Horse dander House dust mite (Dermatophagoides pteronyssinus) Kiwi Latex Lemon Lupin seed Maize/Corn Milk Morphine Mould mix - Penicillium chrysogenum, Cladosporium herbarum, Aspergillus fumigatus, Alternaria alternate</p>	<p>In house documented procedures based on equipment manuals and standard methods as specified</p> <p>Thermofisher Immunocap 250 analyser (fluorescence solid phase immunoassay) SOP IMCHEM 2.1 (Cont'd)</p>



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<p>HUMAN BODY FLUIDS (cont'd)</p> <p>Serum unless otherwise specified</p>	<p>Immunology examination activities (cont'd)</p> <p>Autoimmunity & Allergy (cont'd)</p> <p>Detection and quantification of specific IgE to (cont'd):</p> <p>nGal d 1 Ovomucoid, Egg Nut mix - Peanut, Hazel nut, Brazil nut, Almond, Coconut Oat Orange Peanut Pecan nut Penicilloyl G Penicilloyl V Pholcodine Pistachio Rabbit epithelium, rArah 1, 3, 6, 9 rAra h 2 Peanut rAra h 8 PR-10, Peanut rCor a 1 PR-10, Hazel nut rCor a 14, Hazel nut rCor a 8 LTP, Hazel nut rCor a 9 rPru p 3 LTP, Peach rTri a 19 Omega-5 Gliadin, Wheat Rye Salmon Sesame seed Shrimp Soybean Staphylococcal enterotoxin B Strawberry Suxamethonium (succinylcholine) Timothy grass Tomato Tree mix - Acer negundo, Betula verrucosa, Fagus grandifolia, Quercus alba, Juglans californica Walnut Wheat Lentil Guinea pig</p>	<p>In house documented procedures based on equipment manuals and standard methods as specified</p> <p>Thermofisher Immunocap 250 analyser (fluorescence solid phase immunoassay) Cont'd SOP IMCHEM 2.1</p>



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<p>HUMAN BODY FLUIDS (cont'd)</p> <p>Serum unless otherwise specified</p>	<p>Immunology examination activities (cont'd)</p> <p>Pine nut Celery Chilli pepper Pea Pineapple Blue Mussel Lobster Tuna Beef Pork Milk bos d4 Rice Bakers yeast</p> <p>Quantification of tryptase levels:</p> <p>Mast cell tryptase</p> <p>Detection of Immunoglobulins:</p> <p>Qualitative detection of immunoglobulins</p> <p>Qualitative detection of IgG, IgA, IgM plus Kappa and Lambda light chains</p> <p>Quantitative detection of Monoclonal component</p> <p>Qualitative Detection of Immunoglobulins (Standard Mask): D/E IgG IgA IgM Kappa light chains Lambda light chains</p>	<p>In house documented procedures based on equipment manuals and standard methods as specified</p> <p>Thermofisher Immunocap 250 analyser (fluorescence solid phase immunoassay) Cont'd SOP IMCHEM 2.1</p> <p>Thermofisher Immunocap 250 analyser (fluorescence solid phase immunoassay) SOP IMCHEM 2.2</p> <p>Sebia Capillarys2 system:</p> <p>Capillary zone electrophoresis SOP IIC 1.5</p> <p>Immunofixation SOP IIC 1.5</p> <p>Scanning densitometry SOP IIC 1.5</p> <p>Sebia Hydrasys 2 system Immunofixation SOP IIC 1.2</p>



