

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
Contact Phone No	01 295 8545
Email	bridmuimneach@eurofins.ie
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	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 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

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, 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 greater than 1.00: reactive	CC83
	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).	CC72

				Specimens with S/CO values ≥ 1.00 are considered reactive (R).	
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 Microparticle ImmunoAssay (CMIA)	CE	< 5.0 IU/mL = nonreactive $5.0 - 9.9$ = equivocal ≥ 10.00 = reactive	CC76
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	CC81

					Index ≥ 1.60 : reactive (Positive).	
	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.

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.