

# Schedule of Accreditation



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Accreditation Standard	ISO 15189
Date Initially Awarded	14/02/2005
Scope Classification	Microbiology and virology
Scope Classification	Haematology
Scope Classification	Immunology
Scope Classification	Chemical pathology
Scope Classification	Genetics

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	Three Rock Road, Sandyford Business Estate, Dublin, D18

# Scope of Accreditation

## Head Office

### Chemical Pathology

Category: A

Medical pathology field - Test	Test/assay	Specimen Type	Technique	Equipment/Range of Measurement	Method (CE/Non-CE/In house developed/based on standard method)	Std. Ref & SOP
1061 Clinical Chemistry - .01 Analytes in general use in cardiac, liver function, lipid, renal and other profiles and metabolic studies	Alanine Amino Transferase (ALT) **1, 2, 4	Serum, EDTA, Heparin Plasma	TRIS buffer without PLP	Architect c8000	CE	CC04
	Albumin **1, 2, 4	Serum, Heparin Plasma	BCG	Architect c8000	CE	CC42
	Albumin / Globulin ratio **1, 2, 4		Calculation			CC42
	Albumin/ Creatinine Ratio **1, 2, 4		Calculation			CC12
	Alkaline Phosphatase (ALP) **1, 2, 4	Serum, Heparin Plasma	AMP buffer not IFCC	Architect c8000	CE	CC03
	Alpha 1-AntiTrypsin	Serum, plasma (EDTA, Na-heparin, citrate)	Immunoturbidimetry	Architect c8000	CE	CC150
	Amylase **1, 2, 4	Serum, Heparin Plasma	G3 Substrate	Architect c8000	CE	CC05
	Aspartate Aminotransferase (AST) **1, 2, 4	Serum, Heparin (Na or Li) Plasma	TRIS buffer without PLP	Architect c8000	CE	CC06
	Calcium **1, 2, 4	Serum, Heparin Plasma	Arsenazo III	Architect c8000	CE	CC10
	Carbon Dioxide (CO <sub>2</sub> ) **1, 2, 4		PEP Carboxylase	Architect c8000	CE	CC50
	Ceruloplasmin	Serum, plasma (EDTA, Li-heparin)	Immunoturbidimetry	Architect c8000	CE	CC151
	Chloride (Cl) **1, 2, 4	Serum, Heparin Plasma	Ion-selective electrode diluted (Indirect)	Architect c8000	CE	CC57
	Cholesterol **1, 2, 4		Cholesterol esterase/oxydase	Architect c8000	CE	CC09
	Corrected Calcium **1, 2, 4		Calculation		CE	CC10
	Creatinine **1, 2, 4	Serum, EDTA, Heparin Plasma, Urine	Kinetic Jaffe	Architect c8000	CE	CC12
		Urine	Jaffe	AU640	CE	D34

