# Schedule of Accreditation

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| Organisation Name | Mater Misericordiae University Hospital |
| Trading As | |
| INAB Reg No | 232MT |
| Contact Name | Denise O'Neill |
| Address | Pathology Laboratory, Eccles Street, Dublin, D7 |
| Contact Phone No | 01 8545070 |
| Email | doneill@mater.ie |
| Website | |
| Accreditation Standard | EN ISO 15189 |
| Standard Version | 2022 |
| Date of award of accreditation | 09/06/2009 |

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| Scope Classification | Microbiology and Virology |
| Scope Classification | Blood Transfusion Science |
| Scope Classification | Haematology |
| Scope Classification | Immunology |
| Scope Classification | Chemical Pathology |
| Scope Classification | Genetics |

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 | Mater Misericordiae University Hospital | Pathology Laboratory, Eccles Street, Dublin, Ireland, D7 |

# Scope of Accreditation

## Mater Misericordiae University 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 | Blood Group (ABO & RhD) | Blood in EDTA/Blood with no anticoagulant (Clotted) | Manual gel cards and tube techniques | CE | Not applicable | LP-BT-ROU-07, LP-BT-ROU-42 BSH Guidelines |
| 1020 Transfusion science - .02 Blood grouping including ABO, Rh(D) and other antigens by automated methods | | Blood in EDTA | BioRad IH-500/Automated | CE | Not applicable | LP-BT-ROU-33, BSH Guidelines |
| | Blood Group (ABO & RhD), Confirmation of ABO and RhD group of Blood Transfusion Service Red Blood | Red Blood Cells | BioRad IH-500/Automated | CE | Not applicable | LP-BT-ROU-33, BSH Guidelines |

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| | Cells | | | | | |
| 1020 Transfusion science - .03 Blood group antibody screen | Antibody Screening | Blood in EDTA/Blood with no anticoagulant (Clotted)/Eluate | Manual gel cards | CE | N/A | LP-BT-ROU-33, LP-BT-ROU-08, BSH Guidelines |
| | Antibody Screen | Blood in EDTA | BioRad IH-500/Automated | CE | Not applicable | LP-BT-ROU-33, BSH Guidelines |
| 1020 Transfusion science - .04 Identification of blood group antibodies | Antibody Identification | | Bio-Rad IH-500 /Automated | CE | Not applicable | LP-BT-ROU-09 BCSH Guideline |
| | | Blood in EDTA/Blood with no anticoagulant (Clotted)/Eluate | Manual gel cards and tube techniques | CE | Not applicable | LP-BT-ROU-09, BSH Guidelines |
| 1020 Transfusion science - .05 Cross match compatible donor units | Crossmatch | Blood in EDTA | Bio-Rad IH-500/Automated | CE | Not applicable | LP-BT-ROU-11 BSH Guidelines |
| | | Blood in EDTA/Blood with no anticoagulant (Clotted) | Manual gel cards and electronic issue | CE | Not applicable | LP-BT-ROU-11, BSH Guidelines MHRA Guidance on electronic issue |
| 1020 Transfusion science - .06 Red cell phenotyping | Antigen Type | Blood in EDTA/Red blood cells | Manual gel cards and tube techniques | CE | Not applicable | LP-BT-ROU-10, BSH Guidelines |
| | Phenotype (Rh and K | Blood in EDTA | Bio-Rad IH-500 / Automated | CE | Not applicable | LP-BT-ROU-10 BSH Guidelines |
| 1020 Transfusion science - .07 Antibody elution | Antibody Elution Test | | Elution | CE | Not applicable | LP-BT-ROU-15, BSH Guidelines |
| 1020 Transfusion science - .09 Direct antiglobulin test | Direct Coombes Test (DCT) | | Bio-Rad IH-500 /Automated | CE | Not applicable | LP-BT-ROU-13, BSH Guidelines |
| | Direct Coombes Testing (DCT) | Blood in EDTA/Red blood cells | Manual gel cards | CE | Not applicable | LP-BT-ROU-13, BSH Guidelines |

*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)*

## Mater Misericordiae University Hospital

### 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 |
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| 1061 Clinical Chemistry - .01 Analytes in general use in cardiac, liver function, lipid, renal and other profiles and metabolic studies | 24 hour Urine Amylase **1,2,3,4 | Urine | Calculated | NA | Based on standard method | LI-CCE-0040 |
| | 24 hour Urine Calcium **1,2,3,4 | | Calculated | NA | Based on standard method | LI-CCE-0040 |
| | 24 hour Urine Chloride **1,2,3,4 | | Calculated | NA | Based on standard method | LI-CCE-0040 |
| | 24 hour Urine Creatinine **1,2,3,4 | | Calculated | NA | Based on standard method | LI-CCE-0040 |
| | 24 hour Urine Magnesium **1,2,3,4 | | Calculated | NA | Based on standard method | LI-CCE-0040 |
| | 24 hour Urine Phosphate **1,2,3,4 | | Calculated | NA | Based on standard method | LI-CCE-0040 |
| | 24 hour Urine Potassium **1,2,3,4 | | Calculated | NA | Based on standard method | LI-CCE-0040 |
| | 24 hour Urine Sodium **1,2,3,4 | | Calculated | NA | Based on standard method | LI-CCE-0040 |
| | 24 hour Urine Urate **1,2,3,4 | | Calculated | NA | Based on standard method | LI-CCE-0040 |
| | 24 hour Urine Urea | | Calculated | NA | Based on standard | LI-CCE-0040 |

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| **1,2,3,4 | | | | method | |
| Alanine Aminotransferase (ALT) **1,2,3,4 | Li-Heparin Plasma / Serum | NADH (without P-5'-P) | Abbott Alinity ci series / 5 U/L to 3899 U/L | CE | LI-CCE-0003 LI-CCE-0125 CLSI |
| Albumin/Creatinine Ratio **1,2,3,4 | Urine | Calculated | NA | Based on standard method | LI-CCE-0040 |
| Alkaline Phosphatase (ALP) **1,2,3,4 | Li-Heparin Plasma / Serum | IFCC with PNPP | Abbott Alinity ci series / 9 U/L to 4555 UL | CE | LI-CCE-0003 LI-CCE-0125 CLSI |
| Ammonia **1,2,3,4 | Li-Heparin Plasma | Colorimetric | Abbott Alinity ci series / 14 µmol/l to 998 µmol/l | CE | LI-CCE-0003 LI-CCE-0125 CLSI |
| Amylase **1,2,3,4 | Li-Heparin Plasma/ Serum/ Fluid/ Urine | Enzymatic | Abbott Alinity ci series / 3 U/L to 3300 U/L | CE | LI-CCE-0003 LI-CCE-0125 CLSI |
| Anion Gap **1,2,3,4 | Plasma/Serum | Calculated | NA | Based on standard method | LI-CCE-0040 |
| Aspartate Aminotransferase (AST) **1,2,3,4 | Li-Heparin Plasma/ Serum | Enzymatic | Abbott Alinity ci series / 6 U/L to 5234 U/L | CE | LI-CCE-0003 LI-CCE-0125 CLSI |
| Bicarbonate (Total CO2) **1,2,3,4 | Li-Heparin Plasma / Serum | Enzymatic | Abbott Alinity c series / 5 to 50 mmol/L Highest reportable value (autodilution): >100 mmol/L (1:2) | CE | LI-CCE-0125 CLSI |
| Bilirubin direct **1,2,3,4 | Li-Heparin Plasma/ Serum | Diazo | Abbott Alinity ci series / 1.7 µmol/l to 256.5 µmol/l | CE | LI-CCE-0003 LI-CCE-0125 CLSI |
| Bilirubin Total **1,2,3,4 | Li-Heparin Plasma / Serum | Diazo | Abbott Alinity ci series / 1.71 µmol/l to 427.5 µmol/l | CE | LI-CCE-0003 LI-CCE-0125 CLSI |
| Calcium **1,2,3,4 | Li-Heparin Plasma / | Arsenazo III | Abbott Alinity ci | CE | LI-CCE-0003 |

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| | Serum / Urine | | series / 0.50 mmol/l to 6.00 mmol/l | | LI-CCE-0125 CLSI |
| Calcium Creatinine Clearance **1,2,3,4 | Plasma / Serum / Urine | Calculated | NA | Based on standard method | LI-CCE-0040 |
| Calcium Creatinine Ratio **1,2,3,4 | Urine | Calculated | NA | Based on standard method | LI-CCE-0040 |
| Chloride **1,2,3,4 | Li-Heparin Plasma / Serum / Urine | Ion selective electrode | Abbott Alinity ci series / 50 mmol/l to 150mmol/l / Urine: 20 mmol/l to 300mmol/l | CE | LI-CCE-0003 LI-CCE-0125 CLSI |
| Cholesterol **1,2,3,4 | Li-Heparin Plasma / Serum | Cholesterol oxidase | Abbott Alinity ci series / 0.1 mmol/l to 19.24 mmol/l | CE | LI-CCE-0003 LI-CCE-0125 CLSI |
| Corrected Calcium **1,2,3,4 | | Calculated | N/A | Laboratory Developed Test | LI-CCE-0040 |
| Creatine Kinase (CK) **1,2,3,4 | | Enzymatic | Abbott Alinity ci series / 7 U/L to 4267 U/L | CE | LI-CCE-0003 LI-CCE-0125 CLSI |
| Creatinine **1,2,3,4 | Li-Heparin Plasma / Serum / Fluid / Urine | Enzymatic | Abbott Alinity ci series / 8.8 µmol to 3536 µmol/l Urine: 0.22 mmol/l to 35.6 mmol/l | CE | LI-CCE-0003 LI-CCE-0125 CLSI |
| Creatinine Clearance **1,2,3,4 | Li-Heparin Plasma/ Serum/ Urine | Calculated | N/A | Based on standard method | LP-CCE-0030 |
| eGFR **1,2,3,4 | Li-Heparin Plasma / Serum | Calculated | N/A | Based on standard method | LI-CCE-0040 |
| Fractional Excretion of Sodium **1,2,3,4 | Urine | Calculated | NA | Based on standard method | LI-CCE-0040 |
| Fractional Excretion of | | Calculated | NA | Based on standard | LI-CCE-0040 |

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| Uric Acid **1,2,3,4 | | | | method | |
| Gamma Glutamyl Transferase (GGT) **1,2,3,4 | Li-Heparin Plasma / Serum | Enzymatic | Abbott Alinity ci series / 4 U/L to 8500 U/L | CE | LI-CCE-0003<br>LI-CCE-0125<br>CLSI |
| Glucose **1,2,3,4 | Fluoride EDTA Plasma / CSF / Urine | Hexokinase | Abbott Alinity ci series / 0.28 mmol/l to 44.4 mmol/l | CE | LI-CCE-0003<br>LI-CCE-0125<br>CLSI |
| Hight Density Lipoprotein (HDL) Cholesterol **1,2,3,4 | Li-Heparin Plasma / Serum | Enzymatic | Abbott Alinity ci series / 0.13 mmol/l to 4.66 mmol/l | CE | LI-CCE-0003<br>LI-CCE-0125<br>CLSI |
| Lactate Dehydrogenase (LDH) **1,2,3,4 | Serum / Fluid | Enzymatic | Abbott Alinity ci series / 30 U/L to 4500 U/L | CE | LI-CCE-0003<br>LI-CCE-0125<br>CLSI |
| Lipase **1,2,3,4 | Serum / Plasma | Colorimetric | Abbott Alinity ci series | CE | LI-CCE-0125 |
| Lithium **1,2,3,4 | Serum | Colorimetric | Abbott Architect c16000 | CE | LI-CCE-0003 |
| Low Density Lipoprotein (LDL) **1,2,3,4 | Li-Heparin Plasma / Serum | Enzymatic / Calculated | Abbott Alinity ci series / 0.03 mmol/l to 20.69 mmol/l | CE and Based on standard method | LI-CCE-0003<br>LI-CCE-0040<br>LI-CCE-0125<br>CLSI |
| Magnesium **1,2,3,4 | Plasma/ Serum/ Urine | Arsenazo | Abbott Architect c16000<br>Alinity ci series | CE | LI-CCE-0003<br>LI-CCE-0125 |
| Non HDL Cholesterol **1,2,3,4 | Plasma/Serum | Calculated | N/A | Calculated | LI-CCE-0040 |
| NT-proBNP **1,2,3,4 | EDTA | Chemiluminescent microparticle immunoassay (CIMA) technology | Abbott Allinity/Architect | CE | LI-CCE-0003<br>LI-CCE-0125 |
| Phosphate **1,2,3,4 | Plasma/ Serum/ Urine | Colorimetric | Abbott Architect c16000 | CE | LI-CCE-0003<br>LI-CCE-0125 |

