

# Schedule of Accreditation



|   |   |
|---|---|
| Organisation Name                             | Mercy University Hospital                             |
| Trading As                                    |   |
| INAB Reg No                                   | 297MT   |
| Contact Name                                  | Valerie O'Sullivan                                    |
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| Website                                       | <a href="http://www.muh.ie">http://www.muh.ie</a>     |
| Accreditation Standard                        | EN ISO 15189  |
| Standard Version                              | 2012  |
| Date of award of accreditation                | 06/12/2011  |
| Scope Classification                          | Microbiology and virology                             |
| Scope Classification                          | Blood Transfusion Science                             |
| Scope Classification                          | Haematology   |
| Scope Classification                          | Chemical pathology                                    |
| Services available to the public <sup>1</sup> |   |

<sup>1</sup> Refer to document on interpreting INAB Scopes of Accreditation

| Sites from which accredited services are delivered   |                           |  |
|--|---------------------------|--|
| (the detail of the accredited services delivered at each site are on the Scope of Accreditation) |                           |  |
|  | Name                      | Address  |
| 1  | Mercy University Hospital | Pathology Department, Grenville Place, Cork, Ireland, T12 WE28 |

# Scope of Accreditation

## Mercy 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 | ABO & Rh(D) typing | Whole Blood      | Autovue Innova and Diamed Micro Typing Systems<br>Autovue Innova and Diamed Micro Typing Systems | Automatic, Column Agglutination test, Tube                     |                      | LP-BB-101 ABO and RhD grouping combined with reverse ABO grouping by Diamed Micro typing Systems<br>LP-BB-200, Procedure for performing ABO/RhD groups, Kell types, antibody screens and compatibility tests on the Autovue Innova<br>LP-BB-116, ABO and RhD grouping by tube technique |
| 1020 Transfusion science - .02 Blood grouping including ABO, Rh(D) and                                  |                    | Whole Blood EDTA | Ortho Vision and Diamed Micro  | CE   | N/A                  | LP-BB-101, LP-BB-200, LP-BB-116, BSH guidelines pre   |

|   |                             |                  |   |  |     |   |
|---|-----------------------------|------------------|---|--|-----|---|
| other antigens by automated methods                                     |                             |                  | Typing Systems, Gel Technique                               |  |     | transfusion compatibility procedures  |
| 1020 Transfusion science - .03 Blood group antibody screen              | Antibody Screen             | Plasma           | Autovue Innova and Diamed Micro Typing Systems              | Automatic, Column Agglutination test, Tube |     | LP-BB-103, Antibody Screening using the Diamed Micro Typing Systems<br>LP-BB-200, Procedure for performing ABO/RhD groups, Kell types, antibody screens and compatibility tests on the Autovue Innova |
|   |                             | Whole blood EDTA | Ortho Vision and Diamed Micro Typing Systems, Gel Technique | CE   | N/A | LP-BB-103, LP-BB-200, LP-BB-116, BSH guidelines pre transfusion compatibility procedures  |
| 1020 Transfusion science - .04 Identification of blood group antibodies | Antibody Identification     | Plasma           | Diamed Micro Typing Systems                                 | Column Agglutination test                  |     | LP-BB-104, Antibody investigation   |
| 1020 Transfusion science - .05 Cross match compatible donor units       | Compatibility Testing (IAT) | Plasma Serum     | Diamed Micro Typing Systems                                 | Column Agglutination test                  |     | LP-BB-110, Compatibility Testing, LP-BB-117, Transfusion Reaction Investigation   |
| 1020 Transfusion science - .06 Red cell phenotyping                     | Red cell phenotyping        | Red Cells        | Diamed Micro Typing Systems                                 | Column Agglutination test,                 | N/A | LP-BB-109, Antigen typing of donor units and patient samples  |
|   |                             |                  | Diamed Micro Typing Systems                                 | Column Agglutination test, Tube            |     | LP-BB-109, Antigen typing of donor units and patient samples  |
| 1020 Transfusion science - .99 Miscellaneous tests                      | Direct Coombs Test          |                  | Diamed Micro Typing Systems                                 | Column Agglutination test                  |     | LP-BB-115, performing a DCT and investigation of a positive DCT   |

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

Category: A

| Medical pathology field - Test  | Test/assay                         | Specimen Type | 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 | 24h Creatinine Clearance **1,2,3,4 | Urine         | Calculation | N/A                            | CE based on standard method                                    | LP-BIO-101 LP-BIO-102 |
|   | 24H Urinary Calcium **1,2,3,4      |               | Calculation | N/A                            | CE based on standard method                                    | LP-BIO-101 LP-BIO-102 |
|   | 24H Urinary Chloride **1,2,3,4     |               | Calculation | N/A                            | CE based on standard method                                    | LP-BIO-101 LP-BIO-102 |
|   | 24H Urinary Creatinine **1,2,3,4   |               | Calculation | N/A                            | CE based on standard method                                    | LP-BIO-101 LP-BIO-102 |
|   | 24H Urinary Phosphate **1,2,3,4    |               | Calculation | N/A                            | CE based on standard method                                    | LP-BIO-101 LP-BIO-102 |
|   | 24H Urinary Potassium **1,2,3,4    |               | Calculation | N/A                            | CE based on standard method                                    | LP-BIO-101 LP-BIO-102 |
|   | 24H Urinary Protein **1,2,3,4      |               | Calculation | N/A                            | CE based on standard method                                    | LP-BIO-101 LP-BIO-102 |
|   | 24H Urinary Sodium **1,2,3,4       |               | Calculation | N/A                            | CE based on standard method                                    | LP-BIO-101 LP-BIO-102 |
|   | 24H Urinary Urate **1,2,3,4        |               | Calculation | N/A                            | CE based on standard method                                    | LP-BIO-101 LP-BIO-102 |
|   | 24H Urinary Urea **1,2,3,4         |               | Calculation | N/A                            | CE based on standard method                                    | LP-BIO-101 LP-BIO-102 |
|   | Adjusted Calcium **1,2,3,4         | Plasma/Serum  | Calculation | N/A                            | CE based on standard method                                    | LP-BIO-101 LP-BIO-103 |

