

Schedule of Accreditation



Organisation Name	Eurofins Biomnis Ireland Limited
Trading As	Eurofins Biomnis
INAB Reg No	159MT
Contact Name	Brid Muimneach
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Website	https://www.eurofins.ie/biomnis/
Accreditation Standard	EN ISO 15189
Standard Version	2022
Date of award of accreditation	14/02/2005
Scope Classification	Microbiology and Virology
Scope Classification	Haematology
Scope Classification	Immunology
Scope Classification	Chemical Pathology
Services available to the public ¹	

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	Three Rock Road, Sandyford Business Estate, Dublin, D18
2	Eurofins Biomnis Blackthorn Road Site	Unit 3, Sandyford Business Centre, Sandyford Business Park, Blackthorn Road, Dublin 18, Dublin, Ireland, D18

Scope of Accreditation

Eurofins Biomnis Blackthorn Road Site

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	C Reactive protein (CRP) -High Sensitivity **1, 2, 4	Serum/Plasma	Turbidimetric/Immunturbidimetric	Abbott Alinity c	CE	CC188
	24 Hours Microalbumin**1, 2, 4	Urine	Calculated	Abbott Alinity c - LIS Interface	CE	CC188
	Alanine Amino Transferase (ALT) **1, 2, 4	Serum/Plasma	Spectrophotometry NADH	Abbott Alinity c	CE	CC188
	Albumin **1, 2, 4		Spectrophotometry (Bromocresol Green)	Abbott Alinity c	CE	CC188
	Albumin/ Creatinine Ratio **1, 2, 4		Calculated	Abbott Alinity c - LIS Interface	CE	CC188
	Alkaline Phosphatase (ALP) **1, 2, 4		Spectrophotometry Hydrolysis of Para- Nitrophenyl phosphate	Abbott Alinity c	CE	CC188
	Alpha 1-AntiTrypsin **1, 2, 4		Immunoturbidimetry	Abbott Alinity c	CE	CC188

Amylase **1, 2, 4		Enzymatic + Colorimetric	Abbott Alinity c	CE	CC188
Angiotensin Conversion Enzyme **1, 2, 4		Enzymatic/ Colorimetric Hydrolysis of Furylacryloylphenylalanylglycylglycine (FAPGG)	Abbott Alinity c	CE	CC188
Aspartate Aminotransferase (AST) **1, 2, 4		Spectrophotometry	Abbott Alinity c	CE	CC188
Bilirubin Direct **1, 2, 4		Spectrophotometry, Diazo-Reaction	Abbott Alinity c	CE	CC188
Bilirubin Indirect **1, 2, 4		Calculated	Abbott Alinity c - LIS Interface	CE	CC188
Calcium **1, 2, 3, 4	Serum/ Plasma /Spot Urine	Spectrophotometry, Arsenazo III	Abbott Alinity c	CE	CC188
Calcium, Calculated **1, 2, 4	Serum/Plasma	Calculated	Abbott Alinity c - LIS Interface	CE	C188
		Calculated	Abbott Alinity c - LIS Interface	CE	CC188
Carbon Dioxide (CO ₂) **1, 2, 4		Spectrophotometry, PEP Carboxylase	Abbott Alinity c	CE	CC188
Ceruloplasmin **1, 2, 4		Turbidimetric/ Immunturbidimetric	Abbott Alinity c	CE	CC188
Chloride (Cl) **1, 2, 4	Serum/ Plasma/ Urine	Indirect ISE	Abbott Alinity c	CE	CC188
Cholesterol, **1, 2, 4	Serum/Plasma	Enzymatic	Abbott Alinity c	CE	CC188
Creatinine Enzymatic **1, 2, 4	Serum/ Plasma/ Urine	Enzymatic	Abbott Alinity c	CE	CC188
Creatinine Kinase **1, 2, 4	Serum/Plasma	NAC (N-Acetyl-L-Cystein)	Abbott Alinity c	CE	CC188
Direct LDL **1, 2, 4		Selective resolution of LDL-Particles under dye formation	Abbott Alinity c	CE	CC188
eGFR **1, 2, 4		Calculated	Abbott Alinity c - LIS Interface	CE	CC188
Gamma Glutamyl Transferase (GGT) **1, 2, 4		L-Gammaglutamyl-3-carboxy-4-nitroanilid-Substrate	Abbott Alinity c	CE	CC188
Globulins **1, 2, 4		Calculated	Abbott Alinity c - LIS Interface	CE	CC188
Glucose **1, 2, 4	Plasma	Enzymatic (Hexokinase/ G-6-PDH)	Abbott Alinity c	CE	CC188