	Gamma Glutamyl Transferase (GGT) **1, 2, 4	Serum, Heparin (Na or Li) Plasma	L-Gamma-glutamyl-3-carboxy-4-nitroanilide Substrate	Architect c8000	CE	CC60
	Globulins **1, 2, 4		Calculated	Architect c8000		CC17
	Glucose **1, 2, 4	Sodium Fluoride	Hexokinase + G6PD	Architect c8000	CE	CC11
	HDL **1, 2, 4	Serum, EDTA, Heparin Plasma	Accelerator Selective Detergent	Architect c8000	CE	CC13
	High Sensitivity C Reactive protein (hsCRP) **1, 2, 4	Serum, Heparin (Na or Li) Plasma	Immunoturbidimetric	Architect c8000	CE	CC63
	Homocysteine **1, 2, 4	Serum, EDTA, Li Hep, Heparin Plasma	Microparticle Enzyme Immunoassay	Architect i2000	CE	CC91
	Iron **1, 2, 4	Serum	Ferene	Architect c8000	CE	CC14
	Lactate DeHydrogenase (LDH) **1, 2, 4	Serum, Heparin (Na or Li) Plasma	Lactate to Pyruvate (NADH)	Architect c8000	CE	CC61
	LDL **1, 2, 4	Serum, EDTA, Heparin Plasma	Measured, Liquid Selective Detergent	Architect c8000	CE	CC44
	Lipase **1, 2, 4	Serum	Quinone Dye	Architect c8000	CE	CC147
	Lipoprotein a (Lp(a)) **1, 2, 4	Serum, EDTA, Heparin Plasma	Immunoturbidimetric	Architect c8000	CE	CC49
	Magnesium **1, 2, 4	Serum, Heparin Plasma	Arsenazo III	Architect c8000	CE	CC15
	Microalbumin **1, 2, 4	Urine	Immunoturbidimetric	Architect c8000	CE	CC67
	Phosphate **1, 2, 4	Serum, Heparin Plasma	Phosphomolybdate UV	Architect c8000	CE	CC16
	Potassium (K) **1, 2, 4		Ion-selective electrode diluted (Indirect)	Architect c8000	CE	CC57
	Sodium (Na) **1, 2, 4		Ion-selective electrode diluted (Indirect)	Architect c8000	CE	CC57
	Total Bile Acids **1, 2, 4		Enzymatic / Colorimetric	Architect c8000	CE	CC137
	Total Bilirubin **1, 2, 4	Serum, EDTA, Heparin Plasma	Diazo	Architect c8000	CE	CC68
	Total Protein **1, 2, 4	Serum, Heparin (Na or Li) Plasma	Biuret	Architect c8000	CE	CC17
	Triglycerides **1, 2, 4		Glycerol Phosphate Oxidase	Architect c8000	CE	CC62
	Urea **1, 2, 4		Kinetic Urease	Architect c8000	CE	CC18
	Uric Acid **1, 2, 4		Endpoint Uricase	Architect c8000	CE	CC19
	Urinary Total Protein	Urine	Benzethonium Chloride	Architect c8000	CE	CC154
1061 Clinical Chemistry - .02 Proteins, quantitative analysis	Sex hormone Binding Globulin **1, 2, 4	Serum, Plasma, Heparin (Li)	Chemiluminiscent Microparticle ImmunoAssay (CMIA)	Architect i2000	CE	CC94
1061 Clinical Chemistry - .10 Drugs for therapeutic monitoring	Amikacin **1, 2, 4	Serum, Heparin Plasma, EDTA Plasma	Particle-enhanced turbidimetric immunoassay (PETIA)	Architect i2000	CE	CC86
	Digoxin **1, 2, 4	Serum, Plasma, Heparin (Li)	Particle-enhanced turbidimetric immunoassay	Architect c8000	CE	CC77

			(PETIA)			
	Gentamicin **1, 2, 4	Serum, Heparin Plasma, EDTA Plasma	Particle-enhanced turbidimetric inhibition immunoassay (PETINIA)	Architect i2000	CE	CC95
	Tacrolimus **1, 2, 4	Whole Blood	Chemiluminescent Microparticle ImmunoAssay (CLIA)	Architect i2000	CE	CC110
	Tobramycin **1, 2, 4	Serum, Heparin Plasma, EDTA Plasma	Particle-enhanced turbidimetric inhibition immunoassay (PETINIA)	Architect i2000	CE	CC96
	Valproic Acid **1, 2, 4	Serum, EDTA, Heparin Plasma	Fluorescence Polarisation Immunoassay	Architect c8000	CE	CC78
	Vancomycin **1, 2, 4		Fluorescence Polarisation Immunoassay	Architect c8000	CE	CC84
1061 Clinical Chemistry - .14 Alcohol for non-legal purposes	Ethanol **1, 2, 4	Urine	DRI	AU640	CE	D35
1061 Clinical Chemistry - .15 Drugs for toxicological purposes	6-Acetyl Morphine **1, 2, 4		CEDIA	AU640	CE	D14
	Amphetamine **1, 2, 4	Oral Fluid	CEDIA	AU640	CE	D36
	Amphetamine/Ecstasy **1, 2, 4	Urine	CEDIA	AU640	CE	D18
	Benzodiazepines **1, 2, 4	Oral Fluid	CEDIA	AU640	CE	D39
		Urine	CEDIA	AU640	CE	D24
	Cannabis **1, 2, 4	Oral Fluid	CEDIA	AU640	CE	D37
	Cannabis Metabolites **1, 2, 4	Urine	CEDIA	AU640	CE	D17
	Cocaine **1, 2, 4	Oral Fluid	CEDIA	AU640	CE	D43
		Urine	CEDIA	AU640	CE	D21
	EDDP **1, 2, 4		CEDIA	AU640	CE	D19
	Methadone **1, 2, 4	Oral Fluid	CEDIA	AU640	CE	D41
	Opiates **1, 2, 4		CEDIA	AU640	CE	D40
		Urine	CEDIA	AU640	CE	D10
1061 Clinical Chemistry - .20 Hormones	Cortisol **1, 2, 4	Serum, EDTA, Heparin Plasma	Chemiluminescent Microparticle ImmunoAssay (CMIA)	Architect i2000	CE	CC07
	C-Peptide **1, 2, 4	Serum, Heparin Plasma, EDTA Plasma, Citrate Plasma	Chemiluminescent Microparticle ImmunoAssay (CMIA)	Architect i2000	CE	CC143
	Dehydroepiandrosterone Sulphate (DHEAS) **1, 2, 4		Chemiluminescent Microparticle ImmunoAssay (CMIA)	Architect i2000	CE	CC142
	Follicle Stimulating Hormone (FSH) **1, 2,	Serum, EDTA, Heparin Plasma	Chemiluminescent Microparticle	Architect i2000	CE	CC23

