

# Schedule of Accreditation



|   |   |
|---|---|
| Organisation Name                             | Mater Misericordiae University Hospital         |
| Trading As                                    |   |
| INAB Reg No                                   | 232MT   |
| Contact Name                                  | Denise O'Neill                                  |
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| Website                                       |   |
| Accreditation Standard                        | EN ISO 15189                                    |
| Standard Version                              | 2012  |
| Date of award of accreditation                | 09/06/2009                                      |
| Scope Classification                          | Microbiology and virology                       |
| Scope Classification                          | Blood Transfusion Science                       |
| Scope Classification                          | Haematology                                     |
| Scope Classification                          | Immunology                                      |
| Scope Classification                          | Histopathology and cytopathology                |
| Scope Classification                          | Chemical pathology                              |
| Scope Classification                          | Genetics  |
| 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  | 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 grouping (ABO & RhD)                                       | Blood with EDTA, Blood with no anticoagulant (Clotted) | Manual gel cards and tube techniques | CE   | Not applicable       | LP-BT-ROU-07, LP-BT-ROU-42<br>BSH Guidelines for pre-transfusion compatibility procedures in blood transfusion laboratories, 2012 |
| 1020 Transfusion science - .02 Blood grouping including ABO, Rh(D) and other antigens by automated methods |  | Blood with EDTA  | BioRad IH-1000                       | CE   | Not applicable       | LP-BT-ROU-33, BSH Guidelines for pre-transfusion compatibility procedures in blood transfusion laboratories, 2012                 |
|  | Blood Grouping (ABO & RhD), Confirmation of ABO and RhD group of | Whole blood, Red Blood Cells                           | BioRad IH-1000                       | CE   | Not applicable       | LP-BT-ROU-33, BSH Guidelines for pre-transfusion compatibility  |

|   |   |  |                                       |    |                |  |
|---|---|--|---------------------------------------|----|----------------|--|
|   | Blood Transfusion Service Red Blood Cells |  |                                       |    |                | procedures in blood transfusion laboratories, 2012   |
| 1020 Transfusion science - .03 Blood group antibody screen              | Antibody Screening                        | Blood with EDTA, Blood with no anticoagulant (Clotted), Eluate | BioRad IH-1000                        | CE | Not applicable | LP-BT-ROU-33, LP-BT-ROU-08, BSH Guidelines for pre-transfusion compatibility procedures in blood transfusion laboratories, 2012                            |
|   |   |  | Manual gel cards                      | CE | N/A            | LP-BT-ROU-33, LP-BT-ROU-08, BSH Guidelines for pre-transfusion compatibility procedures in blood transfusion laboratories, 2012                            |
| 1020 Transfusion science - .04 Identification of blood group antibodies | Antibody Identification                   |  | Manual gel cards and tube techniques  | CE | Not applicable | LP-BT-ROU-09, BSH Guidelines for pre-transfusion compatibility procedures in blood transfusion laboratories, 2012  |
| 1020 Transfusion science - .05 Cross match compatible donor units       | Crossmatching                             | Blood with EDTA, Blood with no anticoagulant (Clotted)         | Manual gel cards and electronic issue | CE | Not applicable | LP-BT-ROU-11, BSH Guidelines for pre-transfusion compatibility procedures in blood transfusion laboratories, 2012, MHRA Guidance on electronic issue, 2010 |
| 1020 Transfusion science - .06 Red cell phenotyping                     | Antigen Typing                            | Blood with EDTA, Whole blood, Red blood cells                  | Manual gel cards and tube techniques  | CE | Not applicable | LP-BT-ROU-10, BSH Guidelines for pre-transfusion compatibility procedures in blood transfusion laboratories, 2012  |

|   |  |   |                  |    |                |   |
|---|--|---|------------------|----|----------------|---|
| 1020 Transfusion science - .07 Antibody elution         | Antibody Elution Testing of EDTA specimens | Blood with EDTA                               | Elution          | CE | Not applicable | LP-BT-ROU-15, BSH Guidelines for pre-transfusion compatibility procedures in blood transfusion laboratories, 2012 |
| 1020 Transfusion science - .09 Direct antiglobulin test | Direct Coombes Testing                     | Blood with EDTA, Whole blood, Red blood cells | Manual gel cards | CE | Not applicable | LP-BT-ROU-13, BSH Guidelines for pre-transfusion compatibility procedures in blood transfusion laboratories, 2012 |

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

Chemical Pathology

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 | 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 **1,2,3,4       |                       | Calculated                                   | NA                             | Based on standard method                                       | LI-CCE-0040    |
| 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<br>LI-CCE-0125<br>CLSI                             |                |

|  |  |                         |   |                          |                                    |
|--|--|-------------------------|---|--------------------------|------------------------------------|
| Albumin / Creatinine Ratio **1,2,3,4       | Urine                                  | Calculated              | N/A   | 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<br>LI-CCE-0125<br>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<br>LI-CCE-0125<br>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<br>LI-CCE-0125<br>CLSI |
| Anion Gap **1,2,3,4                        | Li-Heparin Plasma/Serum                | Calculated              | N/A   | 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<br>LI-CCE-0125<br>CLSI |
| Bicarbonate (Total CO2) **1,2,3,4          | Li-Heparin Plasma / Serum              | Enzymatic               | Abbott Alinity ci series / 5 mmol/l to 45 mmol/l                                  | CE                       | LI-CCE-0003<br>LI-CCE-0125<br>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<br>LI-CCE-0125<br>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<br>LI-CCE-0125<br>CLSI |
| Calcium **1,2,3,4                          | Li-Heparin Plasma / Serum / Urine      | Arsenazo III            | Abbott Alinity ci series / 0.50 mmol/l to 6.00 mmol/l                             | CE                       | LI-CCE-0003<br>LI-CCE-0125<br>CLSI |
| Calcium Creatinine Clearance **1,2,3,4     | Li-Heparin Plasma / Serum / Urine      | Calculated              | N/A   | Based on standard method | LI-CCE-0040                        |
| Calcium Creatinine Ratio **1,2,3,4         | Urine                                  | Calculated              | N/A   | 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<br>LI-CCE-0125<br>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<br>LI-CCE-0125<br>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<br>LI-CCE-0125<br>CLSI |
| Creatinine **1,2,3,4                                  | Li-Heparin Plasma / Serum / Fluid / Urine | Enzymatic           | Abbott Alinity ci series / 8.8 µmol to 3536 µmol/l<br>Urine: 0.22 mmol/l to 35.6 mmol/l | CE                        | LI-CCE-0003<br>LI-CCE-0125<br>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          | N/A   | Based on standard method  | LI-CCE-0037                        |
| Fractional Excretion of Uric Acid **1,2,3,4           |   | Calculated          | NA  | Based on standard method  | LI-CCE-0040                        |
| 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  | Li-Heparin Plasma / Serum         | Colorimetric   | Abbott Alinity ci series / 4.0 U/L to 300 U/L   | CE                              | LI-CCE-0125<br>CLSI                               |
| Lithium **1,2,3,4   | Serum                             | Colorimetric   | Abbott Alinity ci series / 0.4 mmol/l to 3.51 mmol/l                                    | CE                              | LI-CCE-0003<br>LI-CCE-0125<br>CLSI                |
| 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   | Li-Heparin Plasma / Serum / Urine | Arsenazo   | Abbott Alinity ci series / 0.25 mmol/l to 3.90 mmol/l                                   | CE                              | LI-CCE-0003<br>LI-CCE-0125<br>CLSI                |
| Non HDL Cholesterol **1,2,3,4                                   | Li-Heparin Plasma / Serum         | Calculated   | N/A   | Based on standard method        | LI-CCE-0040                                       |
| N-terminal pro B-type Natriuretic Peptide (NT-proBNP) **1,2,3,4 | EDTA plasma                       | Chemiluminescent microparticle immunoassay (CIMA) technology | Abbott Alinity ci series / 8.3 ng/l to 35,000 ng/l                                      | CE                              | LI-CCE-0003<br>LI-CCE-0125<br>CLSI                |
| Phosphate **1,2,3,4   | Li-Heparin Plasma / Serum / Urine | Colorimetric   | Abbott Alinity ci series / 0.23 mmol/l to 8.17 mmol/l                                   | CE                              | LI-CCE-0003<br>LI-CCE-0125<br>CLSI                |
| Potassium **1,2,3,4   |                                   | Ion selective electrode (ISE)                                | Abbott Alinity ci series / 1.0 mmol/l to 10.0 mmol/l<br>Urine: 1.0 mmol/l to 300 mmol/l | CE                              | LI-CCE-0003<br>LI-CCE-0125<br>CLSI                |
| Sodium **1,2,3,4  |                                   | Ion selective electrode (ISE)                                | Abbott Alinity ci series / 100 mmol/l to 200 mmol/l<br>Urine: 20 mmol/l to 400 mmol/l   | CE                              | LI-CCE-0003<br>LI-CCE-0125<br>CLSI                |
| Triglycerides **1,2,3,4   | Li-Heparin Plasma / Serum / Fluid | Glycerol Phosphate Oxidase                                   | Abbott Alinity ci series / 0.08 mmol/l to 16.05 mmol/l                                  | CE                              | LI-CCE-0003<br>LI-CCE-0125<br>CLSI                |

|   |  |   |                               |  |                          |                                    |
|---|--|---|-------------------------------|--|--------------------------|------------------------------------|
|   | Troponin I<br>(High sensitivity)<br>**1,2,3,4    | Li-Heparin Plasma                         | Immunoassay                   | Abbott Alinity ci series / 5 ng/l to 50,000 ng/l   | CE                       | LI-CCE-0003<br>LI-CCE-0125<br>CLSI |
|   | Urea **1,2,3,4                                   | Li-Heparin Plasma / Serum / Fluid / Urine | Urease                        | Abbott Alinity ci series / 1.1 mmol/l to 44.6 mmol/l<br>Urine: 14.3 mmol/l to 710.8 mmol/l | CE                       | LI-CCE-0003<br>LI-CCE-0125<br>CLSI |
|   | Uric Acid **1,2,3,4                              | Li-Heparin Plasma / Serum /Urine          | Uricase                       | Abbott Alinity ci series / 200 µmol/l to 2220 µmol/l<br>Urine: 120 µmol/l to 15,280 µmol/l | CE                       | LI-CCE-0003<br>LI-CCE-0125<br>CLSI |
| 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                              | Li-Heparin Plasma / Serum                 | Calculated                    | NA   | Based on standard method | LI-CCE-0040                        |
|   | Microalbumin **1,2,4                             | Urine                                     | Immunoturbidimetric           | Abbott Alinity ci series / 5 mg/l to 500 mg/l  | CE                       | LI-CCE-0003<br>LI-CCE-0125<br>CLSI |
|   | Protein / Creatinine ratio **1,2,3,4             |   | Calculated                    | NA   | Based on standard method | LI-CCE-0040                        |
|   | Protein -Total<br>**1,2,3,4                      | Li-Heparin Plasma / Serum                 | Biuret                        | Abbott Alinity ci series / 8 g/l to 184 g/l  | CE                       | LI-CCE-0003<br>LI-CCE-0125<br>CLSI |
|   |  | Urine / CSF                               | Benzethonium Chloride         | Abbott Alinity ci series / 68 mg/l to 2000 mg/l  | CE                       | LI-CCE-0003<br>LI-CCE-0125<br>CLSI |
|   | Sex Hormone Binding Globulin (SHBG)<br>**1,2,3,4 | Li-Heparin Plasma / Serum                 | Immunoassay                   | Abbott Alinity ci series / 4.5 nmol/l to 250 nmol/l  | CE                       | LI-CCE-0003<br>LI-CCE-0125<br>CLSI |
| 1061 Clinical Chemistry - .05 CO-oximetry                     | Carboxyhaemoglobin<br>**1,2,3,4                  | Blood Heparinised                         | Cooximetry                    | ABL 90 Flex  | CE                       | LP-CCE-0049                        |
|   | Ionised Calcium<br>**1,2,3,4                     |   | Ion selective electrode (ISE) | ABL90 Flex   | CE                       | LP-CCE-0049                        |

|   |                                   |                           |                                       |  |                           |                                    |
|---|-----------------------------------|---------------------------|---------------------------------------|--|---------------------------|------------------------------------|
|   | Methaemoglobin<br>**1,2,3,4       |                           | Cooximetry                            | ABL90 Flex                                       | Based on standard method  | LP-CCE-0049                        |
|   | Oxyhaemoglobin<br>**1,2,3,4       |                           | Cooximetry                            | ABL90 Flex                                       | CE                        | LP-CCE-0049                        |
| 1061 Clinical Chemistry -<br>.06 Blood pH and gas tensions                        | pCO2 **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                     | Blood Heparinised         | Absorption Spectroscopy               | ABL 90 Flex                                      | CE                        | LP-CCE-0049                        |
| 1061 Clinical Chemistry -<br>.07 Other analytes performed on a blood gas analyser | Base Excess<br>**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                        |
|   | Potassium **1,2,3,4               |                           | Ion selective electrode (ISE)         | ABL90 Flex                                       | CE                        | LP-CCE-0049                        |
|   | Sodium **1,2,3,4                  |                           | Ion selective electrode (ISE)         | ABL90 Flex                                       | CE                        | LP-CCE-0049                        |
|   | Standard Bicarbonate<br>**1,2,3,4 |                           | Calculated                            | ABL90 Flex                                       | CE                        | LP-CCE-0049                        |
| 1061 Clinical Chemistry -<br>.10 Drugs for therapeutic monitoring                 | Acetaminophen<br>**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<br>**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<br>**1,2,3,4  |                           | Calculated                            | NA   | Based on standard method  | LI-CCE-0040                        |
|   | Cyclosporin **1,2,3,4             | Blood in EDTA             | LC-MS/MS                              | Waters TQD<br>Waters Xevo TQ                     | Laboratory Developed Test | LP-CCE-0001<br>CLSI C62-A          |

