

# Schedule of Accreditation



Organisation Name	Saolta University Healthcare Group Galway University Hospital (Immunology)
Trading As	University Hospital Galway
INAB Reg No	255MT
Contact Name	Deirdre Cotter
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Accreditation Standard	EN ISO 15189
Standard Version	2022
Date of award of accreditation	16/02/2010
Scope Classification	Immunology
Services available to the public <sup>1</sup>	

<sup>1</sup> Refer to document on interpreting INAB Scopes of Accreditation

Sites from which accredited services are delivered		
(the detail of the accredited services delivered at each site are on the Scope of Accreditation)		
	Name	Address
1	Head Office	Immunology Department, Newcastle Road,, Galway, H91 YR71

# Scope of Accreditation

Head Office

Immunology

Category: A

Medical pathology field - Test	Test/Assay	Specimen Type	Equipment/Technique	Method (CE/Non-CE/In house developed/based on standard method)	Range of measurement	Std. Ref & SOP
1040 Immunology - .01 Quantitative investigation of immunoglobulins G,A,M and D in body fluids	IgG	Cerebrospinal Fluid	Roche COBAS C311 / Immunoturbimetry	CE Method	4.0 - 200 mg/L	IMG.SOP.IC.037 IMG.SOP.IC.030 Ext.Doc.IC.214 Cobas C311 Instruction Manual
	Immunoglobulin A (IgA)	Serum	Roche COBAS C311 / Immunoturbidimetry	CE method	0.04 - 8.0 g/L	IMG.SOP.IC.030 IMG.SOP.IC.037 Ext.Doc.IC.214 Cobas C311 Instruction manual
	Immunoglobulin G (IgG)		Roche COBAS C311 / Immunoturbidimetry	CE method	0.3 - 50.0 g/L	IMG.SOP.IC.030 IMG.SOP.IC.037 Ext.Doc.IC.214 Cobas C311 Instruction Manual
	Immunoglobulin IgG subclass 1 (IgG1)		Optilite / Immunoturbidimetry	CE method	0.15 - 144 g/L	IMG.SOP.IC.039 IMG.SOP.IC.041 Ext.Doc.IC.223 Optilite User Manual

	Immunoglobulin IgG subclass 2 (IgG2)	Serum	Optilite / Immunoturbidimetry	CE method	0.02 - 28 g/L	IMG.SOP.IC.039 IMG.SOP.IC.041 Ext.Doc.IC.224 Optilite User Manual
	Immunoglobulin IgG subclass 3 (IgG3)		Optilite / Immunoturbidimetry	Ce Method	0.0055 - 8.8 g/L	IMG.SOP.IC.039 IMG.SOP.IC.041 Ext.Doc.IC.225 Optilite User Manual
	Immunoglobulin IgG subclass 4 (IgG4)		Optilite / Immunoturbidimetry	CE Method	0.0043 - 64.8 g/L	IMG.SOP.IC.039 IMG.SOP.IC.041 Ext.Doc.IC.226 Optilite User Manual
	Immunoglobulin M (IgM)	Serum	Roche COBAS C311 / Immunoturbidimetry	CE method	0.04 - 6.5 g/L	IMG.SOP.IC.030 IMG.SOP.IC.037 Ext.Doc.IC.214 Cobas C311 Instruction Manual
	Kappa Free Light Chains (KLC)	Serum	Optilite / Immunoturbidimetry	CE Method	0.6 - 127000 mg/L	IMG.SOP.IC.039 IMG.SOP.IC.042 Ext.Doc.IC.221 Optilite User Manual
	Lambda Free Light Chains (LLC)		Optilite / Immunoturbidimetry	CE Method	1.3 - 139000 mg/L	IMG.SOP.IC.039 IMG.SOP.IC.042 Ext.Doc.IC.222 Optilite User Manual
	Serum Protein Electrophoresis (SPEP)	Serum	Sebia Capillarys 3 / Capillary Zone Electrophoresis (CZE)	CE Method	0 - 120 g/L	IMG.SOP.IC.029 IMG.SOP.IC.016 IMG.SOP.IC.012 Ext.Doc.IC.073 Sebia Capillarys 3 User Guide Sebia Hydrasys User Guide
	Urine Protein Electrophoresis (UPEP)	Urine - spot or 24 hour (plain)	Sebia Hydrasys 2 Scan/Hydragel 30 B1-B2 kit/Gel Electrophoresis	CE method	>= 40 mg/L	IMG.SOP.IC.016 IMG.SOP.IC.012 Ext.Doc.IC.073 Sebia Hydrasys User Guide
1040 Immunology - .02 Qualitative investigation of	Immunofixation - Serum	Serum	Sebia Hydrasys 2 Scan / Sebia Hydragel 4 IF	CE Method	Qualitative	IMG.SOP.IC.016 IMG.SOP.IC.010