	4		ImmunoAssay (CMIA)			
	Free Thyroxin (FT4) **1, 2, 4		Chemiluminescent Microparticle ImmunoAssay (CMIA)	Architect i2000	CE	CC31
	Free Triiodothyronine (FT3) **1, 2, 4		Chemiluminescent Microparticle ImmunoAssay (CMIA)	Architect i2000	CE	CC22
	Insulin **1, 2, 4	Serum, EDTA Plasma	Chemiluminescent Microparticle ImmunoAssay (CMIA)	Architect i2000	CE	CC141
	Luteinising Hormone (LH) **1, 2, 4	Serum, EDTA, Plasma	Chemiluminescent Microparticle ImmunoAssay (CMIA)	Architect i2000	CE	CC08
	Oestradiol **1, 2, 4	Serum, EDTA, Heparin (Li) Plasma	Chemiluminescent Microparticle ImmunoAssay (CMIA)	Architect i2000	CE	CC25
	Parathyroid Hormone (PTH) **1, 2, 4	Serum, EDTA, Heparin (Li, Na) Plasma	Chemiluminescent Microparticle ImmunoAssay (CMIA)	Architect i2000	CE	CC26
	Progesterone **1, 2, 4	Serum, EDTA, Heparin Plasma	Chemiluminescent Microparticle ImmunoAssay (CMIA)	Architect i2000	CE	CC20
	Prolactin **1, 2, 4		Chemiluminescent Microparticle ImmunoAssay (CMIA)	Architect i2000	CE	CC24
	Testosterone **1, 2, 4		Chemiluminescent Microparticle ImmunoAssay (CMIA)	Architect i2000	CE	CC21
	Thyrotropine (Thyroid Stimulating Hormone, TSH) **1, 2, 4		Chemiluminescent Microparticle ImmunoAssay (CMIA)	Architect i2000	CE	CC30
	Urinary Cortisol	Urine	Chemiluminescent microparticle immunoassay (CMIA)	Architect i2000	CE	CC07
1061 Clinical Chemistry - .40 Iron studies	Coefficient of saturation **1, 2, 4		Calculation		CE	CC54
	Ferritin **1, 2, 4	Serum, EDTA, Heparin (Li) Plasma	Serum, EDTA, Heparin (Li) Plasma	Architect c8000	CE	CC33
	TIBC **1, 2, 4		Calculation		CE	CC54
	Transferrin **1, 2, 4	Serum, EDTA, Heparin Plasma	Immunoturbidimetric	Architect c8000	CE	CC55
	Unsaturated Iron Binding Capacity (UIBC) **1, 2, 4	Serum, Heparin Plasma	Ferene	Architect c8000	CE	CC54
1061 Clinical Chemistry - .45 Vitamin B12 and folate	Folate **1, 2, 4	Serum, Heparin (Li) Plasma	Chemiluminescent Microparticle ImmunoAssay (CMIA)	Architect i2000	CE	CC58