|  |                    |   |                 |                             |                         |
|--|--------------------|---|-----------------|-----------------------------|-------------------------|
| Alanine aminotransferase (ALT) **1,2,3,4   | Plasma/Serum       | NADH (without P-5'-P)                                   | Architect C8000 | CE Marked Assay             | LP-BIO-101 & LP-BIO-102 |
| Alkaline Phosphatase (ALP) **1,2,3,4       |                    | Para-nitrophenyl Phosphate                              | Architect C8000 | CE Marked Assay             | LP-BIO-101 & LP-BIO-102 |
| Amylase **1,2,3,4                          | Plasma/Serum/Urine | CNPG3 Substrate   | Architect C8000 | CE Marked Assay             | LP-BIO-101 & LP-BIO-102 |
| Aspartate Aminotransferase (AST) **1,2,3,4 | Plasma/Serum       | NADH (without P-5'-P)                                   | Architect C8000 | CE Marked Assay             | LP-BIO-101 & LP-BIO-102 |
| Bilirubin (Total) **1,2,3,4                |                    | Diazonium Salt  | Architect C8000 | CE Marked Assay             | LP-BIO-101 & LP-BIO-102 |
| Calcium **1,2,3,4                          | Plasma/Serum/Urine | Arsenazo III  | Architect C8000 | CE Marked Assay             | LP-BIO-101 & LP-BIO-102 |
| Chloride **1,2,3,4                         |                    | Ion-selective electrode diluted (Indirect)              | Architect C8000 | CE Marked Assay             | LP-BIO-101 & LP-BIO-102 |
| Cholesterol (Total) **1,2,3,4              | Plasma/Serum       | Enzymatic   | Architect C8000 | CE Marked Assay             | LP-BIO-101 & LP-BIO-102 |
| Cholesterol LDL **1,2,3,4                  | Plasma/Serum       | Calculation   | N/A             | CE based on standard method | LP-BIO-101 LP-BIO-102   |
| Cholesterol (HDL) **1,2,3,4                | Serum/ serum       | Accelerator selective detergent                         | Architect C8000 | CE Marked Assay             | LP-BIO-101 LP-BIO-102   |
| Creatine Kinase (CK) **1,2,3,4             | Plasma/Serum       | NAC (N-acetyl-L-cysteine)                               | Architect C8000 | CE Marked Assay             | LP-BIO-101 & LP-BIO-102 |
| Creatinine **1,2,3,4                       | Plasma/Serum/Urine | Kinetic Alkaline Picrate                                | Architect C8000 | CE Marked Assay             | LP-BIO-101 & LP-BIO-102 |
| Gamma Glutamyl Transferase (GGT) **1,2,3,4 | Plasma/Serum       | L-Gamma-glutamyl-3-carboxy-4-nitroanilide Substrate     | Architect C8000 | CE Marked Assay             | LP-BIO-101 & LP-BIO-102 |
| Glucose **1,2,3,4                          |                    | Hexokinase/G-6-PDH                                      | Architect C8000 | CE Marked Assay             | LP-BIO-101 & LP-BIO-102 |
| Lactate Dehydrogenase **1,2,3,4            |                    | IFCC recommended forward reaction - Lactate to Pyruvate | Architect C8000 | CE Marked Assay             | LP-BIO-101 & LP-BIO-102 |
| Magnesium **1,2,3,4                        |                    | Enzymatic   | Architect C8000 | CE Marked Assay             | LP-BIO-101 & LP-BIO-102 |

|  |  |                    |  |   |                             |  |
|--|--|--------------------|--|---|-----------------------------|--|
|  | MDRD GFR<br>**1,2,3,4                      | Plasma/Serum       | Calculation                                | Architect C8000                           | CE based on standard method | Based on manufacturer's guidelines LP-BIO-101 LP-BIO-102 |
|  |  | Plasma/Serum       | Calculation                                | Abbott Architect                          | CE based on standard method | LP-BIO-101 & LP-BIO-102                                  |
|  | Microalbumin<br>**1,2,3,4                  | Urine              | Turbidimetric/Immunoturbidimetric          | Architect C8000                           | CE Marked Assay             | LP-BIO-101 & LP-BIO-102                                  |
|  | Osmolality **1,2,3,4                       | Serum/Urine        | Freezing Point Depression                  | Advanced Instruments Model 3320 Osmometer |                             | LP-BIO-17  |
|  | Phosphorus **1,2,3,4                       | Plasma/Serum/Urine | Phosphomolybdate                           | Architect C8000                           | CE Marked Assay             | LP-BIO-101 & LP-BIO-102                                  |
|  | Potassium **1,2,3,4                        |                    | Ion-selective electrode diluted (Indirect) | Architect C8000                           | CE Marked Assay             | LP-BIO-101 & LP-BIO-102                                  |
|  | Sodium **1,2,3,4                           | Plasma/Serum/Urine | Ion-selective electrode diluted (Indirect) | Architect C8000                           | CE Marked Assay             | LP-BIO-101 & LP-BIO-102                                  |
|  | Triglyceride **1,2,3,4                     | Plasma/Serum       | Glycerol Phosphate Oxidase                 | Architect C8000                           | CE Marked Assay             | LP-BIO-101 & LP-BIO-102                                  |
|  | Troponin I (High Sensitivity) **1,2,3,4    | Plasma             | CMIA                                       | Abbott Architect i2000                    | CE Marked Assay             | LP-BIO-104 & LP-BIO-105                                  |
|  | Urea **1,2,3,4                             | Plasma/Serum/Urine | Urease                                     | Architect C8000                           | CE Marked Assay             | LP-BIO-101 & LP-BIO-102                                  |
|  | Uric acid **1,2,3,4                        |                    | Uricase                                    | Architect C8000                           | CE Marked Assay             | LP-BIO-101 & LP-BIO-102                                  |
|  | Urinary Albumin/Creatinine Ratio **1,2,3,4 | Urine              | Calculation                                | N/A                                       | CE based on standard method | LP-BIO-101 LP-BIO-102                                    |
|  | Urinary Calcium/Creatinine Ratio **1,2,3,4 |                    | Calculation                                | N/A                                       | CE based on standard method | LP-BIO-101 LP-BIO-102                                    |
|  | Urinary Protein/Creatinine Ratio **1,2,3,4 |                    | Calculation                                | N/A                                       | CE based on standard method | LP-BIO-101 LP-BIO-102                                    |
|  | 1061 Clinical Chemistry - .02              | Albumin **1,2,3,4  | Plasma/Serum                               | Bromocresol Purple                        | Architect C8000             | CE Marked Assay  |

