

# Schedule of Accreditation



Organisation Name	Coombe Women and Infants University Hospital
Trading As	The Coombe Hospital
INAB Reg No	218MT
Contact Name	Edel Galvin
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Accreditation Standard	EN ISO 15189
Date of award of accreditation	17/02/2009
Scope Classification	Microbiology and Virology
Scope Classification	Blood Transfusion Science
Scope Classification	Haematology
Scope Classification	Chemical Pathology
Scope Classification	Assisted Reproduction

Services available to the public<sup>1</sup>

<sup>1</sup> 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)		
	<b>Name</b>	<b>Address</b>
1	Head Office	Pathology Department, Cork Street, Dublin, D8

# Scope of Accreditation

## Head Office

### Assisted Reproduction

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
1095 Assisted reproduction - .01 Semen analysis	Sperm Concentration	Human semen/bodily fluid	Manual	Microscope	Based on Standard Method	PATH-MAND-PPG-1 WHO 6th Edition
	Sperm Morphology		Manual	Microscope	Based on Standard Method	PATH-MAND-PPG-1 WHO 6th Edition
	Sperm Motility		Manual	Microscope	Based on Standard Method	PATH-MAND-PPG-1 WHO 6th Edition

## Head Office

### 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	Whole Blood in EDTA	Manual method using tubes.	Tubes - Based on standard method	Not applicable	PATH-TM-PPG-15
	ABO and RhD blood grouping		Manual Method using Grifols DG Gel cards	CE Marked Based on Standard Method	Not Applicable	PATH-TM-PPG-15
			Automated method using Grifols Erytra Eflexis	CE Marked Based on Standard Method	Not Applicable	PATH-TM-PPG-15 PATH-TM-PPG-29
1020 Transfusion science - .02 Blood grouping including ABO, Rh(D) and other antigens by automated methods	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 science - .04 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 science - .05 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 science - .06 Red cell phenotyping	Antigen typing	Red blood cells	Automated method using Grifols Erytra Eflexis	CE Marked Based on Standard Method	Not Applicable
			Manual method using Grifols DG Gel cards	CE Marked Based on Standard Method	Not Applicable
			Manual tubes.	CE marked	Not applicable
1020 Transfusion science - .08 Antibody titration	Antibody Titration	Plasma	Automated method using Grifols Erytra Eflexis	CE Marked Based on Standard Method	Not Applicable
			Manual method using Grifols DG Gel cards	CE Marked Based on Standard Method	Not Applicable
1020 Transfusion science - .09 Direct antiglobulin test	Direct Antiglobulin Test	Whole Blood in EDTA	Automated method using Grifols Erytra Eflexis	CE Marked Based on Standard Method	Not Applicable
			Manual method using Grifols DG Gel cards	CE Marked Based on Standard Method	Not Applicable

1020 Transfusion science - .99 Miscellaneous tests	Measurement of Feto-Maternal Haemorrhage (FMH)	Flow Cytometry on Beckman Coulter DxFLEX using fluorochrome labelled Anti-D antibody to detect RhD Positive foetal cells in RhD Negative maternal circulation	CE Standard Method	Not Applicable	PATH-TM-PPG-11
<i>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)</i>					

## Head Office

### 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 - .02 Proteins, quantitative analysis	Beta-HCG	Plasma / Serum	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		Electrochemiluminescence Immunoassay (ECLIA)	Roche Cobas Pure e402	CE Marked	PATH-BIO-PPG-31

*The hospital pathology laboratory is accredited for the provision of Point of Care testing in accordance with ISO 15189:2022 for the tests identified in category B. For further details please refer to the laboratory's list of equipment and delivery points.*

## Head Office

### Chemical Pathology

Category: B

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 - .05 CO-oximetry	COHb	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 Chemistry - .06 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
	pH		Direct Ion Selective Electrode	Rapidpoint 500, Rapidpoint 400, Rapidlab 1265, Rapidlab 1240	CE based on standard method	PATH-POC-PPG-1

	pO2				
1061 Clinical Chemistry - .07 Other analytes performed on a blood gas analyser	Calcium		Direct Ion Selective Electrode	Rapidpoint 500, Rapidpoint 400, Rapidlab 1265, Rapidlab 1240	CE based on standard method
	Chloride		Direct Ion Selective Electrode	Rapidpoint 500, Rapidpoint 400, Rapidlab 1265	CE based on standard method
	Glucose		Direct Ion Selective Electrode	Rapidpoint 500, Rapidpoint 400, Rapidlab 1265	CE based on standard method
	Lactate		Direct Electrodes	Rapidpoint 500, Rapidpoint 400, Rapidlab 1265	CE based on standard method
	Potassium		Direct Electrodes	Rapidpoint 500, Rapidlab 1265	CE based on standard method
	Sodium		Direct Ion Selective Electrode	Rapidpoint 500, Rapidpoint 400, Rapidlab 1265	CE based on standard method
	Total Bilirubin		Direct Ion Selective Electrode	Rapidpoint 500, Rapidpoint 400, Rapidlab 1265	CE based on standard method
1061 Clinical Chemistry - .65 Pregnancy tests – qualitative	Urinary hCG	Urine	Co-Oximetry	Rapidpoint 500, Rapidlab 1266	CE Marked
<p><i>The hospital pathology laboratory is accredited for the provision of Point of Care testing in accordance with ISO 15189:2022 for the tests identified in category B. For further details please refer to the laboratory's list of equipment and delivery points.</i></p>					