	Homocysteine **1, 2, 4	Serum/Plasma	Chemiluminescent Microparticle Immunoassay (CMIA)	Abbott Alinity I	CE	CC188
	Iron2 **1, 2, 4		Ferene	Abbott Alinity c	CE	CC188
	Lactate DeHydrogenase2(LDH) **1, 2, 4		Oxidation of Lactate to Pyruvate	Abbott Alinity c	CE	CC188
	Lipase **1, 2, 4	Serum / Plasma	Kinetic Colorimetric method	Abbott Alinity c	CE	CC188
	Lipoprotein a **1, 2, 4	Serum/Plasma	Turbidimetric/Immunturbidimetric	Abbott Alinity c	CE	CC188
	Magnesium **1, 2, 4	Serum/ Plasma / Urine	Enzymatic	Abbott Alinity c	CE	CC188
	Microalbumin **1, 2, 4	Urine	Turbidimetric/Immunturbidimetric	Abbott Alinity c	CE	CC188
	NT-proBNP **1, 2, 4	Serum/ Plasma	Chemiluminescent microparticle Immunoassay	Abbott Alinity I	CE	CC188
	Phosphorous**1, 2, 4	Serum/ Plasma/ Urine	Spectrophotometry, Phosphomolybdate	Abbott Alinity c	CE	CC188
	Potassium (K) **1, 2, 4		Indirect ISE	Abbott Alinity c	CE	CC188
	Protein/ Creatinine **1, 2, 4	Urine	Calculated	Abbott Alinity c - LIS Interface	CE	CC188
	Sodium (Na) **1, 2, 4	Serum/ Plasma/ Urine	Indirect ISE	Abbott Alinity c	CE	CC188
	Total Bile Acids **1, 2, 4	Serum/Plasma	Cyclic-enzymatic/colorimetric	Abbott Alinity c	CE	CC188
	Total Bilirubin **1, 2, 4		Spectrophotometry, Diazonium salt	Abbott Alinity c	CE	CC188
	Total Protein **1, 2, 4	Serum/ Plasma	Biuret Reaction	Abbott Alinity c	CE	CC188
	Triglycerides **1, 2, 4		Glycerinphosphate oxidase	Abbott Alinity c	CE	CC188
	Troponin-I, STAT high sensitive **1, 2, 4	Serum/Plasma	Chemiluminescent Microparticle Immunoassay (CMIA)	Abbott Alinity I	CE	CC188
	Ultra HDL Cholesterol **1, 2, 4		Accelerated enzymatic Reaction/selective solvent	Abbott Alinity c	CE	CC188
	Urea **1, 2, 3, 4	Serum/ Plasma/ Urine	Urease	Abbott Alinity c	CE	CC188
	Uric Acid **1, 2, 4		Uricase	Abbott Alinity c	CE	CC188
	Urine Protein **1,2,4	Urine	Benzethonium Chloride	Abbott Alinity C	CE	CC188
1061 Clinical Chemistry - .02	Serum Proteins Electrophoresis **1, 2, 4	Serum	Capillary Electrophoresis	Sebia Capillarys 3 Octa	CE	CC177