|  |  |              |  |                        |                 |                          |
|--|--|--------------|--|------------------------|-----------------|--------------------------|
| Proteins, quantitative analysis                                |  |              |  |                        |                 |                          |
|  | C-reactive Protein **1,2,3,4                     |              | Turbidimetric/Immunoturbidimetric                                | Architect C8000        | CE Marked Assay | LP-BIO-101 & LP-BIO-102  |
|  | Faecal Calprotectin **1,2,3,4                    | Faeces       | Immunoturbidimetric  | Architect C8000        | CE Marked Assay | LP-BIO-316               |
|  |  |              | Immunoturbidimetric  | Architect C8000        | CE Marked Assay | LP-BIO-316               |
|  | Human B-type natriuretic peptide (BNP) **1,2,3,4 | EDTA         | CMIA   | Architect i2000        | CE Marked Assay | LP-BIO-104 & LP-BIO-105  |
|  | Total Protein ***1,2,3,4                         | Plasma/Serum | Biuret   | Architect C8000        | CE Marked Assay | LP-BIO-101 & LP-BIO-102  |
|  | Total Protein **1,2,3,4                          | Urine/CSF    | Benzethonium chloride  | Architect C8000        | CE Marked Assay | LP-BIO-101 & LP-BIO-102  |
| 1061 Clinical Chemistry - .10 Drugs for therapeutic monitoring | Digoxin **1,2,3,4                                | Plasma/Serum | Particle-enhanced turbidimetric inhibition immunoassay (PETINIA) | Architect C8000        | CE Marked Assay | LP-BIO-101 & LP-BIO-102  |
|  | Lithium **1,2,3,4                                | Serum        | Colorimetric   | Architect C8000        | CE Marked Assay | LP-BIO-101 & LP-BIO-102  |
| 1061 Clinical Chemistry - .15 Drugs for toxicological purposes | Paracetamol **1,2,3,4                            | Plasma/Serum | Enzymatic  | Abbott Architect C8000 | CE Marked Assay | LP-BIO-101 & LP-BIO-102  |
|  | Salicylate **1,2,3,4                             |              | Enzymatic/Colorimetric   | Architect C8000        | CE Marked Assay | LP-BIO-101 & LP-BIO-102  |
| 1061 Clinical Chemistry - .20 Hormones                         | Cortisol **1,2,3,4                               |              | CMIA   | Abbott Architect i2000 | CE Marked Assay | LP-BIO-104 & LP-BIO-105  |
|  | Free T4 ***1,2,3,4                               |              | CMIA   | Abbott Architect i2000 | CE Marked Assay | LP-BIO-104 & LP-BIO-105  |
|  | Parathyroid hormone (PTH) **1,2,3,4              | Plasma       | CMIA   | Architect i2000        | CE Marked Assay | LP-BIO-104 & LP-BIO-105  |
|  | PTH**1,2,3,4                                     | EDTA Plasma  | chemiluminescent microparticle immunoassay                       | Abbott i2000           | CE Marked       | LP-BIO-104<br>LP-BIO-105 |



|  |  |              |                     |                          |                 |                             |
|--|--|--------------|---------------------|--------------------------|-----------------|-----------------------------|
|  |  | EDTA/Plasma  | CMIA                | Abbott i2000/4-2500pg/ml | CE Marked       | LP-BIO-104                  |
|  | Thyroid Stimulating Hormone (TSH) **1,2,3,4        | Plasma/Serum | CMIA                | Abbott Architect i2000   | CE Marked Assay | LP-BIO-104 & LP-BIO-105     |
| 1061 Clinical Chemistry - .24 Hormone receptor assays            | Beta Human Chorionic Gonadotropin (BHCG) **1,2,3,4 |              | CMIA                | Abbott Architect i2000   | CE Marked Assay | LP-BIO-104 & LP-BIO-105     |
| 1061 Clinical Chemistry - .40 Iron studies                       | % transferrin Saturation                           |              | Plasma/Serum        | Calculation              | Calculation     | CE based on standard method |
|  | Ferritin **1,2,3,4                                 | Plasma/Serum | CMIA                | Abbott Architect i2000   | CE Marked Assay | LP-BIO-104 & LP-BIO-105     |
|  | Iron **1,2,3,4                                     |              | Ferene              | Architect C8000          | CE Marked Assay | LP-BIO-101 & LP-BIO-102     |
|  | Transferrin **1,2,3,4                              |              | Immunoturbidimetric | Architect C8000          | CE Marked Assay | LP-BIO-101 & LP-BIO-102     |
| 1061 Clinical Chemistry - .45 Vitamin B12 and folate             | Folate **1,2,3,4                                   |              | CMIA                | Abbott Architect i2000   | CE Marked Assay | LP-BIO-104 & LP-BIO-105     |
|  | Vitamin B12 **1,2,3,4                              |              | CMIA                | Abbott Architect i2000   | CE Marked Assay | LP-BIO-104 & LP-BIO-105     |
| 1061 Clinical Chemistry - .47 Vitamin assays                     | Vitamin D **1,2,3,4                                |              | CMIA                | Abbott Architect i2000   | CE Marked Assay | LP-BIO-104 & LP-BIO-105     |
| 1061 Clinical Chemistry - .50 Protein and peptide tumour markers | Alpha-fetoprotein (AFP) **1,2,3,4                  |              | CMIA                | Abbott Architect i2000   | CE Marked Assay | LP-BIO-104 & LP-BIO-105     |
|  | Ca 125 **1,2,3,4                                   |              | CMIA                | Abbott Architect i2000   | CE Marked Assay | LP-BIO-104 & LP-BIO-105     |
|  | Ca 19-9 **1,2,3,4                                  |              | CMIA                | Abbott Architect i2000   | CE Marked Assay | LP-BIO-104 & LP-BIO-105     |
|  | Carcinoembryonic Antigen (CEA) **1,2,3,4           |              | CMIA                | Abbott Architect i2000   | CE Marked Assay | LP-BIO-104 & LP-BIO-105     |

|  |                                     |              |                     |                        |                 |                         |
|--|-------------------------------------|--------------|---------------------|------------------------|-----------------|-------------------------|
|  | Prostate Specific Antigen **1,2,3,4 | Serum        | CMIA                | Abbott Architect i2000 | CE Marked Assay | LP-BIO-104 & LP-BIO-105 |
| 1061 Clinical Chemistry - .71 Faecal Immunochemical test   | Faecal Immunochemical test**1,2,3,4 | Faeces       | Immunoturbidimetric | Architect C8000        | CE Marked Assay | LP-BIO-306              |
|  | Faecal Occult Blood **1,2,4         |              | Immunoturbidimetric | Architect C8000        | CE Marked Assay | LP-BIO-306              |
| 1061 Clinical Chemistry - .80 Quantitative investigation of immunoglobulins G, A, M and in body fluids | Immunoglobulin A **1,2,3,4          | Plasma/Serum | Immunoturbidimetric | Architect C8000        | CE Marked Assay | LP-BIO-101 & LP-BIO-102 |
|  | Immunoglobulin G **1,2,3,4          |              | Immunoturbidimetric | Architect C8000        | CE Marked Assay | LP-BIO-101 & LP-BIO-102 |
|  | Immunoglobulin M **1,2,3,4          |              | Immunoturbidimetric | Architect C8000        | CE Marked Assay | LP-BIO-101 & LP-BIO-102 |
|  | Paraprotein Quantitation**1,2,3,4   | Serum        | Densitometry        | Interlab G26           | CE Marked Assay | LP-BIO-300              |
| 1061 Clinical Chemistry - .81 Qualitative investigation of immunoglobulins G, A, M and in body fluids  | Electrophoresis **1,2,3,4           | Serum/Urine  | Electrophoresis     | Interlab G26           | CE Marked Assay | LP-BIO-300              |
|  | Paraprotein type**1,2,3,4           |              | Immunofixation      | Interlab G26           | CE Marked Assay | LP-BIO-300              |

