

# Schedule of Accreditation

issued by

## United Kingdom Accreditation Service

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



8195

Accredited to  
ISO 15189:2022

### Manchester University NHS Foundation Trust

Issue No: 011 Issue date: 07 March 2025

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Testing performed by the Organisation at the locations specified below

Locations covered by the organisation and their relevant activities

#### Laboratory locations:

Location details	Activity	Location code
<b>Address</b> Department of Immunology Clinical Sciences Building 3 Manchester Royal Infirmary Oxford Road Manchester M13 9WL	Diagnostic testing	A
<b>Address</b> Biochemistry Department. Clinical sciences building Wythenshawe Site Wythenshawe Manchester M23 9LT	Diagnostic testing – Immunoglobulins only	B



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DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used	Location Code
HUMAN BODY FLUIDS	<u>Immunological examinations for the purpose of clinical diagnosis</u>	Documented procedures as indicated based on manufacturers instructions	A
Serum	Total IgE	IMM PROC 0002-using Phadia1000(FEIA)	
	Specific IgE	IMM PROC 0002-using Phadia1000(FEIA)	
	IgG to following: Aspergillus fumigatus Budgie ( <i>Melopsittacus undulatus</i> ) <i>Micropolysporia faeni</i> Pigeon( <i>Streptopelia spp</i> )	IMM PROC 0105-Phadia 250(FEIA)	
	Mast Cell Tryptase		
	<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	A
Blood	Immunochemistry: Serum Free Light Chains IgG Subclasses  Complement Studies: C1 esterase inhibitor	Binding Site Optilite analyser using turbidometry and IMM PROC 0205	
Blood, bone marrow, CSF, pleural fluid, FNA, BAL & peritoneal fluid	<b>Immuno-deficiency and haematological malignancy</b>	Beckman Coulter Navios Flow Cytometer and Duraclone System	
	Acute Leukaemia Panel	IMM PROC 0008	
	Chronic Leukaemia Panel	IMM PROC 0008	
	Cutaneous T Cell Lymphoma	IMM PROC 0008	
	ID Panel (T & B) Lymphocytes	IMM PROC 0151	
	B Cell Maturation Markers EMA Binding Assay	IMM PROC 0151 IMM PROC 0157	
	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 0174	
	Alpha/Beta TCR Double Negative T Cell (DNT) Analysis	IMM PROC 0174	
	T Cell Activation Markers	IMM PROC 0175	
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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		Beckman Navios Flow Cytometer And Duraclone system	
		RID plate reader	
	AP100 CH100	IMM PROC 0136 IMM PROC 0112	
		Dynex DS2 analyser	
Plasma	C1 esterase inhibitor functional activity	IMM PROC 0025 (Manual ELISA – Pathway Diagnostics)	
Serum	Acetyl Choline Receptor Abs (ACHR)	IMM PROC 0155	
Serum	Glutamic Acid Decarboxylase (GAD) Abs	IMM PROC 0147	
Serum	Anti Quantiferon detection	Qiagen Quantiferon Gold Plus TB ELISA kit IMM PROC0061	
Serum	Detection of TSH Receptor	IMM PROC 0188 RSR ELISA KIT	



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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	
	Detection of paraneoplastic neuronal antibodies (Hu, Yo, CV2/CRMP5, Amphiphysin, Ma1, Ma2)	IMM PROC 0180 using RAVO Diagnostica GmbH line blot	
Blood (serum) and urine	Serum Electrophoresis		
	Immunofixation	IMM PROC 0241 Use and Maintenance of Sebia Capillars 3 OCTA Instrumentation & IMM PROC 0242 Use and maintenance of Sebia Hydrasys 2	
	Immunotyping		
	Bence Jones Protein		
	Cryoglobulin Typing	IMM PROC 0243 Interpretation of CZE, Immunotyping and Immunofixation for Electrophoresis	
Urine			
Serum and ETS plasma			
Serum		Euroimmun Line blot processed using the Heidolph Rocking table and read using the Euroimmun flatbed scanner, SOP - IMM PROC 0194 Use of the Euroimmun Autoimmune Inflammatory Myopathies (Myositis) ENA Immunoblot.	
	Autoimmunity: Qualitative detection of the following IgG antibodies for autoimmune inflammatory myopathies: Mi-2 ( $\alpha$ and $\beta$ ), TIF1 $\gamma$ , MDA5, NXP2, SAE1, KU, PM-Scl75, PM-Scl100, Jo1, SRP, PL-7, PL-12, EJ, OJ, Ro52 and cN-1a		



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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	A
Serum	<p>Semi-automated autoimmunity including:</p> <p>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** Skin Ab (Pemphigus/Pemphigoid)* *</p> <p>Endomysial Ab (IgA)*</p>	<p>Quantalyser 2* and 240** using Inova slides and Olympus BX43 indirect fluorescence microscope IMM PROC 0206</p>	



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HUMAN BODY FLUIDS (cont'd)	<u>Immunological examinations for the purpose of clinical diagnosis (cont'd)</u>	Documented procedures as indicated based on manufacturers instructions (cont'd)	A
Serum	Detection of:	Dynex DS2 (ELISA) and manual ELISA	
		IMM PROC 0229	
	Adalimumab drug and antibody levels		
	Infliximab drug and antibody levels		
Serum and plasma (li-hep)		Roche Cobas 8000 (c702)	A & B
	IgA		
	IgG		
	IgM		
	C3, C4		A
	Beta 2 Microglobulin	IMM PROC 0221	
	Rheumatoid Factor		
	SARS-CoV2 Spike antibodies	IMM PROC 0232	
	SARS-CoV2 nucleocapsid antibodies	IMM PROC 0232	
END			