

Schedule of Accreditation



Organisation Name Saolta University Healthcare Group Galway
University Hospital (Immunology)

Trading As

INAB Reg No 255MT

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Accreditation Standard ISO 15189

Date Initially Awarded 16/02/2010

Scope Classification Immunology

Services available to the public¹

¹ 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	IgA	Serum Sample	Roche COBAS c311	ImmunoTurbidimetry	0.1 - 8.0 g/L	IMG.SOP.IC.030 IMG.SOP.IC.037 COBAS c311 Instruction Manual
	IgG	CSF	Optilite	Immunturbidimetry	7.5 - 1350 mg/L	IMG.SOP.IC.039 IMG.SOP.IC.043 Optilite User Manual
		Serum	Roche COBAS c311	ImmunoTurbidimetry	3.0 - 50 g/L	IMG.SOP.IC.030 IMG.SOP.IC.037 COBAS c311 Instruction Manual
	IgG1	Serum Sample	Optilite	Immunturbidimetry	0.15 - 144 g/L	IMG.SOP.IC.039 IMG.SOP.IC.041 Optilite User Manual
	IgG2		Optilite	Immunturbidimetry	0.02 - 28 g/L	IMG.SOP.IC.039 IMG.SOP.IC.041 Optilite User Manual
	IgG3	Serum Sample	Optilite	Immunturbidimetry	0.0055 - 8.8 g/L	IMG.SOP.IC.039 IMG.SOP.IC.041 Optilite User Manual
	IgG4		Optilite	Immunturbidimetry	0.0043 - 64.8 g/L	IMG.SOP.IC.039 IMG.SOP.IC.041 Optilite User Manual
	IgM		Roche COBAS c311	ImmunoTurbidimetry	0.04 - 6.5 g/L	IMG.SOP.IC.030 IMG.SOP.IC.037 COBAS c311 Instruction Manual
	Kappa Free Light Chains	Serum Sample	Optilite	Immunturbidimetry	0.6 - 127000 mg/L	IMG.SOP.IC.039 IMG.SOP.IC.042 Optilite User Manual
	Lambda Free Light Chains		Optilite	Immunturbidimetry	1.3 - 139000 mg/L	IMG.SOP.IC.039 IMG.SOP.IC.042 Optilite User Manual

	Serum Protein Electrophoresis (SPEP)	Serum	Sebia Capillarys 3 Sebia Hydrasys	Capillary zone electrophoresis (CZE) / Gel Electrophoresis	N/A	IMG.SOP.IC.029 IMG.SOP.IC.016 IMG.SOP.IC.012 IMG.SOP.IC.017 Sebia Capillarys 3 User guide Sebia Hydrasys User guide
	Urine Protein Electrophoresis (UPEP)	Urine	Sebia Hydrasys	Gel electrophoresis	N/A	IMG.SOP.IC.016 IMG.SOP.IC.012 IMG.SOP.IC.017 Sebia Hydrasys User guide
1040 Immunology - .02 Qualitative investigation of immunoglobulins G,A,M and D in body fluids	Immunofixation - Serum	Serum	Sebia Hydrasys	Immunofixation Electrophoresis	Qualitative	IMG.SOP.IC.016 IMG.SOP.IC.010 Sebia Hydrasys User guide
	Immunofixation - Urine	Urine	Sebia Hydrasys	Immunofixation Electrophoresis	Qualitative	IMG.SOP.IC.016 IMG.SOP.IC.010 Sebia Hydrasys User guide
	Serum Protein Electrophoresis (SPEP)	Serum	Sebia Capillarys 3 Sebia Hydrasys	Capillary zone electrophoresis (CZE) / Gel Electrophoresis	Qualitative	IMG.SOP.IC.029 IMG.SOP.IC.016 IMG.SOP.IC.012 IMG.SOP.IC.017 Sebia Capillarys 3 User guide Sebia Hydrasys User guide
	Urine Protein Electrophoresis (UPEP)	Urine	Sebia Hydrasys	Gel electrophoresis	Qualitative	IMG.SOP.IC.016 IMG.SOP.IC.012 IMG.SOP.IC.017 Sebia Hydrasys User guide
1040 Immunology - .03 Total IgE	Total IgE	Serum Sample	Phadia 250	Enzyme-Immunoassay	2 - 5000 kU/L	IMG.SOP.AAL.035
1040 Immunology - .04 Allergen - specific IgE	Specific IgE		Phadia 250	Enzyme-Immunoassay	0 - 100 kU/L	IMG.SOP.AAL.035 IMG.SOP.AAL.003
1040 Immunology - .06 Investigation of complement	C1 Esterase Inhibitor		Optilite	ImmunoTurbidimetry	0.08 - 0.88 g/L	IMG.SOP.IC.039 IMG.SOP.IC.040 Optilite User Manual
	C1 esterase inhibitor function		Technoclone C1-INH kit	Spectrophotometry	31 - 125 % activity	IMG.SOP.CEL.008 IMG.SOP.CEL.010
	C3		Roche COBAS c311	ImmunoTurbidimetry	0.04 - 5 g/L	IMG.SOP.IC.030 IMG.SOP.IC.035 COBAS c311 Instruction Manual
	C4		Roche COBAS c311	ImmunoTurbidimetry	0.02 - 1.0 g/L	IMG.SOP.IC.030 IMG.SOP.IC.035 COBAS c311 Instruction Manual
	Complement Activity - Alternative Pathway	Binding Site	Radial Immunodiffusion	37- 150% normal activity	IMG.SOP.CEL.006 IMG.SOP.CEL.007 Alternative Pathway Haemolytic Complement kit Insert	

