


# Schedule of Accreditation

issued by

## United Kingdom Accreditation Service

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

 <p><b>UKAS</b> MEDICAL 8067</p> <p>Accredited to ISO 15189:2012</p>	<p><b>North Bristol NHS Trust</b></p> <p>Issue No: 005    Issue date: 09 July 2021</p>	
	<p>Department of Immunology and Immunogenetics Southmead Hospital Southmead Road Westbury on Trym Bristol BS10 5NB</p>	<p>Contact: Mr Paul Virgo Tel: +44 (0)117 323 6306 E-Mail: paul.virgo@nbt.nhs.uk Website: www.nbt.nhs.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
<p>HUMAN TISSUE AND FLUIDS</p> <p>Serum unless otherwise specified</p>	<p><u>Immunology examination activities for the purpose of clinical diagnosis</u></p> <p>Detection and quantification of specific IgE to the following allergens:</p> <p>Almond Apple rArah2 Aspergillus fumigatus IgE Banana Birch Blue Mussel Brazil 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 Hazel Nut</p>	<p>Manufacturer's instructions for Thermofisher Immunocap 250 analyser (fluorescence solid phase immunoassay) and in-house procedure:</p> <p>IMMALSOP003</p>



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<p>HUMAN TISSUE AND FLUIDS (cont'd)</p> <p>Serum unless otherwise specified (cont'd)</p>	<p><u>Immunology examination activities for the purpose of clinical diagnosis</u> (cont'd)</p> <p>Detection and quantification of specific IgE to the following allergens: (cont'd)</p> <p>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</p>	<p>Manufacturer's instructions for Thermofisher Immunocap 250 analyser fluorescence solid phase immunoassay and in house procedure:</p> <p>IMMALSOP003</p>



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



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HUMAN TISSUE AND FLUIDS (cont'd)  Serum unless otherwise specified (cont'd)	<u>Immunology examination activities for the purpose of clinical diagnosis (cont'd)</u>	Manufacturer's instructions for Thermofisher Immunocap 250 analyser (ELiA) and in-house 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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HUMAN TISSUE AND FLUIDS (cont'd)  Serum unless otherwise specified (cont'd)	<u>Immunology examination activities for the purpose of clinical diagnosis (cont'd)</u>  Detection of Anti Cardiolipin IgG antibodies  Detection of Anti-Cyclic Citrullinated Peptide (CCP) antibodies  ANCA Elisa (PR3/MPO)  Detection of Anti Glomerular Basement Membrane antibodies    Detection of Anti PLA2-R antibodies    Detection of Anti-acetylcholine receptor antibodies (ACHR)	Manufacturer's instructions for Dynex DS2 (ELISA) and in-house procedure:  IMMAISOP021  IMMAISOP021  IMMAISOP021 IMMAISOP023 (manual)  IMMAISOP021 IMMAISOP023 (manual)  Manufacturer's instructions for Dynex DS2 (ELISA). Manual ELISA read on DYNEX DS2 and in-house procedure:  IMMAISOP027  IMMAISOP019



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HUMAN TISSUE AND FLUIDS (cont'd)	<u>Immunology examination activities for the purpose of clinical diagnosis (cont'd)</u>	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 (Scl-70, CENP A, CENP B, RP11, RP155, fibrillarin, NOR90, Th/To, PM-Scl100, PM-Scl75, 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	
	Determination of serum proteins: Immunoglobulins (G,M,A) IgG Subclasses C3/C4 C1Inhibitor Alpha 1 antitrypsin Caeruloplasmin Beta 2 Microglobulin Free Light chains Haptoglobins	Manufacturer's instructions for Binding Site Optilite ( turbidimetric assay) and in house procedure:  IMMICSOP030          IMMICSOP030



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HUMAN TISSUE AND FLUIDS (cont'd)  Serum unless otherwise specified (cont'd)	<u>Immunology examination activities for the purpose of clinical diagnosis</u> (cont'd)	Manufacturers instructions for Fujirebio Lumipulse (chemiluminescence) analyser and in-house procedure
	Detection of Mesothelin antibodies	IMMAISOP034
	Functional Complement Assays	Radial Immunodiffusion (RID) manual assay and in house procedure:
	CH50	IMMICSOP008
	AP50	IMMICSOP008
	C1 Inhibitor	IMMAISOP021 IMMICSOP003
		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
Faeces	Quantitation of faecal haemoglobin	Manufacturers instructions for HM JACKarc Integrated Sphere Latex Turbidimetry and in-house procedure  IMMICSOP033