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| | | | | Alinity ci series | | |
| | Potassium **1,2,3,4 | | Ion selective electrode | Abbott Architect c16000<br>Alinity ci series | CE | LI-CCE-0003<br>LI-CCE-0125 |
| | Sodium **1,2,3,4 | | Ion selective electrode | Abbott Architect c16000<br>Alinity ci series | CE | LI-CCE-0003<br>LI-CCE-0125 |
| | Total CO2 **1,2,3,4 | Plasma/ Serum | Enzymatic | Abbott Architect c16000<br>Alinity ci series | CE | LI-CCE-0003<br>LI-CCE-0125 |
| | Triglycerides **1,2,3,4 | Plasma/ Serum/ Fluid | Glycerol Phosphate Oxidase | Abbott Architect c16000<br>Alinity ci series | CE | LI-CCE-0003<br>LI-CCE-0125 |
| | Troponin I (High sensitivity) **1,2,3,4 | Plasma | Immunoassay | Abbott Architect i2000<br>Alinity ci series | CE | LI-CCE-0003<br>LI-CCE-0125 |
| | Urea **1,2,3,4 | Plasma/ Serum/ Fluid/ Urine | Urease | Abbott Architect c16000<br>Alinity ci series | CE | LI-CCE-0003<br>LI-CCE-0125 |
| | Uric Acid **1,2,3,4 | Plasma/ Serum/Urine | Uricase | Abbott Architect c16000<br>Alinity ci series | CE | LI-CCE-0003<br>LI-CCE-0125 |
| 1061 Clinical Chemistry - .02 Proteins, quantitative analysis | Albumin **1,2,3,4 | Li-Heparin Plasma/ Serum | Bromocresol Green | Abbott Alinity ci series / 3 g/l to 94 g/l | CE | LI-CCE-0003<br>LI-CCE-0125<br>CLSI |
| | C-Reactive Protein (CRP) **1,2,3,4 | Li-Heparin Plasma/ Serum | Immunoturbidimetric | Abbott Alinity ci series / 1 mg/l to 160 mg/l | CE | LI-CCE-0003<br>LI-CCE-0125<br>CLSI |
| | Globulins **1,2,3,4 | Plasma / Serum | Calculated | NA | Based on standard method | LI-CCE-0040 |
| | Microalbumin **1,2,3,4 | Urine | Immunoturbidimetric | Abbott Architect c16000<br>Alinity ci series | CE | LI-CCE-0003<br>LI-CCE-0125 |

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| | Protein / Creatinine ratio **1,2,3,4 | | Calculated | NA | Based on standard method | LI-CCE-0040 |
| | Protein -Total **1,2,3,4 | Plasma/ Serum | Biuret | Abbott Architect c16000<br>Alinity ci series | CE | LI-CCE-0003<br>LI-CCE-0125 |
| | | Urine/ CSF | Benzethonium Chloride | Abbott Architect c16000<br>Alinity ci series | CE | LI-CCE-0003<br>LI-CCE-0125 |
| | SHBG **1,2,3,4 | Plasma / Serum | Immunoassay | Abbott Architect<br>Alinity ci series | CE | LI-CCE-0003<br>LI-CCE-0125 |
| 1061 Clinical Chemistry - .05 CO-oximetry | Carboxyhaemoglobin **1,2,3,4 | Blood Heparinised | Cooximetry | ABL 90 Flex | CE | LP-CCE-0049 |
| | Ionised Calcium **1,2,3,4 | | Ion selective electrode (ISE) | ABL90 Flex | CE | LP-CCE-0049 |
| | Methaemoglobin **1,2,3,4 | Blood | Cooximetry | ABL90 Flex | Based on standard method | LP-CCE-0049 |
| | Oxyhaemoglobin **1,2,3,4 | | Cooximetry | ABL90 Flex | CE | LP-CCE-0049 |
| 1061 Clinical Chemistry - .06 Blood pH and gas tensions | pC02 **1,2,3,4 | | Potentiometric | ABL90 Flex | CE | LP-CCE-0049 |
| | pH **1,2,3,4 | | Potentiometric | ABL90 Flex | CE | LP-CCE-0049 |
| | pO2 **1,2,3,4 | | Potentiometric | ABL90 Flex | CE | LP-CCE-0049 |
| | SO2 **1,2,3,4 | | Absorption Spectroscopy | ABL 90 Flex | CE | LP-CCE-0049 |
| 1061 Clinical Chemistry - .07 Other analytes performed on a blood gas analyser | Base Excess **1,2,3,4 | Blood Heparinised | Calculated | ABL 90 Flex | CE | LP-CCE-0049 |
| | Chloride **2,4 | Blood in heparin | Ion-selective Electrode (ISE) | ABL 90 Flex Plus Analyser | CE | LP-POC-018<br>CLSI C46-A2 |
| | Lactate **1,2,3,4 | Blood Heparinised | Amperometric | ABL90 Flex | CE | LP-CCE-0049 |

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| | Potassium **1,2,3,4 | Blood | Ion selective electrode | ABL90 Flex | CE | LP-CCE-0049 |
| | Sodium **1,2,3,4 | | Ion selective electrode | ABL90 Flex | CE | LP-CCE-0049 |
| | Standard Bicarbonate **1,2,3,4 | | Calculated | ABL90 Flex | Based on standard method | LP-CCE-0049 |
| 1061 Clinical Chemistry - .10 Drugs for therapeutic monitoring | Acetaminophen **1,2,3,4 | Li-Heparin Plasma / Serum | Spectrophotometric | Abbott Alinity ci series / 4 mg/l to 605 mg/l | CE | LI-CCE-0125<br>CLSI |
| | Amikacin **1,2,3,4 | Serum | Particle Enhanced Turbidimetric Assay | Abbott Alinity ci series / 2.0 mg/l to 50 mg/l | CE | LI-CCE-0003<br>LI-CCE-0125<br>CLSI |
| | Carbamazepine **1,2,3,4 | | Petinia | Abbott Alinity ci series / 1.9 mg/l to 20.0 mg/l | CE | LI-CCE-0003<br>LI-CCE-0125<br>CLSI |
| | Corrected Phenytoin **1,2,3,4 | | Calculated | NA | Based on standard method | LI-CCE-0040 |
| | Cyclosporin **1,2,3,4 | Whole Blood | LC-MS/MS | Waters TQD<br>Waters Xevo TQ<br>Waters TQ-XS | Laboratory Developed Test | LP-CCE-0001 |
| | Digoxin **1,2,3,4 | Serum | Particle Enhanced Turbidimetric Assay | Abbott Alinity ci series<br>Abbott Architect c1600 | CE | LI-CCE-0003<br>LI-CCE-0125 |
| | Gentamicin **1,2,3,4 | Li-Heparin Plasma / Serum | Particle Enhanced Turbidimetric Assay | Abbott Alinity ci series /0.5 mg/l to 10 mg/l | CE | LI-CCE-0003<br>LI-CCE-0125<br>CLSI |
| | Methotrexate **1,2,3,4 | Serum | Immunoassay | Abbott Architect i2000<br>Alinity ci series | CE | LI-CCE-0003<br>LI-CCE-0125 |
| | Phenobarbitone **1,2,3,4 | | Petinia | Abbott Architect i2000<br>Alinity ci series | CE | LI-CCE-0003<br>LI-CCE-0125 |

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| | Phenytoin **1,2,3,4 | | Enzyme Immunoassay | Abbott Architect i2000<br>Alinity ci series | CE | LI-CCE-0003<br>LI-CCE-0125 |
| | Sirolimus **1,2,3,4 | Whole blood | LC-MS/MS | Waters TQD MS<br>Waters TQ-XS | Laboratory Developed Test | LP-CCE-0001 |
| | Tacrolimus **1,2,3,4 | | LC-MS/MS | Waters TQD MS<br>Waters Xevo TQ<br>Waters TQ-XS | Laboratory Developed Test | LP-CCE-0001 |
| | Theophylline **1,2,3,4 | Serum | Enzyme Immunoassay | Abbott Alinity ci series | CE | LP-CCE-0064<br>LI-CCE-0125 |
| | Tobramycin **1,2,3,4 | | Particle Enhanced Turbidimetric Assay | Abbott Architect c16000<br>Abbott Alinity ci series | CE | LI-CCE-0003<br>LI-CCE-0125 |
| | Valproate **1,2,3,4 | | Particle Enhanced Turbidimetric Assay | Abbott Architect c16000<br>Abbott Alinity ci series | CE | LI-CCE-0003<br>LI-CCE-0125 |
| | Vancomycin **1,2,3,4 | Plasma/ Serum | Particle Enhanced Turbidimetric Assay | Abbott Architect c16000<br>Abbott Alinity ci series | CE | LI-CCE-0003<br>LI-CCE-0125 |
| | Voriconazole **1,2,3,4 | Serum | LC-MS/MS | Waters TQD MS | Laboratory Developed Test | LP-CCE-0050 |
| 1061 Clinical Chemistry - .14 Alcohol for non-legal purposes | Ethanol **1,2,3,4 | Fluoride EDTA Plasma | Enzymatic | Abbott Alinity ci series / 10 mg/dl to 600 mg/dl | CE | LI-CCE-0003<br>LI-CCE-0125<br>LP-CCE-0064<br>CLSI |
| 1061 Clinical Chemistry - .15 Drugs for toxicological purposes | Salicylate **1,2,3,4 | Plasma/ Serum | Enzymatic | Abbott Architect c16000<br>Alinity ci series | CE | LI-CCE-0003<br>LP-CCE-0064 |
| 1061 Clinical Chemistry - .20 Hormones | Adrenocorticotrophic hormone (ACTH) | EDTA Plasma on ice | Immunometric Assay | Roche Cobas / 1.5 to 2000 ng/L | CE | LP-CCE-0057<br>CLSI |

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| | **1,2,3,4 | | | | | |
| | Androstenedione **1,2,3,4 | Serum | LC-MS/MS | Waters Xevo TQ / 0.1 nmol/L to 44.6 nmol/L | Laboratory Developed Test | LP-CCE-0055<br>CLSI C62-A |
| | Cortisol **1,2,3,4 | Li-Heparin Plasma / Serum | Immunoassay | Abbott Alinity ci series / 27.5 nmol/l to 1650 nmol/l | CE | LI-CCE-0003<br>LP-CCE-0064<br>CLSI |
| | C-Peptide **1,2,3,4 | Plasma / Serum | CMIA (Chemiluminescent microparticple Immunoassay) | Abbott Architect i2000<br>Alinity ci series | CE | LP-CCE-0003<br>LI-CCE-0125 |
| | Follicle Stimulating Hormone (FSH) **1,2,3,4 | | Immunoassay | Abbott Architect i2000<br>Alinity ci series | CE | LI-CCE-0003<br>LI-CCE-0125 |
| | Growth Hormone **1,2,3,4 | Serum | Immunoassay | IDS iSYS / 0 µg/l to 10 µg/l | CE | LP-CCE-0051<br>CLSI |
| | HCG- Total **1,2,3,4 | Li-Heparin Plasma / Serum | Immunoassay | Abbott Alinity ci series / 1.2 IU/l to 15,000 IU/l | CE | LI-CCE-0003<br>LI-CCE-0125<br>CLSI |
| | IGF-1 **1,2,3,4 | Serum | Immunoassay | IDS iSYS / 10 µg/l to 1200 µg/l | CE | LP-CCE-0035<br>CLSI |
| | Insulin **1,2,3,4 | Plasma / Serum | Immunoassay | Abbott Architect i2000<br>Alinity ci series | CE | LI-CCE-0003<br>LI-CCE-0125 |
| | Lutenising Hormone (LH) **1,2,3,4 | | Immunoassay | Abbott Architect i2000<br>Alinity ci series | CE | LI-CCE-0003<br>LI-CCE-0125 |
| | Macroprolactin **1,2,3,4 | | PEG Precipitation | Abbott Architect i2000<br>Alinity ci series | Based on standard method | LP-CCE-0005<br>LI-CCE-0125 |
| | Oestradiol **1,2,3,4 | | Immunoassay | Abbott Architect i2000<br>Alinity ci series | CE | LI-CCE-0003<br>LI-CCE-0125 |
| | Parathyroid Hormone (PTH) **1,2,3,4 | Plasma | Immunoassay | Roche e411 | CE | LP-CCE-0048 |

