Schedule of Accreditation



Organisation Name

Trading As

INAB Reg No

Contact Name

Address

Contact Phone No

Email

Website

Accreditation Standard

Standard Version

Date of award of accreditation

Scope Classification

Scope Classification

Scope Classification

Scope Classification

Services available to the public¹

Coombe Women and Infants University Hospital

The Coombe Hospital

218MT

Edel Galvin

Dolphins Barn, Cork St, Dublin, D8

01 4085678

egalvin@coombe.ie

http://www.coombe.ie

EN ISO 15189

2022

17/02/2009

Microbiology and virology

Blood Transfusion Science

Haematology

Chemical pathology

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						
	National Cervical Screening Laboratory @ Coombe Women and Infants University Hospital	Cork St, Dublin 8, Dublin, Ireland					
2	Head Office	Pathology Department, Cork Street, Dublin, D8					

Scope of Accreditation

Head Office

Blood Transfusion Science

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 science01 Blood grouping including ABO, Rh(D) and other antigens by manual methods	ABO and Rh D blood grouping	Whole Blood in EDTA	Manual method using tubes.	Tubes - Based on standard method	Not applicable	PATH-TM-PPG-15
	ABO and RhD blood grouping		Grifols DG Gel cards	CE Marked Based on Standard Method	Not Applicable	PATH-TM-PPG-15
1020 Transfusion science02 Blood grouping including ABO, Rh(D) and other antigens by automated methods			using Grifols Erytra	CE Marked Based on Standard Method	Not Applicable	PATH-TM-PPG-15 PATH-TM-PPG-29
1020 Transfusion science03 Blood group antibody screen	Antibody Screen	Plasma	Manual - IAT method using tubes.	Tube - Based on standard method	Not applicable	PATH-TM-PPG-16

	Antibody Screening		Automated method using Grifols Erytra Eflexis	CE Marked Based on Standard Method	Not Applicable	PATH-TM-PPG-16 PATH-TM-PPG-29
			Manual IAT method using Grifols DG Gel cards	CE Marked Based on Standard Method	Not Applicable	PATH-TM-PPG-16
1020 Transfusion science04 Identification of blood group antibodies	Antibody Identification		Automated method using Grifols Erytra Eflexis	CE Marked Based on Standard Method	Not Applicable	PATH-TM-PPG-16 PATH-TM-PPG-29
			Manual method using Grifols DC Gel cards	CE Marked Based on Standard Method	Not Applicable	PATH-TM-PPG-16
1020 Transfusion science05 Cross match compatible donor units	Compatibility testing (Crossmatching)		Automated method using Grifols Erytra Eflexis	CE Marked Based on Standard Method	Not Applicable	PATH-TM-PPG-18 PATH-TM-PPG-29
			Manual method using Grifols DG Gel cards	CE Marked Based on Standard Method	Not Applicable	PATH-TM-PPG-18
			Manual tubes.	Based on standard method	Not applicable	PATH-TM-PPG-18
1020 Transfusion science06 Red cell phenotyping	Antigen typing	Red blood cells	Automated method using Grifols Erytra Eflexis	CE Marked Based on Standard Method	Not Applicable	PATH-TM-PPG-17 PATH-TM-PPG-29
			Manual method using Grifols DG Gel cards	CE Marked Based on Standard Method	Not Applicable	PATH-TM-PPG-17
			Manual tubes.	CE marked	Not applicable	PATH-TM-PPG-17
1020 Transfusion science08 Antibody titration	Antibody Titration	Plasma	Automated method using Grifols Erytra Eflexis	CE Marked Based on Standard Method	Not Applicable	PATH-TM-PPG-16 PATH-TM-PPG-29
			Manual method using Grifols DG Gel cards	CE Marked Based on Standard Method	Not Applicable	PATH-TM-PPG-16
1020 Transfusion science09 Direct antiglobulin test	Direct Antiglobulin Test	Whole Blood in EDTA	Automated method using Grifols Erytra Eflexis	CE Marked Based on Standard Method	Not Applicable	PATH-TM-PPG-15 PATH-TM-PPG-29

