


Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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

 <p>UKAS MEDICAL 9556</p> <p>Accredited to ISO 15189:2012</p>	<h3>University of Birmingham</h3> <p>Issue No: 008 Issue date: 05 November 2021</p>	
	<p>Clinical Immunology Service The Medical School Vincent Drive Edgbaston Birmingham B15 2TT</p>	<p>Contact: Dr Alex Richter Tel: +44 (0) 121 414 8223 Fax: +44 (0) 121 414 3069 E-Mail: s.A.G.Richter@bham.ac.uk Website: http://www.birmingham.ac.uk</p>
<p>Testing performed at the above address only</p>		

DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS	<u>Immunology examination activities for the purpose of clinical diagnosis</u>	Procedures documented in relevant equipment manuals and in house documented procedures by the following methods
Serum	<p><u>Immunochemistry</u></p> <p>Detection and quantification of:</p> <p>Immunoglobulins (IgG,A,M)</p> <p>IgG subclasses (IgG 1,2,3,4)</p> <p>Serum Free Light Chains</p> <p>Beta 2 Microglobulin</p> <p>Complement components C3/C4</p> <p>CRP</p>	Hitachi COBAS 6000 turbidimeter SOP: COBAS
Serum/Urine	Rheumatoid Factor latex screen	
	Identification of monoclonal proteins:	SEBIA Hydrasys (immunofixation of monoclonal immunoglobulins) SOP: HYSYSuffix SOP: HYDRASYS2
Serum	Paraprotein identification and quantitation of main protein fractions (albumin, alpha 1, alpha-2, beta-1, beta-2, gamma fractions)	Sebia Capillarys 2 Flex SOP: CZE - Electrophoresis Using the Sebia Capillarys 2 SOP CZE DENS - Densitometry Using the Sebia Capillarys 2



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HUMAN BODY FLUIDS (cont'd)	<u>Immunology examination activities for the purpose of clinical diagnosis (cont'd)</u>	Procedures documented in relevant equipment manuals and in house documented procedures by the following methods
Serum	IgD	Binding Site radial immunodiffusion SOP: IgD SOP : SRID
Serum	C1 esterase inhibitor concentration	Binding Site radial immunodiffusion SOP : C1 INH
Plasma (Citrate)	C1 esterase inhibitor function	Technochrom C1 inhibitor kit, Pathway Diagnostics. SOP: FC1inh
Plasma	Viscosity	Bensons Viscometer. SOP: VISC
Serum	IgG Functional antibodies against :- Tetanus toxoid, Pneumococcal serotypes; 1, 3, 4 ,5, 6B, 7F, 9V, 14, 18, 19A, 19F, 23F, <i>Haemophilus Influenzae b</i> ,	LUMINEX multiplex assay SOP: EP-15PG
Serum	<u>Autoimmune Serology:</u> Antinuclear antibodies Centromere antibodies dsDNA antibodies (crithidia) Neutrophil cytoplasmic antibodies Adrenal/Ovarian/Testicular antibodies Epidermal antibodies Islet cell antibodies Mitochondrial antibodies	Quantalyser 160 – Indirect Immunofluorescence. SOP: IMF



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HUMAN BODY FLUIDS (cont'd)	<u>Immunology examination activities for the purpose of clinical diagnosis (cont'd)</u>	Procedures documented in relevant equipment manuals and in house documented procedures by the following methods
Serum	<u>Autoimmune Serology (cont'd):</u> Smooth muscle antibodies LKM antibodies Gastric parietal cells antibodies Myocardial antibodies Endomysial <u>Neuroantibodies</u> Detection of the following paraneoplastic antibodies: Hu, Yo, Ri, Ma, CV2, amphiphysin, SOX1, Zic4, GAD65 and Tr. MAG antibodies Skeletal Muscle antibodies	Quantalyser 160 – Indirect Immunofluorescence. SOP: IMF
Serum	Detection of liver antibodies : M2/nPDC, gp210, sp100, LKM1, LC1, SLA , f-actin	Immunoblot (D-Tek). SOP : Blue Diver Blot
Serum	dsDNA antibodies ENA antibodies screen ENA antibodies type Cardiolipin antibodies (IgG & M) Cardiolipin antibodies (IgG & M) B2GP1 antibodies (IgG)	Dynex DS2 Immuno Sorbent Assay (ELISA). SOP: DSX SOP: DNA SOP: ENAS SOP: ENAS SOP: ENAT SOP: CLP SOP: B2GP