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| | Progesterone **1,2,3,4 | Plasma / Serum | Immunoassay | Abbott Architect i2000<br>Alinity ci series | CE | LI-CCE-0003<br>LI-CCE-0125 |
| | Prolactin **1,2,3,4 | | Immunoassay | Abbott Architect i2000<br>Alinity ci series | CE | LI-CCE-0003<br>LI-CCE-0125 |
| | T3 free **1,2,3,4 | | Immunoassay | Abbott Architect i2000<br>Alinity ci series | CE | LI-CCE-0003<br>LI-CCE-0125 |
| | T4 free **1,2,3,4 | Plasma/ Serum | Immunoassay | Abbott Architect i2000<br>Alinity ci series | CE | LI-CCE-0003<br>LP-CCE-0064 |
| | Testosterone **1,2,3,4 | Serum | LC-MS/MS | Waters Xevo TQ MS | Laboratory Developed Test | LP-CCE-0055 |
| | Thyroid Stimulating Hormone (TSH) **1,2,3,4 | Plasma / Serum | Immunoassay | Abbott Architect i2000<br>Alinity ci series | CE | LI-CCE-0003<br>LI-CCE-0125 |
| | Urine Free Cortisol **1,2,3,4 | 24 hour Urine | LC-MS/MS | Waters TQD MS | Laboratory Developed Test | LP-CCE-0029 |
| 1061 Clinical Chemistry - .40 Iron studies | Ferritin **1,2,3,4 | Li-Heparin Plasma / Serum | Immunoassay | Abbott Alinity ci series / 1.98 µg/l to 1676 µg/l | CE | LI-CCE-0003<br>LI-CCE-0125<br>CLSI |
| | Iron **1,2,3,4 | Li-Heparin Plasma / Serum | Colorimetric | Abbott Alinity ci series / 0.9 µmol/l to 179 µmol/l | CE | LI-CCE-0003<br>LI-CCE-0125<br>LP-CCE-0064<br>CLSI |
| | Transferrin **1,2,3,4 | Plasma/ Serum | Immunoturbidimetric | Abbott Architect c16000<br>Abbott Alinity ci series | CE | LI-CCE-0003<br>LI-CCE-0125 |
| | Transferrin Saturation **1,2,3,4 | | Calculated | n/a | Based on standard method | LI-CCE-0040 |
| 1061 Clinical Chemistry - | Folate **1,2,3,4 | Plasma / Serum | Immunoassay | Abbott Architect | CE | LI-CCE-0003 |

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| .45 Vitamin B12 and folate | | | | i2000<br>Alinity ci series | | LI-CCE-0125 |
| | Folate Red Cell<br>**1,2,3,4 | Blood in EDTA | Immunoassay | Abbott Alinity ci series / 2.2 ng/ml to 20.0 ng/ml | Based on standard method | LP-CCE-0010<br>LI-CCE-0125<br>CLSI |
| | Vitamin B12 **1,2,3,4 | Plasma / Serum | Immunoassay | Abbott Architect i2000<br>Alinity ci series | CE | LI-CCE-0003<br>LI-CCE-0125 |
| 1061 Clinical Chemistry - .47 Vitamin assays | Active B12/ Holotranscobalamin<br>**1,2,3,4 | Serum | CMIA (Chemiluminescent microparticple Immunoassay) | Abbott Architect Immunoassay<br>Alinity ci series | Based on a standard method | LI-CCE-0115<br>LI-CCE-0125 |
| | Vitamin D **1,2,3,4 | | LC-MS/MS | Waters TQD MS | Laboratory Developed Test | LP-CCE-0002 |
| | | | LC-MSMS | Waters TQ-XS<br>15 nmol/L to 368 nmol/L | In house developed | LP-CCE-0002 |
| 1061 Clinical Chemistry - .50 Protein and peptide tumour markers | Alpha Fetoprotein (AFP) **1,2,3,4 | Plasma / Serum | Immunoassay | Abbott Architect i2000<br>Alinity ci series | CE | LI-CCE-0003<br>LI-CCE-0125 |
| | CA-125 **1,2,3,4 | Li-Heparin Plasma / Serum | Immunoassay | Abbott Alinity ci series / 1.1 KU/l to 1000 KU/l | CE | LI-CCE-0125<br>LI-CCE-0003<br>CLSI |
| | CA-15-3 **1,2,3,4 | | Immunoassay | Abbott Alinity ci series / 0.6 KU/l to 800 KU/l | CE | LI-CCE-0003<br>LI-CCE-0125<br>CLSI |
| | CA-19-9 **1,2,3,4 | | Immunoassay | Abbott Alinity ci series / 2.06 KU/l to 1200 KU/l | CE | LI-CCE-0003<br>LI-CCE-0125<br>CLSI |
| | Calcitonin (hCT)<br>**1,2,3,4 | Serum on ice | Immunoassay | Roche Cobas / 1 to 200,000 ng/L | CE | LP-CCE-0058<br>CLSI |
| | CEA **1,2,3,4 | Plasma / Serum | Immunoassay | Abbott Architect i2000<br>Alinity ci series | CE | LI-CCE-0003<br>LI-CCE-0125 |
| | PSA Total **1,2,3,4 | | Immunoassay | Abbott Architect | CE | LI-CCE-0003 |

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| | | | | i2000<br>Alinity ci series | | LI-CCE-0125 |
| | Thyroglobulin<br>**1,2,3,4 | Serum | Immunoassay | Roche Cobas | CE | LP-CCE-0059 |
| 1061 Clinical Chemistry - .52 Collagen cross-link markers | C-terminal Telopeptide of Type 1 collagen (CTX-1)<br>**1,2,3,4 | EDTA Plasma | Immunoassay | Roche e411 /<br>0.010 to 6.00 µg/L | CE | LP-CCE-0031<br>CLSI |
| | Procollagen Type 1 N-Propeptide (P1NP)<br>**1,2,3,4 | Plasma | Immunoassay | Roche e411 | CE | LP-CCE-0032 |
| 1061 Clinical Chemistry - .56 Biogenic amines | Homocysteine<br>**1,2,3,4 | | CMIA (Chemiluminescent microparticple Immunoassay) | Abbott Architect Immunoassay<br>Alinity ci series | CE | LI-CCE-0118<br>LI-CCE-0125 |
| | Total Homocysteine | Li-Heparin Plasma / HCY-Z gel serum | Chemiluminescent Microparticple Immunoassay (CMIA) | Alinity ci series /<br>1.00 µmol/l to 50.0 µmol/l<br>Highest reportable value (autodilution): >500 umol/L (1:10) | CE | LI-CCE-0125<br>LI-CCE-0118<br>CLSI |
| 1061 Clinical Chemistry - .60 Glycohaemoglobins | HbA1c **1,2,3,4 | Blood in EDTA | HPLC | Arkray HA8190 /<br>20 mmol/mol to 150mmol/mol | CE | LP-CCE-0060<br>LP-CCE-0080<br>CLSI |
| | | | HPLC | Arkray HA8190<br>20 mmol/mol to 150 mmol/mol | CE | LP-CCE-0080 |
| 1061 Clinical Chemistry - .77 Calculi | Stone Analysis<br>**1,2,3,4 | Stone | FT-IR | Nicolet iS10 | Based on a standard method | LP-CCE-0041 |
| 1061 Clinical Chemistry - .78 Intermediary metabolites | 3 -Methoxytyramine<br>**1,2,3,4 | EDTA Plasma on ice | LC-MS/MS | Waters Xevo TQ MS / 65 pmol/L to 10087 pmol/L | Laboratory Developed Test | LP-CCE-0053<br>CLSI C62-A |
| | Plasma Metanephrines<br>**1,2,3,4 | | LC-MS/MS | Waters Xevo TQ MS | Laboratory Developed Test | LP-CCE-0053 |

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| 1061 Clinical Chemistry - .85 Anti-thyroglobulin antibodies | Thyroglobulin Antbodies **1,2,3,4 | Serum | Electrochemiluminescence immunoassay | Roche e411 | Based on standard method | LP-CCE-0059 |
| 1061 Clinical Chemistry - .99 Miscellaneous tests | Free Androgen Index **1,2,3,4 | | Calculated | N/A | Based on standard method | LI-CCE-0040<br>LI-CCE-0008 |
| | Free Testosterone **1,2,3,4 | | Calculated | N/A | Based on standard method | LI-CCE-0040 |
| | Osmolality **1,2,3,4 | Li-Heparin Plasma / Serum / Urine | Freezing Point Depression | Osmo1 | CE | LP-CCE-0009<br>CLSI |
| | Thyroid peroxidase (TPO) antibodies **1,2,3,4 | Plasma / Serum | Immunoassay | Abbott Architect i2000<br>Alinity ci series | CE | LI-CCE-0003<br>LI-CCE-0125 |

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## Mater Misericordiae University Hospital

### 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 - .01 Analytes in general use in cardiac, liver function, lipid, renal and other profiles and metabolic studies | Glucose **4 | Fresh Capillary Blood | Enzymatic and Amperometric | Stat Strip Nova Biomedical hand held device & docking station | Based on standard method | LP-POC-016 |
| | Ketone **4 | | Enzymatic and Amperometric | Stat Strip Nova Biomedical hand held device & docking station | Based on standard method | LP-POC-015 |
| 1061 Clinical Chemistry - .05 CO-oximetry | Haematocrit **2,4 | Blood | Absorption Spectroscopy | ABL 90 Flex | CE | LP-POC-001 |
| | | | Impedance | Prime Plus Blood Gas Analyser | CE | LP-POC-017 |
| | Haemoglobin & Haemoglobin Derivatives **2,4 | | Absorption Spectroscopy | ABL 90 Flex | CE | LP-POC-001 |
| | Haemoglobin **2,4 | | Chemometrics applied to optical absorbance | Prime Plus Blood Gas Analyser | CE | LP-POC-017 |
| | Standard Biocarbonate **1,2,4 | | Calculated | Prime Plus Blood Gas Analyser | CE | LP-POC-017 |
| 1061 Clinical Chemistry - .06 Blood pH and gas | p02 **2,4 | | Amperometric | Abbott i-Stat | CE | LP-POC-010 |

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| | | | Potentiometric | ABL 90 Flex | CE | LP-POC-001 |
| | pC02 **2,4 | | Potentiometric | Abbott i-Stat | CE | LP-POC-010 |
| | pCO2 **2,4 | | ISE Potentiometric | Prime Plus Blood Gas Analyser | CE | LP-POC-017 |
| | | | Potentiometric | ABL 90 Flex | CE | LP-POC-001 |
| | pH **2,4 | | ISE | Abbott i-Stat | CE | LP-POC-010 |
| | | | ISE | ABL 90 Flex | CE | LP-POC-001 |
| | | | ISE | Prime Plus Blood Gas Analyser | CE | LP-POC-017 |
| | pO2 **2,4 | | ISE Amperometric | Prime Plus Blood Gas Analyser | CE | LP-POC-017 |
| | | | Potentiometric | ABL 90 Flex | CE | LP-POC-001 |
| | SO2 **2,4 | | Absorption Spectroscopy | ABL 90 Flex | CE | LP-POC-001 |
| | | | Chemometrics applied to optical absorbance | Prime Plus Blood Gas Analyser | CE | LP-POC-017 |
| 1061 Clinical Chemistry - .07 Other analytes performed on a blood gas analyser | Anion Gap **2,4 | | Calculated | NA | CE | LP-POC-017 |
| | Base Excess **2,4 | | Calculated | ABL 90 Flex | CE | LP-POC-001 |
| | | | Calculated | Prime Plus Blood Gas Analyser | CE | LP-POC-017 |
| | Chloride **2,4 | | ISE | ABL90 | CE | LP-POC-017 |
| | Creatinine | Blood in heparin | Amperometry | ABL 90 Flex Plus Analyser / 10 to 1800 µmol/L | CE | LP-POC-018 CLSI C46-A2 |
| | Glucose **2,4 | Blood | Amperometric | ABL 90 Flex | CE | LP-POC-001 |

