

# Schedule of Accreditation



|   |   |
|---|---|
| Organisation Name                             | Mid Western Regional Hospital Limerick<br>(Serology/Immunology) |
| Trading As                                    |   |
| INAB Reg No                                   | 303MT   |
| Contact Name                                  | Kathleen Keane  |
| Address                                       | University Hospital Limerick, Dooradoyle, Limerick,<br>Limerick |
| Contact Phone No                              | 061 485075  |
| Email   | kathleenmartina.keane@hse.ie                                    |
| Website                                       | <a href="http://www.ulh.ie">http://www.ulh.ie</a>               |
| Accreditation Standard                        | ISO 15189   |
| Date Initially Awarded                        | 05/06/2012  |
| Scope Classification                          | Microbiology and virology                                       |
| Scope Classification                          | Haematology   |
| Services available to the public <sup>1</sup> | No  |

<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  | University Hospital Limerick    | St. Nessian's Road, Dooradoyle, Limerick, Limerick, V94 F858 |
| 2  | Nenagh Hospital-<br>Haematology | Tyone, Nenagh, Tipperary                                     |
| 3  | Ennis Hospital -<br>Haematology | Gord Road, Ennis, Clare                                      |

# Scope of Accreditation

## Ennis Hospital - Haematology

### Haematology

Category: A

| Medical pathology field - Test                                     | Test/Assay                           | Specimen Type  | Technique                       | Range of Measurement/Equipment   | Method (CE/Non-CE/In house developed/based on standard method) | Std. Ref & SOP   |
|--|--------------------------------------|----------------|---------------------------------|----------------------------------|--|--|
| 1030 Haematology - .01 Blood counts                                | Full Blood Count                     | EDTA           | Automated                       | Automated Method - Sysmex XT200i | CE / based on standard method                                  | LP-A-HAE-XT2000i<br>LP-A-HAE-SYSXTFBC  |
| 1030 Haematology - .02 Visual examination of blood films           | Blood film examination               |                | Manual method                   | Staining / microscopy            | CE/based on standard method                                    | LP-L-HAE-FLM-REPORT  |
| 1030 Haematology - .03 Erythrocyte sedimentation rate              | Erythrocyte sedimentation rate (ESR) | Na Citrate     | Automated                       | Desaga S 2000 ESR Analyser       | CE/based on standard method                                    | LP-L-HAE-EQP-SEDIPLUS<br>LP-L-HAE-MAN-ESR                                    |
| 1030 Haematology - .05 Automated differential leucocyte counts     | Automated differential count         | EDTA           | Automated                       | Sysmex XT 2000i                  | CE/based on standard method                                    | LP-A-HAE-SYSXTFBC<br>LP-A-HAE-XT2000i<br>LP-E-HAE-FBCXT<br>LP-A-HAE-SYSXTFBC |
| 1030 Haematology - .06 Automated reticulocyte counts               | Automated Reticulocyte count         |                | Automated                       | Sysmex XT 2000i                  | CE/based on standard method                                    | LP-E-HAE-XT2001<br>LP-A-HAE-XT2000i<br>LP-E-HAE-RETIC                        |
| 1030 Haematology - .41 General haemostasis related tests           | APTT                                 | Na Citrate     | Automated Coagulometric         | IL ACL TOP                       | CE/based on standard method                                    | LP-E-HAE-EQP-ACLTOP LP-E-HAE-APTACLTOP                                       |
|  | D-Dimer                              |                | Automated immunological         | IL ACL TOP                       | CE/based on standard method                                    | LP-E-HAE-EQP-ACLTOP<br>LP-E-HAE-DDIMERACLTOP                                 |
|  | PT / INR                             |                | Automated coagulometric / ratio | IL ACL TOP                       | CE/based on standard method                                    | LP-E-HAE-EQP-ACLTOP LP-E-HAE-PTACLTOP  |
| 1030 Haematology - .57 Screening test for infectious mononucleosis | Monospot                             | Serum / Plasma | Manual method                   | Rapid immuno assay               | CE/based on standard method                                    | LP-L-HAE-MAN-MONOSP  |