		Grifols DG Gel cards	CE Marked Based on Standard Method		PATH-TM-PPG-15
1020 Transfusion science99 Miscellaneous tests	Measurement of Feto- Maternal Haemorrhage (FMH)	, ,	CE Standard Method	Not Applicable	PATH-TM-PPG-11

a 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)

Chemical Pathology

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
	Alanine Amino Transferase (ALT)	Plasma / Serum	Photometric	Architect C8000	CE based on standard method	PATH-BIO-PPG-26
			Photometric	Architect C8000	CE based on standard method	PATH-BIO-PPG-26
	Albumin		Photometric	Architect C8000	CE Marked	PATH-BIO-PPG-26
			Photometric	Architect C8000	CE based on standard method	PATH-BIO-PPG-26
	Alkaline Phosphatase (ALP)		Photometric	Architect C8000	CE based on standard method	PATH-BIO-PPG-26
	Alkalinie Phosphatase (ALP)		Photometric	Architect C8000	CE based on standard method	PATH-BIO-PPG-26
	Ammonia	Plasma	Photometric	Architect C8000	CE based on standard method	PATH-BIO-PPG-26
	Amylase	Plasma / Serum	Photometric	Architect C8000	CE Marked	PATH-BIO-PPG-26
			Photometric	Architect C8000	CE based on standard method	PATH-BIO-PPG-26
	Aspartate Amino Transferase (AST)		Photometric	Architect C8000	CE based on standard method	PATH-BIO-PPG-26
			Photometric	Architect C8000	CE based on standard method	PATH-BIO-PPG-26
	Bile Acids	Plasma/ Serum	Photometric	Architect C8000	CE based on standard method	PATH-BIO-PPG-26

Bilirublin Direct	Plasma / serum	Photometric	Architect C8000	CE based on standard method	PATH-BIO-PPG-26
Bilirublin Total		Photometric	Architect C8000	CE based on standard method	PATH-BIO-PPG-26
Calcium	Plasma / serum/ urine	Indirect Ion Selective Electrode	Architect C8000	CE based on standard method	PATH-BIO-PPG-26
Chloride		Indirect Ion Selective Electrode	Architect C8000	CE based on standard method	PATH-BIO-PPG-26
C-Reactive Protein (CRP)	Plasma / Serum	Immunoturbidimetric	Architect C8000	CE based on standard method	PATH-BIO-PPG-26
C-Reactive Protein (CRP) - Highly Sensitive		Immunoturbidimetric	Architect C8000	CE based on standard method	PATH-BIO-PPG-26
Creatine Kinase (CK) Total		Photometric	Architect C8000	CE based on standard method	PATH-BIO-PPG-26
Creatinine	Plasma / serum / urine	Photometric	Architect C8000	CE based on standard method	PATH-BIO-PPG-26
Creatinine Clearance	Urine	Calculation	LIS	CE based on standard method	
Fructosamine	Serum / Plasma	Photometric	Architect C8000	CE based on standard method	PATH-BIO-PPG-26
Fructosamine(Corrected)	Serum	Calculation	LIS		
Gamma Glutamyl Transferase (GGT)	Plasma / Serum	Photometric	Architect C8000	CE Marked	PATH-BIO-PPG-26
		Photometric	Architect C8000	CE based on standard method	PATH-BIO-PPG-26
Gentamicin		Photometric	Architect C8000	CE based on standard method	PATH-BIO-PPG-26
Globulin	Plasma	Calculation	LIS		
Glucose	Plasma / CSF	Photometric	Architect C8000	CE based on standard method	PATH-BIO-PPG-26
Inorganic Phosphate	Plasma / serum / phosphate	Photometric	Architect C8000	CE based on standard method	PATH-BIO-PPG-26
Lactate Dehydrogenase (LDH)	Plasma / Serum	Photometric	Architect C8000	CE based on standard method	PATH-BIO-PPG-26
		Photometric	Architect C8000	CE based on standard method	PATH-BIO-PPG-26