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|---|---|---|---|---|---|---|
| | Glucose **2,4 | | ISE Amperometric | Prime Plus Blood Gas Analyser | CE | LP-POC-017 |
| | Ionised Calcium **2,4 | | ISE | ABL 90 Flex | CE | LP-POC-001 |
| | Ionised Magnesium **2,4 | | ISE | Prime Plus Blood Gas Analyser | CE | LP-POC-017 |
| | Ionisied Calcium **2,4 | | ISE | Prime Plus Blood Gas Analyser | CE | LP-POC-017 |
| | Lactate **2,4 | | Amperometric | ABL 90 Flex | CE | LP-POC-001 |
| | | | ISE Amperometric | Prime Plus Blood Gas Analyser | CE | LP-POC-017 |
| | Potassium **2,4 | | ISE | Abbott i-Stat | CE | LP-POC-010 |
| | | | ISE | ABL 90 Flex | CE | LP-POC-001 |
| | | | ISE | Prime Plus Blood Gas Analyser | CE | LP-POC-017 |
| | Sodium **2,4 | | ISE | Abbott i-Stat | CE | LP-POC-010 |
| | | | ISE | ABL 90 Flex | CE | LP-POC-001 |
| | | | ISE | Prime Plus Blood Gas Analyser | CE | LP-POC-017 |
| | Standard Bicarbonate **2,4 | | Calculated | ABL 90 Flex | CE | LP-POC-001 |
| | Urea | Blood in Heparin | Potentiometry | ABL 90 Flex Plus Analyser / 1 to 50 mmol/L | CE | LP-POC-018 CLSI C46-A2 |
| 1061 Clinical Chemistry - .61 Hb A1c | Haemoglobin A1c (HbA1c) | Fresh Capillary Whole Blood & Anticoagulated Whole Blood with EDTA, heparin, fluoride/oxalate or citrate | Latex Immune-Agglutination Inhibition & Spectrophotometry | DCA Vantage / 4 to 130 mmol/mol | CE | LP-POC-022 IFCC |

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## Mater Misericordiae University Hospital

### Genetics

**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 |
|---|---|---|---|---|---|---|
| 1075 Molecular genetics - .05 Screening for unidentified pathogenic variant(s) | NGS panels Cardiology:<br>-Atrial Fibrillation<br>-Aortopathies<br>-Arrhythmias and Sudden - Death without Structural Heart Disease<br>-Brugada Syndrome<br>-Cardiac Conduction Disease<br>-Cardiomyopathies and Arrhythmias<br>-Cardiomyopathies<br>-Catecholaminergic Polymorphic Ventricular Tachycardia<br>-Dilated and Arrhythmogenic Cardiomyopathy<br>-Familial hypercholesterolaemia<br>-Hypertrophic Cardiomyopathy<br>-Long QT Syndrome<br>-Non-Compaction Cardiomyopathy<br>-Paediatric or syndromic cardiomyopathy | EDTA Whole blood, DNA | Next Generation Sequencing (NGS) - screening for clinical significant germline SNVs, small (<10) indels and CNVs associated with rare/inherited disorders | Illumina NextSeq2000 | Non-CE | LP-NGS-44<br>LP-NGS-48<br>LP-NGS-49<br><br>American College of Medical Genetics and Genomics (ACMG) and Association for Molecular Pathology (AMP) guidelines Association of Clinical Genomic Science (ACGS) Practice guidelines for Sanger Sequencing Analysis and Interpretation and General Genetic Laboratory Reporting Recommendations |

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|---|---|---|---|---|---|---|
| | -RASopathies<br>-Restrictive Cardiomyopathy<br>-Short QT Syndrome<br>Respiratory:<br>-Pulmonary Arterial Hypertension<br>Ophthalmology:<br>-Anterior Segment Dysgenesis Anophthalmia<br>-Microphthalmia<br>-Cataracts<br>-Infantile Nystagmus<br>-Ocular and Oculo-cutaneous Albinism<br>-Ocular ColobomaOphthalmological Ciliopathies<br>-Optic Neuropathy<br>-Retinal Disorders<br>-Stickler Syndrome<br>-Structural Eye Disease | | | | | |
| | NGS panels<br>Cardiology:<br>Arrhythmogenic Cardiomyopathy<br>Atrial Fibrillation<br>Aortic Diseases<br>Arrhythmias and Sudden Death without Structural Heart Disease<br>Brugada Syndrome<br>Cardiac Conduction Disease<br>Cardiomyopathies and Arrhythmias<br>Cardiomyopathies<br>Congenital Heart | EDTA Whole blood | Next Generation Sequencing (NGS) - screening for clinical significant germline SNPs and small (<10) indels associated with rare and inherited disorders | Illumina NextSeq 500 | CE | LP-NGS-14,<br>LP-NGS-17,<br>LP-NGS-25,<br>LP-NGS-26,<br>LP-NGS-44<br><br>American College of Medical Genetics and Genomics (ACMG) and Association for Molecular Pathology (AMP) guidelines<br><br>Association of Clinical Genomic Science (ACGS) |

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| | Catecholaminergic Polymorphic Ventricular Tachycardia<br>Cardiovascular Diseases<br>Dilated Cardiomyopathy<br>Hypertrophic Cardiomyopathy<br>Long QT Syndrome<br>Non-Compaction Cardiomyopathy<br>RASopathies<br>Restrictive Cardiomyopathy<br>Short QT Syndrome<br>Respiratory:<br>Pulmonary Arterial Hypertension | | | | | |
| | Sanger sequencing | EDTA Whole blood, DNA | Sanger Sequencing - screening for clinically significant germline SNPs and small (<10) indels for the purposes of confirmatory testing, cascade testing & targeted genes | Applied Biosystems SeqStudio | CE | LP-NGS-44, LP-NGS-45 (Sanger Sequencing & Analysis)<br><br>American College of Medical Genetics and Genomics (ACMG) and Association for Molecular Pathology (AMP) guidelines<br><br>Association of Clinical Genomic Science (ACGS)<br>Practice guidelines for Sanger Sequencing Analysis and Interpretation and General Genetic Laboratory Reporting Recommendations |

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| 1075 Molecular genetics - .11 DNA extraction | DNA Extraction | EDTA Whole blood | DNA Isolation | Maxwell RSC 48 | Non-CE | LP-NGS-47 DNA Isolation from Peripheral Blood on the Promega Maxwell |
| | DNA Isolation | | DNA Isolation | Roche MagnaPure 24 | CE | LP-NGS-10 (DNA Isolation from Peripheral Blood on the MagNa Pure 24)<br><br>American College of Medical Genetics and Genomics (ACMG) and Association for Molecular Pathology (AMP) guidelines<br><br>Association of Clinical Genomic Science (ACGS) |

## Mater Misericordiae University Hospital

### 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 | Haematocrit (Hct) **1,2,4 | Blood | Culmulative pulse measurement | Sysmex XN-10/XN 20 | CE | LP-HAE-0067, LP-HAE-0068 |
| | Haemoglobin (Hb) **1,2,4 | | Sodium Lauryl Sulphate (SLS) Haemoglobin | Sysmex XN-10/XN 20 | CE | LP-HAE-0067, LP-HAE-0068 |
| | MCH **1,2,4 | | Calculated from Hb and RBC | Sysmex XN-10/XN 20 | CE | LP-HAE-0067, LP-HAE-0068 |
| | MCHC **1,2,4 | | Calculated from Hb and HCT | Sysmex XN-10/XN 20 | CE | LP-HAE-0067, LP-HAE-0068 |
| | Mean cell volume(MCV) **1,2,4 | | Indirect measurement (mean of RBC volume) | Sysmex XN-10/XN 20 | CE | LP-HAE-0067, LP-HAE-0068 |
| | Platelet count **1,2,3,4 | | Hydrodynamic Focussing Direct Current (DC) detection | Sysmex XN-10/XN 20 | CE | LP-HAE-0067, LP-HAE-0068 |
| | Red cell count(RBC) **1,2,4 | | Hydrodynamic Focussing Direct Current (DC) detection | Sysmex XN-10/XN 20 | CE | LP-HAE-0067, LP-HAE-0068 |
| | White cell count (WBC) **1,2,4 | | Fluorescence Flow Cytometry | Sysmex XN-10/XN 20 | CE | LP-HAE-0067, LP-HAE-0068 |
| 1030 Haematology - .02 Visual examination of blood films | Blood film examination includes Neutrophils, Lymphocytes, Monocytes, Eosinophils, Basophils, Red Cell morphology **2,4 | | Staining/microscopy/Digital imaging | Wescor stainer/ Sysmex SP10 stainer/Microscope/CellaVision DI-60 automated digital imaging analysis system with operator result validation | Based on standard method | LP-HAE-004 LP-HAE-006 LP-HAE-070 LP-HAE-072 |

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| | Blood film examination includes Neutrophils, Lymphocytes, Monocytes, Eosinophils, Basophils, Red Cell morphology **2,4 | Blood in EDTA | Staining/microscopy | Wescor Aerospray Haematology Pro | CE | LP-HAE-007 |
| | Staining of Blood films for the examination of Neutrophils, Lymphocytes, Monocytes, Eosinophils, Basophils, Platelets, Red Cell morphology | | Wrights Giemsa staining | N/A | CE | LP-HAE-107 BSH Guidelines |
| | Staining of Bone marrow aspirate slides | Bone marrow Aspirate | May Grunwald staining | N/A | CE | LP-HAE-107 BSH Guidelines |
| 1030 Haematology - .03 Erthrocyte sedimentation rate | Erythrocyte Sedimentation Rate (ESR) **1,3,4 | Blood | Photo optical based on Westergren method | Sarstedt Sediplus S2000 | CE | LP-HAE-024 |
| 1030 Haematology - .05 Automated differential leucocyte counts | Automated basophil count **1,2,4 | | Fluorescence Flow Cytometry | Sysmex XN-10/XN 20 | CE | LP-HAE-0067, LP-HAE-0068 |
| | Automated eosinophil count **1,2,4 | | Fluorescence Flow Cytometry | Sysmex XN-10/XN 20 | CE | LP-HAE-0067, LP-HAE-0068 |
| | Automated lymphocyte count **1,2,4 | | Fluorescence Flow Cytometry | Sysmex XN-10/XN 20 | CE | LP-HAE-0067, LP-HAE-0068 |
| | Automated monocyte count **1,2,4 | | Fluorescence Flow Cytometry | Sysmex XN-10/XN 20 | CE | LP-HAE-0067, LP-HAE-0068 |
| | Automated neutrophil count **1,2,4 | | Fluorescence Flow Cytometry | Sysmex XN-10/XN 20 | CE | LP-HAE-0067, LP-HAE-0068 |
| 1030 Haematology - .06 Automated reticulocyte counts | Automated reticulocyte count **1,2,4 | | Fluorescence Flow Cytometry | Sysmex XN-10/XN 20 | CE | LP-HAE-0067, LP-HAE-0068 |
| 1030 Haematology - .08 Blood film examinations involving special staining procedures | Iron stain (Bone marrow and Urinary haemosiderin) **2,3,4 | Bone marrow /Urine | Staining/ microscopy | Manual staining technique/ Microscope | Based on standard method | LP-HAE-031 |
| 1030 Haematology - | Malaria Blood film examination **2,4 | Blood | Staining/ microscopy | Manual staining technique/ | Based on | LP-HAE-025, |

| | | | | | | |
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| .09 Examination of malarial parasites | | | | Microscope | standard method | LP-HAE-026 |
| | Malaria screening test **2,4 | | Immunochromatographic card screening test | Manual immunochromatog-raphic card test | CE | LP-HAE-027 |
| 1030 Haematology - .20 Bone marrow examination | Bone marrow examination **1,2,4 | Bone marrow aspirate | Staining/ microscopy | Wescor stainer/Microscope | Based on standard method | LP-HAE-007 |
| | Bone marrow examination **1,2,4 | | Staining/microscopy | Wescor Aerospray Haematology Pro | CE | LP-HAE-040 ICSH guidelines for the standardization of bone marrow specimens and reports 2008 |
| 1030 Haematology - .30 Tests for haemoglobin variants and thalassaemia | Haemoglobin Electrophoresis **1,2,4 | Blood | Capillary Electrophoresis | Sebia Minicap Flex piercing | CE | LP-HAE-083 |
| | HPLC for Haemoglobinopathy **1,2,4 | | High performance liquid chromatography | Biorad D10 | CE | LP-HAE-050 |
| | Sickle cell screen **4 | | Qualitative solubility test for Hb S | Manual test | CE | LP-HAE-028 |
| 1030 Haematology - .36 Screening tests for G6Pd | Glucose 6 Phosphate Dehydrogenase screen **1,2,4 | | Qualitative fluorescence test | Manual test | CE | LP-HAE-029 |
| 1030 Haematology - .40 Limited haemostasis related tests | Activated Protein C resistance **1,4 | | Photo optical | ACL TOP 550 | CE | LP-HAE-089 |
| | Anti Xa level(LMWH) **2,4 | | Chromogenic | ACL TOP 550 | CE | LP-HAE-092 |
| | Anti Xa level(UFH) **2,4 | | Chromogenic | ACL TOP 550 | CE | LP-HAE-097 |