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<p>HUMAN TISSUE AND FLUIDS (cont'd)</p> <p>Serum unless otherwise specified (cont'd)</p> <p>Urine</p> <p>Serum, Body fluids</p> <p>Whole Blood (EDTA)</p> <p>Serum</p> <p>CSF/Serum</p>	<p><u>Immunology examination activities for the purpose of clinical diagnosis</u> (cont'd)</p>	<p>Manufacturer's instructions for SEBIA CAPILLARYS 2 FLEX (capillary electrophoresis) and in-house procedure:</p>
	Detection of serum monoclonal proteins	<p>IMMICSOP014</p> <p>Manufacturer's instructions for SEBIA HYDRASYS (gel electrophoresis and immunofixation) and in-house procedure:</p>
	Identification of serum monoclonal proteins	<p>Serum Immunofixation Electrophoresis IMMICSOP006</p>
	Detection of urine monoclonal proteins	<p>Urine Immunofixation Electrophoresis (IFE) IMMICSOP021/IMMICSOP012</p>
	Detection of Asialotransferrin	<p>IMMICSOP023</p>
	Alpha 1 antitrypsin phenotype	<p>IMMICSOP027</p>
	C3 nephritic factor	<p>IMMICSOP004</p>
	C3 degradation products	<p>IMMICSOP004</p>
	Cryoglobulins	<p>Serum Immunofixation Electrophoresis (IFE) IMMICSOP005</p> <p>Manufacturer's instructions for HELENA SAS3 (Gel electrophoresis) and in-house procedure:</p>
	Alkaline phosphatase isoenzymes	<p>IMMICSOP024</p>
CSF Oligoclonal protein bands	<p>IMMICSOP025</p>	





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HUMAN TISSUE AND FLUIDS (cont'd)  Serum unless otherwise specified (cont'd)	<u>Immunology examination activities for the purpose of clinical diagnosis</u> (cont'd)  Detection and quantitation of: Rheumatoid Factor  Anti Thyroid Peroxidase antibodies	Manufacturer's instructions for R COBAS 6000 (immunoturbidimetric assay) and in-house procedure:  BS/CB/AUTO/ROCHE/4  (Electrochemiluminescence assay) BS/CB/AUTO/ROCHE/4



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HUMAN TISSUE AND FLUIDS (cont'd)	<u>Immunophenotyping examination activities for the purpose of clinical diagnosis</u>	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	IMMIPSOP008
	CD2	IMMIPSOP012
	CD3	IMMIPSOP029
	CD4	IMMIPSOP043
	CD5	IMMIPSOP044
	CD7	
	CD8	
	CD10	
	CD11c	
	CD11b	
	CD13	
	CD14	
	CD15	
	CD19	
	CD20	
	CD22	
	CD23	
	CD25	
	CD26	
	CD30	
	CD33	
	CD34	
	CD36	
	CD38	
	CD41a	
	CD42b	
	CD43	
	CD45	
	CD45RA	
	CD56	
	CD57	
	CD64	
	CD71	
	cCD79a	
	CD79b	
	CD103	
	CD117	
	CD123	
	CD200	
	cMPO	



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HUMAN TISSUE AND FLUIDS (cont'd)	<u>Immunophenotyping examination activities for the purpose of clinical diagnosis</u> (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)  cTdt clgM cCD3 DR GlycoA Kappa Lamda	IMMIPSOP007 GP/PPP/0017  IMMIPSOP008 IMMIPSOP012 IMMIPSOP029 IMMIPSOP043 IMMIPSOP044
Whole Blood (EDTA), Bone Marrow, Lymph Node, Body Fluids	Detection of malignant plasma cells CD19 CD27 CD38 CD45 CD56 CD81 CD117 CD138	IMMIPSOP009 IMMIPSOP007  GP/PPP/0017 IMMIPSOP008 IMMIPSOP012 IMMIPSOP029 IMMIPSOP043 IMMIPSOP044



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<p>HUMAN TISSUE AND FLUIDS (cont'd)</p> <p>Whole Blood (EDTA), Bone Marrow, Lymph Node, Body Fluids</p>	<p><u>Immunophenotyping examination activities for the purpose of clinical diagnosis (cont'd)</u></p> <p>Detection of Minimal Residual Disease (AML, ALL, CLL)</p> <p>CD1a CD2 CD3 CD4CD5 CD7 CD8 CD10 CD13 CD15 CD16 CD19 CD20 CD22 CD33 CD34 CD38 CD45 CD48 CD56 CD58 CD66c CD73 CD79b CD81 CD99 CD117 CD123 CD304 NG2 Dr cCD3</p>	<p>Manufacturer's instructions for Becton Dickinson Facs Lyric(flow cytometry) and in-house procedure:</p> <p>IMMIPSOP021 IMMIPSOP007 GP/PPP/0017 IMMIPSOP008 IMMIPSOP012 IMMIPSOP043 IMMIPSOP044</p>