	Vitamin B12 **1, 2, 4	Serum, EDTA Plasma	Chemiluminescent Microparticle ImmunoAssay (CMIA)	Architect i2000	CE	CC39
1061 Clinical Chemistry - .47 Vitamin assays	250H Vitamin D **1, 2, 4	Serum, Heparin Plasma, EDTA Plasma, Citrate Plasma	Chemiluminescent Microparticle ImmunoAssay (CMIA)	Architect i2000	CE	CC136
1061 Clinical Chemistry - .50 Protein and peptide tumour markers	AlphaFetoProtein (AFP) **1, 2, 4	Serum, EDTA, Heparin (Li, Na) Plasma	Chemiluminescent Microparticle ImmunoAssay (CMIA)	Architect i2000	CE	CC40
	Cancer Antigen 125 (CA 125) **1, 2, 4		Chemiluminescent Microparticle ImmunoAssay (CMIA)	Architect i2000	CE	CC35
	Cancer Antigen 153 (CA 153) **1, 2, 4		Chemiluminescent Microparticle ImmunoAssay (CMIA)	Architect i2000	CE	CC36
	Cancer Antigen 199 (CA 199) **1, 2, 4		Chemiluminescent Microparticle ImmunoAssay (CMIA)	Architect i2000	CE	CC37
	CarcinoEmbryonic Antigen (CEA) **1, 2, 4		Chemiluminescent Microparticle ImmunoAssay (CMIA)	Architect i2000	CE	CC38
	Total prostate Specific Antigen (total PSA) **1, 2, 4	Serum	Chemiluminescent Microparticle ImmunoAssay (CMIA)	Architect i2000	CE	CC32
1061 Clinical Chemistry - .61 Hb A1c	Glycated Haemoglobin (HbA1c) **1, 2, 4	Whole blood	Enzymatic	Architect c8000	CE	CC29
1061 Clinical Chemistry - .65 Pregnancy tests – qualitative	Beta Human Chorionic Gonadotrophin (Beta HCG) **1, 2, 4	Serum, EDTA, Heparin Plasma	Chemiluminescent Microparticle ImmunoAssay (CMIA)	Architect i2000	CE	CC34
1061 Clinical Chemistry - .80 Quantitative investigation of immunoglobulins G, A, M and in body fluids	ImmunoGlobulin A (IgA) **1, 2, 4		Immunturbidimetric	Architect c8000	CE	CC53
	ImmunoGlobulin G (IgG) **1, 2, 4		Immunturbidimetric	Architect c8000	CE	CC52
	ImmunoGlobulin M (IgM) **1, 2, 4	Immunturbidimetric	Architect c8000	CE	CC51	
1061 Clinical Chemistry - .81 Qualitative investigation of immunoglobulins G, A, M and in body fluids	Qualitative investigation of immunoglobulins G, A, M in body fluids **1, 2, 4	Serum	Immunofixation	Sebia Hydrasys	CE	B86
1061 Clinical Chemistry - .82 Total IgE	Immunglobulin E (Total IgE) **1, 2, 4	Serum, EDTA, Heparin Plasma	Immunturbidimetric	Architect c8000	CE	CC47
1061 Clinical Chemistry - .83 Rheumatoid factor – quantitative assays	Rheumatoid Factor (RF) **1, 2, 4	Serum	Immunturbidimetric	Architect c8000	CE	CC56
1061 Clinical Chemistry - .84 Anti-thyroid microsomal antibodies	Anti-Thyroid Peroxidase (Anti-TPO) **1, 2, 4	Serum, EDTA, Heparin (li, Na) Plasma	Chemiluminescent Microparticle ImmunoAssay (CMIA)	Architect i2000	CE	CC46

1061 Clinical Chemistry - .85 Anti-thyroglobulin antibodies	Anti-Thyroglobulin (Anti- Tg) **1, 2, 4	Serum, EDTA, Heparin (Li) Plasma	Chemiluminescent Microparticle ImmunoAssay (CMIA)	Architect i2000	CE	CC45
1061 Clinical Chemistry - .86 C3 and C4	C3 **1, 2, 4	Serum, Heparin Plasma	Immunoturbidimetric	Architect c8000	CE	CC132
	C4 **1, 2, 4		Immunoturbidimetric	Architect c8000	CE	CC133
1061 Clinical Chemistry - .88 b2-microglobulin	B 2 Microglobulin **1, 2, 4	Serum, EDTA, Heparin Plasma	Microparticle Enzyme Immunoassay	Architect c8000	CE	CC90
1061 Clinical Chemistry - .99 Miscellaneous tests	pH **1, 2, 4	Urine	DRI	AU640	CE	D20