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| | Anticoagulant drug monitoring: Rivaroxaban / Apixaban / Dabigatran **2,4 | | Chromogenic | ACL TOP 550 | CE | LP-HAE-093, LP-HAE-095 |
| | Antithrombin **1,2,4 | | Chromogenic | ACL TOP 550 | CE | LP-HAE-089 |
| | Factor II:C assay **1,2,4 | | Photo optical | ACL TOP 550 | CE | LP-HAE-102 |
| | Factor IX:C assay **1,2,4 | | Photo optical | ACL TOP 550 | CE | LP-HAE-103 |
| | Factor V:C assay **1,2,4 | | Photo optical | ACL TOP 550 | CE | LP-HAE-102 |
| | Factor VII:C assay **1,2,4 | | Photo optical | ACL TOP 550 | CE | LP-HAE-102 |
| | Factor VIII:C assay **1,2,4 | | Photo optical | ACL TOP 550 | CE | LP-HAE-103 |
| | Factor X:C assay **1,2,4 | | Photo optical | ACL TOP 550 | CE | LP-HAE-102 |
| | Factor XI:C assay **1,4 | | Photo optical | ACL TOP 550 | CE | LP-HAE-103 |
| | Factor XII:C assay **1,2,4 | | Photo optical | ACL TOP 550 | CE | LP-HAE-103 |
| | Free Protein S **1,2,4 | | Immuno-turbidimetric | ACL TOP 550 | CE | LP-HAE-089 |
| | Heparin Induced Thrombocytopenia screen (HIT) **1,2,3,4 | Serum | Lateral flow immunoassay | N/A | CE | LP-HAE-106 |
| | Lupus anticoagulant **1,2,4 | Blood | Photo optical | ACL TOP 550 | CE | LP-HAE-090 |
| | Lupus Insensitive Activated Partial Thromboplastin Time(APTT) **1,2,4 | | Photo optical | ACL TOP 550 | CE | LP-HAE-096 |
| | Protein C **1,2,4 | | Chromogenic | ACL TOP 550 | CE | LP-HAE-089 |
| 1030 Haematology - .41 General haemostasis related tests | Activated Partial Thromboplastin Time(APTT) **1,2,4 | | Photo optical | ACL TOP 550 | CE | LP-HAE-087 |
| | Activated Partial Thromboplastin Time (APTT) ** 1,2,3,4 | Blood in Sodium Citrate | Clot based manual method | 20 to 180 seconds / Waterbath | CE | LI-HAE-056 BSH Guidelines |
| | APPT Correction test | | Photo optical | 16 to 400 seconds | CE | LP-HAE-098 BSH Guidelines |

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| | D Dimer **1,4 | Blood | Immuno-turbidimetric | ACL TOP 550 | CE | LP-HAE-087 |
| | Fibrinogen (Clauss) **1,4 | | Photo optical | ACL TOP 550 | CE | LP-HAE-087 |
| | International Normalised ratio (INR) **1,4 | | Photo optical | ACL TOP 550 | CE | LP-HAE-087 |
| | Prothrombin Time **1,2,4 | | Photo optical | ACL TOP 550 | CE | LP-HAE-058 |
| | Prothrombin Time (PT) **1,2,3,4 | Blood in Sodium Citrate | Clot based manual method | 9 to 150 seconds / Waterbath | CE | LI-HAE-056 BSH Guidelines |
| | PT Correction test | | Photo optical | 8 to 320 seconds | CE | LP-HAE-098 BSH Guidelines |
| | Thrombin Time **1,2,4 | Blood | Photo optical | ACL TOP 550 | CE | LP-HAE-088 |
| 1030 Haematology - .57 Screening test for infectious mononucleosis | Infectious mononucleosis screen **3,4 | | Immunoassay | Manual test | CE | LP-HAE-030 |
| 1030 Haematology - .70 Immunophenotyping | Acute panel:Antigens tested; Ig G, CD7, CD10, CD45, CD2, HLADR, CD34, CD45, CD117, CD14, CD13, CD33, CD22, CD19, CD15, CD64, CD56,CD11b,CD35,CD300,CD38,CD58,CD81. cMPO, CD79a, CD3 , TdT **2,3,4 | Blood/BMA | Flow cytometry | BD Facs Canto | CE | LP-HAE-075, LP-HAE-078 |
| | Lymphoproliferative panel:Antigens tested; B-Cell panel: CD45, CD5, CD10, CD19, CD38, CD8, CD4, CD3, CD56, Kappa, Lambda, FMC7, CD23, CD22, Ig M, CD79, CD20, CD200,CD43,CD81. T-Cell panel: CD16, CD7, CD56, CD2, CD4, CD8, CD56,CD30,CD26,CD25,CD57. Hairy Cell (extra): CD103, CD11c, CD19, CD45, CD25. Plasma cell (extra): CD138PE **2,3,4 | | Flow cytometry | BD Facs Canto | CE | LP-HAE-075, LP-HAE-077 |
| | PNH screen:Antigens tested;CD235, CD59, FLAER, CD15,CD33,CD14, CD24 **2,3,4 | Blood | Flow cytometry | BD Facs Canto | CE | LP-HAE-075, LP-HAE-079 |

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## Mater Misericordiae University Hospital

### Haematology

**Category: B**

| 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 | Haemoglobin **2,4 | Whole Blood | Modified Azidemethaemoglobin reaction | HemoCue Hb 201 DM Analyser | Based on standard method | LP-POC-002 |
| 1030 Haematology - .40 Limited haemostasis related tests | Activated Clotting Time - Plus (ACT+) | Native Whole Blood | Mechanical Endpoint Clotting Detection | GEM Hemochron 100 / 68 to 1005 s | CE | LP-POC-020<br>BSH Guideline: Point of Care in General Haematology<br>& CLSI POCT14 |
| | INR **1,4 | Capillary Blood Sample | Electrochemical measurement of INR | Coaguchel XS- pro | Based on standard method | LP-POC-003 |
| 1030 Haematology - .41 General haemostasis related tests | EXTEM C **2,4 | Whole blood | Thromboelastometry | ROTEM sigma analsyer | CE | LP-POC-013 |
| | FIBTEM C **2,4 | | Thromboelastometry | ROTEM sigma analsyer | CE | LP-POC-013 |
| | HEPTEM C **2,4 | | Thromboelastometry | ROTEM sigma analsyer | CE | LP-POC-013 |
| | INTEM C **2,4 | | Thromboelastometry | ROTEM sigma analsyer | CE | LP-POC-013 |

*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*

## Mater Misericordiae University Hospital

### Immunology

**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 |
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| 1040 Immunology - .01 Quantitative investigation of immunoglobulins G,A,M and D in body fluids | Investigation of Monoclonal Gammopathies **1,2,4 | Serum | Binding Site Optilite / Turbidimetry<br>Sebia Capillarys 3 / Immunotyping / Electrophoresis.<br>Sebia Hydrasys / Immunofixation | CE | IgG: 0.3 g/L to 140.0 g/L<br>IgA: 0.02 g/l to 70.0 g/L<br>IgM: 0.1 g/L to 150.0 g/L<br>Total Protein: 0.5 g/L to 300 g/L | LP-IMM-0041<br>LP-IMM-0004<br>LP-IMM-0009<br><br>International Myeloma Working Group (IMWG)<br><br>National Institute for Health and Care Excellence (NICE) |
| | | Urine | Sebia Capillarys 3/Electrophoresis.<br>Sebia Hydrasys/immunofixation<br><br>Monoclonal Band calculated using INAB Accredited CCE Urinary Total Protein level (Abbott Architect c16000 Alinity ci series / Turbidimetry) | CE | N/A<br>Identification by Immunofixation<br><br>Urinary Total Protein: 68 mg/L to 2000 mg/L | LP-IMM-0004<br>LP-IMM-0009<br>LP-CCE-0064<br><br>International Myeloma Working Group (IMWG)<br><br>National Institute for Health and Care |

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| | | | | | | Excellence (NICE) |
| | Total Protein **1,2,4 | Serum | Binding Site Optilite/Turbidimetry Sebia Capillarys 3/Immunotyping/Electrophoresis Sebia Hydrasys/Immunofixation | CE Marked | IgG: 0.3 g/L to 140.0 g/L<br>IgA: 0.02 g/l to 70.0 g/L<br>IgM: 0.1 g/L to 150.0 g/L<br>Total Protein: 0.5 g/L to 300 g/L | LP-IMM-0041<br>LP-IMM-0004<br>LP-IMM-0009<br><br>International Myeloma Working Group (IMWG)<br><br>National Institute for Health and Care Excellence (NICE) |
| 1040 Immunology - .03 Total IgE | Quantitative determination of total IgE in serum **1,2,4 | | Phadia Immunocap 250 analyser/ Enzyme Immunoassay | CE | Total IgE: 2.0 kU/mL to 5000 kU/mL | LP-IMM-0012<br><br>National Clinical Programme for pathology (NCP) |
| 1040 Immunology - .04 Allergen - specific IgE | Quantitative investigation of serum samples for Allergen specific IgE **1,2,4 | | Phadia Immunocap 250 analyser/ Enzyme Immunoassay | CE | Specific IgE: 0.1 KuA/L to 100 KuA/L | LP-IMM-0012<br><br>National Clinical Programme for pathology (NCP) |
| | Quantitative investigation of serum samples for Allergen specific IgG **1,2,4 | | Phadia Immunocap 250 analyser/ Enzyme Immunoassay | CE | Specific IgG: 2.0 mgA/L to 200 mgA/L | LP-IMM-0012<br><br>National Clinical Programme for pathology (NCP) |
| 1040 Immunology - .06 Investigation of complement | Quantitative determination of C1 esterase inhibitor, C3 | | Optilite / Turbidmetry | CE | N/A | LP-IMM-0041 |

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| | and C4 of the compliment pathway **1,2,3,4 | | | |
| 1040 Immunology - .12 Detection of autoantibodies in body fluids and biopsy material | Anti-Cardiolipin IgG Antibodies / ACA **1,2,4 | Phadia Immunocap 250 analyser/ Enzyme Immunoassay | CE | ACA IgG: 0.5 GPL - U/ml to 418 GPL-U/ml | LP-IMM-0012 National Clinical Programme for pathology (NCP) |
| | Anti-Cardiolipin IgM Antibodies / ACA **1,2,4 | Phadia Immunocap 250 analyser/ Enzyme Immunoassay | CE | ACA IgM: 0.9 MPL-U/mL to 472 MPL-U/mL | LP-IMM-0012 National Clinical Programme for pathology (NCP) |
| | Anti-Cyclic Citrullinated Peptide / Anti-CCP Antibodies **1,2,4 | Phadia Immunocap 250 analyser/ Enzyme Immunoassay | CE | CCP: 0.4 U/mL to 340 U/mL | LP-IMM-0012 American College of Rheumatology (ACR) Guidelines |
| | Anti-Glutamic Acid Decarboxylase/Anti-GAD Antibodies **1,2,4 | Dynex DS2 Analyser / ELISA | CE | GAD: 5 IU/mL to 2000 IU/mL | LP-IMM-0034 LP-IMM-0015 National Institute for Health and Care Excellence (NICE)<br><br>Sheffield PRU - Autoimmunity |
| | Anti-Intrinsic Factor / Anti-IFA Antibodies **1,2,4 | Phadia Immunocap250 analyser/Enzyme Immunoassay | CE | 0.5 U/mL to 480.0 IU/mL | LP-IMM-0012 National Institute for Health and Care Excellence (NICE)<br><br>Sheffield PRU - Autoimmunity |
| | Anti-Liver Kidney Microsomal (Anti-LKM) Confirmatory | Phadia Immunocap 250 Analyser / Enzyme Immunoassay | CE | 0.4-168 U/ml | LP-IMM-0012<br><br>British Society of |