*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.*

| 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<br>Blood counts                            | Haemaglobin<br>**1,2,3,4   | Blood         | Flow Cytometry             | Advia 2120i                    | CE   | LP-HAE-106<br>LP-HAE-103 |
|   | Haematocrit<br>**1,2,3,4   |               | Calculated parameter       | Advia 2120i                    | Calculated parameter   | LP-HAE-106<br>LP-HAE-103 |
|   | MCH **1,2,3,4  |               | Calculated parameter       | Advia 2120i                    | Calculated parameter   | LP-HAE-106<br>LP-HAE-103 |
|   | MCHC **1,2,3,4   |               | Flow Cytometry             | Advia 2120i                    | Calculated parameter   | LP-HAE-106<br>LP-HAE-103 |
|   | Mean Cell Volume<br>**1,2,3,4  |               | Flow Cytometry             | Advia 2120i                    | CE   | LP-HAE-106<br>LP-HAE-103 |
|   | Platelet Count<br>**1,2,3,4  |               | Flow Cytometry             | Advia 2120i                    | CE   | LP-HAE-106<br>LP-HAE-103 |
|   | Red Cell Count<br>**1,2,3,4  |               | Flow Cytometry             | Advia 2120i                    | CE   | LP-HAE-103<br>LP-HAE-106 |
|   | White cell count<br>**1,2,3,4  |               | Flow Cytometry             | Advia 2120i                    | CE   | LP-HAE-106<br>LP-HAE-103 |
| 1030 Haematology - .02<br>Visual examination of blood films       | Manual Differentiation, red cell morphology and Platelet morphology<br>**1,2,3,4 |               | Staining/microscopy        | Manual                         | CE   | LP-HAE-122<br>LP-HAE-120 |
| 1030 Haematology - .03<br>Erythrocyte sedimentation rate          | ESR (Automated)<br>**1,2,3,4   |               | Sedimentation of red cells | Alifax Test-1                  | CE   | LP-HAE-143               |
| 1030 Haematology - .05<br>Automated differential leucocyte counts | Basophil Count<br>**1,2,3,4  |               | Flow Cytometry             | Advia 2120i                    | CE   | LP-HAE-106<br>LP-HAE-103 |

|   |  |
|---|--|
|   | Eosinophil Count<br>**1,2,3,4                          |
|   | Lymphocyte Count<br>**1,2,3,4                          |
|   | Monocyte Count<br>**1,2,3,4                            |
|   | Neutrophil Count<br>**1,2,3,4                          |
| 1030 Haematology - .06<br>Automated reticulocyte counts                   | Retic count **1,2,3,4                                  |
| 1030 Haematology - .09<br>Examination of malarial parasites               | Malaria Screen<br>**1,2,3,4                            |
| 1030 Haematology - .30<br>Tests for haemoglobin variants and thalassaemia | Sickle Screen<br>**1,2,3,4                             |
| 1030 Haematology - .40<br>Limited haemostasis related tests               | Free Protein S<br>**1,2,3,4                            |
|   | Lupus anticoagulant<br>**1,2,3,4                       |
| 1030 Haematology - .41<br>General haemostasis related tests               | Activated Partial Thromboplastin Time (APTT) **1,2,3,4 |
|   | D-Dimer **1,2,3,4                                      |
|   | Fibrinogen (Clauss)<br>**1,2,3,4                       |
|   | International Normalised Ratio (INR) **1,2,3,4         |
|   | Protein C activity<br>**1,2,3,4                        |

|                             |                        |                   |                          |
|-----------------------------|------------------------|-------------------|--------------------------|
| Flow Cytometry              | Advia 2120i            | CE                | LP-HAE-106<br>LP-HAE-103 |
| Flow Cytometry              | Advia 2120i            | CE                | LP-HAE-106<br>LP-HAE-103 |
| Flow Cytometry              | Advia 2120i            | CE                | LP-HAE-106<br>LP-HAE-103 |
| Flow Cytometry              | Advia 2120i            | CE                | LP-HAE-106<br>LP-HAE-103 |
| Flow Cytometry              | Advia 2120i            | CE                | LP-HAE-106<br>LP-HAE-103 |
| Blood Film                  | Blood Film Examination | Blood Film        | LP-HAE-171               |
| Immunoassay                 | Carestart test kit     | CE                | LP-HAE-171               |
| Haemoglobin Solubility test | Clin-tech sickle test  | CE                | LP-HAE-176               |
| Immunoassay                 | Sysmex CA2100i         | CE                | LP-Hae-160               |
| Clotting assay              | Sysmex CS2100i         | CE                | LP-HAE-162               |
| Clotting assay              | Sysmex CS2100i         | CE                | LP-Hae-159               |
| Immunoturbidimetric assay   | Sysmex CS2100i         | CE                | LP-Hae-159               |
| Clotting assay              | Sysmex CS2100i         | CE                | LP-Hae-159               |
| Ratio calculation           | Sysmex CS2100i         | Ratio calculation | LP-Hae-159               |
| Chromogenic analysis        | Sysmex CA2100i         | CE                | LP-Hae-160               |

|   |  |  |                      |                  |     |            |
|---|--|--|----------------------|------------------|-----|------------|
|   | Prothrombin Time (PT) **1,2,3,4                              |  | Clotting assay       | Sysmex CS2100i   | CE  | LP-Hae-159 |
| 1030 Haematology - .57<br>Screening test for infectious mononucleosis | Infectious Mononucleosis **1,2,3,4                           |  | Immunoassay          |                  | CE  | LP-HAE-147 |
| 1030 Haematology - .80<br>Molecular genetic studies                   | Detection of Factor V Leiden & Prothrombin Variant **1,2,3,4 |  | PCR Amplification    | GeneXpert        | PCR | LP-HAE-172 |
| 1030 Haematology - .99<br>Miscellaneous tests                         | Antithrombin **1,2,3,4                                       |  | Chromogenic analysis | Sysmex CA2100i   | CE  | LP-Hae-160 |
|   | Rheumatoid Factor **1,2,3,4                                  |  | Immunoassay          | Rheumajet RF kit | CE  | LP-HAE-155 |

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*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.*