	Lipid Index	Plasma	Photometric	Architect C8000	CE based on standard method	PATH-BIO-PPG-26
	Magnesium	Plasma / serum	Photometric	Architect C8000	CE based on standard method	PPG-BIO-PPG-26
	Potassium	Plasma / serum/ urine	Indirect Ion Selective Electrode	Architect C8000	CE based on standard method	PATH-BIO-PPG-26
	Protein (Urine/CSF)	Urine / CSF	Photometric	Architect C8000	CE based on standard method	PATH-BIO-PPG-26
	Protein (24hr)	Urine	Calculation	LIS		
	Protein Total	Plasma / serum	Photometric	Architect C8000	CE based on standard method	PATH-BIO-PPG-26
	Protein, Total		Photometric	Architect C8000	CE Marked	PATH-BIO-PPG-26
	Sodium	Plasma / serum / urine	Indirect Ion Selective Electrode	Architect C8000	CE based on standard method	PATH-BIO-PPG-26
	Urea		Photometric	Architect C8000	CE Marked	PATH-BIO-PPG-26
			Photometric	Architect C8000	CE based on standard method	PATH-BIO-PPG-26
	Uric Acid (Urate)	Plasma / Serum	Photometric	Architect C8000	CE Marked	PATH-BIO-PPG-26
	Uric Acid (Urate)		Photometric	Architect C8000	CE based on standard method	PATH-BIO-PPG-26
1061 Clinical Chemistry02 Proteins, quantitative analysis	Beta-HCG		Electrochemiluminescence Immunoassay (ECLIA)	Roche Cobas Pure e402	CE Marked	PATH-BIO-PPG-31
	Free T4		Electrochemiluminescence Immunoassay (ECLIA)	Roche Cobas Pure e402	CE Marked	PATH-BIO-PPG-31
	FSH		Electrochemiluminescence Immunoassay (ECLIA)	Roche Cobas Pure e402	CE Marked	PATH-BIO-PPG-31
	LH		Electrochemiluminescence Immunoassay (ECLIA)	Roche Cobas Pure e402	CE Marked	PATH-BIO-PPG-31
	Oestradiol		Electrochemiluminescence Immunoassay (ECLIA)	Roche Cobas Pure e402	CE Marked	PATH-BIO-PPG-31
	Progesterone		Electrochemiluminescence Immunoassay (ECLIA)	Roche Cobas Pure e402	CE Marked	PATH-BIO-PPG-31
	Prolactin		Electrochemiluminescence Immunoassay (ECLIA)	Roche Cobas Pure e402	CE Marked	PATH-BIO-PPG-31

TSH	Electrochemiluminesc Immunoassay (ECLIA	nce Roche Cobas Pure e402	CE Marked	PATH-BIO-PPG-31
The hospital pathology laboratory is accredited for the identified in category B.	ne provision of Point of Care testing in accord	nce with ISO 15189:20	112 and ISO 22870:2017	7, for the tests

Chemical Pathology

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 Chemistry05 CO-oximetry	СОНЬ	Heparinised Whole Blood	Direct Ion Selective Electrode	Rapidpoint 500, Rapidpoint 400, Rapidlab 1265	CE based on standard method	PATH-POC-PPG-1
	HHb		Direct Ion Selective Electrode	Rapidpoint 500, Rapidpoint 400, Rapidlab 1265	CE based on standard method	PATH-POC-PPG-1
	MetHb		Direct Ion Selective Electrode	rapidpoint 500, Rapidpoint 400, Rapidlab 1265	CE based on standard method	PATH-POC-PPG-1
	O2Hb		Direct Ion Selective Electrode	Rapidpoint 500, Rapidpoint 400, Rapidlab 1265	CE based on standard method	PATH-POC-PPG-1
	Total Haemoglobin		Direct Ion Selective Electrode	Rapidpoint 500, Rapidpoint 400, Rapidlab 1265	CE based on standard method	PATH-POC-PPG-1
1061 Clinical Chemistry06 Blood pH and gas tensions	pCO2		Direct Ion Selective Electrode	Rapidpoint 500, Rapidpoint 400, Rapidlab 1265, Rapidlab 1240	CE based on standard method	PATH-POC-PPG-1
	рН		Direct Ion Selective Electrode	Rapidpoint 500, Rapidpoint 400, Rapidlab 1265, Rapidlab 1240	CE based on standard method	PATH-POC-PPG-1
	pO2		Direct Ion Selective Electrode	Rapidpoint 500, Rapidpoint 400, Rapidlab 1265, Rapidlab 1240	CE based on standard method	PATH-POC-PPG-1