## 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
1030 Haematology - .01 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 Haematology - .02 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 Haematology - .05 Automated differential leucocyte counts	Differential White Cell Count Neutrophils		Analysis of fluorescence by flow cytometry	Sysmex XN2000	CE	PATH-HAE-PPG-27

	Lymphocytes Monocytes Eosinophils Basophils Nucleated Red Blood Cells (NRBC)					
1030 Haematology - .06 Automated reticulocyte counts	Reticulocyte Count Absolute Count Percentage		Analysis of fluorescence by flow cytometry	Sysmex XN2000	CE	PATH-HAE-PPG-27
1030 Haematology - .09 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 Haematology - .31 Tests for foetal Hb (Kleihauer)	Kleihauer	Whole Blood in EDTA	Acid Elution	Guest Medical Kleihauer Kit Microscope	CE	PATH-HAE-PPG-17
1030 Haematology - .40 Limited haemostasis related tests	Lupus Anticoagulant	Sodium Citrate Plasma	Turbidometric detection of clot formation	IL ACL TOP 550	CE	PATH-HAE-PPG-29
1030 Haematology - .41 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

## Head Office

### 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
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 required - .01 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	Yeast	HVS, LVS Urine Oral swabs Skin swabs	Microscope / Microscopy	Based on standard method	N/A	MM-GENITAL-P MM-URINALYSIS-P MM-ORAL-P MM-SS-P

staining with dyes as required - .03 Microscopic examination for fungi		Blood Culture CSF Eye swab IUCD Genital abscess, pus, fluid				MM-BLOODCULTURE-P MM-CSF-P MM-EYE-P
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 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	Sputum/ETT Secretions	N/A / Culture	Based on standard method	N/A	

	other than Mycobacteria					
	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 growth - .02 Culture of fungi	Culture of fungi	Urine CSF Wounds Swabs Tip of UAC/UVC/PICC Expressed breast milk HVS, LVS HVS/Placenta Pairs Endocervical IUCD Bartholin's gland Genital abscess, pus, fluid Sputum/ETT Secretions Blood Cultures	N/A / Culture	Based on standard method	N/A	MM-URINALYSIS-P MM-CSF-P MM-WOUND-P MM-CANULAE-P 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 techniques - .02 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 techniques - .04 Immunochromatographic methods,	NG-Test CARBA 5 Detection of Carbapenemases in Bacterial Culture	Bacterial Cultures	Immuno- chromatographic Assay	CE Based on Standard Method	Positive, 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 acids - .03 Nucleic acid amplification tests, CE marked commercial systems	<p>Positive Blood Cultures on the Biofire FilmArray. Panel includes:</p> <p>Gram Positive Bacteria:</p> <ul style="list-style-type: none"> <li>Enterococcus faecalis</li> <li>Enterococcus faecium</li> <li>Listeria monocytogenes</li> <li>Staphylococcus spp. <ul style="list-style-type: none"> <li>- Staphylococcus aureus</li> <li>- Staphylococcus epidermidis</li> <li>- Staphylococcus lugdunensis</li> </ul> </li> <li>Streptococcus spp. <ul style="list-style-type: none"> <li>- Streptococcus agalactiae (Group B)</li> <li>- Streptococcus pneumoniae</li> <li>- Streptococcus pyogenes (Group A)</li> </ul> </li> </ul> <p>Gram Negative Bacteria:</p> <ul style="list-style-type: none"> <li>Acinetobacter calcoaceticus-baumannii complex</li> <li>Bacteroides fragilis</li> <li>Haemophilus influenzae</li> <li>Neisseria meningitidis (encapsulated)</li> <li>Pseudomonas</li> </ul>	Blood Cultures	Biofire FilmArray	PCR CE Marked	Detected or Not Detected	PATH-MICRO-PPG-20

<p>aeruginosa  <i>Stenotrophomonas</i>  <i>malophilia</i>  <i>Enterobacteriales</i>  - <i>Enterobacter</i>  <i>cloacae</i> complex  - <i>Escherichia coli</i>  - <i>Klebsiella aerogenes</i>  - <i>Klebsiella oxytoca</i>  - <i>Klebsiella pneumoniae</i> group  - <i>Proteus</i> spp.  - <i>Salmonella</i> spp.  - <i>Serratia marcescens</i></p> <p>Yeast:</p> <p><i>Candida albicans</i>  <i>Candida auris</i>  <i>Candida glabrata</i>  <i>Candida krusei</i>  <i>Candida parapsilosis</i>  <i>Candida tropicalis</i>  <i>Cryptococcus</i>  <i>neoformans/gattii</i></p> <p>Antimicrobial resistance genes:</p> <p>CTX-M  IMP  KPC  mcr-1  mecA/C  mecA/C and MREJ (MRSA)  NDM  OXA-48-like  vanA/B  VIM</p>				
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	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)		Cepheid GeneXpert	CE	Detected or Not Detected	PATH-MICRO-PPG-19
1016 Identification of cultured bacteria and fungi using non-nucleic acid based techniques - .01 Biochemical methods , CE marked commercial systems	Dnase	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	CE marked	N/A	MM-SENS-P