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**1,2,3,4                        | CSF, Pleural / pericardial / chest / lymphatic fluids / drains / other fluids, sputa   | Manual              | Based on standard method                                       | N/A   | LP-MIC-1                               |
|   | Manual determination of red cells in urine using dipstick test**1,2,3,4 | Urine, Catheter Specimen Urine, nephrostomy bag samples  | Manual              | Based on standard method                                       | Semi-quantitative blood: negative, +, ++, +++                                     | LP-MIC-250                             |
| 1012 Preparation of films on glass slides followed by microscopic examination with or without fixation and staining with dyes as required - .01<br>Microscopic examination for general bacteriology purposes (including enumeration and description of human cells) | Gram stains**1,2,3,4  | Blood cultures, CSF, Vaginal/cervical/endocervical swabs, abscesses; post-op wounds; deep seated infections; ear, nose and throat related specimens; eye swabs; oral/throat abscesses/swabs; all fluids including drain, joint, pleural, pericardial, chest, lymphatic; IUD; nasal swab; genital swabs; prosthetic swabs/abscesses/devices; pus; rectal swabs for VRE; sinus aspirate; tips; tissues; bone; biopsies; bacterial / isolates | Microscope/Manual   | Based on standard method                                       | Gram positive / negative; cocci / bacilli including Hay's Criteria where required | LP-MIC-283<br>LP-MIC-290<br>LP-MIC-291 |
|   | Red cell count, white cell count, white cell differential**1,2,3,4      | Cerebrospinal fluid, all fluids including drain, joint, pleural, pericardial, chest, lymphatic   | Microscope/Manual   | Based on standard method                                       | Red cells and white cells per cmm.<br>Differential: % polymorphs, % leucocytes    | LP-MIC-231                             |

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|---|--|--|-------------------------------------|--------------------------|----------------------|--|
|   | Urine microscopy**1,2,3,4  | Urine, Catheter Specimen Urine, nephrostomy bag samples  | Microscope/Manual                   | Based on standard method | WCC and RCC per cmm. | LP-MIC-250   |
| 1012 Preparation of films on glass slides followed by microscopic examination with or without fixation and staining with dyes as required - .02<br>Microscopic examination for parasites    | Cryptosporidium **1,2,3,4  | Faeces   | Fluorescent microscopic examination | Based on standard method | Seen / Not Seen      | LP-MIC-244<br>Investigation of Cryptosporidium Species |
|   | Microscopic examination of cryptosporidium by auromine stain**1,2,3,4      |  | Microscope/Manual                   | Based on standard method | Seen / Not Seen      | LP-MIC-244   |
|   | Microscopic examination of cryptosporidium by Ziehl-Neelson stain**1,2,3,4 |  | Microscope/Manual                   | Based on standard method | Seen / Not Seen      | LP-MIC-244   |
| 1012 Preparation of films on glass slides followed by microscopic examination with or without fixation and staining with dyes as required - .03<br>Microscopic examination for fungi        | Microscopic examination of fungi**1,2,3,4                                  | Fungal isolates  | Microscope/Manual                   | Based on standard method | N/A                  | LP-MIC-234   |
| 1012 Preparation of films on glass slides followed by microscopic examination with or without fixation and staining with dyes as required - .04<br>Microscopic examination for mycobacteria | Microscopic examination of mycobacteria by auromine stain                  | Pleural / pericardial / chest / lymphatic fluids / drains / other fluids / swabs / tissues / respiratory samples (sputa, bronchial washings) | Microscope/Manual                   | Based on standard method | Seen / Not Seen      | LP-MIC-221   |
|   | Microscopic examination of mycobacteria by auromine stain**1,2,3,4         |  | Microscope/Manual                   | Based on standard method | Seen / Not Seen      | LP-MIC-221   |

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|   | Microscopic examination of mycobacteria by Ziehl-Neelson stain**1,2,3,4 |  | Microscope/Manual  | Based on standard method | Seen / Not Seen                | LP-MIC-221                                     |
|   | Mycobacterium Culture **1,2,3,4   | Chest / lymphatic fluids / drains / other fluids   | Manual Method using Staining with fluorescent microscope | Based on standard method | N/A                            | LP-MIC-221                                     |
| 1013 Culture of organisms in liquid or agar based culture media with visual or instrument monitoring for growth - .01 Culture of general bacteria | Bacterial Culture**1,2,3,4  | HVs  | Manual   | Microscope               | Normal /Intermediate /Abnormal | LP-MIC-235, LP-MIC-231, LP-MIC-290 LP-MIC-291  |
|   | Culture of blood culture specimens**1,2,3,4                             |  | BacTAlert Virtuo   | CE Marked                | N/A                            | LP-MIC-282, LP-MIC-284, LP-MIC-290, LP-MIC-291 |
|   |   | Blood Culture and fluids from normally sterile sites   | BacTAlert Virtuo   | CE Marked                | N/A                            | LP-MIC-282 LP-MIC-284, LP-MIC-290, LP-MIC-291  |
|   | Culture of CSF**1,2,3,4   | CSF  | Manual   | Based on standard method | N/A                            | LP-MIC-233 LP-MIC-290 LP-MIC-291               |
|   | Culture of faeces **1,2,3,4   | Faeces   | Manual   | Based on standard method | N/A                            | LP-MIC-241 LP-MIC-290 LP-MIC-291               |
|   | Culture of faeces **1,2,3,4   |  | Manual   | Based on standard method | N/A                            | LP-MIC-241 LPMIC-290 LP-MIC291                 |
|   | Culture of miscellaneous specimens for general bacteria**1,2,3,4        | Abscesses; post-op wounds; deep seated infections; ear, nose and throat related specimens; eye swabs; oral/throat abscesses/swabs; all fluids including drain, joint, pleural, pericardial, chest, lymphatic; IUD; nasal swab; genital swabs; prosthetic swabs/abscesses/devices; pus; | Manual   | Based on standard method | N/A                            | LP-MIC-232 LP-MIC-290 LP-MIC-291               |



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|  |  | rectal swabs for VRE; sinus aspirate; tips; tissues; bone; biopsies;  |                    |                          |     |  |
|  | Culture of respiratory specimens<br>**1,2,3,4                      | Sputa, bronchial washings, BAL, ETT specimens   | Manual             | Based on standard method | N/A | LP-MIC-222<br>LP-MIC-290<br>LP-MIC-291                                 |
|  |  |   | Manual             | Based on standard method | N/A | LP-MIC-241<br>LPMIC-290 LP-MIC291                                      |
|  | Culture of screening swabs for CPE using chromogenic agar**1,2,3,4 | Rectal swabs, faeces  | Manual             | Based on standard method | N/A | LP-MIC-232<br>LP-MIC-290<br>LP-MIC-291                                 |
|  | Culture of urine**1,2,3,4  | Urine, Catheter Specimen Urine, nephrostomy bag samples   | Manual             | Based on standard method | N/A | LP-MIC-250 LP-MIC-290 LP-MIC-291                                       |
|  | Culture of miscellaneous specimens for general bacteria**1,2,3,4   | Abscesses; post-op wounds; deep seated infections; ear, nose and throat related specimens; eye swabs; oral/throat abscesses/swabs; all fluids including drain, joint, pleural, pericardial, chest, lymphatic; IUD; nasal swab; genital swabs; prosthetic swabs/abscesses/devices; pus; rectal swabs for VRE; sinus aspirate; tips; tissues; bone; biopsies; | Manual             | Based on standard method | N/A | LP-MIC-232<br>LPMIC-290 LP-MIC291                                      |
| 1013 Culture of organisms in liquid or agar based culture media with visual or instrument monitoring for growth - .02 Culture of fungi | Culture of blood culture specimens**1,2,3,4                        | Blood Culture and fluids from normally sterile sites  | BacTAlert / Manual | CE Marked                | N/A | LP-MIC-282,<br>LP-MIC-283,<br>LP-MIC-284,<br>LP-MIC-290,<br>LP-MIC-291 |
|  | Culture of CSF **1,2,3,4   | CSF   | Manual             | Based on standard method | N/A | LP-MIC-233<br>LP-MIC-290 LP-MIC-291                                    |