	Complement Activity - Classical Pathway	Binding Site	Radial Immunodiffusion	292 - 1171 CH100 U/mL	IMG.SOP.CEL.006 IMG.SOP.CEL.007 Total Haemolytic Complement kit Insert
1040 Immunology - .10 Rheumatoid factor - quantitative assays	Rheumatoid Factor	Roche COBAS c311	ImmunoTurbidimetry	10 - 130 IU/mL	IMG.SOP.IC.030 IMG.SOP.IC.038 COBAS c311 Instruction Manual
1040 Immunology - .12 Detection of autoantibodies in body fluids and biopsy material	ANA Profile-3	EuroImmun	Immunoblot	Qualitative - POS/NEG	IMG.SOP.AAL.030 IMG.SOP.AAL.050
	Anti-GAD	EuroImmun ELISA DS2 ELISA processor	ELISA	5- 2000 IU/mL	IMG.SOP.AAL.051 IMG.SOP.AAL.006 Euroimmun anti-GAD kit insert DS2 Instruction Manual
	Autoimmune Liver Disease profile	EuroImmun	Immunoblot	Qualitative - POS/NEG	IMG.SOP.AAL.040 IMG.SOP.AAL.050
	B-2 Glycoprotein	DS2 - Organtec kit	ELISA	0 - 100 U/mL	IMG.SOP.AAL.014 IMG.SOP.AAL.006
	Cardiolipin (IgG)	DS2 - Organtec kit	ELISA	0 - 120 U/mL	IMG.SOP.AAL.015 IMG.SOP.AAL.006
	Cardiolipin (IgM)	DS2 - Organtec kit	ELISA	0 - 80 U/mL	IMG.SOP.AAL.015 IMG.SOP.AAL.006
	CCP	Phadia 250	Enzyme-Immunoassay	0.4 - 340 EliA U/mL	IMG.SOP.AAL.018 IMG.SOP.AAL.003
	CTD Screen	Phadia 250	Enzyme-Immunoassay	0.03 - > 32 (Ratio)	IMG.SOP.AAL.049 IMG.SOP.AAL.003
	dsDNA	Phadia 250	Enzyme-Immunoassay	0.5 - 379 IU/mL	IMG.SOP.AAL.047 IMG.SOP.AAL.003
	ENA (ENA Symphony)	Phadia 250	Enzyme-Immunoassay	0.7 - 32 (Ratio)	IMG.SOP.AAL.027 IMG.SOP.AAL.003
	ENA Profile	Phadia 250	Enzyme-Immunoassay	0 - 320 EliA U/mL	IMG.SOP.AAL.028 IMG.SOP.AAL.003
	GBM	Phadia 250	Enzyme-Immunoassay	0.8 - 680 EliA U/mL	IMG.SOP.AAL.034 IMG.SOP.AAL.003
	IgA anti-tTG	Phadia 250	Enzyme-Immunoassay	0.1 - 128 EliA U/mL	IMG.SOP.AAL.026 IMG.SOP.AAL.003
	IgG anti-tTG	Phadia 250	Enzyme-Immunoassay	0.6 - 600 EliA U/mL	IMG.SOP.AAL.048 IMG.SOP.AAL.003
	Intrinsic Factor	DS2 - Organtec kit	ELISA	0 - 100 U/mL	IMG.SOP.AAL.011 IMG.SOP.AAL.006
	MPO (Myeloperoxidase)	Phadia 250	Enzyme-Immunoassay	0.2 - 134 IU/mL	IMG.SOP.AAL.029 IMG.SOP.AAL.003
	Myositis Profile	EuroImmun	Immunoblot	Qualitative - POS/NEG	IMG.SOP.AAL.039 IMG.SOP.AAL.050
PR3 (Proteinase-3)	Phadia 250	Enzyme-Immunoassay	0.2 - 177 IU/mL	IMG.SOP.AAL.032 IMG.SOP.AAL.003	
Systemic Sclerosis Profile	EuroImmun	Immunoblot	Qualitative - POS/NEG	IMG.SOP.AAL.041 IMG.SOP.AAL.050	
TPO	Phadia 250	Enzyme-Immunoassay	26 - 3340 IU/mL	IMG.SOP.AAL.019 IMG.SOP.AAL.003	
1040 Immunology - .14 b2-microglobulin	Beta-2 Microglobulin	Roche COBAS c311	ImmunoTurbidimetry	0.1 - 8.0 mg/L	IMG.SOP.IC.030 IMG.SOP.IC.033