immunoglobulins G,A,M and D in body fluids			kit / Immunofixation electrophoresis			Ext.Doc.IC.073 Sebia Hydrasys User guide
	Immunofixation - Urine	Urine - spot or 24 hour (plain)	Sebia Hydrasys 2 Scan/Hydrigel 30 B1-B2 kit/Gel Electrophoresis	CE method	Qualitative	IMG.SOP.IC.016 IMG.SOP.IC.012 Ext.Doc.IC.073 Sebia Hydrasys User Guide
	Serum Protein Electrophoresis (SPEP)	Serum	Sebia Capillarys 3 / Capillary Zone Electrophoresis (CZE)	CE Method	Qualitative	IMG.SOP.IC.029 IMG.SOP.IC.016 IMG.SOP.IC.012 Ext.Doc.IC.073 Sebia Capillarys 3 User Guide Sebia Hydrasys User Guide
	Urine Protein Electrophoresis (UPEP)	Urine - spot or 24 hour (plain)	Sebia Hydrasys 2 Scan/Hydrigel 30 B1-B2 kit/Gel Electrophoresis	CE method	Qualitative	IMG.SOP.IC.016 IMG.SOP.IC.012 Ext.Doc.IC.073 Sebia Hydrasys User Guide
1040 Immunology - .03 Total IgE	Total IgE (TIgE)	Serum	Phadia 250 / Fluoroenzyme Immunoassay	CE Method	2 - 5000 kU/L	IMG.SOP.AAL.035 IMG.SOP.AAL.003 Ext.Doc.AAL.311 Phadia 250 User Manual
1040 Immunology - .04 Allergen - specific IgE	Specific IgE (SIgE)		Phadia 250 // Fluoroenzyme Immunoassay	CE Method	0 - 100 kU/L	IMG.SOP.AAL.020 IMG.SOP.AAL.003 Ext.Doc.AAL.320 Phadia 250 User Manual
1040 Immunology - .06 Investigation of complement	C1 Esterase Inhibitor	Serum	Optilite / Immunoturbidimetry	CE Method	0.08 - 0.88 g/L	IMG.SOP.IC.039 IMG.SOP.IC.040 Ext.Doc.IC.219 Optilite User Manual
	Complement C3		Roche COBAS C311 / Immunoturbidimetry	CE Method	0.04 - 5.0 g/L	IMG.SOP.IC.030 IMG.SOP.IC.035 Ext.Doc.IC.214 Cobas C311 Instruction Manual