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|   | Culture of faeces **1,2,3,4                                       | Faeces  | Manual   | Based on standard method                       | N/A  | LP-MIC-241<br>LP-MIC-290 LP-MIC-291            |
|   | Culture of miscellaneous specimens for Fungi**1,2,3,4             | Abscesses; post-op wounds; deep seated infections; ear, nose and throat related specimens; eye swabs; oral/throat abscesses/swabs; all fluids including drain, joint, pleural, pericardial, chest, lymphatic; IUD; nasal swab; genital swabs; prosthetic swabs/abscesses/devices; pus; rectal swabs for VRE; sinus aspirate; tips; tissues; bone; biopsies; | Manual   | Based on standard method                       | N/A  | LP-MIC-231<br>LP-MIC-290<br>LP-MIC-291         |
|   | Culture of respiratory specimens **1,2,3,4                        | Sputa, bronchial washings, BAL, ETT specimens   | Manual   | Based on standard method                       | N/A  | LP-MIC-222,<br>LP-MIC-290,<br>LP-MIC-291       |
| 1014 Detection of bacterial, parasite, viral or fungal antigens using specific antibodies and appropriate techniques - .01 Slide agglutination,   | Salmonella, shigella and vibrio serology **1,2,3,4                | Bacterial isolates  | Manual   | Based on standard method                       | Pos/Neg  | LP-MIC-290                                     |
| 1014 Detection of bacterial, parasite, viral or fungal antigens using specific antibodies and appropriate techniques - .02 Particle agglutination | Antistreptolysin-O-Titre (ASOT) **1,2,3,4                         | Serum   | Manual   | CE   | <200 Negative<br>>200 Positive                 | LP-MIC-261                                     |
|   | clinical microbiology services ETS application                    | clinical microbiology services ETS application  | clinical microbiology services ETS application | clinical microbiology services ETS application | clinical microbiology services ETS application | clinical microbiology services ETS application |
|   | Salmonella, shigella and E. Coli particle agglutination **1,2,3,4 | Bacterial isolates - species of salmonella, shigella and E. Coli  | Manual / Wellcolex particle agglutination kits | CE marked                                      | Pos/Neg  | LP-MIC-290                                     |
|   | Staphylococcal coagulase test                                     | Bacterial isolates - staphylococcus species   | Manual   | CE marked                                      | Pos/Neg  | LP-MIC-290                                     |

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|   | Streptococcal grouping **1,2,3,4                 | Bacterial isolates - streptococcus species                                   | Manual   | CE marked       | Qualitative agglutination or non-agglutination | LP-MIC-290 |
| 1014 Detection of bacterial, parasite, viral or fungal antigens using specific antibodies and appropriate techniques - .04<br>Immunochromatographic methods,        | Adenovirus detection **1,2,3,4                   | Faeces   | Manual / Lateral flow  | CE marked assay | Pos/Neg  | LP-MIC-242 |
|   | C difficile detection **1,2,3,4                  |  | Manual / Lateral flow  | CE marked       | Pos/Neg  | LP-MIC-243 |
|   |  |  | Sofia Reader / immunochromatographic   | CE marked       | Pos/Neg  | LP-MIC-243 |
|   | Rotavirus **1,2,3,4                              |  | Manual / Lateral flow  | CE marked       | Pos/Neg  | LP-MIC-242 |
|   | Urinary Legionella antigen detection**1,2,3,4    | Urine  | Sofia Reader / immunochromatographic   | CE marked       | Pos/Neg  | LP-MIC-265 |
|   | Urinary Pneumococcal antigen detection **1,2,3,4 |  | Sofia Reader / immunochromatographic   | CE marked       | Pos/Neg  | LP-MIC-265 |
| 1015 Detection and/or identification of bacterial, parasite, fungal and viral nucleic acids - .03<br>Nucleic acid amplification tests, CE marked commercial systems | Detection of SARS-COV-2                          | Nasopharyngeal/Oropharyngeal Swabs /Sputum/BAL specimens                     | Seegene system comprised of Hamilton Nimbus and Biorad CFX96 / Real-time PCR | CE Marked       | Detected/Not Detected                          | LP-MIC-301 |
|   |  | Nasopharyngeal/Oropharyngeal Swabs; nasopharyngeal only / oropharyngeal only | GeneXpert / Real-time PCR  | CE Marked       | Detected/Not Detected                          | LP-MIC-224 |
|   | Detection of SARS-COV-2 **1,2,3,4                | Nasopharyngeal/Oropharyngeal Swabs /Sputum/BAL specimens                     | Seegene system comprised of Hamilton Nimbus and Biorad CFX96 / Real-time PCR | CE Marked       | Detected/Not Detected                          | LP-MIC-301 |
|   |  | Nasopharyngeal/Oropharyngeal Swabs; nasopharyngeal only / oropharyngeal only | GeneXpert / Real-time PCR  | CE Marked       | Detected/Not Detected                          | LP-MIC-224 |

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|  | <p>Detection of bacteria / viruses / fungi in positive blood cultures using the FilmArray Blood Culture Identification 2 (BCID2) Panel Panel **1,2,3,4</p> <p>Targets include 10 antimicrobial resistance genes: CTX-M, IMP, KPC, mcr-1, mecA/C, macA/C and MREJ (MRSA), NDM, OXA-48-like, vanA/B, VIM; 26 bacterial targets: Enterococcus faecalis, Enterococcus faecium, Listeria monocytogenes, Staphylococcus spp, Staphylococcus aureas, Staphylococcus epidermidis, Staphylococcus pneumoniae, Streptococcus pyogenes (Group A), Acinetobacter calcoaceticus-baumannii complex, Bacteroides fragilis, Enterobacteriales, Enterobacter cloacaecomplex, Escherichia coli, Klebsiella aerogenes, Klebsiella oxytoca, Klebsiella pneumoniae group, Proteus spp, Salmonella spp, Serratia marcesens, Haemophilus influenzae, Neisseria meningitidis, Pseudomonas aeruginosa, Stenotrophomonas maltophilia; and 7 yeast targets; Candida albicans, Candida auris, Candida glabrata, Candida krusei, Candida parapsilosis, Candida tropicalis, Cryptococcus neoformans/gattii. 43 targets in total.**1,2,3,4</p> | Positive blood culture samples | Biofire FilmArray FilmArray Blood Culture Identification 2 (BCID2) Panel / Real Time PCR | CE marked | Detected/ Not Detected  | LP-MIC-300 |
|  | <p>Detection of bacterial, viral, and fungal pathogens using the FilmArray Meningitis/Encephalitis Panel (ME) **1,2,3,4</p> <p>Escherichia coli K1<br/>Haemophilus influenzae<br/>Listeria monocytogenes<br/>Neisseria meningitidis<br/>Streptococcus agalactiae</p>  | Cerebrospinal fluid (CSF)      | BIOFIRE FILMARRAY ME Panel   | CE Marked | Detected / Not Detected | LP-MIC-300 |