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| test **1,2,4 | | | | Gastroenterology (BSG)<br><br>Sheffield PRU - Autoimmunity |
| Anti-Mitochondrial / Anti-M2 Antibodies **1,2,4 | Phadia Immunocap 250 analyser/ Enzyme Immunoassay | CE | 0.5 U/mL to 220.0 IU/mL | LP-IMM-0012<br>National Institute for Health and Care Excellence (NICE)<br><br>Sheffield PRU - Autoimmunity |
| Beta-2 Gglycoprotein-1 IgG **1,2,4 | Phadia Immunocap 250 analyser/ Enzyme Immunoassay | CE | ß2GP1 IgG: 0.8 U/mL to 532 U/mL | LP-IMM-0012<br>National Clinical Programme for pathology (NCP) |
| Beta-2 Glycoprotein-1 IgM **1,2,4 | Phadia Immunocap 250 analyser/ Enzyme Immunoassay | CE | ß2GP1 IgM: 0.9 U/mL to 576 U/mL | LP-IMM-0012<br>National Clinical Programme for pathology (NCP) |
| Centromere **1,2,4 | Phadia Immunocap 250 analyser/ Enzyme Immunoassay | CE | Centromere: 0.4 U/mL to 240 U/mL | LP-IMM-0012<br>National Clinical Programme for pathology (NCP) |
| Connective Tissue Disease (CTD) Screen **1,2,4 | Phadia Immunocap250 analyser/ Enzyme Immunoassay | Enzyme Immunoassay | CTD: 0.03 to 32 ratio | LP-IMM-0012<br>LI-IMM-0044<br>National Clinical Programme for pathology (NCP) |
| ds-DNA **1,2,4 | Phadia Immunocap 250 analyser/ Enzyme Immunoassay | CE | dsDNA:0.5 IU/mL to 379 IU/mL | LP-IMM-0012<br>National Clinical Programme for pathology (NCP) |
| Extractable Nuclear Antigen / ENA - Jo-1 | Phadia Immunocap 250 analyser / Enzyme | CE | 0.3 U/mL to 240.0 U/mL | LP-IMM-0012<br>National Clinical |

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| **1,2,4 | Immunoassay | | | Programme for pathology (NCP) |
| Extractable Nuclear Antigen / ENA - La **1,2,4 | Phadia Immunocap 250 analyser / Enzyme Immunoassay | CE | 0.4 U/mL to 320.0 U/mL | LP-IMM-0012 National Clinical Programme for pathology (NCP) |
| Extractable Nuclear Antigen / ENA - RNP70 **1,2,4 | Phadia Immunocap 250 analyser / Enzyme Immunoassay | CE | 0.3 U/mL to 240.0 U/mL | LP-IMM-0012 National Clinical Programme for pathology (NCP) |
| Extractable Nuclear Antigen / ENA - Ro **1,2,4 | Phadia Immunocap 250 analyser / Enzyme Immunoassay | CE | 0.4 U/mL to 240.0 U/mL | LP-IMM-0012 National Clinical Programme for pathology (NCP) |
| Extractable Nuclear Antigen / ENA - Scl-70s **1,2,4 | Phadia Immunocap 250 analyser / Enzyme Immunoassay | CE | 0.6 U/mL to 240.0 U/mL | LP-IMM-0012 National Clinical Programme for pathology (NCP) |
| Extractable Nuclear Antigen / ENA - SmD P-S **1,2,4 | Phadia Immunocap 250 analyser / Enzyme Immunoassay | CE | 0.7 U/mL to 330.0 U/mL | LP-IMM-0012 National Clinical Programme for pathology (NCP) |
| Extractable Nuclear Antigen / ENA - U1RNP **1,2,4 | Phadia Immunocap 250 analyser / Enzyme Immunoassay | CE | 0.5 U/mL to 240.0 U/mL | LP-IMM-0012 National Clinical Programme for pathology (NCP) |
| Glomerular Basement Membrane/GBM **1,2,4 | Phadia Immunocap 250 analyser/ Enzyme Immunoassay | CE | 1.5 U/mL to 680.0 U/mL | LP-IMM-0012 International Consensus on ANCA |
| Myeloperoxidase/ MPO **1,2,4 | Phadia Immunocap 250 analyser/ Enzyme Immunoassay | CE | 0.2 U/mL to 134.0 U/mL | LP-IMM-0012 International Consensus on ANCA |
| Proteinase -3 / PR3 **1,2,4 | Phadia Immunocap 250 analyser/ Enzyme | CE | 0.6 U/mL to 177.0 U/mL | LP-IMM-0012 International |

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| | | | Immunoassay | | | Consensus on ANCA |
| | Rheumatoid Factor/ RF **1,2,4 | | Phadia Immunocap 250 analyser/ Enzyme Immunoassay | CE | 0.6 IU/mL to 200.0 IU/mL | LP-IMM-0012 American College of Rheumatology (ACR) Guidelines |
| | Tissue Transglutaminase / TTG IgA **1,2,4 | | Phadia Immunocap 250 analyser/ Enzyme Immunoassay | CE | 0.2 U/mL to 128.0 U/mL | LP-IMM-0012 National Clinical Programme for pathology (NCP) |
| | Tissue Transglutaminase / TTG IgG **1,2,4 | | Phadia Immunocap 250 analyser/ Enzyme Immunoassay | CE | 0.6 U/mL to 600.0 U/mL | LP-IMM-0012 National Clinical Programme for pathology (NCP) |
| 1040 Immunology - .13 Cryoglobulins | Identification of the presence of Cryoglobulin **2,3,4 | | Sebia Hydrasys / Immunofixation | CE | Presence detected visually | LP-IMM-0011<br><br>National Institute for Health and Care Excellence (NICE) |
| 1040 Immunology - .14 b2-microglobulin | Beta-2-microglobulin **1,2,4 | | Binding Site Optilite / Turbidimetry | CE | 0.3 mg/L to 40.0 mg/L | LP-IMM-0041 International Myeloma Working Group (IMWG)<br><br>National Institute for Health and Care Excellence (NICE) |
| 1040 Immunology - .23 Tests of cellular immunity - quantitation of lymphocytes | Lymphocyte subset analysis for CD16/CD56 Count **1,2,4 | EDTA whole blood | Becton Dickinson FACS CANTO SPA3/ Flow cytometry | CE | Enumeration calculated using Becton Dickenson FacsCanto software | LP-IMM-0001 LP-IMM-0007 International Clinical Cytometry Society (ICCS) |
| | Lymphocyte subset analysis for CD19 Count **1,2,4 | | Becton Dickinson FACS CANTO SPA3/ Flow cytometry | CE | Enumeration calculated using Becton Dickenson | LP-IMM-0001 LP-IMM-0007 International Clinical |

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| | | | | | FacsCanto software | Cytometry Society (ICCS) |
| | Lymphocyte subset analysis for CD3/CD4 Count **1,2,4 | | Becton Dickinson FACS CANTO SPA3/ Flow cytometry | CE | Enumeration calculated using Becton Dickenson FacsCanto software | LP-IMM-0001 LP-IMM-0007 International Clinical Cytometry Society (ICCS) |
| | Lymphocyte subset analysis for CD3/CD8 Count **1,2,4 | | Becton Dickinson FACS CANTO SPA3/ Flow cytometry | CE | Enumeration calculated using Becton Dickenson FacsCanto software | LP-IMM-0001 LP-IMM-0007 International Clinical Cytometry Society (ICCS) |
| 1040 Immunology - .60 Simple slide tests for biochemical and immunological analytes | Anti-Liver Kidney Microsomal/Anti-LKM **1,2,4 | Serum | Helmed automated IFA processor / Indirect Immunofluorescence | CE | 1/10 to 1/40 | LP-IMM-0006 LP-IMM-0030<br><br>British Society of Gastroenterology (BSG)<br><br>Sheffield PRU - Autoimmunity |
| | Anti-Neutrophil Cytoplasmic Antibodies/ANCA **2,4 | | Helmed automated IFA processor / Indirect Immunofluorescence | CE | 1/20 | LP-IMM-0027 LP-IMM-0030<br><br>International Consensus on ANCA International Consensus on ANCA |
| | Anti-Nuclear Antibodies/ANA **1,2,4 | | Helmed automated IFA processor / Indirect Immunofluorescence | CE | 1/40 to 1/640 | LP-IMM-0005 LP-IMM-0030<br><br>National Clinical Programme for Pathology (NCP) |
| | ds -DNA Crithidia **2,4 | | Helmed automated IFA processor / Indirect | CE | 1/10 | LP-IMM-0008 LP-IMM-0030 |

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| | | Immunofluorescence | | | National Clinical Programme for Pathology (NCP) |
| | Endomysial Antibodies/EMA **2,4 | Helmed automated IFA processor / Indirect Immunofluorescence | CE | 1/5 | LP-IMM-0026<br>LP-IMM-0030<br><br>National Clinical Programme for Pathology (NCP) |
| | Mitochondrial Antibodies/AMA **1,2,4 | Helmed Automated IFA Processor / Indirect Immunofluorescence | CE | 1/10 to 1/40 | LP-IMM-0006<br>LP-IMM-0030<br>Sheffield PRU - Autoimmunity<br><br>Sheffield PRU-Autoimmunity |
| | Parietal Cell Antibodies/PCA **1,2,4 | Helmed Automated IFA Processor / Indirect Immunofluorescence | CE | 1/10 to 1/40 | LP-IMM-0006<br>LP-IMM-0030<br>Sheffield PRU - Autoimmunity<br><br>Sheffield PRU-Autoimmunity |
| | Skin Antibodies / BP and PV Antibodies **2,4 | Helmed automated IFA processor / Indirect Immunofluroescence | CE | 1/20 | LP-IMM-0028<br>LP-IMM-0030<br>Sheffield PRU - Autoimmunity |
| | Smooth Muscle Antibodies/SMA **1,2,4 | Helmed automated IFA processor / Indirect Immunofluorescence | CE | 1/10 to 1/160 | LP-IMM-0006<br>LP-IMM-0030<br>Sheffield PRU - Autoimmunity<br><br>Sheffield PRU-Autoimmunity |
| 1040 Immunology - .61 | Serum free light | Binding Site Optilite / | CE | Kappa: 0.6 mg/L to | LP-IMM-0041 |

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| Proteins, quantitative analysis | chains – Free Kappa and Free Lambda **1,2,3,4 | | Turbidimetry | | 127000 mg/L Lambda: 1.3 mg/L to 139000 mg/L | International Myeloma Working Group (IMWG)<br><br>National Institute for Health and Care Excellence (NICE) |
| 1040 Immunology - .99 Miscellaneous tests | Alpha-1-antitrypsin/ATT **1,2,4 | | Binding Site Optilite / Turbidimetry | CE | 0.35 g/L to 5.00 g/L | LP-IMM-004 National Clinical Programme for pathology (NCP) |
| | Antistreptolysin/ASO **1,2,4 | | Binding Site Optilite / Turbidimetry | CE | 5.0 IU/L to 1600.0 IU/L | LP-IMM-0041 WHO Expert Committee |
| | Caeruloplasmin **1,2,4 | | Binding Site Optilite / Turbidimetry | CE | 0.04 g/L to 1.64 g/L | LP-IMM-0041 Sheffield PRU – Clinical Immunochemistry |
| | Calprotectin **1,2,4 | Faeces | Liaison XL Diasorin / Chemiluminescence | CE | 5.0 µg/g to 800.0 µg/g | LP-IMM-0040 National Institute for Health and Care Excellence (NICE) |
| | Haptoglobin **1,2,4 | Serum | Binding Site Optilite / Turbidimetry | CE | 0.026 g/L to 8.0 g/L | LP-IMM-0041 Sheffield PRU – Clinical Immunochemistry |