|                          |                           |                                       |  |   |                           |                                    |
|--------------------------|---------------------------|---------------------------------------|--|---|---------------------------|------------------------------------|
|                          |                           |                                       |  | Waters TQ-XS / 10 ng/ml to 1500 ng/ml                                 |                           |                                    |
| Digoxin **1,2,3,4        | Serum                     | Particle Enhanced Turbidimetric Assay |  | Abbott Alinity ci series / 0.19 µg/l to 5.00 µg/l                     | CE                        | LI-CCE-0003<br>LI-CCE-0125<br>CLSI |
| 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 Alinity ci series / 0.04 µmol/l to 1.50 µmol/l                 | CE                        | LI-CCE-0003<br>LI-CCE-0125<br>CLSI |
| Phenobarbitone **1,2,3,4 |                           | Petinia                               |  | Abbott Alinity ci series / 2.0 mg/l to 80 mg/l                        | CE                        | LI-CCE-0003<br>LI-CCE-0125<br>CLSI |
| Phenytoin **1,2,3,4      |                           | Enzyme Immunoassay                    |  | Abbott Alinity ci series / 1.8 mg/l to 40 mg/l                        | CE                        | LI-CCE-0003<br>LI-CCE-0125<br>CLSI |
| Sirolimus **1,2,3,4      | Blood in EDTA             | LC-MS/MS                              |  | Waters TQD MS / Waters TQ-XS / 1 ng/ml to 51 ng/ml                    | Laboratory Developed Test | LP-CCE-0001<br>CLSI C62-A          |
| Tacrolimus **1,2,3,4     |                           | LC-MS/MS                              |  | Waters TQD MS<br>Waters Xevo TQ<br>Waters TQ-XS / 1 ng/ml to 58 ng/ml | Laboratory Developed Test | LP-CCE-0001<br>CLSI C62-A          |
| Theophylline **1,2,3,4   | Serum                     | Enzyme Immunoassay                    |  | Abbott Alinity ci series / 2.0 mg/l to 40.0 mg/l                      | CE                        | LI-CCE-0125<br>CLSI                |
| Tobramycin **1,2,3,4     |                           | Particle Enhanced Turbidimetric Assay |  | Abbott Alinity ci series / 0.3 µg/l to 10.0 µg/l                      | CE                        | LI-CCE-0003<br>LI-CCE-0125<br>CLSI |
| Valproate **1,2,3,4      |                           | Particle Enhanced Turbidimetric Assay |  | Abbott Alinity ci series / 12.5 mg/l to 150.0 mg/l                    | CE                        | LI-CCE-0003<br>LI-CCE-0125<br>CLSI |

|  |   |                              |   |   |                              |   |
|--|---|------------------------------|---|---|------------------------------|---|
|  | Vancomycin **1,2,3,4                                | Li-Heparin Plasma/<br>Serum  | Particle Enhanced<br>Turbidimetric Assay                | Abbott Alinity ci<br>series / 1.4 mg/l to<br>100.0 mg/l     | CE                           | LI-CCE-0003<br>LI-CCE-0125<br>CLSI                |
|  | Voriconazole<br>**1,2,3,4                           | Serum                        | LC-MS/MS  | Waters TQD MS /<br>0.1 mg/L to 11<br>mg/L                   | Laboratory Developed<br>Test | LP-CCE-0050<br>CLSI C62-A                         |
| 1061 Clinical Chemistry -<br>.14 Alcohol for non-legal<br>purposes   | Ethanol **1,2,3,4                                   | Fluoride EDTA<br>Plasma      | Enzymatic   | Abbott Alinity ci<br>series / 10 mg/dl to<br>600 mg/dl      | CE                           | LI-CCE-0003<br>LI-CCE-0125<br>LP-CCE-0064<br>CLSI |
| 1061 Clinical Chemistry -<br>.15 Drugs for toxicological<br>purposes | Salicylate **1,2,3,4                                | Li-Heparin Plasma /<br>Serum | Enzymatic   | Alinity ci series / 50<br>mg/dl to 1000<br>mg/dl            | CE                           | LI-CCE-0125<br>CLSI                               |
| 1061 Clinical Chemistry -<br>.20 Hormones                            | Adrenocorticotrophic<br>hormone (ACTH)<br>**1,2,3,4 | EDTA Plasma on ice           | Immunometric Assay                                      | Roche Cobas / 1.5<br>to 2000 ng/L                           | CE                           | LP-CCE-0057<br>CLSI                               |
|  | Androstenedione<br>**1,2,3,4                        | Serum                        | LC-MS/MS  | Waters Xevo TQ /<br>0.1 nmol/L to 44.6<br>nmol/L            | Laboratory Developed<br>Test | LP-CCE-0055<br>CLSI C62-A                         |
|  | Cortisol **1,2,3,4                                  | Li-Heparin Plasma /<br>Serum | Immunoassay   | Abbott Alinity ci<br>series / 27.5 nmol/l<br>to 1650 nmol/l | CE                           | LI-CCE-0003<br>LP-CCE-0064<br>CLSI                |
|  | C-Peptide **1,2,3,4                                 | Li-Heparin Plasma /<br>Serum | Chemiluminescent<br>microparticle<br>Immunoassay (CMIA) | Abbott Alinity ci<br>series / 10 pmol/l<br>to 10,000 pmol/l | CE                           | LP-CCE-0003<br>LI-CCE-0125<br>CLSI                |
|  | Follicle Stimulating<br>Hormone (FSH)<br>**1,2,3,4  |                              | Immunoassay   | Abbott Alinity ci<br>series / 0.11 IU/L<br>to 150 IU/L      | CE                           | LI-CCE-0003<br>LI-CCE-0125<br>CLSI                |
|  | Growth Hormone<br>**1,2,3,4                         | Serum                        | Immunoassay   | IDS iSYS / 0 µg/l to<br>10 µg/l                             | CE                           | LP-CCE-0051<br>CLSI                               |
|  | HCG- Total **1,2,3,4                                | Li-Heparin Plasma /<br>Serum | Immunoassay   | Abbott Alinity ci<br>series / 1.2 IU/l to<br>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<br>to 1200 µg/l                          | CE                           | LP-CCE-0035<br>CLSI                               |
|  | Insulin **1,2,3,4                                   | Li-Heparin Plasma /<br>Serum | Immunoassay   | Abbott Alinity ci<br>series / 11.5                          | CE                           | LI-CCE-0003<br>LI-CCE-0125<br>CLSI                |

|  |   |                           |                                |  |                           |   |
|--|---|---------------------------|--------------------------------|--|---------------------------|---|
|  |   |                           |                                | pmol/l to 2153 pmol/l                                  |                           |   |
|  | Lutenising Hormone (LH) **1,2,3,4           |                           | Immunoassay                    | Abbott Alinity ci series / 0.12 IU/l to 250IU/l        | CE                        | LI-CCE-0003<br>LI-CCE-0125<br>CLSI                |
|  | Macroprolactin **1,2,3,4                    |                           | PEG Precipitation / Calculated | Abbott Alinity ci series / 17.22 mIU/l to 4200mIU/l    | Based on standard method  | LP-CCE-0005<br>LI-CCE-0125                        |
|  | Oestradiol **1,2,3,4                        |                           | Immunoassay                    | Abbott Alinity ci series / 88 pmol/l to 3670 pmol/l    | CE                        | LI-CCE-0003<br>LI-CCE-0125<br>CLSI                |
|  | Parathyroid Hormone (PTH) **1,2,3,4         | EDTA Plasma               | Immunoassay                    | Roche e411 / 0.96 to 530 pmol/L                        | CE                        | LP-CCE-0048<br>CLSI                               |
|  | Progesterone **1,2,3,4                      | Li-Heparin Plasma / Serum | Immunoassay                    | Abbott Alinity ci series / 1.62 nmol/l to 127.2 nmol/l | CE                        | LI-CCE-0003<br>LI-CCE-0125<br>CLSI                |
|  | Prolactin **1,2,3,4                         |                           | Immunoassay                    | Abbott Alinity ci series / 17.22 mIU/l to 4200 mIU/l   | CE                        | LI-CCE-0003<br>LI-CCE-0125<br>CLSI                |
|  | T3 free **1,2,3,4                           |                           | Immunoassay                    | Abbott Alinity ci series / 1.9 pmol/l to 30.72 pmol/l  | CE                        | LI-CCE-0003<br>LI-CCE-0125<br>CLSI                |
|  | T4 free **1,2,3,4                           |                           | Immunoassay                    | Abbott Alinity ci series / 5.41 pmol/l to 64.35 pmol/l | CE                        | LI-CCE-0003<br>LI-CCE-0125<br>LP-CCE-0064<br>CLSI |
|  | Testosterone **1,2,3,4                      | Serum                     | LC-MS/MS                       | Waters Xevo TQ MS / 0.1 nmol/L to 39 nmol/L            | Laboratory Developed Test | LP-CCE-0055<br>CLSI C62-A                         |
|  | Thyroid Stimulating Hormone (TSH) **1,2,3,4 | Plasma / Serum            | Immunoassay                    | Abbott Alinity ci series / 0.0083 to 100.0000 mIU/L    | CE                        | LI-CCE-0003<br>LI-CCE-0125                        |
|  | Urine Free Cortisol **1,2,3,4               | 24 hour Urine             | LC-MS/MS                       | Waters TQD MS / 7 nmol/L to 3200 nmol/L                | Laboratory Developed Test | LP-CCE-0029<br>CLSI C62-A                         |
| 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                     |                           | Immunoturbidimetric                               | Abbott Alinity ci series / 0.19 g/l to 5.83 g/l        | CE   | LI-CCE-0003<br>LI-CCE-0125<br>CLSI                |
|  | Transferrin Saturation **1,2,3,4          |                           | Calculated  | N/A  | Based on standard method                         | LI-CCE-0040                                       |
| 1061 Clinical Chemistry - .45 Vitamin B12 and folate             | Folate **1,2,3,4                          | Blood in EDTA             | Immunoassay                                       | Abbott Alinity ci series / 2.2 µg/l to 20.0 µg/l       | CE   | LI-CCE-0003<br>LI-CCE-0125<br>CLSI                |
|  | Folate Red Cell **1,2,3,4                 |                           | 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                     |                           | Li-Heparin Plasma / Serum                         | Immunoassay  | Abbott Alinity ci series / 148 ng/l to 2000 ng/l | CE  |
| 1061 Clinical Chemistry - .47 Vitamin assays                     | Active B12 / Holotranscobalamin **1,2,3,4 | Serum                     | Chemiluminescent microparticle Immunoassay (CMIA) | Abbott Alinity ci series / 5 pmol/l to 128 pmol/l      | CE   | LI-CCE-0115<br>LI-CCE-0125<br>CLSI                |
|  | Vitamin D **1,2,3,4                       |                           | LC-MS/MS  | Waters TQD MS / Waters TQ-XS / 15 nmol/L to 368 nmol/L | Laboratory Developed Test                        | LP-CCE-0002<br>CLSI C62-A                         |
|  |   |                           | LC-MSMS   | Waters TQ-XS 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         | Li-Heparin Plasma / Serum | Immunoassay                                       | Abbott Alinity ci series / 2.0µg/l to 2000 µg/l        | CE   | LI-CCE-0003<br>LI-CCE-0125<br>CLSI                |
|  | 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) **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   | Li-Heparin Plasma / Serum | Immunoassay                                       | Abbott Alinity ci series / 1.73 µg/l to 1500 µg/l                             | CE                         | LI-CCE-0003<br>LI-CCE-0125<br>CLSI |
|   | PSA Total **1,2,3,4   |                           | Immunoassay                                       | Abbott Alinity ci series / 0.1 ng/ml to 100ng/ml                              | CE                         | LI-CCE-0003<br>LI-CCE-0125<br>CLSI |
|   | Thyroglobulin **1,2,3,4                                     | Serum                     | Immunoassay                                       | Roche Cobas / 0.2 to 5000 ng/ml   | CE                         | LP-CCE-0059<br>CLSI                |
| 1061 Clinical Chemistry - .52 Collagen cross-link markers | C-terminal Telopeptide of Type 1 collagen (CTX-1) **1,2,3,4 | EDTA Plasma               | Immunoassay                                       | Roche e411 / 0.010 to 6.00 µg/L   | CE                         | LP-CCE-0031<br>CLSI                |
|   | Procollagen Type 1 N-Propeptide (P1NP) **1,2,3,4            |                           | Immunoassay                                       | Roche e411 / 5.0 to 1200 µg/L   | CE                         | LP-CCE-0032<br>CLSI                |
| 1061 Clinical Chemistry - .56 Biogenic amines             | Homocysteine **1,2,3,4                                      | Li-Heparin Plasma         | Chemiluminescent microparticle Immunoassay (CMIA) | Abbott Alinity ci series / 1.00 µmol/l to 50.0 µmol/l                         | CE                         | LI-CCE-0118<br>LI-CCE-0125<br>CLSI |
| 1061 Clinical Chemistry - .60 Glycohaemoglobins           | HbA1c **1,2,3,4   | Blood in EDTA             | HPLC  | Arkray HA8190 / 20 mmol/mol to 150mmol/mol                                    | CE                         | LP-CCE-0060<br>LP-CCE-0080<br>CLSI |
|   |   |                           | HPLC  | Arkray HA8190 20 mmol/mol to 150 mmol/mol                                     | CE                         | LP-CCE-0080                        |
| 1061 Clinical Chemistry - .77 Calculi                     | Stone Analysis **2,4  | Stone                     | FT-IR   | Nicolet iS10  | Based on a standard method | LP-CCE-0041                        |
| 1061 Clinical Chemistry - .78 Intermediary metabolites    | 3 -Methoxytyramine **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 **1,2,3,4                              |                           | LC-MS/MS  | Waters Xevo TQ MS / Metanephrine 40 pmol/L to 11578 pmol/L<br>Normetanephrine | Laboratory Developed Test  | LP-CCE-0053<br>CLSI C62-A          |



|   |   |                                   |                                      |  |                          |                                    |
|---|---|-----------------------------------|--------------------------------------|--|--------------------------|------------------------------------|
|   |   |                                   |                                      | 60 pmol/L to 13135 pmol/L                      |                          |                                    |
| 1061 Clinical Chemistry - .85 Anti-thyroglobulin antibodies | Thyroglobulin Antibodies **1,2,3,4            | Serum                             | Electrochemiluminescence immunoassay | Roche e411 / 10 to 4000 IU/L                   | 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 | Li-Heparin Plasma / Serum         | Immunoassay                          | Abbott Alinity ci series / 3 IU/l to 1000 IU/L | CE                       | LI-CCE-0003<br>LI-CCE-0125<br>CLSI |