	Complement C4		Roche COBAS C311 / Immunoturbidimetry	CE Method	0.02 - 1.0 g/L	IMG.SOP.IC.030 IMG.SOP.IC.035 Ext.Doc.IC.214 Cobas C311 Instruction Manual
	Evaluation of Alternative Complement Activity Function		DS2 ELISA Processor / Wieslab Complement System Alternative Pathway ELISA kit	CE method	Qualitative	IMG.SOP.AAL.006 IMG.SOP.CEL.016 Ext.Doc.CEL.108 DS2 Instruction Manual
	Evaluation of Classical Complement Activity Function		DS2 ELISA Processor / Wieslab Complement System Alternative pathway ELISA kit	CE method	Qualitative	IMG.SOP.AAL.006 IMG.SOP.CEL.015 Ext.Doc.CEL.107 DS2 Instruction Manual
1040 Immunology - .10 Rheumatoid factor - quantitative assays	Rheumatoid Factor (RF)		Roche COBAS C311 / Immunoturbidimetry	CE Method	10 - 130 g/L	IMG.SOP.IC.030 IMG.SOP.IC.038 Ext.Doc.IC.214 Cobas C311 Instruction Manual
1040 Immunology - .12 Detection of autoantibodies in body fluids and biopsy material	ANA autoantibody profile (nRNP/Sm, Sm, SS-A, Ro52, SS- B, Scl70, PM-Scl, Jo1, CENP B, PCNA, dsDNA, nucleosomes, histones, rib. P-prot, AMA M2)	Serum	EuroBlotOne instrument and Euroimmun ANA profile 3 test kit / Enzyme Immunoassay	CE Method	Qualitative - POS/NEG	IMG.SOP.AAL.030 IMG.SOP.AAL.050 Ext.Doc.AAL.389 EuroblotOne Instruction Manual
	Anti - Myeloperoxidase abs (MPO)		Phadia 250 / Fluoroenzyme Immunoassay	CE Method	0.2 - 134 IU/mL	IMG.SOP.AAL.054 IMG.SOP.AAL.003 Ext.Doc.AAL.185 Phadia 250 User Manual
	Anti Cardiolipin IgG abs (CARD)	Serum	Phadia 250 / Fluoroenzyme Immunoassay	CE Method	0.5 - 418 GPL-U/ml	IMG.SOP.AAL.055 IMG.SOP.AAL.003 Ext.Doc.AAL.405 Phadia 250 User Manual
	Anti Cardiolipin IgM abs (CARD)		Phadia 250 / Fluoroenzyme Immunoassay	CE Method	0.9 - 472 MPL-U/ml	IMG.SOP.AAL.055 IMG.SOP.AAL.003 Ext.Doc.AAL.406

					Phadia 250 User Manual
Anti Intrinsic Factor Abs (IFA)		Phadia 250 / Fluoroenzyme Immunoassay	CE Method	0.5 - 480 EliA U/ml	IMG.SOP.AAL.054 IMG.SOP.AAL.003 Ext.Doc.AAL.413 Phadia 250 User Manual
Anti Parietal cell abs (PCA)		Phadia 250 / Fluoroenzyme Immunoassay	CE Method	0.2 - 169 EliA U/ml	IMG.SOP.AAL.054 IMG.SOP.AAL.003 Ext.Doc.AAL.411 Phadia 250 User Manual
Anti Thyroid Stimulating Hormone Receptor Abs (TRAB)		Phadia 250 / Fluoroenzyme Immunoassay	CE Method	1.5 - 68 IU/l	IMG.SOP.AAL.054 IMG.SOP.AAL.003 Ext.Doc.AAL.372 Phadia 250 User Manual
Anti-Beta 2 Glycoprotein 1 abs (B2GP1)		Phadia 250 / Fluoroenzyme Immunoassay	CE Method	0.8 - 532 EliA U/ml	IMG.SOP.AAL.055 IMG.SOP.AAL.003 Ext.Doc.AAL.407 Phadia 250 User Manual
Anti-Cyclic citrullinated peptide abs (CCP)	Serum	Phadia 250 / Fluoroenzyme Immunoassay	CE Method	0.4 - 340 EliA U/mL	IMG.SOP.AAL.054 IMG.SOP.AAL.003 Ext.Doc.AAL.247 Phadia 250 User Manual
Anti-double stranded DNA abs (dsDNA)		Phadia 250/ Fluoroenzyme Immunoassay	CE Method	0.6 - 379 IU/mL	IMG.SOP.AAL.054 IMG.SOP.AAL.003 Ext.Doc.AAL.321 Phadia 250 User Manual
Anti-Endomysial abs (ENDO)		Helios Slide Processor, Nova Lite Monkey Oesophagus kit / Indirect Immunofluorescence	Based on Standard Method	1/10	IMG.SOP.AAL.052 IMG.SOP.AAL.023 Ext.Doc.AAL.245 Helios IFA Instruction Manual
Anti-Glomerular Basement Membrane Abs (GBM)		Phadia 250 / Fluoroenzyme Immunoassay	CE Method	1.5 - 680 EliA U/mL	IMG.SOP.AAL.054 IMG.SOP.AAL.003 Ext.Doc.AAL.187