						COBAS c311 Instruction Manual
1040 Immunology - .23 Tests of cellular immunity - quantitation of lymphocytes	Lymphocyte Subset Enumeration	Whole Blood	Beckman Coulter Navios	Flow Cytometry	< 8 x 10 ³ cell/uL	IMG.SOP.CEL.001 IMG.SOP.CEL.002 IMG.SOP.CEL.003 IMG.SOP.CEL.011
1040 Immunology - .54 Tryptase	Tryptase	Serum Sample	Phadia 250	Enzyme Immunoassay	1.0 - 200 ug/L	IMG.SOP.AAL.042 IMG.SOP.AAL.013
1040 Immunology - .60 Simple slide tests for biochemical and immunological analytes	ANA		INOVA, Helios IFA	Indirect Immunofluorescence	1/80	IMG.SOP.AAL.052 IMG.SOP.AAL.031 Helios IFA Instruction Manual
	ANA-Titre		INOVA, Helios IFA	Indirect Immunofluorescence	1/80 - 1/1280	IMG.SOP.AAL.052 IMG.SOP.AAL.033 Helios IFA Instruction Manual
	ANCA		INOVA, Helios IFA	Indirect Immunofluorescence	1/20	IMG.SOP.AAL.052 IMG.SOP.AAL.022 Helios IFA Instruction Manual
	Endomysial		INOVA, Helios IFA	Indirect Immunofluorescence	1/10	IMG.SOP.AAL.052 IMG.SOP.AAL.023 Helios IFA Instruction Manual
Tissue Screen	INOVA, Helios IFA	Indirect Immunofluorescence	1/40	IMG.SOP.AAL.052 IMG.SOP.AAL.025 Helios IFA Instruction Manual		
1040 Immunology - .99 Miscellaneous tests	Albumin	CSF	Optilite	Immunoturbidimetry	11 - 16625 mg/L	IMG.SOP.IC.039 IMG.SOP.IC.043 Optilite User Manual
		Serum	Immunoturbidimetry	Roche COBAS c311	2-60g/L	IMG.SOP.IC.030 IMG.SOP.IC.032 COBAS c311 Instruction Manual
	Alpha 1 anti-trypsin	Serum sample	Immunoturbidimetry	Roche COBAS c311	0.2 - 6.0 g/L	IMG.SOP.IC.030 IMG.SOP.IC.031 COBAS c311 Instruction Manual
	Caeruloplasmin		Immunoturbidimetry	Roche COBAS c311	0.03 - 1.4 g/L	IMG.SOP.IC.030 IMG.SOP.IC.034 COBAS c311 Instruction Manual
	Haemophilus Influenza		Vaccuzyme	ELISA	0.11 - 9 mg/L	IMG.SOP.AAL.046
	Haptoglobulin	Serum	Immunoturbidimetry	Roche COBAS c311	0.1 - 5.7 g/L	IMG.SOP.IC.030 IMG.SOP.IC.036 COBAS c311 Instruction Manual
	Oligoclonal IgG banding in CSF	CSF	Sebia	Isoelectric focusing	> 0.031 mg/dL	IMG.SOP.IC.004
	Pneumococcal IgG	Serum Sample	Vaccuzyme	ELISA	3.3 - 270 mg/L	IMG.SOP.AAL.043
	Pneumococcal IgG2		Vaccuzyme	ELISA	1.1 - 90 mg/L	IMG.SOP.AAL.044
Tetanus Toxoid	Vaccuzyme		ELISA	0.01 - 7 IU/mL	IMG.SOP.AAL.045	