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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 directly from the laboratory*

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 / 0.6 to 33.3 mmol/L | CE   | LP-POC-016<br>CLSI C46-A2                              |
|   | Ketone **4                    |                       | Enzymatic and Amperometric                 | Stat Strip Nova Biomedical hand held device & docking station / 0.1 to 7.0 mmol/L  | CE   | LP-POC-015<br>CLSI C46-A2                              |
| 1061 Clinical Chemistry - .05 CO-oximetry   | Haematocrit **2,4             | Blood in heparin      | Calculated                                 | ABL 90 Flex Analyser<br>ABL 90 Flex Plus Analyser                                  | CE   | LP-POC-001<br>LP-POC-018<br>CLSI C46-A2                |
|   |                               |                       | Impedance                                  | Prime Plus Blood Gas Analyser / 12 to 70%  | CE   | LP-POC-017<br>CLSI C46-A2                              |
|   | Haemoglobin **2,4             |                       | Absorption Spectroscopy                    | ABL 90 Flex Analyser<br>ABL 90 Flex Plus Analyser / - 0.48 to 27.7g/dL             | CE   | LP-POC-001<br>LP-POC-018<br>CLSI C46-A2<br>CLSI H15-A3 |
|   | Haemoglobin **2,4             |                       | Chemometrics applied to optical absorbance | Prime Plus Blood Gas Analyser / 5.0 to 25.0 g/dL                                   | CE   | LP-POC-017<br>CLSI H15-A3<br>CLSI C46-A2               |
|   | Haemoglobin Derivatives **2,4 |                       | Absorption Spectroscopy                    | ABL 90 Flex Analyser<br>ABL 90 Flex Plus   | CE   | LP-POC-001<br>LP-POC-018                               |

|   |            |  |  |  |    |   |
|---|------------|--|--|--|----|---|
|   |            |  |  | Analyser /<br>0.0 to 100.0%  |    | CLSI H15-A3<br>CLSI C46-A2              |
| 1061 Clinical Chemistry -<br>.06 Blood pH and gas<br>tensions | pCO2 **2,4 |  | Ion Selective<br>Electrode (ISE)<br>Potentiometric | Prime Plus Blood<br>Gas Analyser<br>/ 0.4 to 26.7 kPa                        | CE | LP-POC-017<br>CLSI C46-A2               |
|   |            |  | Potentiometry                                      | Abbott i-Stat / 0.67<br>to 17.33 kPa   | CE | LP-POC-010<br>CLSI C46-A2               |
|   |            |  | Potentiometry                                      | ABL 90 Flex<br>Analyser<br>ABL 90 Flex Plus<br>Analyser /<br>0.67 - 33.3 kPa | CE | LP-POC-001<br>LP-POC-018<br>CLSI C46-A2 |
|   | pH **2,4   |  | Ion Selective<br>Electrode (ISE)                   | Abbott i-Stat / 6.5<br>to 8.2  | CE | LP-POC-010<br>CLSI C46-A2               |
|   |            |  | Ion Selective<br>Electrode (ISE)                   | ABL 90 Flex<br>Analyser<br>ABL 90 Flex Plus<br>Analyser /<br>6.3 to 8.0      | CE | LP-POC-001<br>LP-POC-018<br>CLSI C46-A2 |
|   |            |  | Ion Selective<br>Electrode (ISE)                   | Prime Plus Blood<br>Gas Analyser / 6.5<br>to 8.0                             | CE | LP-POC-017<br>CLSI C46-A2               |
|   | pO2 **2,4  |  | Amperometry  | Abbott i-Stat / 0.7<br>to 106.6 kPa  | CE | LP-POC-010<br>CLSI C46-A2               |
|   |            |  | Ion Selective<br>Electrode (ISE)<br>Amperometric   | Prime Plus Blood<br>Gas Analyser /<br>0.7 - 102.0 kPa                        | CE | LP-POC-017<br>CLSI C46-A2               |
|   |            |  | Potentiometry                                      | ABL 90 Flex<br>Analyser<br>ABL 90 Flex Plus<br>Analyser /<br>0 to 107 kPa    | CE | LP-POC-001<br>LP-POC-018<br>CLSI C46-A2 |
|   |            |  | Potentiometry                                      | ABL 90 Flex<br>Analyser<br>ABL 90 Flex Plus<br>Analyser<br>/ 0 - 107 kPa     | CE | LP-POC-001<br>LP-POC-018<br>CLSI C46-A2 |

|  |                             |   |   |    |   |
|--|-----------------------------|---|---|----|---|
|  | SO2 **2,4                   | Absorption Spectroscopy                       | ABL 90 Flex Analyser<br>ABL 90 Flex Plus Analyser /<br>2 to 102%      | CE | LP-POC-001<br>LP-POC-018<br>CLSI C46-A2 |
|  |                             | Chemometrics applied to optical absorbance    | Prime Plus Blood Gas Analyser /<br>30 to 100%                         | CE | LP-POC-017<br>CLSI C46-A2               |
| 1061 Clinical Chemistry - .07 Other analytes performed on a blood gas analyser | Anion Gap **2,4             | Calculated                                    | ABL 90 Flex Analyser<br>ABL 90 Flex Plus Analyser                     | CE | LP-POC-001<br>LP-POC-018<br>CLSI C46-A2 |
|  | Base Excess **2,4           | Calculated                                    | ABL 90 Flex Analyser<br>ABL 90 Flex Plus Analyser                     | CE | LP-POC-001<br>LP-POC-018<br>CLSI C46-A2 |
|  |                             | Calculated                                    | Prime Plus Blood Gas Analyser   | CE | LP-POC-017<br>CLSI C46-A2               |
|  | Chloride **2,4              | Ion Selective Electrode (ISE)                 | ABL90 Flex Analyser<br>ABL90 Flex Plus Analyser /<br>70 to 350 mmol/L | CE | LP-POC-001<br>LP-POC-018<br>CLSI C46-A2 |
|  | Creatinine                  | Amperometry                                   | ABL 90 Flex Plus Analyser /<br>10 to 1800 µmol/L                      | CE | LP-POC-018<br>CLSI C46-A2               |
|  | Glucose **2,4               | Amperometry                                   | ABL 90 Flex Analyser<br>ABL 90 Flex Plus Analyser /<br>0 to 60 mmol/L | CE | LP-POC-001<br>LP-POC-018<br>CLSI C46-A2 |
|  | Glucose **2,4               | Ion Selective Electrode (ISE)<br>Amperometric | Prime Plus Blood Gas Analyser /<br>0.8 to 28 mmol/L                   | CE | LP-POC-017<br>CLSI C46-A2               |
|  | Ionised Calcium (iCa) **2,4 | Ion Selective Electrode (ISE)                 | Prime Plus Blood Gas Analyser /<br>0.4 to 10.8 mmol/L                 | CE | LP-POC-017<br>CLSI C46-A2               |
|  | Ionised Calcium (iCa) **2,4 | Ion Selective Electrode (ISE)                 | ABL 90 Flex Analyser<br>ABL 90 Flex Plus                              | CE | LP-POC-001<br>LP-POC-018<br>CLSI C46-A2 |

|                               |  |  |  |    |   |
|-------------------------------|--|--|--|----|---|
|                               |  |  | Analyser /<br>0.2 to 9.99 mmol/L<br>/<br>0.1 to 9.99 mmol/L                    |    |   |
| Ionised Magnesium<br>**2,4    |  | Ion Selective<br>Electrode (ISE)                 | Prime Plus Blood<br>Gas Analyser /<br>0.1 to 1.5 mmol/L                        | CE | LP-POC-017<br>CLSI C46-A2                             |
| Lactate **2,4                 |  | Amperometry                                      | ABL 90 Flex<br>Analyser<br>ABL 90 Flex Plus<br>Analyser /<br>-0.1 to 31 mmol/L | CE | LP-POC-001<br>LP-POC-018<br>CLSI C46-A2               |
|                               |  | Ion Selective<br>Electrode (ISE)<br>Amperometric | Prime Plus Blood<br>Gas Analyser /<br>0.3 to 20.0 mmol/L                       | CE | LP-POC-017<br>CLSI C46-A2                             |
| Potassium **2,4               |  | Ion Selective<br>Electrode (ISE)                 | Abbott i-Stat /<br>2 to 9 mmol/L   | CE | LP-POC-010<br>CLSI C46-A2                             |
|                               |  | Ion Selective<br>Electrode (ISE)                 | ABL 90 Flex<br>Analyser<br>ABL 90 Flex Plus<br>Analyser /<br>0.5 to 25 mmol/L  | CE | LP-POC-001<br>LP-POC-018<br>CLSI C46-A2               |
|                               |  | Ion Selective<br>Electrode (ISE)                 | Prime Plus Blood<br>Gas Analyser /<br>1.0 to 20.0 mmol/L                       | CE | LP-POC-017<br>CLSI C46-A2                             |
| Sodium **2,4                  |  | Ion Selective<br>Electrode (ISE)                 | Abbott i-Stat / 100<br>to 180 mmol/L   | CE | LP-POC-010<br>CLSI C46-A2                             |
|                               |  | Ion Selective<br>Electrode (ISE)                 | ABL 90 Flex<br>Analyser<br>ABL 90 Flex Plus<br>Analyser /<br>7 to 350 mmol/L   | CE | LP-POC-001<br>LP-POC-018<br>CLSI C46-A2               |
|                               |  | Ion Selective<br>Electrode (ISE)                 | Prime Plus Blood<br>Gas Analyser / 80<br>to 200 mmol/L                         | CE | LP-POC-017<br>CLSI C46-A2                             |
| Standard Bicarbonate<br>**2,4 |  | Calculated                                       | ABL 90 Flex<br>Analyser<br>ABL 90 Flex Plus<br>Analyser                        | CE | LP-POC-001<br>LP-POC-017<br>LP-POC-018<br>CLSI C46-A2 |

|                                      |                         |  |   |  |    |                           |
|--------------------------------------|-------------------------|--|---|--|----|---------------------------|
|                                      |                         |  |   | Prime Plus Blood Gas Analyser              |    |                           |
|                                      | Urea                    |  | Potentiometry   | ABL 90 Flex Plus Analyser / 1 to 50 mmol/L | CE | LP-POC-018<br>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<br>IFCC        |

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*Note 2 – New parameters/tests may be added*

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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        | 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, LP-NGS-17, LP-NGS-25, LP-NGS-26, 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) |
|  | 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)   |

|  |               |                  |               |                    |    |  |
|--|---------------|------------------|---------------|--------------------|----|--|
|  |               |                  |               |                    |    | Practice guidelines for Sanger Sequencing Analysis and Interpretation and General Genetic Laboratory Reporting Recommendations   |
| 1075 Molecular genetics - .11 DNA extraction | DNA Isolation | EDTA Whole blood | DNA Isolation | Roche MagnaPure 24 | CE | <p>LP-NGS-10 (DNA Isolation from Peripheral Blood on the MagNa Pure 24)</p> <p>American College of Medical Genetics and Genomics (ACMG) and Association for Molecular Pathology (AMP) guidelines</p> <p>Association of Clinical Genomic Science (ACGS)</p> |



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<br>Blood counts                      | Haematocrit (Hct) **1,2,4  | Blood in EDTA | Culmulative pulse measurement                        | 0.0 % to 75.0 % / Sysmex XN-10 / XN 20  | CE   | LP-HAE-0067, LP-HAE-0068<br>BSH Guidelines           |
|   | Haemoglobin (Hb) **1,2,4   |               | Sodium Lauryl Sulphate (SLS) Haemoglobin             | 0.01g/dl to 26.0g/dl / Sysmex XN-10 / XN 20   | CE   | LP-HAE-0067, LP-HAE-0068<br>BSH Guidelines           |
|   | MCH **1,2,4  |               | Calculated from Hb and RBC                           | N/A / Sysmex XN-10 / XN 20  | CE   | LP-HAE-0067, LP-HAE-0068<br>BSH Guidelines           |
|   | MCHC **1,2,4   |               | Calculated from Hb and HCT                           | N/A / Sysmex XN-10 / XN 20  | CE   | LP-HAE-0067, LP-HAE-0068<br>BSH Guidelines           |
|   | Mean cell volume (MCV) **1,2,4                                       |               | Indirect measurement (mean of RBC volume)            | N/A / Sysmex XN-10 / XN 20  | CE   | LP-HAE-0067, LP-HAE-0068<br>BSH Guidelines           |
|   | Platelet count **1,2,3,4   |               | Hydrodynamic Focussing Direct Current (DC) detection | 0.01 X 10 <sup>9</sup> /l to 5000 x 10 <sup>9</sup> /l / Sysmex XN-10 / XN 20   | CE   | LP-HAE-0067, LP-HAE-0068<br>BSH Guidelines           |
|   | Red cell count (RBC) **1,2,4   |               | Hydrodynamic Focussing Direct Current (DC) detection | 0.01 X 10 <sup>9</sup> /l to 8.6 x 10 <sup>9</sup> /l / Sysmex XN-10/XN 20  | CE   | LP-HAE-0067, LP-HAE-0068<br>BSH Guidelines           |
|   | White cell count (WBC) **1,2,4                                       |               | Fluorescence Flow Cytometry                          | 0.01 x 10 <sup>9</sup> /l to 440 x 10 <sup>9</sup> /l / Sysmex XN-10 / XN 20  | CE   | LP-HAE-0067, LP-HAE-0068<br>BSH Guidelines           |
| 1030 Haematology - .02<br>Visual examination of blood films | Blood film examination includes Neutrophils, Lymphocytes, Monocytes, |               | Staining / Microscopy / Digital imaging              | N/A / Wescor stainer / Sysmex SP50 stainer / Microscope / CellaVision DI-60 automated digital imaging analysis system | Based on standard method                                       | LP-HAE-004<br>LP-HAE-006<br>LP-HAE-070<br>LP-HAE-072 |