1061 Clinical Chemistry - .07 Other analytes performed on a blood gas analyser	Calcium		Direct Ion Selective Electrode	Rapidpoint 500, Rapidpoint 400, Rapidlab 1265	CE based on standard method	PATH-POC-PPG-1
	Chloride		Direct Ion Selective Electrode	Rapidpoint 500, Rapidpoint 400, Rapidlab 1265	CE based on standard method	PATH-POC-PPG-1
	Glucose		Direct Electrodes	Rapidpoint 500, Rapidpoint 400, Rapidlab 1265	CE based on standard method	PATH-POC-PPG-1
	Lactate		Direct Electrodes	Rapidpoint 500, Rapidlab 1265	CE based on standard method	PATH-POC-PPG-1
	Potassium		Direct Ion Selective Electrode	Rapidpoint 500, Rapidpoint 400, Rapidlab 1265	CE based on standard method	PATH-POC-PPG-1
	Sodium		Direct Ion Selective Electrode	Rapidpoint 500, Rapidpoint 400, Rapidlab 1265	CE based on standard method	PATH-POC-PPG-1
	Total Bilirubin		Co-Oximetry	Rapidpoint 500, Rapidlab 1266	CE Marked	PATH-POC-PPG-1
1061 Clinical Chemistry65 Pregnancy tests – qualitative	Urinary hCG	Urine	Chromatographic immunoassay	Siemens Clinitek Status Analyser	CE	PATH-POC-PPG-4

The hospital pathology laboratory is accredited for the provision of Point of Care testing in accordance with ISO 15189:2012 and ISO 22870:2017, for the tests identified in category B.

Haematology

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 Haematology01 Blood counts	Full Blood Count (FBC) Haemoglobin Red Cell Count (RCC) Haematocrit (HCT) Mean Cell Volume (MCV) Mean Cell Haemoglobin (MCH) Mean Cell Haemoglobin Concentration (MCHC) Red Cell Distribution Width (RDW) Platelets White Cell Count (WBC)	Whole Blood in EDTA	Impedance counting, fluorescence analysis by flow cytometry and SLS Haemoglobin measurement on automated cell counter.	Sysmex XN2000	CE marked	PATH-HAE-PPG-27
1030 Haematology02 Visual examination of blood films	Blood Film Examination of white cell, red cell and platelet morphology		Eosin & Thiazin Staining, Microscopy.	RAL Stainer	CE	PATH-HAE-PPG-13
1030 Haematology05 Automated differential leucocyte counts	Differential White Cell Count Neutrophils Lymphocytes Monocytes Eosinophils Basophils		Analysis of fluorescence by flow cytometry	Sysmex XN2000	CE	PATH-HAE-PPG-27

The second second						
	Nucleated Red Blood Cells (NRBC)					
1030 Haematology06 Automated reticulocyte counts	Reticulocyte Count Absolute Count Percentage		Analysis of fluorescence by flow cytometry	Sysmex XN2000	CE	PATH-HAE-PPG-27
1030 Haematology09 Examination of malarial parasites	Examination for Malaria	Peripheral Blood in EDTA	Manual Staining using Field's Stain. Carestart Malaria RDT.	Microscope	CE based on standard method	PATH-HAE-PPG-18
1030 Haematology31 Tests for foetal Hb (Kleihauer)	Kleihauer	Whole Blood in EDTA	Acid Elution	Guest Medical Kleihauer Kit Microscope	CE	PATH-HAE-PPG-17
1030 Haematology40 Limited haemostasis related tests	Lupus Anticoagulant	Sodium Citrate Plasma	Turbidometric detection of clot formation	IL ACL TOP 550	CE	PATH-HAE-PPG-29
1030 Haematology41 General haemostasis related tests	Coagulation Screen Prothrombin Time (PT) Activated Partial Thromboplastin Time (APTT) Fibrinogen		Turbidometric detection of clot formation	IL ACL TOP 550	CE	PATH-HAE-PPG-28