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HUMAN BODY FLUIDS (cont'd): Serum (cont'd)	<p><u>Immunology examination activities for the purpose of clinical diagnosis (cont'd):</u></p> <p><u>Autoimmune Serology: (cont'd)</u></p> <p>Detection and quantification of specific IgE to the following allergens: (cont'd)</p> <p>Apple</p> <p>Apricot</p> <p>Aspergillus fumigatus</p> <p>Aubergine, eggplant</p> <p>Banana</p> <p>Barley</p> <p>Beef</p> <p>Black pepper</p> <p>Brazil nut</p> <p>Budgerigar feathers</p> <p>Budgerigar serum proteins, feathers and droppings</p> <p>Cacao</p> <p>Canary bird feathers</p> <p>Candida albicans</p> <p>Carrot</p> <p>Cashew nut</p> <p>Cat dander</p> <p>Cheese, cheddar type</p> <p>Cherry</p>	<p>Procedures documented in relevant equipment manuals and in house documented procedures by the following methods</p> <p>Immucap 250 (Fluoro Enzyme) Immuno Assay ELISA. SOP: Immucap 250-SOP</p>



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<p>HUMAN BODY FLUIDS (cont'd):</p> <p>Serum (cont'd)</p>	<p><u>Immunology examination activities for the purpose of clinical diagnosis</u> (cont'd):</p> <p><u>Autoimmune Serology:</u> (cont'd)</p> <p>Detection and quantification of specific IgE to the following allergens: (cont'd)</p> <p>Chick pea</p> <p>Chicken</p> <p>Chilipepper</p> <p>Cladosporium herbarum</p> <p>Coconut</p> <p>Cod</p> <p>Coffee</p> <p>Common wasp (Yellow jacket)</p> <p>Crab</p> <p>Curry (Santa Maria)</p> <p>Dog dander</p> <p>Egg white</p> <p>Egg yolk</p> <p>Gerbil epithelium</p> <p>Grape</p> <p>Grapefruit</p> <p>Green pepper (unripe seed)</p> <p>Guinea pig epithelium</p> <p>Hamster epithelium</p>	<p>Procedures documented in relevant equipment manuals and in house documented procedures by the following methods</p> <p>Immucap 250 (Fluoro Enzyme) Immuno Assay ELISA. SOP: Immucap 250-SOP</p>



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<p>HUMAN BODY FLUIDS (cont'd):</p> <p>Serum (cont'd)</p>	<p><u>Immunology examination activities for the purpose of clinical diagnosis</u> (cont'd):</p> <p><u>Autoimmune Serology:</u> (cont'd)</p> <p>Detection and quantification of specific IgE to the following allergens: (cont'd)</p> <p>Hazel nut</p> <p>Honey bee</p> <p>Horse dander</p> <p>House dust mite</p> <p>Kiwi</p> <p>Latex</p> <p>Lemon</p> <p>Lentil</p> <p>Maize, Corn</p> <p>Mango</p> <p>Melon</p> <p>Micropolyspora faenii</p> <p>Milk</p> <p>Mouse serum proteins</p> <p>Mushroom (champignon)</p> <p>Mutton</p> <p>Oat</p> <p>Onion</p> <p>Orange</p> <p>Papaya</p>	<p>Procedures documented in relevant equipment manuals and in house documented procedures by the following methods</p> <p>Immucap 250 (Fluoro Enzyme) Immuno Assay ELISA. SOP: Immucap 250-SOP</p>



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<p>HUMAN BODY FLUIDS (cont'd):</p> <p>Serum (cont'd)</p>	<p><u>Immunology examination activities for the purpose of clinical diagnosis</u> (cont'd):</p> <p><u>Autoimmune Serology:</u> (cont'd)</p> <p>Detection and quantification of specific IgE to the following allergens: (cont'd)</p> <p>Parrot feathers</p> <p>Passion fruit</p> <p>Pea</p> <p>Peach</p> <p>Peanut</p> <p>Pear</p> <p>Pecan nut</p> <p>Penicilloyl G</p> <p>Penicilloyl V</p> <p>Pigeon droppings</p> <p>Pigeon feathers</p> <p>Pigeon serum proteins, feathers and droppings</p> <p>Pine nut</p> <p>Pineapple</p> <p>Pistachio</p> <p>Plum</p> <p>Pork</p> <p>Potato</p> <p>Rabbit epithelium</p> <p>Raspberry</p>	<p>Procedures documented in relevant equipment manuals and in house documented procedures by the following methods</p> <p>Immunocap 250 (Fluoro Enzyme) Immuno Assay ELISA. SOP: Immunocap 250-SOP</p>



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<p>HUMAN BODY FLUIDS (cont'd):</p> <p>Serum (cont'd)</p>	<p><u>Immunology examination activities for the purpose of clinical diagnosis (cont'd):</u></p> <p><u>Autoimmune Serology: (cont'd)</u></p> <p>Detection and quantification of specific IgE to the following allergens: (cont'd)</p> <p>Rat epithelium, serum proteins and urine proteins</p> <p>Rice</p> <p>Rye</p> <p>Salmon</p> <p>Sesame seed</p> <p>Shrimp</p> <p>Soybean</p> <p>Spinach</p> <p>Strawberry</p>	<p>Procedures documented in relevant equipment manuals and in house documented procedures by the following methods</p> <p>Immucap 250 (Fluoro Enzyme) Immuno Assay ELISA. SOP: Immucap 250-SOP</p>