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## Head Office

### Genetics

Category: A

Medical pathology field - Test	Test/assay	Specimen Type	Technique	Equipment	Method (CE/Non-CE/In house developed/based on standard method)	Std. Ref & SOP
1076 Molecular pathology - .01 Assay for somatic variants in DNA sequence(s)	Identification of the C282Y and H63D in the HFE human gene	EDTA Whole blood	Real time PCR	Maxwell 16 / Applied Biosystem7500	CE	MB01



Medical pathology field - Test	Test/Assay	Specimen Type	Technique	Range of Measurement/Equipment	Method (CE/Non-CE/In house developed/based on standard method)	Std. Ref & SOP
1030 Haematology - .01 Blood counts	Haematocrit **1, 4	EDTA Whole Blood	Calculated from the RBC & MCV	Sysmex XE2100D	CE	H49
	Haemoglobin **1, 4		CyanmethHb colorimetric method	Sysmex XE2100D	CE	H49
	MCH **1, 4		Calculation derived from HGB, RBC & MCV	Sysmex XE2100D	CE	H49
	MCHC **1, 4		FC laser optics. Utilizing RBC channel/Mie group	Sysmex XE2100D	CE	H49
	Mean Cell Volume **1, 4		Indirect Measurement (mean of the RBC Vol)	Sysmex XE2100D	CE	H49
	Red Cell Count **1, 4		FC laser optics. Mie's theory	Sysmex XE2100D	CE	H49
	White Cell Count **1, 4		Flow Cytometry (FC)	Sysmex XE2100D	CE	H49
1030 Haematology - .02 Visual examination of blood films	Blood Film & White Cell Differential. Includes Neutrophils, Lymphocytes, Monocytes, Eosinophils, Basophils Leucocytes **4		Staining/ Microscopy	Manual	CE	H04
1030 Haematology - .03 Erythrocyte sedimentation rate	Erythrocyte Sedimentation Rate (ESR) **1, 4		Photo-Metric Kinetic Technology	Micro Test 1	CE	H09
1030 Haematology - .05 Automated differential leucocyte counts	Basophil Count **1, 4		Indirect Measurement of WBC by algorigrams/ cluster analysis	Sysmex XE2100D	CE	H49
	Eosinophil Count **1, 4		Indirect Measurement of WBC by algorigrams/ cluster analysis	Sysmex XE2100D	CE	H49
	Lymphocyte Count **1, 4		Indirect Measurement of WBC by algorigrams/ cluster analysis	Sysmex XE2100D	CE	H49
	Monocyte Count **1, 4		Indirect Measurement of WBC by algorigrams/ cluster analysis	Sysmex XE2100D	CE	H49

	Neutrophil Count **1, 4		Indirect Measurement of WBC by algorithms/ cluster analysis	Sysmex XE2100D	CE	H49
	Platelet Count **1, 4		FC laser optics. Utilizing RBC channel/Mie map.	Sysmex XE2100D	CE	H49
1030 Haematology - .09 Examination of malarial parasites	Examination for Malarial parasites **4		Staining/ Microscopy	Manual	CE	H47
1030 Haematology - .41 General haemostasis related tests	Activated Partial Thromboplastin Time (APTT) **1, 4	Plasma	Photo Optical Technology	Sysmex CA540	CE	H34
	Fibrinogen **1, 4		Photo Optical Technology	Sysmex CA540	CE	H35
	Prothrombin Time (PT) **1, 4		Photo Optical Technology	Sysmex CA540	CE	H33