# Nenagh Hospital- Haematology

## 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                            | Full Blood Count                     | EDTA          | Automated | Automated Method - Sysmex XT200i  | CE / based on standard method                                  | LP-A-HSE-XT2000i<br>LP-A-HAE-SYSXTFBC     |
| 1030 Haematology - .03<br>Erythrocyte sedimentation rate          | Erythrocyte sedimentation rate (ESR) | NaCitrate     | Automated | Desaga S2000 ESR Analyser         | CE/based on standard method                                    | LP-L-HAE-EQP-SEDIPLUS<br>LP-L-HAE-MAN-ESR |
| 1030 Haematology - .05<br>Automated differential leucocyte counts | Automated Differential Count         | EDTA          | Automated | Automated method - Sysmex XT2000i | CE/based on standard method                                    | LP-A-HAE-SYSXTFBC<br>LP-A-HAE-XT2000i     |
| 1030 Haematology - .06<br>Automated reticulocyte counts           | Automated reticulocyte               |               | Automated | Automated method - Sysmex XT2000i | CE/based on standard method                                    | LP-A-HAE-XT2000i LP-A-HAE-SYSXTFBC        |

Haematology

Category: A

| Medical pathology field - Test   | Test/Assay                   | Specimen Type   | Technique                   | Range of Measurement/Equipment        | Method (CE/Non-CE/In house developed/based on standard method) | Std. Ref & SOP  |
|--|------------------------------|-----------------|-----------------------------|---------------------------------------|--|---|
| 1030 Haematology - .01 Blood counts  | Full Blood Count             | EDTA            | Automated                   | Automated Method - Advia 2120 / 2120i | CE / based on standard method                                  | LP-L-HAE-FBC-ADVIA<br>LP-L-HAE-EQP-ADVIA_2120   |
| 1030 Haematology - .02 Visual examination of blood films                             | Blood film                   |                 | Staining / microscopy       | Manual method                         | CE/based on standard method                                    | LI-L-HAE-FLM-MAN<br>LP-L-HAE-FLM-REPORT<br>LP-L-HAE-FLM-STAIN<br>LP-L-HAE-EQP-HEMATEK |
|  | Manual differentials         |                 | Staining / microscopy       | Manual method                         | CE/based on standard method                                    | LI-L-HAE-FLM-DIFFM  |
| 1030 Haematology - .03 Erthrocyte sedimentation rate                                 | ESR                          | Na Citrate      | Westergen method            | Desaga S 2000 ESR analyser            | CE/based on standard method                                    | LP-L-HAE-MAN-ESR<br>LP-L-HAE-EQP-SEDIPLUS   |
| 1030 Haematology - .05 Automated differential leucocyte counts                       | Automated Differential Count | EDTA            | Automated                   | Automated method - Advia 2120 / 2120i | CE/based on standard method                                    | LP-L-HAE-FBC-ADVIA<br>LP-L-HAE-EQP-ADVIA_2120   |
| 1030 Haematology - .06 Automated reticulocyte counts                                 | Automated reticulocyte count |                 | Automated                   | Automated method - Advia 2120 / 2120i | CE/based on standard method                                    | LP-L-HAE-FBC-ADVIA<br>LP-L-HAE-EQP-ADVIA_2120   |
| 1030 Haematology - .08 Blood film examinations involving special staining procedures | Perls prussian blue stain    |                 | Staining / microscopy       | Manual method                         | CE/based on standard method                                    | LP-L-HAE-FLM-PPB  |
| 1030 Haematology - .09 Examination of malarial parasites                             | Malaria antigen              | Plasma          | Immunochromatographic test  | Manual method                         | CE/based on standard method                                    | LP-L-HAE-FLM-MALAB  |
|  | Malaria film                 | EDTA            | Staining / microscopy       | Manual method                         | CE/based on standard method                                    | LP-L-HAE-FLM-MALST  |
| 1030 Haematology - .20 Bone marrow examination                                       | Bone marrow aspirates        | Blood           | Staining / microscopy       | Manual method                         | CE/based on standard method                                    | LP-L-HAE-FLM-BM   |
| 1030 Haematology - .30 Tests for haemoglobin variants and thalassaemia               | Sickle screening             | EDTA            | Qualitative solubility test | Manual method                         | CE/based on standard method                                    | LP-L-HAE-MAN-SICKLP   |
| 1030 Haematology - .40 Limited   | Activated Protein C          | Citrated plasma | Clotting assay              | Automated method - STAGO evolucion    | CE/based on standard method                                    | LP-L-HAE-COA-APC-R  |