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*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*

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| *directly from the laboratory* |

## Mater Misericordiae University Hospital

### 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 & |
|---|---|---|---|---|---|---|
| 1011 Macroscopic examination and description | Macroscopic examination and description of specimens | Sputum/Fluids/Faeces/CSF | Manual/Visual | Based on standard method | Qualitative | LP-MIC-RC<br>LP-MIC-RC<br>LP-MIC-RC<br>LP-MIC-RC<br>,LP-MIC-R<br>LP-MIC-RC<br>LP-MIC-RC<br>UK SMI |
| 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) | Fluids in EDTA /, CSF | Urine | Microscope/Staining and Microscopy | Based on standard method | Quantitative for red blood cells and white blood cells. % polymorphonuclear cells and % mononuclear cells | LP-MIC-RC<br>LP-MIC-RC<br>LP-MIC-RC<br>LP-MIC-ID<br>UK SMI, |
| | Gram stain | Tissue/Fluids/ Corneal scrapings/Sinus Aspirates/ Pus/ Bone/ Theatre swabs/CSF/Vaginal/Endocervical/Cervical | Microscope / Staining and Microscopy | Based on standard method | Presence or absence of bacteria and white blood | LP-MIC-ID<br>LP-MIC-RC<br>LP-MIC-RC |

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| | | and Urethral swabs in Amies transport medium | | | cells | LP-MIC-RC<br>UK SMI |
| 1012 Preparation of films on glass slides followed by microscopic examination with or without fixation and staining with dyes as required - .02 Microscopic examination for parasites | Microscopic examination for Cryptosporidium | Faeces | Microscope / Staining and Microscopy | Based on standard method | Presence or absence of cysts and oocytes | LP-MIC-RC<br>LP-MIC-RC<br>UK SMI |
| | Microscopic examination for ova & parasites | Urine/Faeces | Microscope / Concentration and Microscopy | Based on standard method | Protozoa: presence of cysts and oocytes Helminths:presence or absence of eggs or larvae | LP-MIC-RC<br>UK SMI |
| 1012 Preparation of films on glass slides followed by microscopic examination with or without fixation and staining with dyes as required - .03 Microscopic examination for fungi | Microscopic examination for fungi using potassium hydroxide (KOH) and Calcofluor white stain | BAL/Skin/Hair/Nails | Microscope / Staining and Microscopy | Based on standard method | Presence or absence of fungal hyphae | LP-MIC-RC<br>LP-MIC-RC<br>UK SMI |
| 1012 Preparation of films on glass slides followed by microscopic examination with or without fixation and staining with dyes as required - .04 Microscopic examination for mycobacteria | Microscopic examination for acid-fast bacilli (AFB) using Auramine O Stain | Respiratory samples, tissue/bone samples, fluids/CSF | Microscope / Concentration, Staining and Microscopy | Based on standard method | Presence or absence of acid fast bacilli (AFB) | LP-MIC-RC<br>LP-MIC-IDI<br>UK SMI |
| 1013 Culture of | Culture of cerebrospinal fluid | CSF | Manual/Culture | Based on | Qualitative | LP-MIC-RC |

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| organisms in liquid or agar based culture media with visual or instrument monitoring for growth - .01 Culture of general bacteria | (CSF) specimens | | | standard method | | UK SMI PHE UK Standards Microbiolog Investigatio Cerebrospi Fluid |
| | Culture of faecal specimens | Faeces | Manual/Agar and enrichment culture | Based on standard method | Qualitative | LP-MIC-RC LP-MIC-RC UK SMI |
| | Culture of genital tract & associated specimens | Swabs: Vaginal, Endocervical, Cerevical, Urethral, Rectal, Pharyngeal in Amies transport medium. Bartholins gland aspirate, pus and IUD | Manual/Culture | Based on standard method | Qualitative | LP-MIC-RC LP-MIC-RC UK SMI |
| | Culture of respiratory specimens for bacterial pathogens other than Mycobacteria | Respiratory samples | Manual/Culture | Based on standard method | Qualitative | LP-MIC-RC LP-MIC-RC UK SMI |
| | Culture of specimens from superficial & deep seated infections | Wounds/Tissue/ Fluids/Swabs in Amies transport medium/IV tips | Manual/Agar and enrichment culture | Based on standard method | Qualitative | LP-MIC-RC LP-MIC-RC UK SMI |
| | Culture of urine specimens | Urine | Manual/Culture | Based on standard method | Qualitative | LP-MIC-RC LP-MIC-RC UK SMI |
| | Screening of specimens for Carbapenemase-producing Enterobacteriaceae (CPE), Methicillin-resistant Staphylococcus aureus (MRSA), Methicillin-susceptible Staphylococcus aureus (MSSA), Vancomycin-resistant Enterococci (VRE) and Candida | Swabs in Amies transport medium & Faeces | Manual/Culture | Based on standard method | Qualitative | LP-MIC-RC LP-MIC-RC UK SMI |
| 1013 Culture of organisms in liquid or agar based culture | Culture of fungi | Skin/Nails/Hair/Respiratory samples/Corneal scrapings/Contact lens/CSF/Tissues/Fluids/Swabs (in Amies | Manual/Culture | Based on standard method | Qualitative | LP-MIC-RC UK SMI |

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| media with visual or instrument monitoring for growth - .02 Culture of fungi | | transport medium)/Urines | | | | |
| 1013 Culture of organisms in liquid or agar based culture media with visual or instrument monitoring for growth - .03 Culture of mycobacteria | Culture of Mycobacteria | Blood culture and bone marrow (Myco/F lytic Culture vials) | BACTEC FX / Advanced fluorescence detection technology | CE | Qualitative | LP-MIC-RC UK SMI |
| | | Respiratory samples/tissue/bone samples/fluids/CSF/urine | BacTALERT 3D / Automated colorimetric microbial detection | CE | Mycobacterium tuberculosis ≤14 cfu Mycobacterium kansasii≤4cfu Mycobacterium avium ≤15 cfu | LP-MIC-RC UK SMI |
| 1014 Detection of bacterial, parasite, viral or fungal antigens using specific antibodies and appropriate techniques - .01 Slide agglutination, | Salmonella, Shigella and Vibrio typing | Isolate on nutrient agar slope | Manual/Slide agglutination | CE | Visible agglutination in the presence of homologous cultures | LP-MIC-RC UK SMI |
| 1014 Detection of bacterial, parasite, viral or fungal antigens using specific antibodies and appropriate techniques - .02 Particle agglutination | Identification of E. coli 0157 using latex agglutination test | Isolate | Manual/Particle agglutination | CE | Visible agglutination in the presence of homologous cultures | LP-MIC-IDI |
| | Identification of Staphylococcus aureus using Pastorex agglutination test | | Manual/Particle agglutination | CE | Visible agglutination in the presence of homologous cultures | LP-MIC-IDI |
| | Identification of Streptococcus pneumoniae using Dry Spot | Blood culture and isolates | Manual/Particle agglutination | CE | Visible agglutination in the | LP-MIC-IDI UK SMI |

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| | Pnemo latex agglutination test | | | | presence of homologous cultures | |
| | Streptococcal Grouping using latex agglutination test | Isolate | Manual/Particle agglutination | CE | Visible agglutination in the presence of homologous cultures | LP-MIC-IDI |
| 1014 Detection of bacterial, parasite, viral or fungal antigens using specific antibodies and appropriate techniques - .03 Enzyme immunoassay, | Detection of Aspergillus galactomannan antigen | Bronchoalveolar Lavage (BAL) and serum | Allsheng Microplate reader / ELISA Spectrophotometry | CE | BAL: Not detected= <1; Detected= >1. Serum: Not detected= <0.5; Detected= >0.5 | LP-MIC-RG UK SMI |
| | Detection of latent tuberculosis infection using the QuantiFERON®-TB Plus Assay. | Blood (QFT-Plus) | Diasorin Liason XL / Chemiluminescence assay | CE | Assay range: up to 10 IU/ml of IFN-gamma | LP-MIC-RG UK SMI WHO Guid |
| 1014 Detection of bacterial, parasite, viral or fungal antigens using specific antibodies and appropriate techniques - .04 Immunochromatographic methods, | Detection of Aspergillus galactomannan antigen | Bronchoalveolar Lavage (BAL) | IMMY Cube Reader / Immunochromatography assay | CE | Qualitative | LP-MIC-IDI UK SMI HSPC Nati guidelines prevention nosocomia aspergillosi EORTC/MS criteria for diagnosis c invasive fu disease |
| | Detection of Cryptococcal Antigen | CSF & serum | Manual/Immuno-chromatographic assay | CE | Qualitative | LP-MIC-RG UK SMI |
| | Detection of Legionella urinary antigen | Urine | Manual/Immuno-chromatographic assay | CE | Presence or absence of L. | LP-MIC-RG UK SMI |

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| | | | | | pneumophila serogroup 1 antigen | |
| | Detection of Mycobacterium tuberculosis (MTB) complex using the BD MGIT TBc assay | Isolates | Manual/Immuno-chromatographic assay | CE | Presence or absence of MPT64 antigen | LP-MIC-RC UK SMI |
| | Detection of OXA-48, KPC, NDM, VIM and IMP carbapenemase enzymes using the O.K.N.V.I RESIST-5 | | Manual/Immunochromatographic assay | CE | Qualitative | LP-MIC-RC IDEN-23, Eucast Gui UK SMI |
| | Detection of streptococcus pneumoniae urinary antigen | Urine | Manual/Immuno-chromatographic assay | CE | Presence or absence of Streptococcus pneumoniae antigen LOD:1:250 dilution | LP-MIC-RC |
| | Detection of urinary hCG | | Manual/Immuno-chromatographic assay | CE | Samples containing <25 mIU/mL hCG may test positive, but samples containing <5 mIU/mL hCG should be negative | LP-MIC-RC |
| 1015 Detection and/or identification of bacterial, parasite, fungal and viral nucleic acids - .01 Nucleic acid probe hybridization, CE marked commercial systems | FilmArray Meningitis / Encephalitis ME panel | CSF | Amplification and detection of target DNA and RNA on FilmArray 2.0 | CE marked | Qualitiative | LP-MIC-RC PHE UK Standards Microbiolog Investigatic Cerebrospi Fluid, PHE UK Standards Microbiolog Good Labo Practice wh Performing |

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| | | | | | | Molecular Amplificatio Assays |
| | HAIN CM | DNA Extract from positive culture bottles | PCR Thermal Cycler & Twincubator / Amplification and detection of target DNA | CE marked | Qualitiative | LP-MIC-RC PHE UK Standards: Investigatio specimens Mycobacte species, Good Labo Practice wh Performing Molecular Amplificatio Assays |
| | HAIN MTBC | | PCR Thermal Cycler & Twincubator / Amplification and detection of target DNA | CE marked | Qualitiative | LP-MIC-RC PHE UK Standards Investigatio specimens Mycobacte species, PHE UK Standards Microbiolog Good Labo Practice wh Performing Molecular Amplificatio Assays |
| 1015 Detection and/or identification of bacterial, parasite, fungal and viral nucleic acids - .03 Nucleic acid | Chlamydia trachomatis and Neisseria gonorrhoeae | Endocervical/ Cervical Genxpert swabs/UTM viral transport media & FVU | Cepheid GeneXpert / Amplification and detection of target DNA | CE marked | Detected / Not detected | LP-MIC-RC PHE UK Standards Microbiolog Chlamydia |