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| Streptococcus pneumoniae<br>Cytomegalovirus (CMV)<br>Enterovirus<br>Herpes simplex virus 1 (HSV-1)<br>Herpes simplex virus 2 (HSV-2)<br>Human herpes virus 6 (HHV-6)<br>Human parechovirus<br>Varicella zoster virus (VZV)<br>Cryptococcus neoformans/gattii   |  |  |           |                       |  |
| Detection of Carbapenemase Producing Enterobacteriaceae genes (KPC, VIM, IMP, NDM and OXA-48) by PCR **1,2,3,4   | Bacterial isolates/ Rectal swabs       | GeneXpert / Real-time PCR  | CE Marked | Detected/Not Detected | LP-MIC-224<br>LP-MIC-232   |
| Detection of enteric pathogens by molecular methods. Targets include: Yersinia enterocolitica, Shigella, Enteroinvasive E. Coli, E. Coli 0157, C. Difficile toxin A/B, Shigatox 1/2, Salmonella, Campylobacter, Astrovirus, Norovirus G2, Adenovirus, Sapovirus, Norovirus G1, Rotavirus**1,2,3,4        | Faeces                                 | Seegene system comprised of Hamilton Nimbus and Biorad CFX96 / Real-time PCR | CE Marked | Detected/Not Detected | LP-MIC-301   |
| Detection of enteric pathogens by molecular methods. Targets include: Yersinia enterocolitica, Shigella, Enteroinvasive E. Coli, Faeces E. Coli 0157, C. Difficile toxin A/B, Shigatox 1/2, Salmonella, Campylobacter, Astrovirus, Norovirus G2, Adenovirus, Sapovirus, Norovirus G1, Rotavirus**1,2,3,4 |  | Nimbus and Biorad CFX96 / Real-time PCR                                      | CE Marked | Detected/Not Detected | LP-MIC-301   |
| Detection of Influenza A/Influenza B/RSV **1,2,3,4   | Nasopharyngeal/Oropharyngeal Specimens | GeneXpert/PCR  | CE marked | Detected/Not Detected | LP-MIC-224<br>Operation of the Cepheid GeneXpert Instrument System |
| Detection of Influenza A/Influenza B/RSV/ Sars CoV2 Plus**1,2,3,4  | Nasopharyngeal/Oropharyngeal Swabs     | GeneXpert  | CE Marked | Detected/Not Detected | LP-MIC-100,<br>LP-MIC-224  |

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| Detection of M. Tuberculosis and rifampicin resistance by PCR **1,2,3,4  | Sputum                              | GeneXpert / Real-time PCR   | CE marked | Detected / Not Detected | LP-MIC-224 |
| Detection of Norovirus by PCR **1,2,3,4  | Faeces                              | GeneXpert / Real-time PCR   | CE Marked | Detected / Not Detected | LP-MIC-224 |
| Detection of respiratory pathogens using Filmarray Respiratory Panel**1,2,3,4 Targets include: 19 viral targets : Adenovirus, Coronavirus 229E, Coronavirus HKU1, Coronavirus OC43, Coronavirus NL63, Middle East Respiratory Syndrome CoronaVirus (Mers-CoV), Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2), Human Metapneumovirus, Human Rhinovirus/Enterovirus, Influenza A, Influenza A/H1, Influenza A/H1-2009, Influenza A/H3, Influenza B, Parainfluenza 1, Parainfluenza 2, Parainfluenza 3, Parainfluenza 4, RSV and 4 bacterial targets: Bordetella pertussis, Bordetella parapertussis, Chlamydomphila pneumoniae, Mycoplasma pneumoniae (23 targets in total) | Nasopharyngeal /oropharyngeal swabs | Biofire FilmArray FilmArray Respiratory 2.1+ Panel (RP2.1+) / Real-time PCR | CE Marked | Detected/Not Detected   | LP-MIC-300 |
| Detection of respiratory pathogens using Filmarray Respiratory Panel**1,2,3,4<br><br>Targets include: 19 viral targets : Adenovirus, Coronavirus 229E, Coronavirus HKU1, Coronavirus OC43, Coronavirus NL63, Middle East Respiratory Syndrome CoronaVirus (Mers-CoV), Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2), Human Metapneumovirus, Human Rhinovirus/Enterovirus, Influenza A, Influenza A/H1, Influenza A/H1-2009, Influenza A/H3, Influenza B, Parainfluenza 1, Parainfluenza 2,  |                                     | Biofire FilmArray FilmArray Respiratory 2.1+ Panel (RP2.1+) / Real-time PCR | CE marked | Detected/ Not Detected  | LP-MIC-300 |

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|--|---|--|--|--------------------------|-----------------------|------------|
|  | Parainfluenza 3, Parainfluenza 4, RSV and 4 bacterial targets: Bordetella pertussis, Bordetella parapertussis, Chlamydomphila pneumoniae, Mycoplasma pneumoniae (23 targets in total) |  |  |                          |                       |            |
|  | Detection of SARS-CoV-2, Influenza A/Influenza B/RSV  | Nasopharyngeal/Oropharyngeal; Nasal/Throat Specimens | GeneXpert/ Real-time PCR                         | CE Marked                | Detected/Not Detected | LP-MIC-224 |
|  | Detection of SARS-CoV-2, Influenza A/Influenza B/RSV **1,2,3,4  | Nasopharyngeal/Oropharyngeal Swabs                   | GeneXpert/ Real-time PCR                         | CE Marked                | Detected/Not Detected | LP-MIC-224 |
| 1016 Identification of cultured bacteria and fungi using non-nucleic acid based techniques - .01 Biochemical methods , CE marked commercial systems        | Identification of bacteria**1,2,3,4   | Bacterial isolates                                   | Biomerieux Vitek 2 Compact / Biochemical methods | CE marked                | N/A                   | LP-MIC-273 |
|  | Identification of yeast using the VITEK 2® yeast identification card (YST)**1,2,3,4   | Yeast isolates                                       | Biomerieux Vitek 2 Compact / Biochemical methods | CE marked                | N/A                   | LP-MIC-273 |
| 1016 Identification of cultured bacteria and fungi using non-nucleic acid based techniques - .04 Identification using MALDI-TOF Spectroscopy               | Identification of cultured bacteria and fungi**1,2,3,4  | Bacterial and fungal isolates                        | Mass Spectrometry Bruker Maldi-tof               | CE Marked                | N/A                   | LP-MIC-302 |
| 1017 Measurement of antimicrobial activity and application of clinical interpretive criteria to general bacteria (rapidly growing aerobes) - .01 Anaerobes | Antimicrobial susceptibility testing of anaerobes using disc diffusion **1,2,3,4  | Anaerobic bacterial isolates                         | Manual / zone diameter                           | Based on standard method | S/I/R                 | LP-MIC-272 |
|  | Antimicrobial susceptibility testing of anaerobes using disc diffusion **1,2,3,4  |  | Manual / zone diameter                           | Based on standard method | N/A                   | LP-MIC-272 |