|                           |                        |                                  |                                    |                             |  |
|---------------------------|------------------------|----------------------------------|------------------------------------|-----------------------------|--|
| haemostasis related tests | Resistance assay       |                                  |                                    |                             | LI-L-HAE-COA-SPIN<br>LP-L-HAE-COA-SPEC<br>LP-L-HAE-EQP-STA-R   |
|                           | Antithrombin III assay | Colorimetric / Chromogenic assay | Automated method - STAGO evolucion | CE/based on standard method | LP-L-HAE-COA-ATIII<br>LI-L-HAE-COA-SPIN<br>LP-L-HAE-COA-SPEC<br>LP-L-HAE-COA-TPHIL<br>LP-L-HAE-EQP-STA-R |
|                           | Anti-XA assay          | Colorimetric / Chromogenic assay | Automated method - STAGO evolucion | CE/based on standard method | LP-L-HAE-COA-XA<br>LI-L-HAE-COA-SPIN<br>LP-L-HAE-COA-SPEC<br>LP-L-HAE-EQP-STA-R                          |
|                           | Factor II assay        | Clotting assay                   | Automated method - STAGO evolucion | CE/based on standard method | LP-L-HAE-COA-EXFACT<br>LI-L-HAE-COA-SPIN<br>LP-L-HAE-COA-SPEC<br>LP-L-HAE-EQP-STA-R                      |
|                           | Factor IX assay        | Clotting assay                   | Automated method - STAGO evolucion | CE/based on standard method | LP-L-HAE-COA-INFAC<br>LI-L-HAE-COA-SPIN<br>LP-L-HAE-COA-SPEC<br>LP-L-HAE-EQP-STA-R                       |
|                           | Factor V assay         | Clotting assay                   | Automated method - STAGO evolucion | CE/based on standard method | LP-L-HAE-COA-EXFACT<br>LI-L-HAE-COA-SPIN<br>LP-L-HAE-COA-SPEC<br>LP-L-HAE-EQP-STA-R                      |
|                           | Factor VII assay       | Clotting assay                   | Automated method - STAGO evolucion | CE/based on standard method | LP-L-HAE-COA-EXFACT<br>LI-L-HAE-COA-SPIN<br>LP-L-HAE-COA-SPEC<br>LP-L-HAE-EQP-STA-R                      |
|                           | Factor VIII assay      | Clotting assay                   | Automated method - STAGO evolucion | CE/based on standard method | LP-L-HAE-COA-INFAC<br>LP-L-HAE-COA-LOVIII<br>LI-L-HAE-COA-SPIN<br>LP-L-HAE-COA-SPEC<br>LP-L-HAE-         |

|                          |                                  |                                    |                             |   |
|--------------------------|----------------------------------|------------------------------------|-----------------------------|---|
|                          |                                  |                                    |                             | EQP-STA-R   |
| Factor X assay           | Clotting assay                   | Automated method - STAGO evolucion | CE/based on standard method | LP-L-HAE-COA-EXFACT<br>LI-L-HAE-COA-SPIN<br>LP-L-HAE-COA-SPEC<br>LP-L-HAE-EQP-STA-R                       |
| Factor XI assay          | Clotting assay                   | Automated method - STAGO evolucion | CE/based on standard method | LP-L-HAE-COA-INFAC<br>LI-L-HAE-COA-SPIN<br>LP-L-HAE-COA-SPEC<br>LP-L-HAE-EQP-STA-R                        |
| Factor XII assay         | Clotting assay                   | Automated method - STAGO evolucion | CE/based on standard method | LP-L-HAE-COA-FXII<br>LI-L-HAE-COA-SPIN<br>LP-L-HAE-COA-SPEC<br>LP-L-HAE-EQP-STA-R                         |
| Free protein S assay     | Immuno-turbidimetric assay       | Automated method - STAGO evolucion | CE/based on standard method | LP-L-HAE-COA-FREEPS<br>LI-L-HAE-COA-SPIN<br>LP-L-HAE-COA-SPEC<br>LP-L-HAE-COA-TPHIL<br>LP-L-HAE-EQP-STA-R |
| Lupus like anticoagulant | Clotting                         | Automated method - STAGO evolucion | CE/based on standard method | LP-L-HAE-COA-LLA<br>LI-L-HAE-COA-SPIN<br>LP-L-HAE-COA-SPEC<br>LP-L-HAE-EQP-STA-R                          |
| Mixing studies           | Clotting assay                   | Automated method - STAGO evolucion | CE/based on standard method | LP-L-HAE-COA-MIX<br>LI-L-HAE-COA-SPIN<br>LP-L-HAE-COA-SPEC<br>LP-L-HAE-EQP-STA-R                          |
| Protein C                | Colorimetric / Chromogenic assay | Automated method - STAGO evolucion | CE/based on standard method | LP-L-HAE-COA-PROTC<br>LI-L-HAE-COA-SPIN<br>LP-L-HAE-COA-SPEC<br>LP-L-HAE-COA-TPHIL<br>LP-L-HAE-EQP-STA-R  |
| Protein S                | Clotting assay                   | Automated method - STAGO evolucion | CE/based on standard method | LP-L-HAE-COA-PROTS<br>LI-L-HAE-   |

