


# 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 8195</p> <p>Accredited to ISO 15189:2012</p>	<p><b>Manchester University NHS Foundation Trust</b></p> <p>Issue No: 007 Issue date: 05 October 2021</p>	
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<p><b>Testing performed at the above address only</b></p>		

### DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS	<u>Immunological examinations for the purpose of clinical diagnosis</u>	Documented procedures as indicated based on manufacturers instructions
Serum	Total IgE	IMMPROC0002-using Phadia1000(FEIA)
	Specific IgE	IMMPROC0002-using Phadia1000(FEIA)
	IgG to following: Aspergillus fumigatus Budgie ( <i>Melopsittacus undulatus</i> ) <i>Micropolysporia faeni</i> Pigeon ( <i>Streptopelia spp</i> ) <i>Thermoactinomyces vulga</i> Mast Cell Tryptase Anti TPO	IMMPROC0105-Phadia 250(FEIA)
	<b>Autoimmunity</b> Anti-nuclear antibody Ab to ENA Ab to dsDNA Ab to GBM Ab to MPO Ab to PR3 Anti Cardiolipin Ab IgG Anti Cardiolipin Ab IgM Anti CCP Ab Anti B2 Glycoprotein IgG Anti B2 Glycoprotein IgM tTG IgA tTG IgG	IMM PROC 0104-using Bio-Rad Bioplex 2200 (Multiplex flow immunoassay)



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HUMAN BODY FLUIDS	<u>Immunological examinations for the purpose of clinical diagnosis</u>	Documented procedures as indicated based on manufacturers instructions
Blood	Immunochemistry: Serum Free Light Chains IgG Subclasses	Binding Site Optilite analyser using turbidometry and IMMPROC0205
Blood, bone marrow, CSF, pleural fluid, FNA, BAL & peritoneal fluid	Complement Studies: C1 esterase inhibitor	
	<b>Immuno-deficiency and haematological malignancy</b>	Beckman Coulter NaviosFlow cytometer and FP1000 automated sample preparation
	Acute Leukaemia Panel	IMM PROC 0008
	Chronic Leukaemia Panel	IMM PROC 0008
	ID Panel (T & B) Lymphocytes	IMM PROC 0008
	B Cell Maturation Markers	IMM PROC 0151
	CD4 Enumeration	IMM PROC 0151
	CD34 Enumeration	IMM PROC 0011
	EMA Binding Assay	IMM PROC 0156
	Platelet Glycoprotein Assay	IMM PROC 0157
	LAD Markers	IMM PROC 0173
	Naïve, Memory & Effector T cells	IMM PROC 0153
	Neutrophil Function (DHR)	IMM PROC 0009
	L Selectin Shedding Assay	IMM PROC 0160
	NK Cells	IMM PROC 0152
	Alpha/Beta TCR Double Negative T Cell (DNT) Analysis	IMM PROC 0174
	T Cell Activation Markers	IMM PROC 0175
Peripheral blood in heparin	Dihydrorhodamine (DHR) Neutrophil Oxidative Burst Assay	IMM PROC 0223
Blood	Analysis of Eosin-5-Maleimide (EMA) Binding	IMM PROC 0156
Serum	CD34 enumeration	Beckman Navios Flow Cytometer and IMM PROC 0011
	Immune Monitoring(CD3, CD4, CD8, CD16+56, CD19 counts)	Beckman Aquios Flow Cytometer and IMM PROC 0214



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HUMAN BODY FLUIDS	<u>Immunological examinations for the purpose of clinical diagnosis</u>	Documented procedures as indicated based on manufacturers instructions
Whole blood	IgD/CD27 B Cell Maturation marker Assay	Beckman Navios Flow Cytometer And Duraclone system IMM PROC 0151
	T Cell Subsets Assay for Identification of Naïve, Memory and Effector T cells	IMM PROC 0153
Peripheral blood with EDTA or heparin, bone marrow	Cell markers as below for immunotyping of leukaemia and lymphomas  CD14, CD117, CD19, CD33, CD34, CD13 CD10, CD22, CD2, CD45	IMM PROC 008
	AP100 CH100	RID plate reader MM PROC 0136 IMM PROC 0112
Plasma	C1 esterase inhibitor functional activity	IMM PROC 0025 (Manual ELISA – Pathway Diagnostics)
Serum	Acetyl Choline Receptor Abs (ACHR)	IMM PROC 0155 (Manual ELISA – RSR Limited)
Serum	Glutamic Acid Decarboxylase (GAD) Abs	IMM PROC 0147 (Manual ELISA – RSR Limited)
	Anti Quantiferon detection	Qiagen Quantiferon Gold Plus TB ELISA kit and DS2 analyser IMMRPOC0061