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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 - .04 Allergen - specific IgE	Specific IGE **1, 2, 3, 4	Serum, Heparin Plasma, EDTA Plasma	Phadia Immunocap 250 / FluroEnzyme ImmunoAssay (FEIA)	CE	Panels are reported as Positive or Negative only. Individual allergens are reported in kIU/L, ranging from less than 0.10 to greater than 100. A result of > 0.10 kIU/L is interpreted as positive.	CC99
1040 Immunology - .12 Detection of autoantibodies in body fluids and biopsy material	Anti Cardiolipin IgG Antibodies **1, 2, 3, 4	Serum, Plasma	Phadia Immunocap 250 / Enzyme Linked ImmunoAssay (ELIA)	CE	Negative: < 10.0 GPL-U/mL Weak positive: 10.0 - 40.0 GPL-U/mL Positive: > 40.0 GPL-U/mL	CC102
	Anti Cardiolipin IgM Antibodies **1, 2, 3, 4		Phadia Immunocap 250 / Enzyme Linked ImmunoAssay (ELIA)	CE	Negative: < 10.0 GPL-U/mL Weak positive: 10.0 - 40.0 GPL-U/mL Positive: > 40.0 GPL-U/mL	CC103
	Anti CENP Antibodies **1, 2, 3, 4		Phadia Immunocap 250 / Enzyme Linked ImmunoAssay (ELIA)	CE	Less than 7 EliA U/mL	CC122
	Anti Cyclic Citrullinated Peptide (CCP) Antibodies **1, 2, 3, 4	Serum, Heparin Plasma, EDTA Plasma, Citrate Plasma	Architect i2000 / Chemiluminescent Microparticle Immunoassay (CMIA)	CE	< 5.0 U/mL: Negative ≥ 5.0 U/mL: Positive	CC148
	Anti Double Stranded DNA Antibodies **1, 2, 3, 4	Serum, Plasma	Phadia Immunocap 250 / Enzyme Linked ImmunoAssay (ELIA)	CE	Less than 10 IU/mL	CC118
	Anti Gliadin IgA Antibodies **1, 2, 3, 4		Phadia Immunocap 250 / Enzyme Linked ImmunoAssay (ELIA)	CE	Negative: < 7.0 U/mL Borderline: 7.0 - 10.0 U/mL Positive: > 10.0 U/mL	CC104
	Anti Gliadin IgG Antibodies **1, 2, 3, 4		Phadia Immunocap 250 / Enzyme Linked ImmunoAssay (ELIA)	CE	Negative: < 7.0 U/mL Weak positive: 7.0 - 10.0 U/mL Positive: > 10.0 U/mL	CC105
	Anti Glomerular		Phadia Immunocap	CE	Negative: < 7.0	CC107

Basement Membrane (GBM) Antibodies **1, 2, 3, 4		250 / Enzyme Linked ImmunoAssay (ELIA)		U/mL Weak positive: 7.0 - 10.0 U/mL Positive: > 10.0 U/mL	
Anti JO-1 Antibodies **1, 2, 3, 4		Phadia Immunocap 250 / Enzyme Linked ImmunoAssay (ELIA)	CE	Less than 7 EliA U/mL	CC119
Anti LA Antibodies **1, 2, 3, 4		Phadia Immunocap 250 / Enzyme Linked ImmunoAssay (ELIA)	CE	Less than 7 EliA U/mL	CC124
Anti Mitochondrial Antibodies **1, 2, 3, 4		Phadia Immunocap 250 / Enzyme Linked ImmunoAssay (ELIA)	CE	Negative: < 4.0 IU/mL Equivocal: 4.0 IU/mL to 6.0 IU/mL Positive: > 6.0 IU/mL	CC149
Anti Myeloperoxidase (MPO) Antibodies **1, 2, 3, 4		Phadia Immunocap 250 / Enzyme Linked ImmunoAssay (ELIA)	CE	Less than 3.5 IU/mL (<3.5 = negative; 3.5-5.0 = equivocal; >5.0 = positive)	CC127
Anti PR3 Antibodies **1, 2, 3, 4		Phadia Immunocap 250 / Enzyme Linked ImmunoAssay (ELIA)	CE	Anti-PR3: less than 2.0 IU/mL (<2.0 = negative; 2.0-3.0 = equivocal; >3.0 = positive)	CC126
Anti RO Antibodies **1, 2, 3, 4		Phadia Immunocap 250 / Enzyme Linked ImmunoAssay (ELIA)	CE	Less than 7 EliA U/mL	CC123
Anti SCL-70 Antibodies **1, 2, 3, 4		Phadia Immunocap 250 / Enzyme Linked ImmunoAssay (ELIA)	CE	Less than 7 EliA U/mL	CC121
Anti Sm Antibodies **1, 2, 3, 4		Phadia Immunocap 250 / Enzyme Linked ImmunoAssay (ELIA)	CE	Less than 7 EliA U/mL	CC120
Anti Tissue Transglutaminase IgA Antibodies **1, 2, 3, 4	Serum, EDTA Plasma, Citrate Plasma	Phadia Immunocap 250 / Enzyme Linked ImmunoAssay (ELIA)	CE	Less than 7.0 U/mL	CC106
Anti U1RNP Antibodies **1, 2, 3, 4	Serum, Plasma	Phadia Immunocap 250 / Enzyme Linked ImmunoAssay (ELIA)	CE	Less than 5 EliA U/mL	CC125
Anti $\beta$ 2 - Glycoprotein I IgG Antibodies **1, 2, 3, 4		Phadia Immunocap 250 / Enzyme Linked ImmunoAssay (ELIA)	CE	Negative: < 7.0 U/mL Weak positive: 7.0 U/mL to 10.0 U/mL Positive: > 10.0 U/mL	CC113
Anti $\beta$ 2 - Glycoprotein I IgM Antibodies **1, 2, 3, 4		Phadia Immunocap 250 / Enzyme Linked ImmunoAssay (ELIA)	CE	Negative: < 7.0 U/mL Borderline: 7.0 U/mL to 10.0 U/mL Positive: > 10.0 U/mL	CC108
Antinuclear Antibodies **1, 2, 3, 4		Phadia Immunocap 250 / Enzyme Linked ImmunoAssay (ELIA)	CE	Ratio less than 0.7	CC117

