Schedule of Accreditation

Organisation Name	Eurofins Biomnis Ireland Limited
Trading As	Eurofins Biomnis
INAB Reg No	159MT
Contact Name	Brid Muimneach
Address	Three Rock Road, Sandyford Business Estate, Dublin, D18
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Website	https://www.eurofins.ie/biomnis/
Accreditation Standard	EN ISO 15189
Standard Version	2012
Date of award of accreditation	14/02/2005

Scope Classification	Microbiology and virology
Scope Classification	Immunology
Scope Classification	Chemical pathology
Scope Classification	Genetics

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 Blackthorne Road Site	Unit 3, Sandyford Business Centre,, Sandyford Business Park,, Blackthorn Road,, Dublin 18, Dublin, Ireland, D18 E528

Scope of Accreditation

Eurofins Biomnis Blackthorne 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 - .71 Faecal Immunochemical test	Faecal Immunochemical Testing (FIT)	Faeces	Latex turbidimetry	OC-Sensor Pledia Faecal Occult Blood	CE	BCC69

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	Whole Blood EDTA	ViennaLab HFE mpx REalFast™ Assa	ABI 7500 FAST	CE	MB55

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
	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	CC188

				considered reactive (R).	
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 ImmunoAssay (CMIA)	CE	Index less than 1.20 : nonreactive (Negative) Index 1.20 - 1.59 : equivocal; Index >/= 1.60 : reactive (Positive).	CC188

	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

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 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.

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
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
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, 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
	Cytomegalovirus IgG **1, 2, 4	Serum, EDTA, Heparin Plasma	Architect i2000 / 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)	CC75
	Cytomegalovirus IgM **1, 2, 4		Architect i2000 / Chemiluminescent Microparticle ImmunoAssay (CMIA)	CE	<0.85 Index are considered nonreactive Index 0.85 to 1.00: Grayzone, Index	CC83

				greater than 1.00: reactive	
Hepatitis B Core Antibody **1, 2, 4	Serum, Heparin (Li) Plasma	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).	CC72
Hepatitis B Surface Antibody (Anti-Hbs) **1, 2, 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, 4	Serum, EDTA, Heparin Plasma	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).	CC28
Hepatitis C Antibody **1, 2, 4		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).	CC74
HIV Ab/Ag Combo **1, 2, 4	Serum, EDTA, Li Hep, Heparin Plasma	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).	CC73
Rubella IgG **1, 2, 4	Serum, EDTA, Heparin Plasma	Architect i2000 / Chemiluminescent	CE	< 5.0 IU/mL = nonreactive	CC76

			Microparticle ImmunoAssay (CMIA)		5.0 – 9.9 = equivocal ≥ 10.00 = reactive	
	Rubella IgM **1, 2, 4		Architect i2000 / Chemiluminescent Microparticle ImmunoAssay (CMIA)	CE	Index less than 1.20 : nonreactive (Negative) Index 1.20 - 1.59 : equivocal; repeat in 7 to 14 days Index >/= 1.60 : reactive (Positive).	CC81
	Syphilis (Treponema pallidum) Antibody **1, 2, 4	Serum, EDTA, Heparin (li, Na) Plasma	Architect i2000 / 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.	CC41

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.
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