Proteins, quantitative analysis						
1061 Clinical Chemistry - .10 Drugs for therapeutic monitoring	Amikacin **1, 2, 4	Serum/ Plasma	Homogeneous particle-enhanced turbidimetric inhibition immunoassay (PETINIA).	Abbott Alinity c	CE	CC188
	Digoxin **1, 2, 4		Particle-enhanced turbidimetric inhibition immunoassay(PETINIA)	Abbott Alinity c	CE	CC188
	Gentamicin **1, 2, 4		Particle-enhanced turbidimetric inhibition immunoassay(PETINIA)	Abbott Alinity c	CE	CC188
	Lithium **1, 2, 4		Colorimetric Method	Abbott Alinity c	CE	CC188
	Phenytoin **1, 2, 4		Enzyme immunoassay	Abbott Alinity c	CE	CC188
	Tacrolimus **1, 2, 4	Whole Blood EDTA	Manual Pre-treatment precipitation. Chemiluminescent Microparticle Immunoassay (CMIA)	Abbott Alinity I	CE	CC188
	Theophylline **1, 2, 4	Serum/ Plasma	Enzyme immunoassay	Abbott Alinity c	CE	CC188
	Valproic Acid **1, 2, 4		Particle-enhanced turbidimetric inhibition immunoassay(PETINIA)	Abbott Alinity c	CE	CC188
	Vancomycin **1, 2, 4		Particle-enhanced turbidimetric inhibition immunoassay(PETINIA)	Abbott Alinity c	CE	CC188
1061 Clinical Chemistry - .14 Alcohol for non-legal purposes	Ethanol **1, 2, 4	Urine	Enzymatic (Alcohol dehydrogenase)	Abbott Alinity c	CE	CC188
1061 Clinical Chemistry - .15 Drugs for toxicological purposes	Amphetamine/Methamphetamine **1, 2, 4		Enzymatic Immunoassay	Abbott Alinity c	CE	CC188
	Barbiturates **1, 2, 4		Enzymatic Immunoassay	Abbott Alinity c	CE	CC188
	Benzodiazepines **1, 2, 4		Enzymatic Immunoassay	Abbott Alinity c	CE	CC188
	Cannabinoids **1, 2, 4		Enzymatic Immunoassay	Abbott Alinity c	CE	CC188
	Cocaine **1, 2, 4		Enzyme immunoassay	Abbott Alinity c	CE	CC188
	Ecstasy **1, 2, 4		Enzyme immunoassay	Abbott Alinity c	CE	CC188

	EDDP **1, 2, 4		Immunalysis assay	Abbott Alinity c	CE	CC188
	Heroin Metabolite (6AM) **1, 2, 4		CEDIA assay	Abbott Alinity c	CE	CC188
	Methadone (semiquantitative) **1, 2, 4		Enzyme immunoassay	Abbott Alinity c	CE	CC188
	Opiates **1, 2, 4		Enzyme immunoassay	Abbott Alinity c	CE	CC188
1061 Clinical Chemistry - .20 Hormones	Beta Human Chorionic Gonadotrophin (Beta HCG) **1, 2, 4	Serum/ Plasma	Chemiluminescent Microparticle Immunoassay (CMIA)	Abbott Alinity I	CE	CC188
	Cortisol **1, 2, 4	Serum/ Plasma / Urine	Chemiluminescent Microparticle Immunoassay (CMIA)	Abbott Alinity I	CE	CC188
	C-Peptide **1, 2, 4	Serum/ Plasma	Chemiluminescent Microparticle Immunoassay (CMIA)	Abbott Alinity I	CE	CC188
	Dehydroepiandrosterone Sulphate (DHEAS) **1, 2, 4		Chemiluminescent Microparticle Immunoassay (CMIA)	Abbott Alinity I	CE	CC188
	Follicle Stimulating Hormone (FSH) **1, 2, 4		Chemiluminescent Microparticle Immunoassay (CMIA)	Abbott Alinity I	CE	CC188
	Free Thyroxine (FT4) **1, 2, 4		Chemiluminescent Microparticle Immunoassay (CMIA)	Abbott Alinity I	CE	CC188
	Free Triiodothyronine (FT3) **1, 2, 4		Chemiluminescent Microparticle Immunoassay (CMIA)	Abbott Alinity I	CE	CC188
	Insulin **1, 2, 4		Chemiluminescent Microparticle Immunoassay (CMIA)	Abbott Alinity I	CE	CC188
	Intact Parathyroid Hormone (PTH) **1, 2, 4	EDTA Plasma	Chemiluminescent Microparticle Immunoassay (CMIA)	Abbott Alinity I	CE	CC188
	Luteinising Hormone (LH) **1, 2, 4	Serum/ Plasma	Chemiluminescent Microparticle Immunoassay (CMIA)	Abbott Alinity I	CE	CC188
	Macroprolactin **1, 2, 4		Calculated, Prolactin and PEG Precipitation	Abbott Alinity I	CE	CC188
	Oestradiol **1, 2, 4		Chemiluminescent Microparticle Immunoassay (CMIA)	Abbott Alinity I	CE	CC188
	Progesterone **1, 2, 4		Chemiluminescent Microparticle Immunoassay (CMIA)	Abbott Alinity I	CE	CC188
	Prolactin **1, 2, 4		Chemiluminescent Microparticle Immunoassay (CMIA)	Abbott Alinity I	CE	CC188
	Sex hormone Binding Globulin		Chemiluminescent Microparticle	Abbott Alinity I	CE	CC188