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HUMAN BODY FLUIDS	<u>Immunological examinations for the purpose of clinical diagnosis</u>	Documented procedures as indicated based on manufacturers instructions
Serum	Detection of TSH receptor antibodies	IMMPROC 0188 using RSR ELISA kit
	Detection of paraneoplastic neuronal antibodies (Hu, Yo, CV2/CRMP5, Amphiphysin, Ma1, Ma2)	IMMPROC 0180 using RAVO Diagnostica GmbH line blot
Blood (serum) and urine	Detection of serum proteins <ul style="list-style-type: none"> <li>- Serum albumin</li> <li>- Alpha-1 globulins</li> <li>- Alpha-2 globulins</li> <li>- Beta globulins</li> <li>- Gamma globulins</li> </ul>	IMM PROC 0164 using SAS 3 and SAS 4 gel electrophoresis
	Detection of: <ul style="list-style-type: none"> <li>- Anti IgG</li> <li>- Anti IgA</li> <li>- Anti IgM</li> <li>- Anti- Kappa</li> <li>- Anti- lambda</li> </ul>	IMM PROC 0164 by Serum Immunodisplacement using Helena Biosciences V8 capillary zone electrophoresis. IMM PROC 0165 by serum or urine immunofixation using SAS 3 and 4 gel electrophoresis
	Paraprotein quantitation	IMM PROC 0165 by SAS 3 and 4 gel electrophoresis
Urine	Bence Jones protein	
Serum and ETS plasma	Cryoglobulin typing	IMM PROC 0053 by diffusion and SAS 3 and 4 gel electrophoresis
Serum	Qualitative detection of the following IgG antibodies for autoimmune inflammatory myopathies: Mi-2 ( $\alpha$ and $\beta$ ), TIF1 $\gamma$ , MDA5, NXP2, SAE1, KU, proteins of the nucleolar PM-Scl macromolecular complex (PM-Scl75 and PM-Scl100), Jo1, SRP, PL-7, PL-12, EJ, OJ and Ro-52	Euroimmun Line blot processed using the Heidolph Rocking table and read using the Euroimmun flatbed scanner, SOP - IMM PROC 194 Use of the Euroimmun Autoimmune Inflammatory Myopathies (Myositis) ENA Immunoblot.



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HUMAN BODY FLUIDS	<u>Immunological examinations for the purpose of clinical diagnosis</u>	Documented procedures as indicated based on manufacturers instructions
Serum	Semi-automated autoimmunity including:  ANCA** Anti-Nuclear Ab (ANA)** Anti-Mitochondria Ab (AMA)** Smooth Muscle Ab (SMA)** Liver Kidney Microsomal Ab (LKM)** Gastric Parietal Cell Ab (GPC) Crithidia Ab** Pancreatic Islet Cell Ab (PIC)* Skin Ab (Pemphigus/Pemphigoid)* Adrenal Ab* Ovary Ab* Testis Ab* Cardiac Ab* Endomysial Ab (IgA)*	Quantalyser 2* and 240** using Inova slides and Olympus BX43 indirect fluorescence microscope IMMPROC 0206
Serum	Detection of:  Adalimumab drug levels  Adalimumab drug and antibody levels  Infliximab drug levels	Dynex DS2 (ELISA) and manual ELISA  IMM PROC 0229
Serum and plasma (li-hep)	IgA  IgG  IgM  C3, C4  Beta 2 Microglobulin	Roche Cobas 8000 (c702)  IMM PROC 0224  IMM PROC 0225  IMM PROC 0226  IMM PROC 0222  IMM PROC 0221



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HUMAN BODY FLUIDS  Serum and plasma (li-hep)	<u>Immunological examinations for the purpose of clinical diagnosis</u>  Anti TPO antibodies  Rheumatoid factor	Documented procedures as indicated based on manufacturers instructions  Roche Cobas 8000 (c702)  IMM PROC 0228 (Roche elecsys antithyroid specific peroxidase)  IMM PROC 0223
END		