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| amplification tests, CE marked commercial systems | | | | | | trachomatis Infection – Testing by Acid, Good Labo Practice wh Performing Molecular Amplificatio Assays |
| | CRE | Isolates & rectal swabs (Copan dual swab) | Cepheid GeneXpert / Amplification and detection of target DNA | CE marked | Detected / Not detected | LP-MIC-RG PHE UK Standards Microbiolog Good Labo Practice wh Performing Molecular Amplificatio Assays |
| | Detection of Carbenpenamse using FlowFlex Technology | Rectal swab (Copan faecal swab) | Roche FlowFlex PCR Technology | CE Marked | KPC: cut off 37, OXA 48: cut off 37, VIIM cut off 38, IMP cut off 38, NDM cut off | LP-MIC-RG PHE UK Standards Microbiolog Good Labo Practice wh Performing Molecular Amplificatio Assays |
| | Identification of M. tuberculosis complex direct from specimens using Xpert MTB/RIF Ultra kit on the Cepheid GeneXpert Dx System | Sputum (Direct) | Cepheid GeneXpert / Amplification and detection of target DNA | CE marked | Detected / Not detected | LP-MIC-RG PHE UK Standards Microbiolog Good Labo Practice wh Performing Molecular |

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| | Sputum sediment | Cepheid GeneXpert / Amplification and detection of target DNA | CE marked | Detected / Not detected | LP-MIC-RC PHE UK Standards Microbiolog Good Labo Practice wh Performing Molecular Amplificatio Assays, PHE UK Standards Investigatio specimens Mycobacte species |
| Molecular detection of bacteria and virsues on BioFire ME panel | CSF | Biomeriux Biofire Torch / Amplification and detection of target DNA | CE marked | Qualitative | LP-MIC-RC |
| Molecular detection of bacteria on BioFire Joint infection panel on the Biofire Torch | Synovial fluids | Biomeriux Biofire Torch / Amplification and detection of target DNA | CE marked | Qualitative | LP-MIC-RC |
| Molecular detection of bacteria on BioFire Joint infection panel on the FilmArray | | Amplification and detection of target DNA on the FilmArray | CE marked | Qualitative | LP-MIC-RC PHE UK Standards Microbiolog Good Labo Practice wh |

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| | | | | | Performing Molecular Amplificatio Assays |
| Molecular detection of Carbapenemase Producing Enterobacterales (CPE) using Cepheid Genexpert system | Rectal swab (Copan faecal swab) | Cepheid Genexpert / Amplification and detection of target DNA on system | In House Developed | N/A | PHE UK Standards Laboratory Practice wh Performing Molecular Amplificatio Assays LP-MIC-RC |
| Molecular detection of COVID/FLU/RSV on Cepheid GeneXpert DX System | Nasopharangeal(Genexpert/UTM) | Cepheid GeneXpert / Amplification and detection of target DNA | CE marked | Detected / Not detected | LP-MIC-RC PHE UK Standards Microbiolog Good Labo Practice wh Performing Molecular Amplificatio Assays |
| Molecular detection of mecA and mecC in MRSA isolates using XPERT NG | Isolates | Cepheid GeneXpert / Amplification and detection of target DNA | CE marked | Detected / Not detected | LP-MIC-RC PHE UK Standards Microbiolog Good Labo Practice wh Performing Molecular Amplificatio Assays |
| Molecular detection of respiratory viruses and bacteria on BioFire RP2.1 Plus on the BioFire Torch | Nasopharyngeal (Genexpert/UTM) | Biomeriux Biofire Torch / Amplification and detection of target DNA | CE marked | Qualitative | LP-MIC-RC |

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| Molecular detection of respiratory viruses and bacteria on BioFire RP2.1 Plus on the FilmArray | Nasopharangeal (Genexpert/UTM) | BioFire RP2.1 Plus on the Film Array / Amplification and detection of target DNA | CE marked | Qualitative | LP-MIC-RG<br>LP-MIC-RG<br>PHE UK<br>Standards<br>Microbiolog<br>Good Labo<br>Practice wh<br>Performing<br>Molecular<br>Amplificatio<br>Assays |
| Molecular detection of Trichomonas vaginalis | First void urine/ Endocervical swab | Cepheid GeneXpert / Amplification and detection of target DNA | CE marked | Detected / Not detected | LP-MIC-RG<br>PHE UK<br>Standards<br>Microbiolog<br>Good Labo<br>Practice wh<br>Performing<br>Molecular<br>Amplificatio<br>Assays |
| Molecular detection of Aspergillus fumigatus, Aspergillus terreus, Aspergillus flavus, Aspergillus species and azole-resistance markers TR34 and TR46 | Bronchoalveolar Lavage | Pathonostics PneumoGenius Roche Lightcycler 480 II / Amplification and detection of target DNA on EntericBio system | CE Marked | N/A | PHE UK<br>Standards<br>Microbiolog<br>Investigatio<br>Good Pract<br>when Perfo<br>Molecular<br>Amplificatio<br>Assays<br>LP-MIC-RG |
| Molecular screen for Norovirus, Asterovirus, Sapovirus, Adenovirus and Rotavirus using Entericbio system | Faeces | Entericbio workstation Roche Lightcycler 480 II / Amplification and detection of target DNA on EntericBio system | CE Marked | N/A | PHE UK<br>Standards<br>Microbiolog<br>Investigatio<br>Gastroente<br>PHE UK<br>Standards |

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| Molecular screen for Salmonella, Shigella/Enteroinvasive E. coli (EIEC), Campylobacter, STEC/VTEC, Gardia and Cryptosporidium using Entericbio system | | Entericbio workstation Roche Lightcycler 480 II / Amplification and detection of target DNA on EntericBio system | CE Marked | N/A | PHE UK Standards<br>Microbiolog<br>Investigatio<br>Gastroente<br>PHE UK Standards<br>Microbiolog<br>Investigatio<br>Good Prac<br>when Perfo<br>Molecular<br>Amplificatio<br>Assays<br>LP-MIC-RG |
| Molecular screen for Toxigenic Clostridium difficile using Entericbio system | | Entericbio workstation Roche Lightcycler 480 II / Amplification and detection of target DNA on EntericBio system | CE Marked | N/A | PHE UK Standards<br>Microbiolog<br>Investigatio<br>Gastroente<br>PHE UK Standards<br>Microbiolog<br>Investigatio<br>Good Prac<br>when Perfo<br>Molecular<br>Amplificatio<br>Assays<br>LP-MIC-RG |

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| Norovirus Genogroup I and II | | Cepheid GeneXpert / Amplification and detection of target DNA | CE marked | Detected / Not detected | LP-MIC-RC PHE UK Standards Microbiolog Good Labo Practice wh Performing Molecular Amplificatic Assays, PHE UK Standards Investigatic Faecal Specimens Enteric Pathogens |
| Toxigenic Clostridium difficile | | Amplification and detection of target DNA on BD Max | Based on standard method | Detected / Not detected | LP-MIC-RC PHE UK Standards Microbiolog Good Labo Practice wh Performing Molecular Amplificatic Assays, PHE UK Standards Investigatic Faecal Specimens Enteric Pathogens |
| Verification of VRE Viasure molecular assay on Roche Flow flex system | Rectal swabs | Roche FlowFlex system / Amplification and detection of target DNA | CE marked | Qualitative | LP-MIC-RC PHE UK Standards Microbiolog |

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| | Verification of VRE Viasure molecular assay on Roche FlowFlex System | | Roche FlowFlex Syatem / Amplification and detection of target DNA | CE marked | Qualitative | LP-MIC-RC |
| | Xpert CARBA-R | Rectal swabs & Isolates | Cepheid GeneXpert / Amplification and detection of target DNA | CE marked | N/A | LP-MIC-RC |
| 1016 Identification of cultured bacteria and fungi using non-nucleic acid based techniques - .01 Biochemical methods , CE marked commercial systems | API 32C for identification of yeasts | Isolates | Biochemical reactions | CE marked | Qualitative | LP-MIC-IDI |
| | API NH | | N/A / Fermentation, decarboxylation etc | CE marked | Qualitative | LP-MIC-IDI |
| | Dnase | | N/A / Hydrolysis of DNA | Based on standard method | Qualitative | LP-MIC-IDI |
| | Phenotypic confirmation of ESBL's | | Disc diffusion | Based on standard method | Qualitative | LP-MIC-IDI Eucast Gui |
| | VITEK Identification | | VITEK 2XL / Fermentation, decarboxylation etc | CE marked | Qualitative | LP-MIC-RC |
| 1016 Identification of cultured bacteria and fungi using non-nucleic acid based techniques - .03 Identification of fungi by microscopic morphology | Lactophenol cotton blue | Fungal Isolates | Microscope / Staining & Microscopy | Based on standard method | Presence/Absence of fungal hyphae | LP-MIC-RC PHE UK Standards Microbiolog Investigatio Dermatolog Specimens Superficial |

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| 1016 Identification of cultured bacteria and fungi using non-nucleic acid based techniques - .04 Identification using MALDI-TOF Spectroscopy | Identification using MALDI-TOF Spectroscopy | Isolates | VITEK MS / Mass Spectrophotometry | CE marked | Qualitative | LP-MIC-RC |
| 1017 Measurement of antimicrobial activity and application of clinical interpretive criteria to general bacteria (rapidly growing aerobes) - .01 Anaerobes | Antimicrobial susceptibility testing | Anaerobic Bacterial isolates | Minimum inhibitory strip diffusion & disc diffusion | CE marked | Qualitative | LP-MIC-RC ED-MIC-RE |
| | | Isolates | N/A / Disc diffusion | CE marked | Refer to Eucast Guidelines | LP-MIC-RC Eucast Gui |
| | | | VITEK 2XL / Broth MIC | CE marked | Refer to Eucast Guidelines | LP-MIC-RC Eucast Gui |
| | | Neisseria Gonorrhoea isolates | Minimum inhibitory strip diffusion | CE marked | Qualitative | LP-MIC-RC ED-MIC-RE |
| | Cefpodoxime combination disc kit | Isolates | N/A / Disc diffusion | CE marked | Refer to Eucast Guidelines | LI-MIC-36, Eucast Gui |
| | Minimum inhibitory concentration | | N/A / Minimum inhibitory strip diffusion | CE marked | Refer to Eucast Guidelines | LP-MIC-RC Eucast Gui |
| | Total ESBL confirmation kit | | N/A / Disc diffusion | CE marked | Refer to Eucast Guidelines | LI-MIC-36, Eucast Gui |
| 1017 Measurement of antimicrobial activity and application of clinical interpretive criteria to general bacteria (rapidly growing aerobes) - .02 | HAIN MTBDRplus | Extract from positive culture bottles | PCR Thermal Cycler & Twincubator / Amplification and detection of target DNA | CE marked | Qualitative | LP-MIC-RC PHE UK Standards Microbiolog Good Labo Practice wh Performing |

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| Mycobacteria | | | | | | Molecular Amplificatio Assays |
| | | | PCR Thermal Cycler & Twincubator / Amplification and detection of target DNA | CE marked | Qualitative | LP-MIC-RG PHE UK Standards Microbiolog Good Labo Practice wh Performing Molecular Amplificatio Assays |
| 1017 Measurement of antimicrobial activity and application of clinical interpretive criteria to general bacteria (rapidly growing aerobes) - .03 Yeasts | Detection of azole resistance in Aspergillus species using the VIP check plate | Aspergillus isolates | Broth MIC | CE marked | Qualitative | LP-MIC-RG HPSC Nati guidelines prevention nosocomia aspergillosi EORTC/MS criteria for diagnosis c invasive fu disease |
| | Yeast one Sensititre | Isolates | N/A / Broth MIC | CE marked | N/A | LP-MIC-RG PHE UK Standards Microbiolog Chlamydia trachomatis Infection – Testing by Acid, CLSI Performanc Standards AST of Yea |

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| 1017 Measurement of antimicrobial activity and application of clinical interpretive criteria to general bacteria (rapidly growing aerobes) - .05 Other categories of organism (as specified ) | Colistin susceptability | | Bruker UMIC Colistin Microtitre / Broth microdilution | CE marked | 0.0625 mg/L to 64 mg/L | LP-MIC-RC EUCAST Guidelines |
| | Yeast one Sensititre | | Broth microdilution | CE marked | N/A | LP-MIC-RC CLSI Performanc Standards AST of Yea |
| 1018 Detection of antibody response to infection using appropriate CE marked commercial techniques - .02 Enzyme immunoassay, using CE marked commercial systems | Wako™ β-D-Glucan assay for detection of 1-3 β glucans | Serum | Toxinometer / Kinetic turbidimetric method | CE marked | All positive results (greater than or equal to 7pg/mL) | LP-MIC-RC HPSC Nati guidelines prevention nosocomia aspergillosi EORTC/MS criteria for diagnosis c invasive fu disease |