	**1, 2, 4
	T3 Total **1, 2, 4
	T4 Total **1, 2, 4
	Testosterone **1, 2, 4
	Thyrotropine (Thyroid Stimulating Hormone, TSH) **1, 2, 4
1061 Clinical Chemistry - .40 Iron studies	Ferritin **1, 2, 4
	TIBC **1, 2, 4
	Transferrin **1, 2, 4
	Transferrin Saturation **1, 2, 4
	Unsaturated Iron Binding Capacity (UIBC) **1, 2, 4
1061 Clinical Chemistry - .45 Vitamin B12 and folate	Folate **1, 2, 4
	Vitamin B12 **1, 2, 4
1061 Clinical Chemistry - .47 Vitamin assays	25 OH Vitamin D **1, 2, 4
1061 Clinical Chemistry - .50 Protein and peptide tumour markers	AlphaFetoProtein (AFP) **1, 2, 4
	Cancer Antigen 125 (CA 125) **1, 2, 4
	Cancer Antigen 153 (CA 153) **1, 2, 4

Immunoassay (CMIA)			
Chemiluminescent Microparticle Immunoassay (CMIA)	Abbott Alinity I	CE	CC188
Chemiluminescent Microparticle Immunoassay (CMIA)	Abbott Alinity I	CE	CC188
Chemiluminescent Microparticle Immunoassay (CMIA)	Abbott Alinity I	CE	CC188
Chemiluminescent Microparticle Immunoassay (CMIA)	Abbott Alinity I	CE	CC188
Chemiluminescent Microparticle Immunoassay (CMIA)	Abbott Alinity I	CE	CC188
Calculated	Abbott Alinity c - LIS Interface	CE	CC188
Immunoturbidimetric	Abbott Alinity c	CE	CC188
Calculated	Abbott Alinity c - LIS Interface	CE	CC188
Ferene	Abbott Alinity c	CE	CC188
Chemiluminescent Microparticle Immunoassay (CMIA)	Abbott Alinity I	CE	CC188
Chemiluminescent Microparticle Immunoassay (CMIA)	Abbott Alinity I	CE	CC188
Chemiluminescent Microparticle Immunoassay (CMIA)	Abbott Alinity I	CE	CC188
Chemiluminescent Microparticle Immunoassay (CMIA)	Abbott Alinity I	CE	CC188
Chemiluminescent Microparticle Immunoassay (CMIA)	Abbott Alinity I	CE	CC188
Chemiluminescent Microparticle Immunoassay (CMIA)	Abbott Alinity I	CE	CC188

	Cancer Antigen 199 (CA 19-9XR) **1, 2, 4		Chemiluminescent Microparticle Immunoassay (CMIA)	Abbott Alinity I	CE	CC188
	CarcinoEmbryonic Antigen (CEA) **1, 2, 4		Chemiluminescent Microparticle Immunoassay (CMIA)	Abbott Alinity I	CE	CC188
	Total prostate Specific Antigen (total PSA) **1, 2, 4		Chemiluminescent Microparticle Immunoassay (CMIA)	Abbott Alinity I	CE	CC188
1061 Clinical Chemistry - .61 Hb A1c	Haemoglobin A1c (HbA1c)	EDTA Whole Blood	High Performance Liquid Chromatography (HPLC)	Tosoh	CE	BCC83
1061 Clinical Chemistry - .71 Faecal Immunochemical test	Faecal Immunochemical Testing (FIT)	Faeces	Latex turbidimetry	OC-Sensor Pledia Faecal Occult Blood	CE	BCC69
1061 Clinical Chemistry - .80 Quantitative investigation of immunoglobulins G, A, M and in body fluids	ImmunoGlobulin A (IgA) **1, 2, 4	Serum/ Plasma	Immunoturbidimetric	Abbott Alinity c	CE	CC188
	ImmunoGlobulin G (IgG) **1, 2, 4		Immunoturbidimetric	Abbott Alinity c	CE	CC188
	ImmunoGlobulin M (IgM) **1, 2, 4		Immunoturbidimetric	Abbott Alinity c	CE	CC188
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	Immunoglobulin E (Total IgE) **1, 2, 4	Serum/ Plasma	Immunoturbidimetric	Abbott Alinity c	CE	CC188
1061 Clinical Chemistry - .83 Rheumatoid factor – quantitative assays	Rheumatoid Factor (RF) **1, 2, 4		Immunoturbidimetric	Abbott Alinity c	CE	CC188
1061 Clinical	Anti-Thyroid Peroxidase (Anti-		Chemiluminescent Microparticle	Abbott Alinity I	CE	CC188