					Phadia 250 User Manual
Anti-Glutamic Acid Decarboxylase Abs (GAD)		DS2 ELISA processor / Euroimmun Anti GAD ELISA kit	CE Method	0.59- 2000 IU/mL	IMG.SOP.AAL.051 IMG.SOP.AAL.006 Ext.Doc.AAL.357 Euroimmun anti-GAD kit insert DS2 Instruction Manual
Anti-Neutrophil Cytoplasmic Abs (ANCA)		Helios Slide Processor, Nova Lite ANCA ANA kit / Indirect Immunofluorescence	Based on Standard Method	1/20	IMG.SOP.AAL.052 IMG.SOP.AAL.022 Ext.Doc.AAL.391 Helios IFA Instruction Manual
Anti-Nuclear Antibodies (ANA)		Helios Slide Processor, Nova Lite Hep-2 ANA kit / Indirect Immunofluorescence	Based on Standard Method	1/80	IMG.SOP.AAL.052 IMG.SOP.AAL.031 Ext.Doc.AAL.241 Helios IFA Instruction Manual
Anti-Nuclear Antibody titre (ANAT)		Helios Slide Processor, Nova Lite Hep-2 ANA kit / Indirect Immunofluorescence	Based on Standard Method	1/80 - 1/1280	IMG.SOP.AAL.052 IMG.SOP.AAL.033 Ext.Doc.AAL.241 Helios IFA Instruction Manual
Anti-Phospholipase A2 receptor Ab (PLA2R)		DS2 ELISA processor / Euroimmun Anti-PLA2R ELISA kit	CE Method	0.6 - 1500 RU/mL	IMG.SOP.AAL.053 IMG.SOP.AAL.006 Ext.Doc.AAL.361 Euroimmun APLA2R ELISA instructions for use
Anti-Proteinase 3 abs (PR3)		Phadia 250 / Fluoroenzyme Immunoassay	CE Method	0.6 - 177 IU/mL	IMG.SOP.AAL.054 IMG.SOP.AAL.003 Ext.Doc.AAL.186 Phadia 250 User Manual
Anti-Thyroid peroxidase abs (TPO)	Serum	Phadia 250 / Fluoroenzyme-ImmunoAssay	Ce Method	4 - 1542 IU/mL	IMG.SOP.AAL.054 IMG.SOP.AAL.003 Ext.Doc.AAL.371 Phadia 250 User Manual