Microbiology and Virology

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
1011 Macroscopic examination and description	Macroscopic examination and description of specimens	CSF, Semen	N/A / Visual	Based on standard method	N/A	MM-CSF-P MM-SEMEN-I
1012 Preparation of films on glass slides followed by microscopic examination with or without fixation and staining with dyes as required01 Microscopic examination for general bacteriology purposes (including enumeration and description of human cells)	Cell counts	Urine, CSF, Semen	Microscope / Microscopy	Based on standard method	N/A	MM-URINALYSIS-P MM-CSF-P MM-SEMEN-I
	Gram staining	Blood Cultures CSF Eye swabs HVS, LVS IUCD Genital abscess, pus, fluid	Microscope / Staining and Microscopy	Based on standard method	N/A	MM- BLOODCULTURE-P MM-CSF-P MM-EYE-P MM-GENITAL-P
1012 Preparation of films on glass slides followed by microscopic examination with or without fixation and staining with dyes as required03 Microscopic examination for fungi	Yeast	HVS, LVS Urine Oral swabs Skin swabs Blood Culture CSF Eye swab IUCD	Microscope / Microscopy	Based on standard method	N/A	MM-GENITAL-P MM-URINALYSIS-P MM-ORAL-P MM-SS-P MM- BLOODCULTURE-P MM-CSF-P MM-EYE-P

		Genital abscess, pus, fluid				
1013 Culture of organisms in liquid or agar based culture media with visual or instrument monitoring for growth01 Culture of general bacteria	Culture of blood culture specimens	Blood cultures	BacT Alert	CE marked	N/A	MM- BLOODCULTURE-P
	Culture of CSF specimens	CSF	N/A / Culture	Based on standard method	N/A	MM-CSF-P
	Culture of faecal specimens	Faeces	N/A / Agar and enrichment culture	Based on standard method	N/A	MM-FAECES-P
	Culture of genital tract & associated specimens	HVS, LVS HVS/Placenta Pairs Endocervical IUCD Bartholin's gland Genital abscess, pus, fluid	N/A / Culture	Based on standard method	N/A	MM-GENITAL-P
	Culture of specimens from superficial & deep seated infections	Wounds Tip of UAC/UVC/PICC Expressed breast milk Swabs	N/A / Agar and enrichment culture	Based on standard method	N/A	MM-WOUND-P MM-CANULAE-P MM-UMB-P MM-EAR-P MM-EYE-P MM-ORAL-P MM-NASAL-P MM-SS-P PATH-MICRO-PPG-7
	Culture of Sputum/ETT Secretions for bacterial pathogens other than Mycobacteria	Sputum/ETT Secretions	N/A / Culture	Based on standard method	N/A	
	Culture of urine specimens	Urine	N/A / Culture	Based on standard method	N/A	MM-URINALYSIS-P
1013 Culture of organisms in liquid or agar based culture media with visual or instrument monitoring for	Culture of fungi	Urine CSF Wounds Swabs	N/A / Culture	Based on standard method	N/A	MM-URINALYSIS-P MM-CSF-P MM-WOUND-P MM-CANULAE-P