|   |                      |  |                                       |                                       |   |  |
|---|----------------------|--|---------------------------------------|---------------------------------------|---|--|
|   |                      |  |                                       |                                       | COA-SPIN<br>LP-L-HAE-<br>COA-SPEC<br>LP-L-HAE-<br>COA-TPHIL<br>LP-L-HAE-<br>EQP-STA-R |  |
|   | Reptilase            |  | Clotting assay                        | Automated method -<br>STAGO evolucion | CE/based on<br>standard method  | LP-L-HAE-<br>COA-TTREPT<br>LI-L-HAE-<br>COA-SPIN<br>LP-L-HAE-<br>COA-SPEC<br>LP-L-HAE-<br>EQP-STA-R      |
|   | Thrombin time        |  | Clotting assay                        | Automated method -<br>STAGO evolucion | CE/based on<br>standard method  | LP-L-HAE-<br>COA-TTREPT<br>LI-L-HAE-<br>COA-SPIN<br>LP-L-HAE-<br>COA-SPEC<br>LP-L-HAE-<br>EQP-STA-R      |
|   | VWF Antigen<br>assay |  | Immuno-turbidimetric<br>assay         | Automated method -<br>STAGO evolucion | CE/based on<br>standard method  | LP-L-HAE-<br>COA-VWF<br>LI-L-HAE-<br>COA-SPIN<br>LP-L-HAE-<br>COA-SPEC<br>LP-L-HAE-<br>EQP-STA-R         |
| 1030 Haematology -<br>.41 General<br>haemostasis related<br>tests | APTT                 |  | Clotting assay                        | Automated method -<br>STAGO evolucion | CE/based on<br>standard method  | LP-L-HAE-<br>COA-APTT<br>LI-L-HAE-<br>COA-SPIN<br>LP-L-HAE-<br>COA-SPEC<br>LP-L-HAE-<br>EQP-STA-R        |
|   | D Dimer              |  | Immuno-turbidimetric<br>assay         | Automated method -<br>STAGO evolucion | CE/based on<br>standard method  | LP-L-HAE-<br>COA-<br>DDIMERS<br>LI-L-HAE-<br>COA-SPIN<br>LP-L-HAE-<br>COA-SPEC<br>LP-L-HAE-<br>EQP-STA-R |
|   | Fibrinogen           |  | Clotting assay                        | Automated method -<br>STAGO evolucion | CE/based on<br>standard method  | LP-L-HAE-<br>COA-FIB<br>LI-L-HAE-<br>COA-SPIN<br>LP-L-HAE-<br>COA-SPEC<br>LP-L-HAE-<br>EQP-STA-R         |
|   | PT / INR             |  | Clotting assay / ratio<br>calculation | Automated method -<br>STAGO evolucion | CE/based on<br>standard method  | LP-L-HAE-<br>COA-PTINR<br>LI-L-HAE-<br>COA-SPIN<br>LP-L-HAE-<br>COA-SPEC<br>LP-L-HAE-<br>EQP-STA-R       |
| 1030 Haematology -  | Ristocetin           |  | Platelet aggregation                  | Automated - Sysmex                    | CE/based on   | LP-L-HAE-  |