|   |   |                         |   |  |                          |   |
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|   | Eosinophils, Basophils, Red Cell morphology **2,4         |                         |   | with operator result validation  |                          | BSH Guidelines                              |
| 1030 Haematology - .03<br>Erythrocyte sedimentation rate                                | Erythrocyte Sedimentation Rate (ESR) **1,3,4              | Blood in sodium citrate | Photo optical based on Westergren method  | 0 to 147mm / Sarstedt Sediplus S2000   | CE                       | LP-HAE-024<br>BSH Guidelines                |
| 1030 Haematology - .05<br>Automated differential leucocyte counts                       | Automated basophil count **1,2,4                          | Blood in EDTA           | Fluorescence Flow Cytometry               | 0.03 x 10 <sup>9</sup> /l to 440 x 10 <sup>9</sup> /l / Sysmex XN-10 / XN 20 | CE                       | LP-HAE-0067, LP-HAE-0068<br>BSH Guidelines  |
|   | Automated eosinophil count **1,2,4                        |                         | Fluorescence Flow Cytometry               | 0.03 x 10 <sup>9</sup> /l to 440 x 10 <sup>9</sup> /l / Sysmex XN-10 / XN 20 | CE                       | LP-HAE-0067, LP-HAE-0068<br>BSH Guidelines  |
|   | Automated lymphocyte count **1,2,4                        |                         | Fluorescence Flow Cytometry               | 0.03 x 10 <sup>9</sup> /l to 440 x 10 <sup>9</sup> /l / Sysmex XN-10 / XN 20 | CE                       | LP-HAE-0067, LP-HAE-0068<br>BSH Guidelines  |
|   | Automated monocyte count **1,2,4                          |                         | Fluorescence Flow Cytometry               | 0.03 x 10 <sup>9</sup> /l to 440 x 10 <sup>9</sup> /l / Sysmex XN-10 / XN 20 | CE                       | LP-HAE-0067, LP-HAE-0068<br>BSH Guidelines  |
|   | Automated neutrophil count **1,2,4                        |                         | Fluorescence Flow Cytometry               | 0.03 x 10 <sup>9</sup> /l to 440 x 10 <sup>9</sup> /l / Sysmex XN-10 / XN 20 | CE                       | LP-HAE-0067, LP-HAE-0068<br>BSH Guidelines  |
| 1030 Haematology - .06<br>Automated reticulocyte counts                                 | Automated reticulocyte count **1,2,4                      |                         | Fluorescence Flow Cytometry               | 0.01 x 10 <sup>9</sup> /l to 720 x 10 <sup>9</sup> /l / Sysmex XN-10 / XN 20 | CE                       | LP-HAE-0067, LP-HAE-0068<br>BSH Guidelines  |
| 1030 Haematology - .08<br>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<br>BSH Guidelines                |
| 1030 Haematology - .09<br>Examination of malarial parasites                             | Malaria Blood film examination **2,4                      | Blood in EDTA           | Staining / microscopy                     | N/A / Manual staining technique / Microscope                                 | Based on standard method | LP-HAE-025,<br>LP-HAE-026<br>BSH Guidelines |
|   | Malaria screening test **2,4                              |                         | Immunochromatographic card screening test | N/A / Manual immunochromatographic card test                                 | CE                       | LP-HAE-027<br>BSH Guidelines                |
| 1030 Haematology - .20<br>Bone marrow examination                                       | Bone marrow examination **1,2,4                           | Bone marrow aspirate    | Staining / microscopy                     | N/A / Wescor stainer / Microscope  | Based on standard method | LP-HAE-007<br>LP-HAE-040<br>BSH Guidelines  |

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| 1030 Haematology - .30<br>Tests for haemoglobin variants and thalassaemia | Haemoglobin Electrophoresis **1,2,4                                      | Blood in EDTA           | Capillary Electrophoresis              | N/A / Sebia Minicap Flex piercing   | CE | LP-HAE-083<br>BSH Guidelines             |
|   | HPLC for Haemoglobinopathy **1,2,4                                       |                         | High performance liquid chromatography | % HbA2: 1.5 to 11.4 %, % Hb F: 0.8 to 16.5 % / Biorad D10   | CE | LP-HAE-050<br>BSH Guidelines             |
|   | Sickle cell screen **4   |                         | Qualitative solubility test for Hb S   | N/A / Manual test   | CE | LP-HAE-028<br>BSH Guidelines             |
| 1030 Haematology - .36<br>Screening tests for G6Pd                        | Glucose 6 Phosphate Dehydrogenase screen **1,2,4                         |                         | Qualitative fluorescence test          | N/A / Manual test   | CE | LP-HAE-029<br>BSH Guidelines             |
| 1030 Haematology - .40<br>Limited haemostasis related tests               | Activated Protein C resistance **1,4                                     | Blood in sodium citrate | Photo optical                          | 10 to 250 seconds / ACL TOP 550   | CE | LP-HAE-089<br>BSH Guidelines             |
|   | Anti Xa level (LMWH) **2,4   | Blood in sodium citrate | Chromogenic                            | 0.04 IU/ml to 2.00 IU/ml / ACL TOP 550  | CE | LP-HAE-092<br>BSH Guidelines             |
|   | Anti Xa level (UFH) **2,4  | Blood in sodium citrate | Chromogenic                            | 0.04 IU/ml to 2.00 IU/ml / ACL TOP 550  | CE | LP-HAE-097<br>BSH Guidelines             |
|   | Anticoagulant drug monitoring: Rivaroxaban / Apixaban / Dabigatran **2,4 |                         | Chromogenic                            | Rivaroxaban: 20ng/ml to 1000 ng/ml<br>Apixaban: 15 ng/ml to 1000 ng/ml<br>Dabigatran: 20 ng/ml to 2000ng/ml / ACL TOP 550 | CE | LP-HAE-093, LP-HAE-095<br>BSH Guidelines |
|   | Antithrombin **1,2,4   |                         | Chromogenic                            | 10 % to 150 % / ACL TOP 550   | CE | LP-HAE-089<br>BSH Guidelines             |
|   | Factor II:C assay **1,2,4  |                         | Photo optical                          | 0.008 IU/ml to 1.5 IU/ml / ACL TOP 550  | CE | LP-HAE-102<br>BSH Guidelines             |
|   | Factor IX:C assay **1,2,4  |                         | Photo optical                          | 0.001 IU/ml to 1.5 IU/ml / ACL TOP 550  | CE | LP-HAE-103<br>BSH Guidelines             |
|   | Factor V:C assay **1,2,4   |                         | Photo optical                          | 0.005 IU/ml to 1.5 IU/ml / ACL TOP 550  | CE | LP-HAE-102<br>BSH Guidelines             |
|   | Factor VII:C assay **1,2,4   |                         | Photo optical                          | 0.003 IU/ml to 1.5 IU/ml / ACL TOP 550  | CE | LP-HAE-102<br>BSH Guidelines             |

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|--|---|---------------|----------------------|---|----|------------------------------|
|  | Factor VIII:C assay<br>**1,2,4  |               | Photo optical        | 0.001 IU/ml to 1.5 IU/ml /<br>ACL TOP 550   | CE | LP-HAE-103<br>BSH Guidelines |
|  | Factor X:C assay<br>**1,2,4   |               | Photo optical        | 0.008 IU/ml to 1.5 IU/ml /<br>ACL TOP 550   | CE | LP-HAE-102<br>BSH Guidelines |
|  | Factor XI:C assay<br>**1,4  |               | Photo optical        | 0.001 IU/ml to 1.5 IU/ml /<br>ACL TOP 550   | CE | LP-HAE-103<br>BSH Guidelines |
|  | Factor XII:C assay<br>**1,2,4   |               | Photo optical        | 0.01 IU/ml to 1.5 IU/ml /<br>ACL TOP 550  | CE | LP-HAE-103<br>BSH Guidelines |
|  | Free Protein S<br>**1,2,4   |               | Immuno-turbidimetric | 11 % to 150 % / ACL TOP<br>550  | CE | LP-HAE-089<br>BSH Guidelines |
|  | Lupus anticoagulant<br>**1,2,4  |               | Photo optical        | DRVVS: 16 to 240<br>seconds, DRVVC:<br>16 to 121 seconds,<br>SCT : 10 to 400 seconds /<br>ACL TOP 550 | CE | LP-HAE-090<br>BSH Guidelines |
|  | Lupus Insensitive<br>Activated Partial<br>Thromboplastin Time<br>(APTT) **1,2,4 |               | Photo optical        | 16 to 400 seconds / ACL<br>TOP 550  | CE | LP-HAE-091<br>BSH Guidelines |
|  | Protein C **1,2,4   |               | Chromogenic          | 10 % to 150 % / ACL TOP<br>550  | CE | LP-HAE-089<br>BSH Guidelines |
| 1030 Haematology - .41<br>General haemostasis<br>related tests           | Activated Partial<br>Thromboplastin Time<br>(APTT) **1,2,3,4                    |               | Photo optical        | 16 to 400 seconds / ACL<br>TOP 550  | CE | LP-HAE-087<br>BSH Guidelines |
|  | D Dimer **1,4   |               | Immuno-turbidimetric | 0.22 ug/ml to 128 ug/ml /<br>ACL TOP 550  | CE | LP-HAE-087<br>BSH Guidelines |
|  | Fibrinogen (Clauss)<br>**1,4  |               | Photo optical        | 0.35 g/L to 10.0 g/L / ACL<br>TOP 550   | CE | LP-HAE-087<br>BSH Guidelines |
|  | International<br>Normalised ratio<br>(INR) **1,4                                |               | Photo optical        | 0.67 ISI to 26 ISI<br>/ ACL TOP 550   | CE | LP-HAE-087<br>BSH Guidelines |
|  | Prothrombin Time<br>**1,2,3,4   |               | Photo optical        | 8 to 320 seconds /<br>ACL TOP 550   | CE | LP-HAE-058<br>BSH Guidelines |
|  | Thrombin Time<br>**1,2,4  |               | Photo optical        | 5 to 300 seconds / ACL<br>TOP 550   | CE | LP-HAE-088<br>BSH Guidelines |
| 1030 Haematology - .57<br>Screening test for<br>infectious mononucleosis | Infectious<br>mononucleosis<br>screen **3,4                                     | Blood in EDTA | Immunoassay          | N/A / Manual test   | CE | LP-HAE-030<br>BSH Guidelines |

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| 1030 Haematology - .70<br>Immunophenotyping | Acute panel: Antigens tested; IgG, 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<br>**2,3,4  | Blood in EDTA / BMA in RPMI | Flow cytometry | 0 to 100% / BD Facs Canto | Based on standard method    | LP-HAE-075, LP-HAE-078<br>BSH Guidelines |
|   | Lymphoproliferative panel: Antigens tested; B-Cell panel: CD45, CD5, CD10, CD19, CD38, CD8, CD4, CD3, CD56, Kappa, Lambda, FMC7, CD23, CD22, IgM, 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<br>**2,3,4 |                             | Flow cytometry | 0 to 100% / BD Facs Canto | Based on standard method    | LP-HAE-075, LP-HAE-077<br>BSH Guidelines |
|   | PNH screen: Antigens tested; CD235, CD59, FLAER, CD15, CD33, CD14, CD24 **2,3,4  |                             | Flow cytometry | 0 to 100% / BD Facs Canto | Laboratory developed method | LP-HAE-075, LP-HAE-079<br>BSH Guidelines |

*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*

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<br>Blood counts                      | Haemoglobin (Hb) **2,4                     | Fresh Capillary Blood or Blood in EDTA | Modified Azidemethaemoglobin reaction  | HemoCue Hb 201 DM Analyser / 0 - 25.6 g/dL | CE   | LP-POC-002<br>CLSI H15-A3   |
| 1030 Haematology - .40<br>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 & CLSI POCT14 |
|   | International Normalised ratio (INR) **1,4 | Fresh Capillary Blood                  | Electrochemical measurement of INR     | Coaguchel XS Pro 0.8 - 8.0                 | CE   | LP-POC-003<br>BSH Guideline: Point of Care in General Haematology & CLSI POCT14 |
| 1030 Haematology - .41<br>General haemostasis related tests | EXTEM C **2,4                              | Blood in sodium citrate                | Thromboelastometry                     | ROTEM sigma analyser                       | CE   | LP-POC-013<br>BSH Guideline: Point of Care in General Haematology               |
|   | FIBTEM C **2,4                             |  | Thromboelastometry                     | ROTEM sigma analyser                       | CE   | LP-POC-013<br>BSH Guideline: Point of Care in General Haematology               |
|   | HEPTEM C **2,4                             |  | Thromboelastometry                     | ROTEM sigma analyser                       | CE   | LP-POC-013<br>BSH Guideline: Point of Care in General Haematology               |
|   | INTEM C **2,4                              |  | Thromboelastometry                     | ROTEM sigma analyser                       | CE   | LP-POC-013<br>BSH Guideline: Point  |

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|   |  |  |  |  |  | of Care in General Haematology |
| <p><i>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".</i></p> <p><i>Note 1 - Range may be extended for the test</i></p> <p><i>Note 2 – New parameters/tests may be added</i></p> <p><i>Note 3 – New matrices may be added</i></p> <p><i>Note 4 – Changes to equipment/kits where the underlying methodology does not change</i></p> <p><i>For further details please refer to the laboratory's 'List of flexible scope changes', available directly from the laboratory</i></p> |  |  |  |  |  |                                |



