

Schedule of Accreditation



Organisation Name	Connolly Hospital
Trading As	
INAB Reg No	220MT
Contact Name	Mary-Frances Mc Elroy
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Accreditation Standard	EN ISO 15189
Standard Version	2012
Date of award of accreditation	17/02/2009
Scope Classification	Microbiology and virology
Scope Classification	Blood Transfusion Science
Services available to the public ¹	Yes

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	Pathology Connolly Hospital	Blanchardstown , Pathology Department, Dublin, D15

Scope of Accreditation

Pathology Connolly Hospital

Blood Transfusion Science

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
1020 Transfusion science - .01 Blood grouping including ABO, Rh(D) and other antigens by manual methods	ABO and Rh D blood grouping	Red blood cells	Manual method using DiaMed gels	CE	Not applicable	LM-BT-0001
			Manual method using tubes			
1020 Transfusion science - .02 Blood grouping including ABO, Rh(D) and other antigens by automated methods	ABO and Rh(D) blood grouping		Automated method using the Biorad IH500 analyser	CE	Not applicable	LM-BT-0001, LP-BT-0066
1020 Transfusion science - .03 Blood group antibody screen	Antibody screening	Plasma	Automated method using the Biorad IH500 analyser	CE	Not applicable	LM-BT-0002, LP-BT-0066
			Manual IAT method using DiaMed gels	CE		
1020 Transfusion science - .04 Identification of blood group antibodies	Antibody identification		Manual method using DiaMed IAT and enzyme gel methods	CE	Not applicable	LM-BT-0003
	Antibody panels		Automated method using the Biorad IH500 analyser	CE	Not applicable	LM-BT-0003, LP-BT-0066

1020 Transfusion science - .05 Cross match compatible donor units	Compatibility testing		Manual method using DiaMed gels Manual method using tubes	CE	Not applicable	LM-BT-0004
	Crossmatch		Automated method using the Biorad IH500 analyser	CE	Not applicable	LM-BT-0004
			Automated method using the Biorad IH500 analyser	CE	Not applicable	LM-BT-0004
	Electronic crossmatch	Red blood cells	Electronic crossmatch by the laboratory information system Telepath	based on standard method	Not applicable	LP-BT-0068
1020 Transfusion science - .06 Red cell phenotyping	Antigen typing		Manual methods using DiaMed and tube methods	CE	Not applicable	LM-BT-0006
	Rh and K antigen typing		Automated method using the Biorad IH500 analyser	CE	Not applicable	LM-BT-0006, LP-BT- 0066
1020 Transfusion science - .09 Direct antiglobulin test	Direct antiglobulin Test		Automated method using the Biorad IH500 analyser	CE	Not applicable	LM-BT-0005, LP-BT- 0066
1020 Transfusion science - .99 Miscellaneous tests			Manual methods using DiaMed gels	CE	Not applicable	LM-BT-0005

The hospital blood bank has been assessed and is competent to comply with Articles 14 and 15 of the EU Directive 2002/98/EC (S.I. 360/2005 and S.I. 547/2006)

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
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	CSF Urines MSU & CSU Faeces Sputum / BAL / Bronchial Washings Pus /Abscess /Post Operative Wound / Deep Seated Infections Abdominal / Peritoneal Fluids Ascitic Fluids Pleural Fluids Bile Pericaridal Fluids Joint Fluids Tissues & Bone Ear, Nose, Throat, Mouth Skin & Superficial Wounds Genital Specimens - HVS, Endocervical, Penile, Urethral, Vulval Tips MRSA Screening - Nasal, Groin & Wound VRE Screening - Rectal CPE screening	Culture/enrichment culture	CE marked/Based on standard method	N/A	LP-MICRO-0027 LP-MICRO-0026 LP-MICRO-0007 LP-MICRO-0012 LP-MICRO-0013 LP-MICRO-0014 LP-MICRO-0015 LP-MICRO-0017 LP-MICRO-0023 LP-MICRO-0024 LP-MICRO-0025 LP-MICRO-0018 LP-MICRO-0022 LP-MICRO-0020 LP-MICRO-0006 LP-MICRO-0010 LP-MICRO-0011
1013 Culture of organisms	Culture of Fungi -	CSF	Culture/enrichment	CE marked/Based	N/A	LP-MICRO-0026 LP-

in liquid or agar based culture media with visual or instrument monitoring for growth - .02 Culture of fungi	Yeast	Urines MSU & CSU Faeces Sputum / BAL / Bronchial Washings Pus /Abscess /Post Operative Wound / Deep Seated Infections Abdominal / Peritoneal Fluids Ascitic Fluids Pleural Fluids Bile Pericaridal Fluids Joint Fluids Tissues & Bone Ear, Nose, Throat, Mouth Skin & Superficial Wounds Genital Specimens - HVS, Endocervical, Penile, Urethral, Vulval Tips	culture	on standard method		MICRO-0102
1014 Detection of bacterial, parasite, viral or fungal antigens using specific antibodies and appropriate techniques - .02 Particle agglutination	GonoGen GC Test Binax Now Legionella Urinary Antigen Card Binax Now S. pneumoniae Antigen Card RIDAQUICK Norovirus RIDAQUICK Rotavirus / Adenovirus Combi Remel™ Nitrocefin Discs Pregnancy test-Rapid Response Kit/Omega Cassette format pregnancy test	Isolate/Genital specimens as per 1012 and 1013 Urines Urines Faeces Faeces Isolate Urine	Immunochromatographic Methods	CE marked	N/A	LP-MICRO-0097 LP-MICRO-0058 LP-MICRO-0064 LP-MICRO-0014 LP-MICRO-0015 LP-MICRO-0069 LP-MICRO-0008
	Investigation of	Faeces	BioMerieux Vitek MS	CE marked	N/A	LP-MICRO-0012 LP