|  |                  |                |                   |                                       |                             |   |
|--|------------------|----------------|-------------------|---------------------------------------|-----------------------------|---|
| .45 Tests of platelet function                                     | cofactor assay   |                |                   |                                       | standard method             | COA-RI_COF                                    |
| 1030 Haematology - .55 Iron studies                                | Ferritin         | Serum          | MEIA              | Automated method / Advia Centaur      | CE/based on standard method | LP-L-HAE-HMT-FERR                             |
| 1030 Haematology - .57 Screening test for infectious mononucleosis | Monospot         | Serum / plasma | Manual            | Manual                                | CE/based on standard method | LP-L-HAE-MAN-MONOSP                           |
| 1030 Haematology - .58 Vitamin B12 and folate (serum and red cell) | Serum folate     | Serum          | MEIA              | Automated method / Advia Centaur      | CE/based on standard method | LP-L-HAE-HMT-FOL                              |
|  | Vitamin B12      |                | MEIA              | Automated method / Advia Centaur      | CE/based on standard method | LP-L-HAE-HMT-VB12                             |
| 1030 Haematology - .62 Plasma viscosity                            | Plasma viscosity | EDTA / plasma  | Capillary method  | Benson viscometer                     | CE/based on standard method | LP-L-HAE-MAN-PVISC<br>LP-L-HAE-EQP-BENSON     |
| 1030 Haematology - .70 Immunophenotyping                           | CD4 counts       | EDTA           | Immunophenotyping | Automated method FC500 flow cytometer | CE/based on standard method | LP-L-HAE-FLO-IMMUNE MON<br>LP-L-HAE-EQP-FC500 |
|  | CD8 counts       |                | Immunophenotyping | Automated method FC500 flow cytometer | CE/based on standard method | LP-L-HAE-FLO-IMMUNE MON<br>LP-L-HAE-EQP-FC500 |



| 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:<br>Sputum<br>CSF<br>Fluids | CAPD Fluid<br>CSF<br>Other body fluids<br>Pleural fluid<br>Sputum  | N/A / Manual  | CE/based on standard method                                    | N/A                  | LP-L-MIC-CAPD<br>LP-L-MIC-CSF<br>LP-L-MIC-FLUID<br>LP-L-MIC-SPUTA  |
| 1012 Preparation of films on glass slides followed by microscopic examination with or without fixation and staining with dyes as required - .01 Microscopic examination for general bacteriology purposes (including enumeration and description of human cells) | Microscopic examination of:<br>General Bacteriology                    | All swabs<br>Antral washout<br>Blood<br>Bone marrow<br>Bronchial lavage / brushings<br>washings<br>Cannulae and associated swabs<br>CAPD<br>Contact lens cases and cleaning fluid<br>Corneal scrapings<br>CSF<br>Endotracheal tubes<br>Faeces<br>Gastric washing<br>Middle ear effusion<br>Other body fluids<br>Pleural Fluid<br>Post-mortem specimens<br>Pus / Exudates<br>Semen<br>Sinus aspirate / washout<br>Sputum<br>Tissue<br>Urine | Light/fluorescent microscope / Microscopic examination with or without fixation and staining with dyes for enumeration and description of human cells | CE/based on standard method                                    | N/A                  | LP-L-MIC-TISSUE<br>LP-L-MIC-BC<br>LP-L-MIC-BILE<br>LP-L-MIC-BORD<br>LP-L-MIC-CANUL<br>LP-L-MIC-CAPD<br>LP-L-MIC-CSF<br>LP-L-MIC-EAR<br>LP-L-MIC-EYE<br>LP-L-MIC-FAECES<br>LP-L-MIC-FLUID<br>LP-L-MIC-GENITAL<br>LP-L-MIC-LEG<br>LP-L-MIC-MOUTH<br>LP-L-MIC-NOSE<br>LP-L-MIC-OCP<br>LP-L-MIC-SINUS<br>LP-L-MIC-SPUTA<br>LP-L-MIC-TB<br>LP-L-MIC-THROAT<br>LP-L-MIC-URINE<br>LP-L-MIC-WOUNDS |
| 1012 Preparation of films on glass slides followed by microscopic examination with or without fixation and staining with dyes as required - .02 Microscopic examination for parasites  | Microscopic examination of:<br>Parasites                               |  | Light/fluorescent microscope / Microscopic examination with or without fixation and staining with dyes for enumeration and description of human cells | CE/based on standard method                                    | N/A                  | LP-L-MIC-TISSUE<br>LP-L-MIC-BC<br>LP-L-MIC-BILE<br>LP-L-MIC-BORD<br>LP-L-MIC-CANUL<br>LP-L-MIC-CAPD<br>LP-L-MIC-CSF<br>LP-L-MIC-EAR  |