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<p>HUMAN BODY FLUIDS (cont'd):</p> <p>Serum (cont'd)</p>	<p><u>Immunology examination activities for the purpose of clinical diagnosis (cont'd):</u></p> <p><u>Autoimmune Serology: (cont'd)</u></p> <p>Detection and quantification of specific IgE to the following allergens: (cont'd)</p> <p>Timothy grass</p> <p>Tomato</p> <p>Tuna</p> <p>Walnut</p> <p>Wheat</p> <p>Yeast</p> <p>Detection and quantification of specific IgE to allergen components:</p> <p>Alpha-gal Thyroglobulin Bovine</p> <p>nGal d 1 Ovomuroid, Egg</p> <p>nGal d 2 Ovalbumin, Egg</p> <p>rApi m 1 Phospholipase A2, Honey bee</p> <p>rAra h 1 Peanut</p> <p>rAra h 2 Peanut</p> <p>rAra h 3 Peanut</p> <p>rAra h 8 PR-10, Peanut</p> <p>rAra h 9 LTP, Peanut</p> <p>rBet v 1 PR-10, Birch</p> <p>rCor a 1 PR-10, Hazel nut</p>	<p>Procedures documented in relevant equipment manuals and in house documented procedures by the following methods</p> <p>Immucap 250 (Fluoro Enzyme) Immuno Assay ELISA. SOP: Immucap 250-SOP</p>



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HUMAN BODY FLUIDS (cont'd): Serum (cont'd)	<p><u>Immunology examination activities for the purpose of clinical diagnosis (cont'd):</u></p> <p><u>Autoimmune Serology: (cont'd)</u></p> <p>Detection and quantification of specific IgE to allergen components (cont'd):</p> <p>rCor a 8 LTP, Hazel nut</p> <p>rMal d 1 PR-10, Apple</p> <p>rMal d 3 LTP, Apple</p> <p>rPru p 3 LTP, Peach</p> <p>rVes v 1 Phospholipase A1, Common wasp</p> <p>rVes v 5 Common wasp</p> <p>Mixed trees (Maple, Birch, Oak, Elm, walnut)</p> <p>Mixed weed (Ragweed Mugwort, Oxeye daisy, dandelion, Goldenrod)</p> <p>Mixed nut (Peanut, Hazel nut, Brazil nut, Almond, Coconut)</p> <p>Mixed Seafood (Fish, Shrimp, Blue mussel, Tuna, Salmon)</p> <p>Mixed Cage Birds (Budgerigar, Parrot, Canary, Parakeet, Finch)</p> <p>MPO/PR3 IgG antibodies</p> <p>tTG antibodies (IgA quant)</p> <p>M2 Mitochondrial antibodies GAD antibodies</p>	<p>Procedures documented in relevant equipment manuals and in house documented procedures by the following methods</p> <p>Immucap 250 (Fluoro Enzyme) Immuno Assay ELISA. SOP: Immucap 250-SOP</p> <p>Euroimmune ELISA SOP: M2 SOP: GAD</p>



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Serum and CSF	<u>Neuroimmunology</u> Oligoclonal IgG bands	In-house Isoelectric focussing and Western blotting. SOP: IEF
Serum	NMDAR, AMPAR1, AMPAR2, GABA B1R, LGI1, CASPR2 PLA2, MOG, NMO	Immunofluorescence (Sprinter) SOP: IMFS
Body Fluids	Tau protein	In-house electrophoresis and Western blotting. SOP: Tau
Serum	Detection of cerebellar antibodies: Hu, Yo, Ri, Ma2, Ma1, CV2, amphiphysin, SOX1, Zic4, GAD65, Tr.	Immunoblot (Ravo). SOP : Blue Diver Blot
Serum	Detection of Ganglioside antibodies: (GM1, GM2, GM3, GM4, GD1a, GD1b, GD2, GD3, GT1a, GT1b, sulphatide, GQ1b)	Immunoblot (Generic Assays). SOP : Blue Diver Blot
	<u>Immunophenotyping examination activities for the purpose of clinical diagnosis and disease monitoring:</u>	
	<u>Cellular Immunology</u>	<u>Becton Dickinson FACSCanto II</u> (flow cytometry) with specific reference to: SOP: BD FACS Lyse Wash Assistant SOP: CELLPREP
Whole Blood (EDTA)	Quantification of T, B and NK cell subsets	SOP: TBNK
	Quantification of dual negative CD4/CD8 T cell subsets	SOP: Immunodeficiency_FC
Whole Blood (Lithium heparin)	Neutrophil function tests	PhagoBurst™ kit from BD. SOP: SOP-Neutrophil Burst



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Whole Blood (EDTA) / Bone Marrow/ CSF / Body Fluids / Lymph Node	Leukaemia/lymphoma type	<p>SOP: LPD SOP: Acute Leukaemia Screen SOP: B-ALL Screen SOP: T-ALL Screen SOP: AL cytoplasmic SOP: Myeloid screen SOP: AML SOP: PML stain SOP: Myeloma Flow</p>
Whole Blood (EDTA)	Paroxysmal nocturnal hemoglobinuria	SOP: PNH

END