Chemistry - .84 Anti-thyroid microsomal antibodies	TPO) **1, 2, 4		Immunoassay (CMIA)			
1061 Clinical Chemistry - .85 Anti-thyroglobulin antibodies	Anti-Thyroglobulin (Anti-Tg) **1, 2, 4		Chemiluminescent Microparticle Immunoassay (CMIA)	Abbott Alinity I	CE	CC188
1061 Clinical Chemistry - .86 C3 and C4	C3 **1, 2, 4		Immunoturbidimetry	Abbott Alinity c	CE	CC188
	C4 **1, 2, 4		Immunoturbidimetry	Abbott Alinity c	CE	CC188
1061 Clinical Chemistry - .88 b2-microglobulin	B 2 Microglobulin **1, 2, 4	Serum / Plasma	Turbidimetric/ Immunoturbidimetry	Abbott Alinity c	CE	CC188
1061 Clinical Chemistry - .99 Miscellaneous tests	Free Androgen Index **1, 2, 4	Serum/ Plasma	Calculated	Abbott Alinity c - LIS Interface	CE	CC188
	Urinary pH **1, 2, 4	Urine	DRI pH-Detect Test	Abbott Alinity c	CE	CC188

The laboratory has been awarded flexible scope in the scope classifications as noted in the scope document and in accordance with the laboratory's 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 laboratory's 'List of flexible scope changes', available directly from the laboratory

Eurofins Biomnis Blackthorn Road Site

Haematology

Category: A

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	Full Blood Count **1, 4	EDTA Whole Blood	Flow Cytometry/ Spectrophotometry/ Calculation / (FC)	Sysmex XN-2000 Sysmex XN -1000	CE	BH18, H62
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		Capillary photometric-kinetic technology	ALIFAX TEST 1 BCL	CE	H09, H62
1030 Haematology - .05 Automated differential leucocyte counts	Automated differential leucocyte counts **1, 4		FC / Indirect Measurement of WBC by algorigrams/ cluster analysis	Sysmex XN-2000	CE	BH18
1030 Haematology - .06 Automated reticulocyte counts	Reticulocytes		Fluorescence	Sysmex XN-2000	CE	BH18
1030 Haematology - .41 General haemostasis related tests	Activated Partial Thromboplastin Time **1, 4	Citrated plasma 3.2%	Clotting Time	STAGO Compact Max	CE	H60, H62
	D-Dimer		Photometry (turbidometric)	STAGO STA Compact Max	CE	H60, H62
	Fibrinogen **1, 4		Clotting Time	STAGO Compact Max	CE	H60, H62
	Prothrombin Time		Clotting Time	STAGO Compact Max	CE	H60, H62

	**1, 4					
<i>The laboratory has been awarded flexible scope in the scope classifications as noted in the scope document and in accordance with the laboratory's approved and documented procedures.</i> <i>Note 1 - Range may be extended for the test</i> <i>Note 2 – New parameters/tests may be added</i> <i>Note 3 – New matrices may be added</i> <i>Note 4 – Changes to equipment/kits where the underlying methodology does not change</i> <i>For further details please refer to the laboratory's 'List of flexible scope changes', available directly from the laboratory</i>						

