

Schedule of Accreditation



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|--------------------------------|---|
| 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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| Website | http://www.coombe.ie |
| 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 public¹

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 | 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 |
| 1020 Transfusion science - .02 Blood grouping including ABO, Rh(D) and other antigens by automated methods | | | 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 - .03 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 |

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|---|--|---------------------|---|--|----------------|----------------------------------|
| 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 | 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 science - .08 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 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 | PATH-TM-PPG-15 PATH-TM-PPG-29 |
| | | | Manual method using Grifols DG Gel cards | CE Marked Based on Standard Method | Not Applicable | PATH-TM-PPG-15 |

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| 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 |
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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)

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 |

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| | 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 Chemistry - .65 Pregnancy tests – qualitative | Urinary hCG | Urine | Chromatographic immunoassay | Siemens Clinitek Status Analyser | CE | PATH-POC-PPG-4 |

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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 |

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|---|---|--------------------------|---|---|-----------------------------|-----------------|
| | 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 |

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|---|--|--|-----------------------------------|--------------------------|-----|--|
| 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 | |

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|---|---|---|------------------------------|-----------------------------|--------------------|--|
| | 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 IUUCD 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 |

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| | 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.</p> <p>Panel includes:</p> <p>Gram Positive Bacteria:</p> <p>Enterococcus faecalis</p> <p>Enterococcus faecium</p> <p>Listeria monocytogenes</p> <p>Staphylococcus spp.</p> <p>- Staphylococcus aureus</p> <p>- Staphylococcus epidermidis</p> <p>- Staphylococcus lugdunensis</p> <p>Streptococcus spp.</p> <p>- Streptococcus agalactiae (Group B)</p> <p>- Streptococcus pneumoniae</p> <p>- Streptococcus pyogenes (Group A)</p> <p>Gram Negative Bacteria:</p> <p>Acinetobacter calcoaceticus-baumannii complex</p> <p>Bacteroides fragilis</p> <p>Haemophilus influenzae</p> <p>Neisseria meningitidis (encapsulated)</p> <p>Pseudomonas</p> | Blood Cultures | Biofire FilmArray | PCR CE Marked | Detected or Not Detected | PATH-MICRO-PPG-20 |

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| | 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 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 | | | | |
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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 |