Anti-Tissue Specific Ab Screen (anti - nuclear abs, anti-mitochondrial abs, anti-smooth muscle abs, anti-gastric parietal cell abs)	Serum	Helios Slide Processor, Nova Lite ANA KSL kit / Indirect Immunofluorescence	Based on Standard Method	1/40	IMG.SOP.AAL.052 IMG.SOP.AAL.025 Ext.Doc.AAL.230 Helios IFA Instruction Manual
Anti-tissue transglutaminase Abs (tTg) - IgA		Phadia 250 / Fluoroenzyme Immunoassay	CE Method	0.1 - 128 EliA U/mL	IMG.SOP.AAL.026 IMG.SOP.AAL.003 Ext.Doc.AAL.324 Phadia 250 User Manual
Anti-tissue transglutaminase abs (tTg) IgG		Phadia 250 / Fluoroenzyme Immunoassay	CE Method	0.6 - 600 EliA U/mL	IMG.SOP.AAL.054 IMG.SOP.AAL.003 Ext.Doc.AAL.322 Phadia 250 User Manual
Autoimmune Liver Disease profile (AMA-M2, M2-3E (BPO), Sp100, PML, gp120, LKM-1, LC-1, SLA/LP, Ro-52)		EuroBlotOne instrument and Euroimmun Autoimmune Liver diseases kit (IgG) / Enzyme Immunoassay	CE Method	Qualitative - POS/NEG	IMG.SOP.AAL.040 IMG.SOP.AAL.050 Ext.Doc.AAL.079 EuroblotOne Instruction Manual
Connective Tissue Disease screen (CTD)		Phadia 250 / Fluoroenzyme Immunoassay	CE Method	0.03 - > 32 (Ratio)	IMG.SOP.AAL.054 IMG.SOP.AAL.003 Ext.Doc.AAL.382 Phadia 250 User Manual
ENA Profile (SmDp, U1RNP, SS-A/Ro, SS-B/La, Scl-70, Jo1)	Serum	Phadia 250 / Fluoroenzyme Immunoassay	CE method	SmDp: 0.7– ≥330 U/ml U1RNP: 0.5 – ≥240 U/ml Ro: 0.4 – ≥240 U/ml La: 0.4 – ≥320 U/ml Scl-70: 0.6 – ≥240 U/ml Jo1: 0.3 – ≥240 U/ml	IMG.SOP.AAL.054 IMG.SOP.AAL.003 Ext.Doc.AAL.404 Ext.Doc.AAL.178 Ext.Doc.AAL.175 Ext.Doc.AAL.173 Ext.Doc.AAL.174 Ext.Doc.AAL.172 Phadia 250 User Manual
Extractable Nuclear Antigen Screen (ENA Symphony)		Phadia 250 / Fluoroenzyme Immunoassay	CE method	0.09 - 55 (ratio)	IMG.SOP.AAL.054 IMG.SOP.AAL.003 Ext.Doc.AAL.370



						Phadia 250 User Manual
	Myositis Autoantibody profile (Mi-2 $\alpha$ , Mi-2 $\beta$ , TIF1 $\gamma$ , MDA5, NXP2, SAE1, Ku, PM-Scl100, PM-Scl75, Jo1, SRP, PL-7, PL-12, EJ, OJ, Ro-52, cN-1A, HMGCR)		EuroBlotONE instrument and Euroimmun Autoimmune Inflammatory myopathies kit (IgG) / Enzyme Immunoassay	CE Method	Qualitative - POS/NEG	IMG.SOP.AAL.039 IMG.SOP.AAL.050 Ext.Doc.AAL.389 Euroblot One instruction manual
	Systemic Sclerosis Antibody Profile (Scl-70, CENP A, CENP B, RP11, RP155, Fibrillarin, NOR90, Th/To, PM-Scl100, PM-Scl75, Ku, PDGFR, Ro-52)	Serum	EuroBlotOne instrument and Euroimmun Systemic Sclerosis kit / Enzyme Immunoassay	CE Method	Qualitative - POS/NEG	IMG.SOP.AAL.041 IMG.SOP.AAL.050 Ext.Aoc.AAL.051 EuroblotOne Instruction Manual
1040 Immunology - .13 Cryoglobulins	Cryoglobulins	Serum	Sebia Hydrasys Immunofixation	In House method	Qualitative	IMG.SOP.IC.003 Sebia Hydrasys User Guide
1040 Immunology - .14 b2- microglobulin	Beta-2-Microglobulin (B2M)		Roche COBAS C311 / Immunoturbidimetry	Ce Method	0.2 - 8.0 g/L	IMG.SOP.IC.030 IMG.SOP.IC.033 Ext.Doc.IC.214 Cobas C311 Instruction Manual
1040 Immunology - .23 Tests of cellular immunity - quantitation of lymphocytes	Lymphocyte Subset Enumeration	Whole Blood (EDTA)	BD FACS Lyric BD FACS Duet / Fluorescent Flow Cytometry	CE Method	< 8 x 10 <sup>3</sup> cell/uL	IMG.SOP.CEL.012 IMG.SOP.CEL.013 BD FACS Lyric Clinical System Instructions for use BD FACS Duet Sample Preparation system - Instructions for use
1040 Immunology - .54 Tryptase	Tryptase	Serum	Phadia 250 / Fluoroenzyme immunoassay	CE Method	1.0 - 200 ug/L	IMG.SOP.AAL.042 IMG.SOP.AAL.003 Ext.Doc.AAL.248 Phadia 250 User Manual