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|---|--|--|--|-------------|-------|---------------------------|
|   | Minimum inhibitory concentration of anaerobes using MIC strips **1,2,3,4 |  | Manual / MIC Strips                                | CE Marked   | S/I/R | LP-MIC-272                |
|   | Minimum inhibitory concentration of anaerobes using MIC strips **1,2,3,4 |  | Manual / MIC Strips                                | CE Marked   | N/A   | LP-MIC-272                |
| 1017 Measurement of antimicrobial activity and application of clinical interpretive criteria to general bacteria (rapidly growing aerobes) - .03 Yeasts                                       | Minimum inhibitory concentration using MIC strips **1,2,3,4              | Yeast isolates   | Manual / MIC Strips                                | CE Marked   | S/I/R | LP-MIC-272                |
| 1017 Measurement of antimicrobial activity and application of clinical interpretive criteria to general bacteria (rapidly growing aerobes) - .05 Other categories of organism (as specified ) | Antimicrobial resistance using disc diffusion **1,2,3,4                  | Urine Culture, Mycobacterium Culture, Respiratory Cultures, Tissues, biopsies, bone and prosthetic devices, Abscesses, post-op, wounds and deep seated infections, Eye Swab, Superficial wounds and intravascular cannulae, Ear, Nose, Throat, related specimens, Fluid Culture, MRSA Culture, CSF Culture, Genital tract and associated Culture, Faeces Culture | Manual   | MIC Discs   | N/A   | LP-MIC-271<br>LP-MIC-272  |
|   | Antimicrobial Susceptibility Testing using VITEK 2 ® Compact**1,2,3,4    | Isolate  | CE Marked  | VITEK 2 AST | S/I/R | LP-MIC-273                |
|   |  | Other bacterial isolates - to include but not limited to staphylococcus, streptococcus, enterobacteriales, pseudomonads, acinetobacter, enterococcus, haemophilus, moraxella, neisseria, campylobacter, Stenotrophomonas maltophilia and other gram-negative bacilli   | VITEK 2 Compact / Minimum Inhibitory Concentration | CE Marked   | S/I/R | LP-MIC-273                |
|   | Antimicrobial resistance using disc diffusion **1,2,3,4                  | Urine Culture, Mycobacterium Culture, Respiratory Cultures, Tissues, biopsies, bone and  | MIC Discs  | Manual      | N/A   | LP-MIC-272,<br>LP-MIC-271 |



|   |   |  |   |           |  |                                    |
|---|---|--|---|-----------|--|------------------------------------|
|   |   | prosthetic devices, Abscesses, post-op, wounds and deep seated infections, Eye Swab, Superficial wounds and intravascular cannulae, Ear, Nose, Throat, related specimens, Fluid Culture, MRSA Culture, CSF Culture, Genital tract and associated Culture, Faeces Culture |   |           |  |                                    |
|   | Minimum inhibitory concentration using MIC strips **1,2,3,4 | Other bacterial isolates - to include but not limited to staphylococcus, streptococcus, enterobacterales, pseudomonads, acinetobacter, enterococcus, haemophilus, moraxella, neisseria, campylobacter, Stenotrophomonas maltophilia and other gram-negative bacilli      | Manual / MIC Strips   | CE Marked | S/I/R  | LP-MIC-272                         |
| 1018 Detection of antibody response to infection using appropriate CE marked commercial techniques - .02 Enzyme immunoassay, using CE marked commercial systems                         | HIV Ag/Ab using Abbott Architect **1,2,3,4                  | Blood  | Abbott Architect / chemiluminescent microparticle immunoassay | CE Marked | <1.0 S/CO = Negative ≥1.0 = Positive             | LP-MIC-100, LP-MIC-101, LP-MIC-103 |
| 1018 Detection of antibody response to infection using appropriate CE marked commercial techniques - .07 Chemiluminescent microparticle immunoassay, using CE marked commercial systems | Hep A IgM using Abbott Architect **1,2,3,4                  | Serum  | Abbott Architect / chemiluminescent microparticle immunoassay | CE Marked | <0.8 Non reactive 0.8-1.2 Grayzone >1.2 Reactive | LP-MIC-100                         |
|   | Hepatitis B Antibody using Abbott Architect **1,2,3,4       |  | Abbott Architect / chemiluminescent                           | CE Marked | 2.5 -1000 mIU/ml                                 | LP-MIC-100                         |

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|--|--|--------------|---|--|---|--|
|  |  |              | microparticle immunoassay                                     |  |   |  |
|  | Hepatitis B sAg using Abbott Architect **1,2,3,4         |              | Abbott Architect / chemiluminescent microparticle immunoassay | CE Marked                                  | <1.0 S/CO = Negative<br>≥1.0 = Positive | LP-MIC-100   |
|  | Hepatitis BsAg Antibody using Abbott Architect **1,2,3,4 | Blood/ Serum | Abbott Architect  | Chemiluminescent microparticle immunoassay | N/A                                     | LP-MIC-100<br>Operation of the Abbott Architect i1000 SR |
|  | Hepatitis C Antibody using Abbott Architect **1,2,3,4    | Serum        | Abbott Architect / chemiluminescent microparticle immunoassay | CE Marked                                  | <1.0 S/CO = Negative<br>≥1.0 = Positive | LP-MIC-100   |
|  | HIV Ag/Ab using Abbott Architect **1,2,3,4               |              | Abbott Architect / chemiluminescent microparticle immunoassay | CE Marked                                  | <1.0 S/CO = Negative<br>≥1.0 = Positive | LP-MIC-100   |
| 1029 Miscellaneous - .99 Miscellaneous tests | Gentamycin **1,2,3,4                                     |              | Abbott Architect / chemiluminescent microparticle immunoassay | CE Marked                                  | 0.11 to 11.16 mg/L                      | LP-MIC-100   |
|  | Pregnancy Test **1,2,3,4                                 | Urine        | Sofia Reader / immunochromatographic                          | CE Marked                                  | Pos/Neg                                 | LP-MIC-265   |
|  | Vancomycin **1,2,3,4                                     | Serum        | Abbott Architect / chemiluminescent                           | CE Marked                                  | 0.24 - 100.00 ug/ml                     | LP-MIC-100   |

*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.*