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 - .04 Allergen - specific IgE	Specific IGE **1, 2, 4	Serum	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, 4		Phadia 250 / FluroEnzyme ImmunoAssay (FEIA)	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, 4		Phadia 250 / FluroEnzyme ImmunoAssay (FEIA)	CE	Negative: < 10.0 MPL-U/mL Weak positive: 10.0 - 40.0 MPL-U/mL Positive: > 40.0 MPL-U/mL	CC103
	Anti Cyclic Citrullinated Peptide (CCP) Antibodies **1, 2, 4		Alinity I/ Chemiluminescent microparticle Immunoassay	CE	< 5.0 U/mL: Negative ≥ 5.0 U/mL: Positive	CC188
	Anti Double Stranded DNA Antibodies **1, 2, 4		Phadia 250 / FluroEnzyme ImmunoAssay (FEIA)	CE	Less than 10 IU/mL	CC118
	Anti Gliadin IgA Antibodies **1, 2, 4		Phadia 250 / FluroEnzyme	CE	Negative: < 7.0 U/mL Borderline: 7.0 - 10.0	CC104

			ImmunoAssay (FEIA)		U/mL Positive: > 10.0 U/mL	
	Anti Gliadin IgG Antibodies **1, 2, 4		Phadia 250 / FluroEnzyme ImmunoAssay (FEIA)	CE	Negative: < 7.0 U/mL Weak positive: 7.0 - 10.0 U/mL Positive: > 10.0 U/mL	CC105
	Anti Glomerular Basement Membrane (GBM) Antibodies **1, 2, 4		Phadia 250 / FluroEnzyme ImmunoAssay (FEIA)	CE	Negative: < 7.0 U/mL Weak positive: 7.0 - 10.0 U/mL Positive: > 10.0 U/mL	CC107
	Anti Mitochondrial Antibodies **1, 2, 3, 4		Phadia 250 / FluroEnzyme ImmunoAssay (FEIA)	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, 4		Phadia 250 / FluroEnzyme ImmunoAssay (FEIA)	CE	Negative <3.5 IU/mL; Equivocal 3.5-5.0 IU/mL; Positive: >5.0 IU/mL	CC127
	Anti PR3 Antibodies **1, 2, 4		Phadia 250 / FluroEnzyme ImmunoAssay (FEIA)	CE	Negative: <2.0 IU/mL; Equivocal 2.0-3.0 IU/mL Positive >3.0 IU/mL	CC126
	Anti Tissue Transglutaminase IgA Antibodies **1, 2, 4		Phadia 250 / FluroEnzyme ImmunoAssay (FEIA)	CE	Negative: less than 7 U/mL Weak Positive: 7 - 10 U/mL Positive: greater than 10 U/mL	CC106
	Anti β2 - Glycoprotein I IgG Antibodies **1, 2, 4		Phadia 250 / FluroEnzyme ImmunoAssay (FEIA)	CE	Negative: < 7.0 U/mL Weak positive: 7.0 U/mL to 10.0 U/mL Positive: > 10.0 U/mL	CC113
	Anti β2 - Glycoprotein I IgM Antibodies **1, 2, 4		Phadia 250 / FluroEnzyme ImmunoAssay (FEIA)	CE	Negative: < 7.0 U/mL Weak Positive: 7.0 U/mL to 10.0 U/mL Positive: > 10.0 U/mL	CC108
	Antinuclear Antibodies **1, 2, 4		Phadia 250 / FluroEnzyme ImmunoAssay (FEIA)	CE	Ratio less than 0.7	CC117
	Anti-TSH Receptor Antibodies (TRAB) **1,2,4		Abbott Alinity i, Chemiluminescent Microparticle	CE	< 3.1 IU/L: Negative; ≥ 3.1 IU/L: Positive	CC189