1040 Immunology - .99 Miscellaneous tests	Albumin	Cerebrospinal Fluid	Roche Cobas C311 / Immunoturbidimetry	CE method	36 - 2400 mg/L	IMG.SOP.IC.032 IMG.SOP.IC.030 Ext.Doc.IC.214 Cobas C311 Instruction Manual
		Serum	Roche COBAS c311 / Immunoturbidimetry	CE Method	2-60g/L	IMG.SOP.IC.030 IMG.SOP.IC.032 Ext.Doc.IC.214 COBAS c311 Instruction Manual
	Alpha 1 anti-trypsin (A1AT)	Serum	Roche COBAS c311 / Immunoturbidimetry	CE Method	0.2 - 6.0 g/L	IMG.SOP.IC.030 IMG.SOP.IC.031 Ext.Doc.IC.214 COBAS c311 Instruction Manual
	Antibodies to Haemophilus influenzae B		DS2 ELISA processor / Vaccuzyme HIB ELISA kit	CE Method	0.11 - 9 mg/L	IMG.SOP.AAL.046 IMG.SOP.AAL.006 Ext.Doc.AAL.218
	Antibodies to Pneumococcal Capsular Polysaccharide (PCP) IgG		DS2 ELISA processor / Vaccuzyme PCP IgG ELISA kit	CE Method	3.3 - 270 mg/L	IMG.SOP.AAL.043 IMG.SOP.AAL.006 Ext.Doc.AAL.215
	Antibodies to Pneumococcal Capsular Polysaccharide (PCP) IgG2		DS2 ELISA processor / Vaccuzyme PCP IgG2 ELISA kit	CE Method	1.1 - 90 mg/L	IMG.SOP.AAL.044 IMG.SOP.AAL.006 Ext.Doc.AAL.216
	Antibodies to Tetanus Toxoid (TTAB)		DS2 ELISA processor / Vaccuzyme TTAB ELISA kit	CE Method	0.01 - 7 IU/mL	IMG.SOP.AAL.045 IMG.SOP.AAL.006 Ext.Doc.AAL.217
	Caeruloplasmin (CAER)		Roche COBAS c311 / Immunoturbidimetry	CE Method	0.03 - 1.4 g/L	IMG.SOP.IC.030 IMG.SOP.IC.034 Ext.Doc.IC.214 COBAS c311 Instruction Manual
	Haptoglobin (HAPT)		Serum	Roche COBAS c311 / Immunoturbidimetry	CE Method	0.1 - 5.7 g/L

						COBAS c311 Instruction Manual
	Interferon Gamma Release assay (IGRA) / Quantiferon	Quantiferon-TB Gold Plus Blood collection tubes	Diasorin Liaison XS analyser / Chemiluminescent Immunoassay (CLIA)	CE Method	0 - 10 IU/ml	IMG.SOP.QFT.001 Ext.Doc.QFT.012 Diasorin Liaison XS User Manual
	Oligoclonal IgG banding in CSF	Cerebrospinal Fluid and paired Serum	Sebia Hydrasys 2 Scan / Sebia Hydragel 9 CSF isofocusing kit / isoelectric focusing	CE Method	> 0.031 mg/dL	IMG.SOP.IC.006 Ext.Doc.IC.073