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HUMAN BODY FLUIDS (cont'd) Serum unless otherwise specified Urine Urine Serum unless otherwise specified Serum unless otherwise specified Serum/Plasma/CSF Serum/Plasma Serum/Plasma Serum/CSF	<u>Immunology examination activities (cont'd)</u> Detection of urine monoclonal proteins Detection of: IgG IgA IgM Kappa light chains Lambda light chains (free and bound) Detection and quantification of Immunoglobulins and specific proteins: Immunoglobulin G Immunoglobulin A Immunoglobulin M Immunoglobulin E Complement C3 Complement C4 Beta-2 microglobulin Haptoglobin Rheumatoid factor Detection and quantification of Immunoglobulins and specific proteins: Immunoglobulin G Immunochemical C1 esterase inhibitor Low level IgA IgG Subclasses 1-4 Albumin Freelite Lambda light chain Freelite Kappa light chain Detection of Immunoglobulins: Oligoclonal band detection	In house documented procedures based on equipment manuals and standard methods as specified Urine protein electrophoresis SOP IIC 1.29 SOP IIC 1.30 Immunofixation SOP IIC 1.4 Beckman AU5800 Immunoassay SOP AUM54 SOP AUM53 SOP AUM55 SOP AUM56 SOP AUM58 SOP AUM59 SOP AUM57 SOP AUM61 SOP AUM62 Oplitite analyser using: SOP IIC 1.46 Sebia Analyser Hydrasys and Iso Electric Focussing using SOP AUIMM 3.11



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HUMAN BODY FLUIDS (cont'd)	Immunology examination activities (cont'd)	In house documented procedures based on equipment manuals and standard methods as specified
Serum unless otherwise specified	Detection of autoantibodies: Anti M2 antibody Anti A.fumigatus (IgG) Anti M. faeni/ A.thermophylae mix (IgG) Anti-Pigeon serum proteins (IgG) Anti-TPO Intrinsic factor antibodies	Fluorescence solid phase immunoassay on the Thermofisher Immunocap 250 analyser SOP AUIMM 4.6 SOP AUIMM 4.3
Faecal extract Serum/Plasma/CSF	Calprotectin Quantification of: TTG IgA TTG IgG ANA screen dsDNA Ro	Biorad BIOPLEX 2000 particle flow immunoassay analyser: SOP's AUIMM 2.1, AUIMM 2.2, AUIMM 2.3
Serum/Plasma/CSF	La Sm RNP SCL-70 Centromere MPO PR3 GBM CCP ACLA IgG ACLA IgM ABeta2GP1 IgG Jo1 Sm/RNP Ribosomal P	Biorad BIOPLEX 2000 particle flow immunoassay analyser: SOP's AUIMM 2.1, AUIMM 2.2, AUIMM 2.3, AUIMM 2.4, AUIMM 2.5, AUIMM 2.6



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<p>HUMAN BODY FLUIDS (cont'd)</p> <p>Serum unless otherwise specified</p>	<p>Immunology examination activities (cont'd)</p> <p>Detection of autoantibodies:</p> <p>Auto Immune liver screen (ANA, SMA, GPC, MITO, LKM) ANCA screen Adrenal auto antibody Bullous auto antibody</p> <p>Endomysial auto antibody Neuronal auto antibody</p> <p>Hep2 auto antibody screen Crithidia lucilliae dsDNA screen</p> <p>Paraneoplastic antibody screen for: Anti Hu Anti Yo Anti Ri Anti CV2 Anti Amphiphysin Anti Ma1 Anti Ma2</p>	<p>In house documented procedures based on equipment manuals and standard methods as specified</p> <p>Indirect Immunofluorescence using the Eurostar UV microscope and Werfen Quantalyser slide processor or Manual IIF preparation following: SOP's AUIMM 1.1, 1.2, 1.3, 1.4, 1.5, 1.6, 1.7, 1.8, 1.9</p> <p>Manual Immunoblot using Ravo Diagnostics reagents SOP IAI 5.1</p>