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   |
|--|--|---------------|--|--|----------------------|--|
| 1051 Histopathology - .01<br>Processing fixed specimens for<br>Histopathological testing | Cut-up<br>Tissue processing<br>Embedding<br>Microtomy<br>Automated<br>Haemotxylin and<br>Eosin Staining<br>Coverslipping<br>Megablocks | Human tissue  | Sakura VIP Processors<br>Sakura Embedding<br>Centre<br>Microtomes<br>Nikon Microscope<br>Microwriters<br>Bioptics Pixarray<br>Digital Specimen<br>Radiography System<br>Specimen Camera<br>Leica HistoCore<br>SPECTRA Stainer and<br>Coverslipper<br>Peloris Tissue<br>processor | Based on standard<br>method                                    | N/A                  | LP-HIS-CU-001<br>LP-HIS-CU-002<br>LP-HIS-CU-003<br>LP-HIS-CU-004<br>LP-HIS-CU-005<br>LP-HIS-EQ-003<br>LP-HIS-EQ-035<br>LP-HIS-EQ-038<br>LP-HIS-EQ-041<br>LP-HIS-EQ-009<br>LP-HIS-EQ-037<br>LP-HIS-EQ-011<br>LP-HIS-EQ-016<br>LP-HIS-EQ-020<br>LP-HIS-BO-001<br>LP-HIS-EQ-004<br>LP-HIS-RL-001<br>LP-HIS-RL-002<br>LP-HIS-RL-003<br>LP-HIS-RL-004<br>LP-HIS-EQ-001<br>LP-HIS-EQ-002<br>LP-HIS-EQ-005<br>LP-HIS-EQ-019<br>LP-HIS-EQ-026<br>LP-HIS-EQ-044<br>International<br>Collaboration on<br>Cancer Reporting<br>(ICCR) guidelines for<br>dissection and |

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|  |  |  |   |                                    |     | Reporting.<br>Royal College of Physicians of Ireland (RCPI), Guidelines for the Implementation of a National Quality Assurance Programme in Histopathology (Version 6.11,2018)  |
| 1051 Histopathology - .02<br>Processing fresh specimens for frozen section examination | Frozen Section<br>Cryotomy and staining  |  | Microflow BSC Class 1<br>Safety Cabinet<br>Leica CM1950<br>Cryostat<br>Leica Linear Stainer<br>ST4020 | CE                                 | N/A | LP-HIS-EQ-042<br>LP-HIS-EQ-025<br>LP-HIS-RF-001<br>LP-HIS-EQ-015<br><br>International Collaboration on Cancer Reporting (ICCR) guidelines for dissection and Reporting.<br><br>Royal College of Physicians of Ireland (RCPI), Guidelines for the Implementation of a National Quality Assurance Programme in Histopathology (Version 6.11,2018) |
| 1051 Histopathology - .03<br>Histochemistry  | Automated and Manual<br>PAS and Diastase-PAS<br>Gomori's Trichrome<br>Gram stain<br>Perl's Prussian Blue<br>Reticulin (Silver method)<br>Ziehl-Neelsen<br>Alcian Blue<br>Alcian Blue-PAS | Human Tissue/<br>Human Fluid/ FFPE<br>tissue | Dako Artisan Link Pro<br>Stainer<br>Leica HistoCore<br>SPECTRA Stainer and<br>Coverslipper            | CE and based on<br>standard method | N/A | LP-HIS-ST-001<br>LP-HIS-ST-002<br>LP-HIS-EQ-017<br>LP-HIS-EQ-046<br>LI-HIS-022<br>LP-HIS-ST-014<br>LP-HIS-ST-016<br>LP-HIS-ST-009<br>LP-HIS-ST-011<br>LP-HIS-ST-007<br>LP-HIS-ST-012<br>LP-HIS-ST-017   |

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|  | <p>Amyloid<br/>Orcein<br/>Grocott<br/>Martius scarlet blue<br/>Masson Fontana<br/>Elastic Van Gieson<br/>CAE Method<br/>Masson Trichrome<br/>Van Gieson method<br/>Warthin and Starry<br/>method<br/>Oil Red O method<br/>Delipidisation of Fresh<br/>Specimens</p> |  |            |                             |     | <p>LP-HIS-ST-015<br/>LP-HIS-ST-008<br/>LP-HIS-ST-006<br/>LP-HIS-ST-013<br/>LP-HIS-ST-003<br/>LP-HIS-ST-005<br/>LP-HIS-ST-004<br/>LP-HIS-ST-010<br/>LP-HIS-ST-018<br/>LP-HIS-ST-019<br/>LP-HIS-ST-020<br/>LP-HIS-ST-027<br/>LP-HIS-ST-021<br/>LP-HIS-ST-022</p> <p>International<br/>Collaboration on<br/>Cancer Reporting<br/>(ICCR) guidelines for<br/>dissection and<br/>Reporting.</p> <p>Royal College of<br/>Physicians of Ireland<br/>(RCPI), Guidelines for<br/>the Implementation of<br/>a National Quality<br/>Assurance<br/>Programme in<br/>Histopathology<br/>(Version 6.11,2018)</p> |
| 1051 Histopathology - .04<br>Histological interpretation-<br>medical renal pathology | <p>Diagnostic<br/>Interpretation and<br/>reporting of Human<br/>tissue specimens.</p> <p>Specialist Areas<br/>excluded:<br/>Medical Renal<br/>Pathology<br/>Paediatric Pathology<br/>Perinatal Pathology</p>  | Human tissue /<br>Human fluid / FFPE<br>tissue | Microscope | Based on standard<br>method | N/A | <p>LP-HIS-EQ-002</p> <p>International<br/>Collaboration on<br/>Cancer Reporting<br/>(ICCR) guidelines for<br/>dissection and<br/>Reporting.</p> <p>Royal College of<br/>Physicians of Ireland</p>   |

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|  | Neuropathology<br><br>Specialist areas included:<br>Breast Screening Pathology  |   |   |    |     | (RCPI), Guidelines for the Implementation of a National Quality Assurance Programme in Histopathology (Version 6.11,2018)  |
| 1051 Histopathology - .09 Immunohistochemistry | ACTM<br>ACTS<br>AE13<br>ALK<br>AFP<br>AR<br>BCAT<br>BCL2<br>BCL6<br>Ber EP4<br>CALP<br>CA125<br>CAIX<br>CAM<br>CALC<br>CALR<br>C4D<br>CD1A<br>CD2<br>CD3<br>CD4<br>CD5 (4C7)<br>CD8<br>CD10<br>CD15<br>CD19<br>CD20<br>CD23<br>CD30<br>CD31<br>CD34<br>CD45<br>CD56<br>CD57<br>CD68 | Human Tissue/<br>Human Fluid/ FFPE tissue | AutomatedUltraview<br>DAB detection<br>Ultraview APAP<br>detection Optiview<br>DAB detection<br>Inform Her2 ISH<br>detection<br>IHC DS uDAB uAP<br>Red Ventana<br>Benchmark Ultra<br>Microtomes<br>Nikon Microscope<br>Leica HistoCore<br>SPECTRA Stainer and<br>Coverslipper | CE | N/A | LP-HIS-IM-005<br>LP-HIS-IM-006<br>LP-HIS-EQ-005<br>LP-HIS-EQ-002<br>LP-HIS-EQ-014<br>LP-HIS-EQ-019<br>LP-HIS-EQ-020<br>LP-HIS-EQ-022<br>LP-HIS-EQ-024<br>LP-HIS-EQ-031<br>LP-HIS-EQ-032<br>LP-HIS-EQ-046<br><br>International<br>Collaboration on<br>Cancer Reporting<br>(ICCR) guidelines for<br>dissection and<br>Reporting.<br><br>Royal College of<br>Physicians of Ireland<br>(RCPI), Guidelines for<br>the Implementation of<br>a National Quality<br>Assurance<br>Programme in<br>Histopathology<br>(Version 6.11,2018) |

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|  | CD79A<br>CD99<br>CD117<br>CD138<br>CDX2<br>CEA<br>CHROM<br>CK5/6<br>CK7<br>CK19<br>CK20<br>CK34Be12<br>CMYC<br>CMV<br>CYD1<br>DBA44<br>DES<br>DOG1<br>D2-40<br>ECAD<br>EMA<br>ERSP1<br>F XIIIa<br>GATA3<br>GAST<br>HCG<br>HER4B5 Breast<br>HER4B5 Gastric<br>HHV8<br>HMB<br>HLO<br>HSA<br>HSV1<br>HSV2<br>IgG4<br>INH<br>KLC<br>LLC<br>LYSO<br>MAMA<br>MELA<br>MIB1<br>MLH1<br>MSH2 |  |  |  |  |  |
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|  | MSH6<br>MPO<br>MUM1<br>MYF4<br>NAP<br>NSE<br>PAX8<br>P16<br>P53<br>P63<br>P120 Catenin<br>PLD-1 (SP142)<br>PLD-1 (SP263)<br>PLAP<br>PMS2<br>PR<br>PRAME<br>PSA<br>PSMA<br>RACE<br>RCC<br>SATB2<br>SMMS<br>SOX-10<br>SOX-11<br>SYN<br>S100<br>TDTI<br>TG<br>TLE<br>TTF1<br>VIM<br>WT1<br><br>Double-stain protocols<br>CAL/BER<br>D240/AE1-3<br>LCDS (KLC/LLC)<br>P63/CK5/6<br>P63/SMMS<br>PRAME/MELA<br>PRCA<br>(P63/CK34B/RACE)<br>TTF1/NAP |  |  |  |  |  |
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| 1051 Histopathology - .11<br>Chromogenic / bright-field<br>in situ hybridisation | EBER<br>Inform Her2 ISH<br>detection. List of<br>probes:<br>Inform HER2 Dual ISH<br>DNA, DNA Probe<br>cocktail | FFPE TISSUE | VENTANA BenchMark<br>ULTRA IHC stainer<br>Microtomes<br>Nikon Microscope<br>Leica HistoCore<br>Spectra Stainer<br>Coverslipper /<br>Chromogenic in situ<br>hybridisation | CE | N/A | LP-HIS-IM-005<br>LP-HIS-IM-006<br>LP-HIS-EQ-002<br>LP-HIS-EQ-005<br>LP-HIS-EQ-014<br>LP-HIS-EQ-019<br>LP-HIS-EQ-020<br>LP-HIS-EQ-046<br><br>International<br>Collaboration on<br>Cancer Reporting<br>(ICCR) guidelines for<br>dissection and<br>Reporting.<br><br>Royal College of<br>Physicians of Ireland<br>(RCPI), Guidelines for<br>the Implementation of<br>a National Quality<br>Assurance<br>Programme in<br>Histopathology<br>(Version 6.11,2018) |
|  | Inform Kappa ISH   |             | VENTANA BenchMark<br>ULTRA IHC stainer<br>Microtomes Nikon<br>Microscope Leica<br>HistoCore Spectra<br>Stainer Coverslipper /<br>Chromogenic in situ<br>hybridisation    | CE | N/A | LP-HIS-IM-005<br>LP-HIS-IM-006<br>LP-HIS-EQ-002<br>LP-HIS-EQ-005<br>LP-HIS-EQ-014<br>LP-HIS-EQ-019<br>LP-HIS-EQ-020<br>LP-HIS-EQ-046<br><br>International<br>Collaboration on<br>Cancer Reporting<br>(ICCR) guidelines for<br>dissection and<br>Reporting.<br><br>Royal College of<br>Physicians of Ireland  |

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|  |                              |   |    |     | (RCPI), Guidelines for the Implementation of a National Quality Assurance Programme in Histopathology (Version 6.11,2018)   |
|  | Inform Lambda ISH            | VENTANA BenchMark<br>ULTRA IHC stainer<br>Microtomes Nikon<br>Microscope Leica<br>HistoCore Spectra<br>Stainer Coverslipper /<br>Chromogenic in situ<br>hybridisation | CE | N/A | <p>LP-HIS-IM-005<br/>LP-HIS-IM-006<br/>LP-HIS-EQ-002<br/>LP-HIS-EQ-005<br/>LP-HIS-EQ-014<br/>LP-HIS-EQ-019<br/>LP-HIS-EQ-020<br/>LP-HIS-EQ-046</p> <p>International Collaboration on Cancer Reporting (ICCR) guidelines for dissection and Reporting.</p> <p>Royal College of Physicians of Ireland (RCPI), Guidelines for the Implementation of a National Quality Assurance Programme in Histopathology (Version 6.11,2018)</p> |
| 1051 Histopathology - .13<br>Molecular testing | Idylla BRAF Mutation<br>Test | Idylla RT-PCR   | CE | N/A | <p>LP-HIS-EQ-045</p> <p>International Collaboration on Cancer Reporting (ICCR) guidelines for dissection and Reporting.</p> <p>Royal College of</p>   |



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|  |                           |               |    |     | Physicians of Ireland (RCPI), Guidelines for the Implementation of a National Quality Assurance Programme in Histopathology (Version 6.11,2018)  |
|  | Idylla KRAS Mutation Test | Idylla RT-PCR | CE | N/A | LP-HIS-EQ-045<br><br>International Collaboration on Cancer Reporting (ICCR) guidelines for dissection and Reporting.<br><br>Royal College of Physicians of Ireland (RCPI), Guidelines for the Implementation of a National Quality Assurance Programme in Histopathology (Version 6.11,2018) |
|  | Idylla MSI Mutation Test  | Idylla RT-PCR | CE | N/A | LP-HIS-EQ-045<br><br>International Collaboration on Cancer Reporting (ICCR) guidelines for dissection and Reporting.<br><br>Royal College of Physicians of Ireland (RCPI), Guidelines for the Implementation of a National Quality Assurance Programme in                                    |