growth02 Culture of fungi		Tip of UAC/UVC/PICC Expressed breat milk HVS, LVS HVS/Placenta Pairs Endocervical IUCD Bartholin's gland Genital abscess, pus, fluid Sputum/ETT Secretions Blood Cultures				MM-GENITAL-P MM-UMB-P MM-EAR-P MM-EYE-P MM-ORAL-P MM-NASAL-P MM-SS-P PATH-MICRO-PPG-7 MM-SPUTA-P MM- BLOODCULTURE-P
1014 Detection of bacterial, parasite, viral or fungal antigens using specific antibodies and appropriate techniques02 Particle agglutination	Pastorex	Isolate	N/A / Particle agglutination	CE marked	N/A	
	Streptococcal Grouping Latex Kit		N/A / Particle agglutination	CE marked	N/A	
1014 Detection of bacterial, parasite, viral or fungal antigens using specific antibodies and appropriate techniques04 Immunochromatographic methods,	NG-Test CARBA 5 Detection of Carbapenemases in Bacterial Culture	Bacterial Cultures	Immuno- chromatographic Assay	CE Based on Standard Method	Positve, Negative	SOP TBC
	Urinary hCG	Urine	N/A / Immuno- chromatographic assay	CE marked	N/A	PATH-MICRO-MI-69
1015 Detection and/or identification of bacterial, parasite, fungal and viral nucleic acids03 Nucleic acid amplification tests, CE marked commercial systems	Cultures on the Biofire FilmArray. Panel includes:	Blood Cultures	Biofire FilmArray	PCR CE Marked	Detected or Not Detected	PATH-MICRO-PPG- 20

aureus			
- Staphylococcus			
epidermidis			
- Staphylococcus			
lugdunensis			
Streptococcus spp.			
- Streptococcus			
agalactiae (Group B)			
- Streptococcus			
pneumoniae			
- Streptococcus			
pyogenes (Group A)			
, , , , , ,			
Gram Negative			
Bacteria:			
Acinetobacter Acinetobacter			
calcoaceticus-			
baumannii complex			
Bacteroides fragilis			
Haemophilus			
influenzae			
Neisseria meningitidis			
(encapsulated)			
Pseudomonas			
aeruginosa			
Stenotrophomonas			
maltophilia			
Enterobacterales			
- Enterobacter			
cloacae complex			
- Escherichia coli			
- Klebsiella aerogenes			
- Klebsiella oxytoca - Klebsiella			
pneumoniae group			
- Proteus spp.			
- Salmonella spp.			
- Serratia marcescens			
Yeast:			
Candida albicans			
Candida auris			
Candida glabrata			
Candida krusei			
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	Candida parapsilosis Candida tropicalis Cryptococcus neoformans/gattii Antimicrobial resistance genes: CTX-M IMP KPC mcr-1 mecA/C mecA/C and MREJ (MRSA) NDM OXA-48-like					
	vanA/B VIM SARS-CoV-2	Nasopharyngeal Swab	Cepheid GeneXpert	CE	Detected or Not Detected	PATH-MICRO-PPG- 12
	Xpert Xpress CoV- 2/Flu/RSV plus kit Targets: SARS-CoV-2 Influenza A Influenza B RSV (both A & B, reported only as RSV)		Cephid GeneXpert	CE	Detected Detected or Not Detected	PATH-MICRO-PPG- 19
1016 Identification of cultured bacteria and fungusing non-nucleic acid based techniques01 Biochemical methods, C marked commercial systems		Isolates	N/A / Hydrolysis of DNA	Based on standard method	N/A	MM-DNASE-I
	Phenotypic confirmation of ESBL's		Disc diffusion	Based on standard method	NA	MM-ESBL-CONFIRM-I
	VITEK Identification		Vitek 2 Compact / Measurement of metabolic activities	CE marked	N/A	MM-VTK2SETUP-I

1017 Measurement of antimicrobial activity and application of clinical interpretive criteria to general bacteria (rapidly growing aerobes)01 Anaerobes	Antimicrobial susceptibility testing	N/A / Disc diffusion	CE marked	N/A	MM-SENS-P
		Vitek 2 Compact / Broth MIC	CE marked	N/A	MM-VTK2SETUP-I
	Cefpodoxime combination disc kit	N/A / Disc diffusion	CE marked	N/A	MM-ESBLCONFIRM-I
	Minimum inhibitory concentration	N/A / Minimum inhibitory strip diffusion		N/A	MM-SENS-P