	faeces specimens for bacterial pathogens					MICRO-0013 LP- MICRO-0014 LP- MICRO-0090 LP- MICRO-0093 National Standards Methods, Health Protection Agency UK. BioMerieux Vitek MS User Manual
	Mastalex MRSA Wellcolex Shigella Wellcolex Salmonella Pastorex Staph-Plus Wellcolex E. coli 0157:H7	Isolates	Particle Agglutination	CE marked	N/A	LP-MICRO-0068 LP-MICRO-0079 LP-MICRO-0009 LP-MICRO-0065 LP-MICRO-0057
	TechLab C. diff Quik Check Complete	Faeces	Enzyme Immunoassay	CE marked	N/A	LP-MICRO-0013
1015 Detection and/or identification of bacterial, parasite, fungal and viral nucleic acids - .03 Nucleic acid amplification tests, CE marked commercial systems	Molecular Identification of Influenzae A & Influenzae B viral RNA using the Xpert Flu Assay. Molecular identification of SARS-CoV-2 using the Cepheid Xpert Xpress SARS CoV-2 Assay. Molecular identification of SARS-CoV-2 using the Allplex 2019 CoV Assay. Molecular identification of CPE isolates using the Xpert CARBA-R Kit. Molecular identification of CPE isolates using the Allplex Enter-DK kit. Molecular identification of respiratory pathogens	Nasopharyngeal swabs Nasopharyngeal swabs Nasopharyngeal swabs Isolate Rectal swab Nasopharyngeal swabs Nasopharyngeal swabs Nasopharyngeal swabs Faeces Nasopharyngeal swabs	Cepheid GeneXpert Cepheid GeneXpert Seegene Hamilton and Biorad CFX96 Cepheid GeneXpert Seegene Hamilton and Biorad CFX96 Cepheid GeneXpert Seegene Hamilton and Biorad CFX96 Seegene Hamilton and Biorad CFX96 Seegene Hamilton and Biorad CFX96 Eplex Molecular Platform	CE Marked	Not applicable	LP-MICRO-0090 ; LP- MICRO-0094 LP-MICRO-0107; LP- MICRO-0090 LP-MICRO-0107; LP- MICRO-0104 LP-MICRO-0105; LP- MICRO-0090 LP-MICRO-0104; LP- MICRO-105 LP-MICRO-0110; LP- MICRO-0113 LP-MICRO-0112; LP- MICRO-0113 LP-MICRO-0112; LP- MICRO-0113 LP-MICRO-0106 LP-MICRO-0111; LP- MICRO-0113

	<p>using the Xpert Xpress SARS-CoV-2 /FLU /RSV kit.</p> <p>Molecular Identification of respiratory pathogens using the Allplex SARS-CoV-2 /FLU /RSV Kit</p> <p>Molecular identification of respiratory pathogens using the Allplex SARS-CoV-2 Assay (4 gene Variant)</p> <p>Molecular identification of faecal pathogens using the Allplex GI bacteria I and II Assay.</p> <p>Molecular Identification of respiratory pathogens using the GenMark Dx Eplex RP2 kit.</p>					
	<p>Molecular Identification of respiratory pathogens using the Xpert® Xpress CoV-2/Flu/RSV plus kit. **3,4</p>	Nasopharyngeal swabs	GeneXpert	CE Marked	Not applicable	LP-MICRO-0090
1017 Measurement of antimicrobial activity and application of clinical interpretive criteria to general bacteria (rapidly growing aerobes) - .03 Yeasts	Antimicrobial susceptibility testing	Isolate - Bacteria/Yeast	Vitek Compact 2.0; EUCAST Method; Gradient MICs; ESBL confirmation discs	CE marked	Not applicable	LP-MICRO-0035; LP-MICRO-0036; LP-MICRO-0082
	Candida sensitivity tests	Isolates	BioMerieux Vitek 2 Compact Kit	CE marked	N/A	LP-MICRO-0035 LP MICRO-0015
1017 Measurement of antimicrobial activity and application of clinical	Determination of minimum inhibitory concentrations		Gradient Strips	CE marked	N/A	LP-MICRO-0036 Etest procedure, BioMerieux MICE procedure,

interpretive criteria to general bacteria (rapidly growing aerobes) - .05 Other categories of organism (as specified)						Oxoid EUCAST Susceptability Guidelines, www.eucast.org
1029 Miscellaneous - .99 Miscellaneous tests	Ulti med Hcg test	Urine	BTNX Rapid Response Hcg Test	CE marked	N/A	Ulti med Hcg Card Kit Insert BTNX Rapid Response Hcg Kit Insert.
	Urine Cell Counts		Sedimax	CE Marked	Not applicable	LP-MICRO-0119

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