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|  |   |                       |  |                          |     | Histopathology<br>(Version 6.11,2018)   |
|  | Idylla NRAS Mutation Test   |                       | Idylla RT-PCR  | CE                       | N/A | LP-HIS-EQ-045<br><br>International Collaboration on Cancer Reporting (ICCR) guidelines for dissection and Reporting.<br><br>Royal College of Physicians of Ireland (RCPI), Guidelines for the Implementation of a National Quality Assurance Programme in Histopathology (Version 6.11,2018)  |
| 1052 Cytopathology - .02<br>Non gynaecological<br>cytology | Cytology Sample Preparation and Description<br><br>Cytology sample Description<br>Cytology Sample Preparation<br>Cytology Sample Staining<br><br>Diagnostic interpretation and reporting of non-gynae samples | Human tissue or fluid | Thin Prep<br>Megafuge<br>Shandon Cytospin<br>Microflow Class II<br>Cabinet<br>Leica ST5010 (XL<br>Autostainer) | Based on standard method | N/A | LP-HIS-CY-001<br>LP-HIS-CY-002<br>LP-HIS-CY-003<br>LP-HIS-CY-004<br>LP-HIS-CY-005<br>LP-HIS-CY-006<br>LP-HIS-CY-007<br>LP-HIS-CY-008<br>LP-HIS-CY-009<br>LP-HIS-CY-010<br>LP-HIS-CY-011<br>LP-HIS-EQ-008<br>LP-HIS-EQ-025<br>LP-HIS-EQ-029<br>LP-HIS-EQ-030<br>LP-HIS-EQ-039<br>LP-HIS-EQ-002<br>LP-HIS-EQ-024<br>LP-HIS-EQ-031<br>LP-HIS-EQ-044<br>ED-HIS-MAN-037<br><br>International |

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|   |   |                              |   |    |     | <p>Collaboration on Cancer Reporting (ICCR) guidelines for dissection and Reporting.</p> <p>Royal College of Physicians of Ireland (RCPI), Guidelines for the Implementation of a National Quality Assurance Programme in Histopathology (Version 6.11,2018)</p>   |
| 1052 Cytopathology - .03<br>Cytochemistry | Oil Red O method<br>Delipidisation of Fresh Specimens<br>Ziehl-Neelsen<br>Grocott | Human Tissue/<br>Human Fluid | Thin Prep<br>Megafuge<br>Shandon Cytospin<br>Leica ST5010 (XL Autostainer)<br>Microflow Class II Cabinet<br>Dako Artisan Stainer<br>Leica HistoCore Spectra Stainer<br>Coverslipper | CE | N/A | <p>LP-HIS-ST-013<br/>LP-HIS-EQ-008<br/>LP-HIS-EQ-030<br/>LP-HIS-EQ-039<br/>LP-HIS-EQ-025<br/>LP-HIS-EQ-017<br/>LP-HIS-EQ-046<br/>LP-HIS-EQ-002<br/>LP-HIS-MAN-037</p> <p>International Collaboration on Cancer Reporting (ICCR) guidelines for dissection and Reporting.</p> <p>Royal College of Physicians of Ireland (RCPI), Guidelines for the Implementation of a National Quality Assurance Programme in Histopathology (Version 6.11,2018)</p> |



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   |
|---|---|---------------|---|--|--|--|
| 1040 Immunology - .01<br>Quantitative investigation of immunoglobulins G,A,M and D in body fluids | Investigation of Monoclonal Gammopathies<br>**1,2,3,4 | Serum         | Binding Site Optilite / Turbidimetry<br>Sebia Capillarys 3 / Immunotyping / Electrophoresis<br>Sebia Hydrasys / Immunofixation<br><br>Monoclonal Band calculated using INAB Accredited CCE Serum Total Protein level (Abbott Architect c16000 Alinity ci series/Turbidimetry) | CE   | IgG: 0.165 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><br>Total Protein: 5 g/L to 184.0 g/L | LP-IMM-0041<br>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 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 – 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 Excellence (NICE)              |

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| 1040 Immunology - .03<br>Total IgE  | Quantitative determination of total IgE in serum<br>**1,2,3,4                                       | Serum   | Phadia Immunocap 250 analyser/ Enzyme Immunoassay | CE                                      | Total IgE: 2.0 kU/mL to 5000 kU/mL  | LP-IMM-0012<br>National Clinical Programme for pathology (NCP) |
| 1040 Immunology - .04<br>Allergen - specific IgE  | Quantitative investigation of serum samples for Allergen specific IgE **1,2,3,4                     |   | Phadia Immunocap 250 analyser/ Enzyme Immunoassay | CE                                      | Specific IgE: 0.0 KuA/L to 100 KuA/L  | LP-IMM-0012<br>National Clinical Programme for pathology (NCP) |
|   | Quantitative investigation of serum samples for Allergen specific IgG **1,2,3,4                     |   | Phadia Immunocap 250 analyser/ Enzyme Immunoassay | CE                                      | Specific IgG: 2.0 mgA/L to 200 mgA/L  | LP-IMM-0012<br>National Clinical Programme for pathology (NCP) |
| 1040 Immunology - .06<br>Investigation of complement                                    | Quantitative measurement of C1 esterase inhibitor, C3 and C4 of the compliment pathway<br>**1,2,3,4 |   | Binding Site Optilite / Turbidimetry              | CE                                      | C1 Inhibitor: 0.08 g/L to 0.88 g/L<br>C3: 0.025 g/L to 6.0 g/L<br>C4: 0.0064 g/L to 1.8 g/L | LP-IMM-0041<br>Sheffield PRU – Clinical Immunochemistry        |
| 1040 Immunology - .12<br>Detection of autoantibodies in body fluids and biopsy material | Anti - Cardioliplin IgG Antibodies / ACA<br>**1,2,3,4   | Phadia Immunocap 250 analyser/ Enzyme Immunoassay | CE  | ACA IgG: 0.5 GPL - U/ml to 418 GPL-U/ml | LP-IMM-0012<br>National Clinical Programme for pathology (NCP)                              |  |
|   | Anti - Cardioliplin IgM Antibodies / ACA<br>**1,2,3,4   | Phadia Immunocap 250 analyser/ Enzyme Immunoassay | CE  | ACA IgM: 0.9 MPL-U/mL to 472 MPL-U/mL   | LP-IMM-0012<br>National Clinical Programme for pathology (NCP)                              |  |
|   | Anti -Cyclic Citrullinated Peptide/ Anti-CCP Antibodies<br>**1,2,3,4                                | Phadia Immunocap 250 analyser/ Enzyme Immunoassay | CE  | CCP: 0.4 U/mL to 340 U/mL               | LP-IMM-0012<br>American College of Rheumatology (ACR) Guidelines                            |  |
|   | Anti-Glutamic Acid Decarboxylase / Anti-GAD Antibodies<br>**1,2,3,4                                 | Dynex DS2 Analyser/ ELISA                         | CE  | GAD: 5 IU/mL to 2000 IU/mL              | LP-IMM-0034<br>LP-IMM-0015<br>National Institute for  |  |

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|   |  |    |                                  |   | Health and Care Excellence (NICE)<br>Sheffield PRU - Autoimmunity |
| Anti-Intrinsic Factor / Anti-IFA Antibodies **1,2,3,4 | Phadia Immunocap 250 analyser / Enzyme Immunoassay | CE | 0.5 U/mL to 480.0 IU/mL          | LP-IMM-0012<br>National Institute for Health and Care Excellence (NICE)<br>Sheffield PRU - Autoimmunity |   |
| Anti-Mitochondrial/ Anti-M2 Antibodies **1,2,3,4      | 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>Sheffield PRU - Autoimmunity |   |
| Beta2 Glycoprotein-1 IgG **1,2,3,4                    | Phadia Immunocap 250 analyser/ Enzyme Immunoassay  | CE | β2GP1 IgG: 0.8 U/mL to 532 U/mL  | LP-IMM-0012<br>National Clinical Programme for pathology (NCP)  |   |
| Beta2 Glycoprotein-1 IgM **1,2,3,4                    | Phadia Immunocap 250 analyser/ Enzyme Immunoassay  | CE | β2GP1 IgM: 0.9 U/mL to 576 U/mL  | LP-IMM-0012<br>National Clinical Programme for pathology (NCP)  |   |
| Centromere **1,2,3,4                                  | 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)  |   |

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| Connective Tissue Disease Screen / CTD<br>**1,2,3,4      | Phadia Immunocap250 analyser / Enzyme Immunoassay  | CE | CTD: 0.03 to 32 ratio        | LP-IMM-0012 LI-IMM-0044<br>National Clinical Programme for pathology (NCP) |
| ds-DNA **1,2,3,4   | 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 – JO1<br>**1,2,3,4     | Phadia Immunocap 250 analyser / Enzyme Immunoassay | CE | 0.3 U/mL to 240.0 U/mL       | LP-IMM-0012<br>National Clinical Programme for pathology (NCP)             |
| Extractable Nuclear Antigen / ENA - La<br>**1,2,3,4      | Phadia Immunocap 250 analyser / Enzyme Immunoassay | CE | 0.4 U/mL to 320.0 U/mL       | LP-IMM-0012<br>National Clinical Programme for pathology (NCP)             |
| Extractable Nuclear Antigen / ENA - RNP70<br>**1,2,3,4   | Phadia Immunocap 250 analyser / Enzyme Immunoassay | CE | 0.3 U/mL to 240.0 U/mL       | LP-IMM-0012<br>National Clinical Programme for pathology (NCP)             |
| Extractable Nuclear Antigen / ENA - Ro<br>**1,2,3,4      | Phadia Immunocap 250 analyser / Enzyme Immunoassay | CE | 0.4 U/mL to 240.0 U/mL       | LP-IMM-0012<br>National Clinical Programme for pathology (NCP)             |
| Extractable Nuclear Antigen / ENA - SCL70s<br>**1,2,3,4  | Phadia Immunocap 250 analyser / Enzyme Immunoassay | CE | 0.6 U/mL to 240.0 U/mL       | LP-IMM-0012<br>National Clinical Programme for pathology (NCP)             |
| Extractable Nuclear Antigen / ENA - SmD P-S<br>**1,2,3,4 | Phadia Immunocap 250 analyser / Enzyme Immunoassay | CE | 0.7 U/mL to 330.0 U/mL       | LP-IMM-0012<br>National Clinical Programme for pathology (NCP)             |



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|   | Extractable Nuclear Antigen / ENA - U1RNP **1,2,3,4 | Phadia Immunocap 250 analyser / Enzyme Immunoassay | CE | 0.5 U/mL to 240.0 U/mL     | LP-IMM-0012<br>National Clinical Programme for pathology (NCP)          |
|   | Glomerular Basement Membrane / GBM **1,2,3,4        | Phadia Immunocap 250 analyser / Enzyme Immunoassay | CE | 1.5 U/mL to 680.0 U/mL     | LP-IMM-0012<br>International Consensus on ANCA                          |
|   | Myeloperoxidase / MPO **1,2,3,4                     | Phadia Immunocap 250 analyser / Enzyme Immunoassay | CE | 0.2 U/mL to 134.0 U/mL     | LP-IMM-0012<br>International Consensus on ANCA                          |
|   | Proteinase -3 / PR3 **1,2,3,4                       | Phadia Immunocap 250 analyser/ Enzyme Immunoassay  | CE | 0.6 U/mL to 177.0 U/mL     | LP-IMM-0012<br>International Consensus on ANCA                          |
|   | Rheumatoid Factor / RF **1,2,3,4                    | Phadia Immunocap 250 analyser / Enzyme Immunoassay | CE | 0.6 IU/mL to 200.0 IU/mL   | LP-IMM-0012<br>American College of Rheumatology (ACR) Guidelines        |
|   | Tissue Transglutaminase / TTG IgA **1,2,3,4         | Phadia Immunocap 250 analyser / Enzyme Immunoassay | CE | 0.2 U/mL to 128.0 U/mL     | LP-IMM-0012<br>National Clinical Programme for pathology (NCP)          |
|   | Tissue Transglutaminase / TTG IgG **1,2,3,4         | Phadia Immunocap 250 analyser / Enzyme Immunoassay | CE | 0.6 U/mL to 600.0 U/mL     | LP-IMM-0012<br>National Clinical Programme for pathology (NCP)          |
| 1040 Immunology - .13<br>Cryoglobulins    | Identification of the presence of Cryoglobulin      | Sebia Hydrasys / Immunofixation                    | CE | Presence detected visually | LP-IMM-0011<br>National Institute for Health and Care Excellence (NICE) |
| 1040 Immunology - .14<br>b2-microglobulin | Beta-2-microglobulin (B2M) **1,2,3,4                | Binding Site Optilite / Turbidimetry               | CE | 0.3 mg/L to 40.0 mg/L      | LP-IMM-0041<br>International Myeloma                                    |

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|  |  |                  |  |    |  | Working Group (IMWG)<br>National Institute for Health and Care Excellence (NICE)                      |
| 1040 Immunology - .23<br>Tests of cellular immunity - quantitation of lymphocytes      | Lymphocyte subset analysis for CD16/CD56 Count **1,2,3,4 | EDTA whole blood | Becton Dickinson FACS CANTO SPA3/ Flow cytometry             | CE | Enumeration calculated using Becton Dickenson FacsCanto software | LP-IMM-0001 LP-IMM-0007<br>International Clinical Cytometry Society (ICCS)                            |
|  | Lymphocyte subset analysis for CD19 Count **1,2,3,4      |                  | Becton Dickinson FACS CANTO SPA3/ Flow cytometry             | CE | Enumeration calculated using Becton Dickenson FacsCanto software | LP-IMM-0001 LP-IMM-0007<br>International Clinical Cytometry Society (ICCS)                            |
|  | Lymphocyte subset analysis for CD3/CD4 Count **1,2,3,4   |                  | Becton Dickinson FACS CANTO SPA3 / Flow cytometry            | CE | Enumeration calculated using Becton Dickenson FacsCanto software | LP-IMM-0001 LP-IMM-0007<br>International Clinical Cytometry Society (ICCS)                            |
|  | Lymphocyte subset analysis for CD3/CD8 Count **1,2,3,4   |                  | Becton Dickinson FACS CANTO SPA3 / Flow cytometry            | CE | Enumeration calculated using Becton Dickenson FacsCanto software | LP-IMM-0001 LP-IMM-0007<br>International Clinical Cytometry Society (ICCS)                            |
| 1040 Immunology - .60<br>Simple slide tests for biochemical and immunological analytes | Anti-Liver Kidney Microsomal / Anti-LKM **1,2,3,4        | Serum            | Helmed Automated IFA Processor / Indirect Immunofluorescence | CE | 1/10 to 1/40   | LP-IMM-0006, LP-IMM-0030<br>British Society of Gastroenterology (BSG)<br>Sheffield PRU - Autoimmunity |