	Calprotectin **1, 2, 3, 4	Faeces	Phadia Immunocap 250 / Enzyme Linked ImmunoAssay (ELIA)	CE	<50 ug/g: Calprotectin level not suggestive of organic pathology. 50-200 ug/g: Organic pathology cannot be excluded. A repeat sample in 4 to 6 weeks is advised. >200 ug/g: Calprotectin level is consistent with organic pathology.	CC139
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1012 Preparation of films on glass slides followed by microscopic examination with or without fixation and staining with dyes as required - .01 Microscopic examination for general bacteriology purposes (including enumeration and description of human cells)	Gram Stain **2, 3, 4	Swabs, tissue, fluid, pus, urine.	Gram Stain; Light Microscope	CE	Present/absent	GM15
	Microscopy **3, 4	Urine	Light/fluorescent microscope	CE	Present/absent	CM 38
1012 Preparation of films on glass slides followed by microscopic examination with or without fixation and staining with dyes as required - .02 Microscopic examination for parasites	Parasitology **2, 3, 4	Faeces, urine, sellotape tests	Light Microscope	CE	Present/absent	CM64
1012 Preparation of films on glass slides followed by microscopic examination with or without fixation and staining with dyes as required - .03 Microscopic examination for fungi	Mycology **2, 3, 4	Hair, nail, skin scrapings	Light/fluorescent microscope	CE	Present/absent	CM50
1014 Detection of bacterial, parasite, viral or fungal antigens using specific antibodies and appropriate techniques - .04 Immunochromatographic methods,	Clostridium difficile toxin **2, 3, 4	Faeces	Kit	CE	Positive/Negative	GM75
	GDH **2, 3, 4		Kit	CE	Positive/Negative	CM66
	Helicobacter pylori stool antigen **2, 3, 4		Kit	CE	Positive/Negative	GM82
1016 Identification of cultured bacteria and fungi using non-nucleic acid based techniques - .01 Biochemical methods , CE marked commercial systems	Organism Identification **2, 3, 4	Swabs, tissue, fluid, pus, faeces, urine, tips, IUCD.	Vitek 2 Compact, ID Kits	CE	Organism ID	GM69, GM39, GM40, GM41, GM42, GM43, GM44, GM79
			Vitek 2 Compact/ManualDisk diffusion/Minimum Inhibitory Concentration	CE	Variable	CM63
1017 Measurement of antimicrobial activity and application of clinical interpretive criteria to general bacteria (rapidly growing aerobes) - .05 Other categories of organism (as specified )	Susceptibility Testing **1, 2, 3, 4					