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HUMAN BODY FLUIDS (cont'd)	<p>Immunology examination activities (cont'd)</p> <p>Detection of autoantibodies:</p> <p>Nucleosomes</p> <p>Histones</p> <p>Anti Glutamic acid decarboxylase</p> <p>Detection of autoantibodies:</p> <p>Anti Acetyl Choline receptor antibody</p>	<p>In house documented procedures based on equipment manuals and standard methods as specified</p> <p>ELISA detection and quantification using Molecular Devices Tecan LT-4500 plate reader</p> <p>Generic Assays reagent (manual process) SOP AUIMM 3.3</p> <p>Organtec reagent (manual process) SOP AUIMM 3.2</p> <p>RSR reagent (manual process) SOP AUIMM 3.8</p> <p>ELISA detection and quantification using Molecular Devices Tecan LT-4500 plate reader</p> <p>RSR reagent (manual process) SOP AUIMM 3.9</p>



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HUMAN BODY FLUIDS (cont'd)	Immunology examination activities (cont'd)	In house documented procedures based on equipment manuals and standard methods as specified
Serum unless otherwise specified	Detection of autoantibodies:	ELISA detection and quantification using Dynex DS2 automatic plate processor
	Detection and semi-quantification of autoantibodies:	
	Functional antibodies against Tetanus toxoid	Binding site reagent SOP IMCHEM 148
	Functional antibodies against S.pneumoniae	SOP IMCHEM 1.3
	Functional antibodies against H. influenza	DS2 SOP IMCHEM 1.2
Blood/ CSF/ Bone marrow	C1 Esterase (functional)	Quidel reagent (manual process) SOP IMCHEM 3.3
	CH50	Manual RID SOP IMCHEM 3.1 Binding site reagent
	Flow Cytometry CD4 Count for Monitoring: CD3,8,45 and 4 mix	BD FACS Lyric Flow Cytometer SOP FLOW126
	Lymphocyte Subsets: CD3, CD4, CD8, CD16/CD56, CD45 and CD19	BD reagent SOP FLOW106
	Paroxysmal Nocturnal Haemoglobinuria (PNH): CD235a, CD55/CD59 tandem mix, CD45, CD24, CD15 and FLAER	BD reagent SOP FLOW123



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HUMAN BODY FLUIDS (cont'd)	Immunology examination activities (cont'd)	In house documented procedures based on equipment manuals and standard methods as specified
Blood/ CSF/ Bone marrow (cont'd)	Flow Cytometry (cont'd)	BD FACS Lyric Flow Cytometer
	Neutrophil Oxidative Burst: Percentage of phagocytic cells which produce reactive oxidants (conversion of DHR 123 to R 123) and their enzymatic activity (amount of R 123 per cell)	BD Glycotope Biotechnology kit (Phagoburst) SOP FLOW127
	HLA-B27	VH Bio (B27) and DB (CD3) SOP FLOW124
	Estimation of Fetomaternal Haemorrhage (FMH)	NBTS reagent (BRAD3 and AEVZ) SOP FLOW134
	Leukaemia and Lymphoma Immunophenotyping	BD FACS Lyric Flow Cytometer SOP FLOW124
	Acute screen: CD34, CD7, CD71, CD45, CD5, CD10, CD19, CD20, CD15, CD117, CD34, DR, CD33, CD3, CD2, CD13, CD14, CD64, CD41a, GPA, CD61, TDT and MPO	BD reagent SOP FLOW124, FLOW108
	B Cell abnormality: BD CD5, CD10, CD19, CD38, CD103, CD22, CD20, CD79b, FMC7, CD23, CD25, CD11C, Kappa/Lambda, CD38, CD56, CD138 and TDT	BD reagent SOP FLOW106 SOP FLOW 107 SOP FLOW 124
	T Cell abnormality: BD CD3, CD25, DR, CD69, CD45A, CD27, CD8, CD26, CD7 and CD4	BD reagent SOP FLOW124
Serum/Plasma	Myositis Immunoblot	Dot Diver Analyser SOP AUIMM 3.4
Serum/Plasma	Scleroderma Immunoblot	Dot Diver Analyser SOP AUIMM 3.5
END		