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| Anti-Neutrophil<br>Cytoplasmic<br>Antibodies / ANCA<br>**1,2,3,4 | Helmed Automated IFA<br>Processor / Indirect<br>Immunofluorescence | CE | 1/20          | LP-IMM-0027, LP-<br>IMM-0030<br><br>International<br>Consensus on ANCA                    |
| Antinuclear Antibodies<br>/ ANA **1,2,3,4                        | Helmed Automated IFA<br>Processor / Indirect<br>Immunofluorescence | CE | 1/40 to 1/640 | LP-IMM-0005, LP-<br>IMM-0030<br><br>National Clinical<br>Programme for<br>Pathology (NCP) |
| ds-DNA Crithidia<br>**1,2,3,4                                    | Helmed Automated IFA<br>Processor / Indirect<br>Immunofluorescence | CE | 1/10          | LP-IMM-0008, LP-<br>IMM-0030<br><br>National Clinical<br>Programme for<br>Pathology (NCP) |
| Endomysial<br>Antibodies / EMA<br>**1,2,3,4                      | Helmed Automated IFA<br>Processor / Indirect<br>Immunofluorescence | CE | 1/5           | LP-IMM-0026, LP-<br>IMM-0030<br><br>National Clinical<br>Programme for<br>Pathology (NCP) |
| Mitochondrial<br>Antibodies / AMA<br>**1,2,3,4                   | Helmed Automated IFA<br>Processor / Indirect<br>Immunofluorescence | CE | 1/10 to 1/40  | LP-IMM-0006, LP-<br>IMM-0030<br><br>Sheffield PRU -<br>Autoimmunity                       |
| Parietal Cell<br>Antibodies / PCA<br>**1,2,3,4                   | Helmed Automated IFA<br>Processor / Indirect<br>Immunofluorescence | CE | 1/10 to 1/40  | LP-IMM-0006, LP-<br>IMM-0030<br><br>Sheffield PRU -<br>Autoimmunity                       |
| Skin antibodies / BP<br>and PV Antibodies<br>**1,2,3,4           | Indirect<br>Immunofluorescence                                     | CE | 1/20          | LP-IMM-0028<br>LP-IMM-0030,<br>Sheffield PRU -<br>Autoimmunity                            |
| Smooth Muscle<br>Antibodies / SMA<br>**1,2,3,4                   | Helmed Automated IFA<br>Processor / Indirect<br>Immunofluorescence | CE | 1/10 to 1/160 | LP-IMM-0006, LP-<br>IMM-0030  |

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|  |   |        |   |    |   | Sheffield PRU - Autoimmunity  |
| 1040 Immunology - .61<br>Proteins, quantitative analysis | Serum free light chains – Free Kappa and Free Lambda<br>**1,2,3,4 |        | Binding Site Optilite / Turbidimetry    | CE | Kappa: 0.6 mg/L to 127000 mg/L<br>Lambda: 1.3 mg/L to 139000 mg/L | LP-IMM-0041<br><br>International Myeloma Working Group (IMWG)<br><br>National Institute for Health and Care Excellence (NICE) |
| 1040 Immunology - .99<br>Miscellaneous tests             | Alpha-1-antitrypsin (AAT) **1,2,3,4                               |        | Binding Site Optilite / Turbidimetry    | CE | 0.35 g/L to 5.00 g/L  | LP-IMM-004<br><br>National Clinical Programme for pathology (NCP)   |
|  | Antistreptolysin **1,2,3,4  |        | Binding Site Optilite / Turbidimetry    | CE | 5.0 IU/L to 1600.0 IU/L   | LP-IMM-0041<br><br>WHO Expert Committee   |
|  | Caeruloplasmin **1,2,3,4  |        | Binding Site Optilite / Turbidimetry    | CE | 0.04 g/L to 1.64 g/L  | LP-IMM-0041<br><br>Sheffield PRU – Clinical Immunochemistry   |
|  | Calprotectin **1,2,3,4  | Faeces | Liaison XL Diasorin / Chemiluminescence | CE | 5.0 µg/g to 800.0 µg/g  | LP-IMM-0040<br><br>National Institute for Health and Care Excellence (NICE)   |
|  | Haptoglobin **1,2,3,4   | Serum  | Binding Site Optilite / Turbidimetry    | CE | 0.026 g/L to 8.0 g/L  | LP-IMM-0041<br><br>Sheffield PRU – Clinical Immunochemistry   |

*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*

Category: A

| Medical pathology field - Test  | Test/assay   | Specimen Type               | Equipment/Technique     | Method (CE/Non-CE/In house developed/ based on standard method) | Range of measurement  | Std. ref & SOP  |
|---|--|-----------------------------|-------------------------|---|---|---|
| 1011 Macroscopic examination and description  | Macroscopic examination and description of specimens | Sputum, Fluids, Faeces, CSF | N/A / Visual            | Based on standard method  | Qualitative   | LP-MIC-ROU-02<br>LP-MIC-ROU-03<br>LP-MIC-ROU-06<br>LP-MIC-ROU-14,<br>PHE UK Standards Investigation of Faecal Specimens for Enteric Pathogens,<br>PHE UK Standards for Microbiology Investigation of Cerebrospinal Fluid,<br>PHE UK Standards for Microbiology Investigation for Fluids from Normally Sterile Sites |
| 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) | Cell counts & Differential                           | Urine, fluids in EDTA, CSF  | Microscope / Microscopy | Based on standard method  | Presence or absence of red blood cells white blood cells and epithelial cells | LP-MIC-ROU-05<br>LP-MIC-ROU-03<br>LP-MIC-ROU-14<br>LP-MIC-IDEN-05,<br>PHE UK Standards UK Standards Investigation of urine,<br>PHE UK Standards for Microbiology Investigation of Cerebrospinal Fluid,<br>PHE UK Standards Investigation of Faecal  |

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|  |   |  |   |                          |  | Specimens for Enteric Pathogens  |
|  | Gram staining   | Tissue/Fluids/ Corneal scrapings, CSF, Vaginal, Endocervical, Urethral swabs in Amies transport medium | Microscope / Staining and Microscopy                              | Based on standard method | Presence or absence of bacteria                              | LP-MIC-IDEN-08, PHE UK Standards UK Standards Investigation of urine, PHE UK Standards for Microbiology Investigation of Cerebrospinal Fluid, PHE UK Standards Investigation of Faecal Specimens for Enteric Pathogens, PHE UK Standards Investigation of genital tract and associated specimens, PHE Guidance on the detection of gonnorrhoea in England, PHE UK Standards for Microbiology Investigation of Sinus Aspirate |
|  | Urine cell counts using analyser Sedimax Contrast Pro for the investigation of UTIs | Urine  | Sedimax Pro Contrast / Bright field and phase contrast microscopy | CE marked                | Particle concentration (HPF or / $\mu$ L)                    | LP-MIC-ROU-05, PHE UK Standards UK Standards Investigation of urine  |
| 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   | Faeces   | Microscope / Staining and Microscopy                              | Based on standard method | Presence or absence of cysts and oocytes                     | LP-MIC-ROU-26, PHE UK Standards Investigation of Faecal Specimens for Enteric Pathogens  |
|  | Ova & Parasites   | Urine, Faeces  | Microscope / Concentration and Microscopy                         | Based on standard method | Protozoa: presence of cysts and oocytes<br>Helminths:presenc | LP-MIC-ROU-26, PHE UK Standards Investigation of   |

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|   |   |  |   |                          | e or absence of eggs or larvae                 | Specimens other than Blood for Parasites   |
| 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        | KOH Calcofluor white                            | BAL, Skin hair, nails  | Microscope / Staining and Microscopy                | Based on standard method | Presence or absence of fungal hyphae           | LP-MIC-ROU-02, PHE UK Standards for Microbiology Investigation of Dermatological Specimens for Superficial Mycoses   |
| 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 | Auramine O for AFB                              | 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-ROU-15, PHE UK Standards Investigation of specimens for Mycobacterium species   |
| 1013 Culture of organisms in liquid or agar based culture media with visual or instrument monitoring for growth - .01 Culture of general bacteria   | Culture of CSF specimens                        | CSF  | N/A / Culture                                       | Based on standard method | Qualitative                                    | LP-MIC-ROU-14, PHE UK Standards for Microbiology Investigation of Cerebrospinal Fluid  |
|   | Culture of faecal specimens                     | Faeces   | N/A / Agar and enrichment culture                   | Based on standard method | Qualitative                                    | LP-MIC-ROU-06 LP-MIC-ROU-12, PHE UK Standards Investigation of Faecal Specimens for Enteric Pathogens  |
|   | Culture of genital tract & associated specimens | Swabs: Vaginal, Endocervical, Urethral, Rectal, Pharyngeal in Amies transport medium. Bartholins gland aspirate, pus & IUD | N/A / Culture                                       | Based on standard method | Qualitative                                    | LP-MIC-ROU-07, LP-MIC-ROU-13, PHE UK Standards Investigation of genital tract and associated specimens, PHE Guidance on the detection of gonorrhoea in England |



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| Culture of respiratory specimens for bacterial pathogens other than Mycobacteria | Respiratory samples   | N/A / Culture                     | Based on standard method | Qualitative | LP-MIC-ROU-02, LP-MIC-ROU-08, PHE UK Standards for Microbiology Investigation of Bronchoalveolar Lavage, Sputum and Associated Specimens  |
| Culture of specimens from superficial & deep seated infections                   | Wounds/Tissue/ Fluids/Swabs in Amies transport medium/IV tips | N/A / Agar and enrichment culture | Based on standard method | Qualitative | LP-MIC-ROU-03, LP-MIC-ROU-09, PHE UK Standards for Microbiology Investigation of tissues and biopsies from deep-seated sites and organs, PHE UK Standards for Microbiology Investigation for Fluids from Normally Sterile Sites, PHE UK Standards Investigation of Intravascular Cannulae and Associated Specimens, PHE UK Standards for Microbiology Investigation of Sinus Aspirate |
| Culture of urine specimens   | Urine   | N/A / Culture                     | Based on standard method | Qualitative | LP-MIC-ROU-05, LP-MIC-ROU-11, PHE UK Standards UK Standards Investigation of urine  |
| Screening of specimens for MDRO  | Swabs in Amies transport medium & Faeces                      | N/A / Culture                     | Based on standard method | Qualitative | LP-MIC-ROU-04, LP-MIC-ROU-10, Eucast Guidelines, PHE UK Standards Investigation of Specimens for Screening for MRSA   |

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|  |                  | Swabs in Amies transport medium & Faeces   | N/A / Culture | CE marked                | Qualitative | LP-MIC-ROU-04,<br>LP-MIC-ROU-10,<br>PHE UK Standards<br>Investigation of<br>Specimens for Screening<br>for MRSA  |
| 1013 Culture of organisms in liquid or agar based culture media with visual or instrument monitoring for growth - .02 Culture of fungi | Culture of fungi | Skin, Nails, Hair, Respiratory samples, Corneal scrapings, Contact lens, CSF, Tissues/Fluids, Swabs (in Amies transport medium), Urines, | N/A / Culture | Based on standard method | Qualitative | LP-MIC-ROU-17,<br>LP-MIC-ROU-02,<br>LP-MIC-ROU-03,<br>LP-MIC-ROU-14,<br>LP-MIC-ROU-05,<br>LP-MIC-ROU-07,<br>PHE UK Standards for<br>Microbiology<br>Investigation of<br>Dermatological<br>Specimens for<br>Superficial Mycoses,<br>PHE UK Standards for<br>Microbiology<br>Investigation of<br>Bronchoalveolar Lavage,<br>Sputum and Associated<br>Specimens,<br>PHE UK Standards for<br>Microbiology<br>Investigation of<br>Cerebrospinal Fluid,<br>PHE UK Standards for<br>Microbiology<br>Investigation of tissues<br>and biopsies from deep-<br>seated sites and organs,<br>PHE UK Standards<br>Investigation of<br>Intravascular Cannulae<br>and Associated<br>Specimens,<br>PHE UK Standards for<br>Microbiology<br>Investigation<br>for Fluids from<br>Normally Sterile Sites |

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| 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 (Myco/F lytic Culture vials)                  | BACTEC FX / Advanced fluorescence detection technology    | CE marked | Range of time to detection 8-16 days  | LP-MIC-ROU-15, PHE UK Standards Investigation of specimens for Mycobacterium species  |
|   |  | Respiratory samples, tissue/bone samples, fluids/CSF, Urine | BacTALERT 3D / Automated colorimetric microbial detection | CE marked | Mycobacterium tuberculosis ≤14 cfu<br>Mycobacterium kansasii ≤4cfu<br>Mycobacterium avium ≤15 cfu | LP-MIC-ROU-15, PHE UK Standards Investigation of specimens for Mycobacterium species  |
| 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                              | N/A / Slide agglutination                                 | CE marked | Visible agglutination in the presence of homologous cultures                                      | LP-MIC-ROU-12, PHE UK Standards for Microbiology for investigation of Gastroenteritis, PHE UK Standards Investigation of Faecal Specimens for Enteric Pathogens |
| 1014 Detection of bacterial, parasite, viral or fungal antigens using specific antibodies and appropriate techniques - .02 Particle agglutination | Dry spot Pnemo                         | Blood   | N/A / Particle agglutination                              | CE marked | Visible agglutination in the presence of homologous cultures                                      | LP-MIC-IDEN-06  |
|   | E. coli 0157 Latex                     | Isolate   | N/A / Particle agglutination                              | CE marked | Visible agglutination in the presence of homologous cultures                                      | LP-MIC-IDEN-07  |
|   | Pastorex                               |   | N/A / Particle agglutination                              | CE marked | Visible agglutination in the presence of homologous cultures                                      | LP-MIC-IDEN-11  |