1018 Detection of antibody response to infection using appropriate CE marked commercial techniques - .02 Enzyme immunoassay, using CE marked commercial systems	Anti-Human T-lymphocytes Virus I+II (HTLV I+II) **1, 2, 3, 4	Serum, Plasma, Potassium EDTA	Architect i2000 / Chemiluminescent Microparticle ImmunoAssay (CMIA)	CE	Specimens with S/CO values < 1.00 are considered nonreactive (NR). Specimens with S/CO values ≥ 1.00 are considered reactive (R).	CC93
	Anti-Streptolysin-O	Serum	Architect c8000	CE	Up to 7 years: less than 100 IU/mL Greater than 7 years: less than 200 IU/mL	CC153
	Cytomegalovirus IgG **1, 2, 3, 4	Serum, EDTA, Heparin Plasma	Architect i2000 / Chemiluminescent Microparticle ImmunoAssay (CMIA)	CE	< 6 AU/mL = Negative	CC75
	Cytomegalovirus IgM **1, 2, 3, 4		Architect i2000 / Chemiluminescent Microparticle ImmunoAssay (CMIA)	CE	Less than or equal to 0.85 Index = Negative 0.86 – 1.00 = Equivocal >1.00 = Positive	CC83
	Hepatitis B Core Antibody **1, 2, 3, 4	Serum, Heparin (Li) Plasma	Architect i2000 / Chemiluminescent Microparticle ImmunoAssay (CMIA)	CE	Negative	CC72
	Hepatitis B Surface Antibody (Anti-Hbs) **1, 2, 3, 4	Serum, EDTA, Heparin (Na) Plasma	Architect i2000 / Chemiluminescent Microparticle ImmunoAssay (CMIA)	CE	Greater than 10 IU/mL: reactive	CC48
	Hepatitis B Surface Antigen (Hbs Ag) **1, 2, 3, 4	Serum, EDTA, Heparin Plasma	Architect i2000 / Chemiluminescent Microparticle ImmunoAssay (CMIA)	CE	Negative	CC28
	Hepatitis C Antibody **1, 2, 3, 4		Architect i2000 / Chemiluminescent Microparticle ImmunoAssay (CMIA)	CE	Negative	CC74
	Hepatitis C Antigen **1, 2, 3, 4		Architect i2000 / Chemiluminescent Microparticle ImmunoAssay (CMIA)	CE	Negative	CC134
	HIV Ab/Ag Combo **1, 2, 3, 4	Serum, EDTA, Li Hep, Heparin Plasma	Architect i2000 / Chemiluminescent Microparticle ImmunoAssay (CMIA)	CE	Negative	CC73
	Quantiferon TB Gold **1, 2, 3, 4	Blood	Dynex DS2	CE	Positive/Negative	CM72
	Rubella IgG **1, 2, 3, 4	Serum, EDTA, Heparin Plasma	Architect i2000 / Chemiluminescent Microparticle ImmunoAssay (CMIA)	CE	< 5.0 IU/mL = negative 5.0 – 9.9 = equivocal >= 10 = positive	CC76
	Rubella IgM **1, 2, 3, 4		Architect i2000 / Chemiluminescent Microparticle ImmunoAssay (CMIA)	CE	Index less than 1.20 = negative Index 1.20 – 1.60 = equivocal; repeat in 7 to 14	CC81

					days Index >= 1.60 = positive	
	Syphilis (Treponema pallidum) Antibody **1, 2, 3, 4	Serum, EDTA, Heparin (li, Na) Plasma	Architect i2000 / Chemiluminescent Microparticle ImmunoAssay (CMIA)	CE	Negative	CC41
1029 Miscellaneous - .99 Miscellaneous tests	Urine Dipstick **1, 2, 3, 4	Urine	Colorimetric	CE	Variable	CM69

*The laboratory has been awarded flexible scope in the P9 categories as noted in the scope document and in accordance with the laboratories approved and documented procedures.*

*Note 1 - Range may be extended for the test*

*Note 2 – New parameters / tests may be added*

*Note 3 – New matrices may be added*

*Note 4 – Changes to equipment / kits where the underlying methodology does not change*

*For further details please refer to the laboratories ‘Master list of Flexible scope changes’, available directly from the laboratory.*