			Immunoassay (CMIA)			
	Determination of Anti-Intrinsic Factor Antibodies **1, 2, 4		Phadia 250 / FluroEnzyme ImmunoAssay (FEIA)	CE	Negative: < 7 U/mL; Equivocal: 7-10 U/mL; Positive: > 10 U/mL	CC159
	Determination of Anti-Parietal Cell Antibodies **1, 2, 4		Phadia 250 / FluroEnzyme ImmunoAssay (FEIA)	CE	Negative: < 7 U/mL; Equivocal: 7-10 U/mL; Positive: > 10 U/mL	CC156
	ENA Antibody Typing **1, 2, 4		Phadia 250 / FluroEnzyme ImmunoAssay (FEIA)	CE	Anti-Sm, anti-SSA/RO, anti-SSB/La, anti-Scl-70, anti-Jo-1 and anti-centromere Antibodies: each less than 7 EliA U/mL. Anti-U1 RNP: less than 5 EliA U/mL.	CC119-125
1040 Immunology - .99 Miscellaneous tests	Calprotectin **1, 2, 4	Faeces	Phadia 250 / FluroEnzyme ImmunoAssay (FEIA)	CE	<50 ug/g : Negative. Calprotectin level not suggestive of organic pathology. 50-100 ug/g : Gray Zone. Organic pathology cannot be excluded. A repeat sample in 4 to 6 weeks is suggested. >100 ug/g : Positive. Calprotectin level is consistent with organic pathology.	CC139

Microbiology and Virology

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
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, 4	Serum, Heparin, EDTA Plasma	Abbott Alinity i / 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).	CC188
	Antistreptolysin-O **1, 2, 4	Serum	Turbidimetric/Immunturbidimetric	Abbott Alinity c	Up to 7 years: less than 100 IU/mL Greater than 7 years: less than 200 IU/mL	CC188
	Cytomegalovirus IgG **1, 2, 4	Serum, EDTA, Heparin Plasma	Abbott Alinity i / Chemiluminescent Microparticle ImmunoAssay (CMIA)	CE	Specimens with concentration values <6.0 AU/mL are considered nonreactive(NR). Specimens with concentration values ≥6.0 AU/mL are considered reactive (R)	CC188
	Cytomegalovirus IgM **1, 2, 4		Abbott Alinity i / Chemiluminescent Microparticle ImmunoAssay (CMIA)	CE	<0.85 Index are considered nonreactive Index 0.85 to 0.99: Grayzone, Index ≥ 1.00: reactive	CC188

Hepatitis B Core Antibody **1, 2, 4	Serum, Heparin (Li) Plasma	Abbott Alinity i / 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).	CC188
Hepatitis B Surface Antibody (Anti-Hbs) **1, 2, 4	Serum, EDTA, Heparin Plasma	Abbott Alinity i / Chemiluminescent Microparticle ImmunoAssay (CMIA)	CE	Greater than 10 IU/mL: reactive	CC188
Hepatitis B Surface Antigen (Hbs Ag) **1, 2, 4		Abbott Alinity i / 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).	CC188
Hepatitis C Antibody **1, 2, 4		Abbott Alinity i / 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).	CC188
HIV Ab/Ag Combo **1, 2, 4	Serum, EDTA, Plasma, Heparin Plasma	Abbott Alinity i / 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).	CC188
Rubella IgG **1, 2, 4	Serum, EDTA, Heparin Plasma	Abbott Alinity i / Chemiluminescent Microparticle ImmunoAssay (CMIA)	CE	< 5.0 IU/mL = nonreactive 5.0 – 9.9 = equivocal ≥ 10.00 = reactive	CC188
Rubella IgM **1, 2, 4		Abbott Alinity i / Chemiluminescent Microparticle	CE	Index less than 1.20 : nonreactive	CC188

			ImmunoAssay (CMIA)		(Negative) Index 1.20 - 1.59 : equivocal; Index ≥ 1.60 : reactive (Positive).	
	Syphilis (Treponema pallidum) Antibody **1, 2, 4		Abbott Alinity i / Chemiluminescent Microparticle ImmunoAssay (CMIA)	CE	Specimens with S/CO values < 1.00 are considered nonreactive. Specimens with S/CO values ≥ 1.00 are considered reactive.	CC188

Head Office

Haematology

Category: A

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
1033 Molecular pathology - .01 Assay for somatic variants in DNA sequence(s)	Identification of the C282Y and H63D in the HFE human gene	Whole Blood EDTA	ViennaLab HFE mpx REalFast™ Assa	ABI 7500 FAST	CE	MB55
<i>The laboratory has been awarded flexible scope in the scope classifications as noted in the scope document and in accordance with the laboratory's approved and documented procedures.</i> <i>Note 1 - Range may be extended for the test</i> <i>Note 2 – New parameters/tests may be added</i> <i>Note 3 – New matrices may be added</i> <i>Note 4 – Changes to equipment/kits where the underlying methodology does not change</i> <i>For further details please refer to the laboratory's 'List of flexible scope changes', available directly from the laboratory</i>						