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|   | Streptococcal Grouping Latex Kit  |                        | N/A / Particle agglutination                   | CE marked | Visible agglutination in the presence of homologous cultures                   | LP-MIC-IDEN-13  |
| 1014 Detection of bacterial, parasite, viral or fungal antigens using specific antibodies and appropriate techniques - .03 Enzyme immunoassay,            | QuantiFERON®-TB Plus - Detection of latent tuberculosis infection using the QuantiFERON®-TB Plus Assay. | Blood (QFT-Plus)       | Diasorin Liason XL / Chemiluminescence assay   | CE marked | Assay range: up to 10 IU/ml of IFN-gamma                                       | LP-MIC-ROU-51, PHE UK Standards Investigation of specimens for Mycobacterium species, WHO Guidelines on the management of latent tuberculosis infection |
| 1014 Detection of bacterial, parasite, viral or fungal antigens using specific antibodies and appropriate techniques - .04 Immunochromatographic methods, | BD MGIT TBc   | Isolates               | N/A / Immunochromatographic assay              | CE marked | Presence or absence of MPT64 antigen   | LP-MIC-ROU-34, PHE UK Standards Investigation of specimens for Mycobacterium species  |
|   | Cryptococcal Antigen  | CSF & serum            | N/A / Immunochromatographic assay              | CE marked | CSF: Qualitative<br>Serum: semi-quantitative C5 – C95 Interval 1.0 – 1.5 ng/mL | LP-MIC-ROU-23, PHE UK Standards for Microbiology Investigation of Cerebrospinal Fluid   |
|   | Legionella Urinary antigen  | Urine                  | N/A / Immunochromatographic assay              | CE marked | Presence or absence of L. pneumophila serogroup 1 antigen                      | LP-MIC-ROU-25, PHE UK Standards UK Standards Investigation of urine   |
|   | OLM™ Lateral Flow Device  | Bronchoalveolar Lavage | Immunochromatographic assay                    | CE marked | Presence or absence of Aspergillus antigen                                     | LP-MIC-IDEN-25  |
|   | Resist-5 O.O.K.N.V  | Isolates               | Coris Bioconcept / Immunochromatographic assay | CE marked | N/A  | VT-MIC-2022-02, LP-MIC-ROU-19, ED-MIC-REF-53  |
|   | Streptococcus pneumoniae Urinary antigen  | Urine                  | N/A / Immunochromatographic assay              | CE marked | LOD:1:250 dilution   | LP-MIC-ROU-27   |

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|  | Urinary hCG                                     |   | N/A / Immuno-chromatographic assay   | CE marked | Samples containing <25 mIU/mL hCG may test positive, but samples containing <5 mIU/mL hCG should be negative | LP-MIC-ROU-24   |
| 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 | Qualitative  | LP-MIC-ROU-45, PHE UK Standards for Microbiology Investigation of Cerebrospinal Fluid, PHE UK Standards for Microbiology: Good Laboratory Practice when Performing Molecular Amplification Assays |
|  | HAIN CM   | DNA Extract from positive culture bottles                             | PCR Thermal Cycler & Twincubator / Amplification and detection of target DNA | CE marked | Qualitative  | LP-MIC-ROU-32, PHE UK Standards: Investigation of specimens for Mycobacterium species, Good Laboratory Practice when Performing Molecular Amplification Assays                                    |
|  | HAIN MTBC                                       |   | PCR Thermal Cycler & Twincubator / Amplification and detection of target DNA | CE marked | Qualitative  | LP-MIC-ROU-32, PHE UK Standards Investigation of specimens for Mycobacterium species, PHE UK Standards for Microbiology: Good Laboratory Practice when Performing Molecular Amplification Assays  |
| 1015 Detection and/or identification of bacterial, parasite, fungal and  | 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-ROU-39, PHE UK Standards for Microbiology Chlamydia  |

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| viral nucleic acids - .03<br>Nucleic acid<br>amplification tests, CE<br>marked commercial<br>systems   |  |   |           |   |  | trachomatis Infection –<br>Testing by Nucleic Acid,<br>Good Laboratory<br>Practice when<br>Performing Molecular<br>Amplification Assays   |
| Chlamydia trachomatis and<br>Neisseria gonorrhoea  | FVU  | Amplification and<br>detection of target DNA<br>on BD Max           | CE marked | Detected /<br>Not detected  |  | LP-MIC-ROU-44,<br>PHE UK Standards for<br>Microbiology Chlamydia<br>trachomatis Infection –<br>Testing by Nucleic Acid,<br>Good Laboratory<br>Practice when<br>Performing Molecular<br>Amplification Assays |
| CRE  | Isolates & rectal swabs (Copan<br>dual swab) | Cepheid GeneXpert /<br>Amplification and<br>detection of target DNA | CE marked | Detected /<br>Not detected  |  | LP-MIC-ROU-42,<br>PHE UK Standards for<br>Microbiology: Good<br>Laboratory Practice<br>when Performing<br>Molecular Amplification<br>Assays   |
| Detection of Carbenpenamse<br>using FlowFlex Technology  | Rectal swab (Copan faecal swab)              | Roche FlowFlex PCR<br>Technology                                    | CE Marked | KPC: cut off 37,<br>OXA 48: cut off 37,<br>VIIM cut off 38, IMP<br>cut off 38, NDM cut<br>off |  | LP-MIC-ROU-51,<br>PHE UK Standards for<br>Microbiology: Good<br>Laboratory Practice<br>when Performing<br>Molecular Amplification<br>Assays   |
| Faecal Molecular screen for<br>Bacterial Enteric Pathogens   | Faeces                                       | Amplification and<br>detection of target DNA<br>on BD Max           | CE Marked | Qualitative   |  | LP-MIC-ROU-46,<br>PHE UK Standards<br>Investigation of Faecal<br>Specimens for Enteric<br>Pathogens,<br>Good Laboratory<br>Practice when<br>Performing Molecular<br>Amplification Assays                    |
| Identification of M. tuberculosis<br>complex direct from specimens<br>using Xpert MTB/RIF Ultra kit on | Sputum (Direct)                              | Cepheid GeneXpert /<br>Amplification and<br>detection of target DNA | CE marked | Detected /<br>Not detected  |  | LP-MIC-ROU-49,<br>PHE UK Standards for<br>Microbiology: Good<br>Laboratory Practice   |

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| the Cepheid GeneXpert Dx System   |                               |   |           |                         | when Performing Molecular Amplification Assays, PHE UK Standards Investigation of specimens for Mycobacterium species  |
|   | Sputum sediment               | Cepheid GeneXpert / Amplification and detection of target DNA       | CE marked | Detected / Not detected | LP-MIC-ROU-49, PHE UK Standards for Microbiology: Good Laboratory Practice when Performing Molecular Amplification Assays, PHE UK Standards Investigation of specimens for Mycobacterium species |
| Molecular detection of bacteria and viruses on BioFire ME panel                       | CSF                           | Biomeriux Biofire Torch / Amplification and detection of target DNA | CE marked | Qualitative             | LP-MIC-ROU-65  |
| 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-ROU-71  |
| 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-ROU-71, PHE UK Standards for Microbiology: Good Laboratory Practice when Performing Molecular Amplification Assays  |
| Molecular detection of COVID/FLU/RSV on Cepheid GeneXpert DX System                   | Nasopharyngeal(Genexpert/UTM) | Cepheid GeneXpert / Amplification and detection of target DNA       | CE marked | Detected / Not detected | LP-MIC-ROU-68, PHE UK Standards for Microbiology: Good Laboratory Practice when Performing Molecular Amplification Assays  |

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| Molecular detection of COVID/FLU/RSV using Viasure assay on Roche Flow Flex System                 | Nasopharangeal (Genexpert/UTM)      | Roche FlowFlex System / Amplification and detection of target DNA                | CE marked | Detected / Not detected | LP-MIC-ROU-67, PHE UK Standards for Microbiology: Good Laboratory Practice when Performing Molecular Amplification 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-ROU-19, PHE UK Standards for Microbiology: Good Laboratory Practice when Performing Molecular Amplification 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-ROU-65   |
| 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-ROU-65, LP-MIC-ROU-45, PHE UK Standards for Microbiology: Good Laboratory Practice when Performing Molecular Amplification 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-ROU-39, PHE UK Standards for Microbiology: Good Laboratory Practice when Performing Molecular Amplification Assays   |
| Norovirus Genogroup I and II   | Faeces                              | Cepheid GeneXpert / Amplification and detection of target DNA                    | CE marked | Detected / Not detected | LP-MIC-ROU-40, PHE UK Standards for Microbiology: Good Laboratory Practice when Performing Molecular Amplification Assays, PHE UK Standards Investigation of Faecal |



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|   |   |                         |   |                          |                         | Specimens for Enteric Pathogens   |
|   | Toxigenic Clostridium difficile                                       |                         | Amplification and detection of target DNA on BD Max               | Based on standard method | NA                      | LP-MIC-ROU-47   |
|   |   |                         | Amplification and detection of target DNA on BD Max               | Based on standard method | Detected / Not detected | LP-MIC-ROU-22, PHE UK Standards for Microbiology: Good Laboratory Practice when Performing Molecular Amplification Assays, PHE UK Standards Investigation of Faecal Specimens for 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-ROU-69, PHE UK Standards for Microbiology: Good Laboratory Practice when Performing Molecular Amplification Assays   |
|   | Verification of VRE Viasure molecular assay on Roche FlowFlex System  |                         | Roche FlowFlex System / Amplification and detection of target DNA | CE marked                | Qualitative             | LP-MIC-ROU-69   |
|   | Xpert CARBA-R   | Rectal swabs & Isolates | Cepheid GeneXpert / Amplification and detection of target DNA     | CE marked                | N/A                     | LP-MIC-ROU-42   |
| 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-IDEN-26  |
|   | API NH  |                         | N/A / Fermentation, decarboxylation etc                           | CE marked                | Qualitative             | LP-MIC-IDEN-01  |

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|  | Dnase                                       |  | N/A / Hydrolysis of DNA                             | Based on standard method   | Qualitative                       | LP-MIC-IDEN-15   |
|  | Phenotypic confirmation of ESBL's           |  | Disc diffusion                                      | Based on standard method   | Qualitative                       | LP-MIC-IDEN-24, Eucast Guidelines  |
|  | VITEK Identification                        |  | VITEK 2XL / Fermentation, decarboxylation etc       | CE marked                  | Qualitative                       | LP-MIC-ROU-19  |
| 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-ROU-17, PHE UK Standards for Microbiology Investigation of Dermatological Specimens for Superficial Mycoses |
| 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-ROU-19  |
| 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-ROU-18<br>ED-MIC-REF-53   |
|  |   | Isolates                                 | N/A / Disc diffusion                                | CE marked                  | Refer to Eucast Guidelines        | LP-MIC-ROU-20, Eucast Guidelines   |
|  |   |  | VITEK 2XL / Broth MIC                               | CE marked                  | Refer to Eucast Guidelines        | LP-MIC-ROU-20, Eucast Guidelines   |
|  | Neisseria Gonorrhoea isolates               | Minimum inhibitory strip diffusion       | CE marked   | Qualitative                | LP-MIC-ROU-20<br>ED-MIC-REF-53    |  |
|  | Cefpodoxime combination disc kit            | Isolates                                 | N/A / Disc diffusion                                | CE marked                  | Refer to Eucast Guidelines        | LI-MIC-36, Eucast Guidelines   |
| Minimum inhibitory concentration   |   | N/A / Minimum inhibitory strip diffusion | CE marked   | Refer to Eucast Guidelines | LP-MIC-ROU-20, Eucast Guidelines  |  |

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|   | Total ESBL confirmation kit  |                                       | N/A / Disc diffusion   | CE marked | Refer to Eucast Guidelines | LI-MIC-36, Eucast Guidelines  |
| 1017 Measurement of antimicrobial activity and application of clinical interpretive criteria to general bacteria (rapidly growing aerobes) - .02 Mycobacteria | HAIN MTBDRplus   | Extract from positive culture bottles | PCR Thermal Cycler & Twincubator / Amplification and detection of target DNA | CE marked | Qualitative                | LP-MIC-ROU-32, PHE UK Standards for Microbiology: Good Laboratory Practice when Performing Molecular Amplification Assays                               |
|   |  |                                       | PCR Thermal Cycler & Twincubator / Amplification and detection of target DNA | CE marked | Qualitative                | LP-MIC-ROU-32, PHE UK Standards for Microbiology: Good Laboratory Practice when Performing Molecular Amplification 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-ROU-64, HPSC National guidelines for prevention of nosocomial aspergillosis, EORTC/MSGERC criteria for diagnosis of invasive fungal disease      |
|   | Yeast one Sensitre   | Isolates                              | N/A / Broth MIC  | CE marked | N/A                        | LP-MIC-ROU-18, PHE UK Standards for Microbiology Chlamydia trachomatis Infection – Testing by Nucleic Acid, CLSI Performance Standards for AST of Yeast |
| 1017 Measurement of antimicrobial activity and application of clinical interpretive criteria to general bacteria (rapidly growing aerobes) - .05 Other        |  |                                       | Broth microdilution  | CE marked | N/A                        | LP-MIC-ROU-18, CLSI Performance Standards for AST of Yeast  |

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| categories of organism (as specified )  |   |                |   |           |  |  |
| 1018 Detection of antibody response to infection using appropriate CE marked commercial techniques - .02 Enzyme immunoassay, using CE marked commercial systems | Platelia™ Aspergillus antigen in serum and Bronchoalveolar Lavage (BAL) for the Detection of Aspergillus Galactomannan antigen. | Serum and BALs | Dynex DS2 / Immunoenzymatic sandwich microplate assay | CE marked | Index <50 Negative, Index > or equal to 50: Positive,  | LP-MIC-ROU-56, HPSC:National Guidelines for the prevention of Nosocomial Aspergillosis, EORTC/MSGERC criteria for diagnosis of invasive fungal disease |
|   | 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-ROU-57, HPSC National guidelines for prevention of nosocomial aspergillosis, EORTC/MSGERC criteria for diagnosis of invasive fungal disease     |