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HUMAN TISSUE AND FLUIDS (cont'd)	<u>Immunophenotyping examination activities for the purpose of clinical diagnosis (cont'd)</u>	Manufacturer's instructions for Becton Dickinson Facs Lyric(flow cytometry) and in-house procedure:
Whole Blood (EDTA)	Immunodeficiency screen CD3 CD4 CD8 CD19 CD45 CD56/16	IMMIPSOP023 IMMIPSOP045  IMMIPSOP036
Whole Blood (EDTA)	Quantification of memory B cells IgD IgM CD19 CD27	IMMIPSOP027 IMMIPSOP007 IMMIPSOP012 IMMIPSOP043 IMMIPSOP044
Whole Blood (EDTA)	Quantification of dual negative CD4/CD8 cells CD3 CD4 CD8 TCR (alpha/beta)	IMMIPSOP028 IMMIPSOP007 IMMIPSOP012 IMMIPSOP043 IMMIPSOP044
Whole Blood (EDTA)	Quantification of T cell subsets CD3 CD4 CD8 CD45	IMMIPSOP015 IMMIPSOP045
Whole Blood (EDTA)	Identification of PNH clones FLAER CD14 CD15 CD45 CD55 CD59 GlycoA	IMMIPSOP010 IMMIPSOP007 GP/PPP/0017 IMMIPSOP012 IMMIPSOP043 IMMIPSOP044



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HUMAN TISSUE AND FLUIDS (cont'd)	<u>Immunophenotyping examination activities for the purpose of clinical diagnosis (cont'd)</u>	Manufacturer's instructions for Becton Dickinson Facs Lyric(flow cytometry)and in-house procedure:
Whole Blood (Heparin)	Functional Assays Neutrophil function tests	IMMIPSOP012 IMMIPSOP043 IMMIPSOP044 IMMIPSOP019
Whole Blood (Heparin)	Lymphocyte function tests	IMMIPSOP011
Whole Blood (Heparin)	CD40 Ligand	IMMIPSOP011
Whole Blood (Test specific samples vials)	Tb interferon gamma release assay	Manufacturer's instructions for DYNEX DS2 (ELISA) and QUANTIFERON assay and in-house procedure: IMMIPSOP041



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<p>HUMAN TISSUE AND FLUIDS (cont'd)</p> <p>Serum unless otherwise specified (cont'd)</p> <p>Whole Blood (EDTA or Citrate), Lymph Node, Spleen</p>	<p><u>Histocompatibility and Immunogenetics examination activities for the purpose of clinical diagnosis</u></p>	<p>Extraction of DNA. using Promega Maxwell RSC automated extraction platform in-house procedure:</p> <p>TTTYP SOP046</p>
<p>DNA. extracted from sample types listed above</p>	<p>PCR HLA typing HLA class I/II HLA-A, B, C, DRB1, DRB3/4/5, DQB1, DQA1, DPB1 and DPA1</p> <p>HLA B57/B*57:01</p> <p>HLA B27 Ankylosing Spondylitis</p> <p>HLA B51 (5) Behcets Syndrome</p> <p>HLA DR15(2), DQ6(DQB1*06:02) Narcolepsy</p> <p>HLA A29 Birdshot Retinopathy</p> <p>HLA-DQ2 and HLA DQ8 Coeliac disease</p>	<p>Manufacturer's instructions for G STORM PCR and Immucor Gamma Luminex LX100 PCR-SSO assay and Lifecodes kit and in-house procedures:</p> <p>TTTYP SOP 048 TTTYP SOP049</p>
<p>Whole Blood (EDTA or Citrate), Lymph Node, Spleen</p>	<p>Cytotoxic Crossmatch</p>	<p>Manual cytotoxicity assay with fluorescence microscopy and in-house procedure: TTRENSOP005</p>



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HUMAN TISSUE AND FLUIDS (cont'd)	<u>Histocompatibility and Immunogenetics examination activities for the purpose of clinical diagnosis (cont'd)</u>	Manufacturer's instructions for Luminex 200 (multiplex bead assay with fluorescence detection) and in-house procedure:
Serum unless otherwise specified (cont'd)		
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		