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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 - .41 HLA - B27	Detection of HLA-B27	Whole Blood EDTA	ViennaLab HLA-B27 RealFast™ Assay; • ABI 7500 FAST	CE	HLA-B27 Positive / HLA-B27 Negative	MB54

The laboratory has been awarded flexible scope in the scope classifications as noted in the scope document and in accordance with the laboratory's 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

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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
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
	Investigation of urine samples	Urine	Sysmex UF5000/Automated particle counting	CE	WBCs (cells/μL), RBCs (cells/μL), Bacteria (Present / Absent), Yeasts (Present / Absent), Casts (Present / Absent/Morphology), Crystals (Present / Absent/ Morphology), and Epithelial cells (Present / Absent)	GM116
	Microscopy **3, 4		Light microscope	CE	Present/Absent	CM38

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
1013 Culture of organisms in liquid or agar based culture media with visual or instrument monitoring for growth - .01 Culture of general bacteria	Culture of general bacteria **2, 3, 4	Swabs, tissue, fluid, pus, faeces, urine, tips, IUCD.	Manual/ Manual culture in agar based media with incubation of specimens at defined temperatures for defined periods. Visual observation of growth.	CE	N/A	CM18, CM19, CM20, CM21, CM22, CM23, CM26, CM27, CM28, CM29, CM30, CM38, CM39, CM41, CM42, CM43, CM44, CM45, CM47, CM48, CM49, CM50, CM54, CM56, CM68, CM70, CM73
1013 Culture of organisms in liquid or agar based culture media with visual or instrument monitoring for growth - .02 Culture of fungi	Culture of fungi **2, 3, 4	Skin, hair, nail	"Manual/ Manual culture in agar based media with incubation of specimens at defined temperatures for defined periods. Visual observation of growth."	CE	N/A	CM50
1014 Detection of bacterial, parasite, viral or fungal antigens using specific antibodies and appropriate techniques - .04 Immunochromatographic	Clostridium difficile toxin **2, 4	Faeces	Immunochromatographic Kit	CE	Positive/Not Detected	GM75

methods,						
	Detection of Carbapenemases **2, 3, 4 (Includes testing for KPC, NDM, VIM, OXA-48 and IMP)	Bacterial Isolate	Immunochromatographic Kit	CE	Positive/Negative	CM62
	GDH **2, 4	Faeces	Immunochromatographic Kit	CE	Positive/Not Detected	CM66
	Helicobacter pylori stool antigen **2, 4		Immunochromatographic Kit	CE	Positive/Not Detected	GM82
1015 Detection and/or identification of bacterial, parasite, fungal and viral nucleic acids - .03 Nucleic acid amplification tests, CE marked commercial systems	Detection of Chlamydia trachomatis (CT) and/or Neisseria gonorrhoeae	Vaginal/Endocervical swabs and Urine	Roche Cobas 4800	CE	Detected / Not Detected	MB52
	Detection of High Risk (HR) Human Papillomavirus (HPV)	Thin Prep Cervical Liquid Based Cytology	Roche Cobas 4800	CE	HR HPV 16 Detected, HR HPV 18 Detected, HR HPV Other Detected, HR HPV 16 Not Detected, HR HPV 18 Not Detected, HR HPV Other Not Detected, HR HPV Indeterminate	MB51
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 and XL, ID Kits	CE	Organism ID	GM69, GM39, GM40, GM41, GM42, GM43, GM44, GM79, GM110, CM38 and CM76
1017 Measurement of antimicrobial activity and application of clinical interpretive criteria to	Susceptibility Testing **1, 2, 3, 4		Vitek 2 Compact and XL/ManualDisk diffusion/Minimum Inhibitory Concentration	CE	Variable	CM63, CM80

general bacteria (rapidly growing aerobes) - .05 Other categories of organism (as specified)						
1029 Miscellaneous - .99 Miscellaneous tests	Urine Dipstick **1, 2, 3, 4	Urine	Colorimetric	CE	Variable	CM69

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