|  |  |  |   |                             |     |  |
|--|--|--|---|-----------------------------|-----|--|
|  |  |  |   |                             |     | LP-L-MIC-EYE<br>LP-L-MIC-FAECES<br>LP-L-MIC-FLUID<br>LP-L-MIC-GENITAL<br>LP-L-MIC-LEG<br>LP-L-MIC-MOUTH<br>LP-L-MIC-NOSE<br>LP-L-MIC-OCP<br>LP-L-MIC-SINUS<br>LP-L-MIC-SPUTA<br>LP-L-MIC-TB<br>LP-L-MIC-THROAT<br>LP-L-MIC-URINE<br>LP-L-MIC-WOUNDS  |
| 1012 Preparation of films on glass slides followed by microscopic examination with or without fixation and staining with dyes as required - .04 Microscopic examination for mycobacteria | Microscopic examination of: Mycobacteria |  | Light/fluorescent microscope / Microscopic examination with or without fixation and staining with dyes for enumeration and description of human cells | CE/based on standard method | N/A | LP-L-MIC-TISSUE<br>LP-L-MIC-BC<br>LP-L-MIC-BILE<br>LP-L-MIC-BORD<br>LP-L-MIC-CANUL<br>LP-L-MIC-CAPD<br>LP-L-MIC-CSF<br>LP-L-MIC-EAR<br>LP-L-MIC-EYE<br>LP-L-MIC-FAECES<br>LP-L-MIC-FLUID<br>LP-L-MIC-GENITAL<br>LP-L-MIC-LEG<br>LP-L-MIC-MOUTH<br>LP-L-MIC-NOSE<br>LP-L-MIC-OCP<br>LP-L-MIC-SINUS<br>LP-L-MIC-SPUTA<br>LP-L-MIC-TB<br>LP-L-MIC-THROAT<br>LP-L-MIC-URINE<br>LP-L-MIC-WOUNDS |
| 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: General bacteria             | As per specimen type in classification in 1012 | BacTAlert 3D system / BacT Alert/Manual   | CE/based on standard method | N/A | LI-L-MIC-CPESCREEN<br>LI-L-MIC-TISSUE<br>LI-L-MIC--VRE<br>LP-L-MIC-BC<br>LP-L-MIC-BILE   |

|   |                          |  |   |                             |     |  |
|---|--------------------------|--|---|-----------------------------|-----|--|
|   |                          |  |   |                             |     | LP-L-MIC-BORD<br>LP-L-MIC-CANUL<br>LP-L-MIC-CAPD<br>LP-L-MIC-CSF<br>LP-L-MIC-EAR<br>LP-L-MIC-ESBL<br>LP-L-MIC-EYE<br>LP-L-MIC-FAECES<br>LP-L-MIC-FLUID<br>LP-L-MIC-GENITAL<br>LP-L-MIC-LEG<br>LP-L-MIC-MOUTH<br>LP-L-MIC-MRSA<br>LP-L-MIC-NOSE<br>LP-L-MIC-SINUS<br>LP-L-MIC-SPUTA<br>LP-L-MIC-TB<br>LP-L-MIC-THROAT<br>LP-L-MIC-URINE<br>LP-L-MIC-WOUNDS  |
| 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 |  | BacTAlert 3D system / BacT Alert/Manual | CE/based on standard method | N/A | LI-L-MIC-CPESCREEN<br>LI-L-MIC-TISSUE<br>LI-L-MIC--VRE<br>LP-L-MIC-BC<br>LP-L-MIC-BILE<br>LP-L-MIC-BORD<br>LP-L-MIC-CANUL<br>LP-L-MIC-CAPD<br>LP-L-MIC-CSF<br>LP-L-MIC-EAR<br>LP-L-MIC-ESBL<br>LP-L-MIC-EYE<br>LP-L-MIC-FAECES<br>LP-L-MIC-FLUID<br>LP-L-MIC-GENITAL<br>LP-L-MIC-LEG<br>LP-L-MIC-MOUTH<br>LP-L-MIC-MRSA<br>LP-L-MIC-NOSE<br>LP-L-MIC-SINUS |

|  |  |   |   |                               |     |  |
|--|--|---|---|-------------------------------|-----|--|
|  |  |   |   |                               |     | LP-L-MIC-SPUTA<br>LP-L-MIC-TB<br>LP-L-MIC-THROAT<br>LP-L-MIC-URINE<br>LP-L-MIC-WOUNDS  |
| 1014 Detection of bacterial, parasite, viral or fungal antigens using specific antibodies and appropriate techniques - .03 Enzyme immunoassay,                   | Qualitative detection of H.pylori antigen in stool specimens by Enzyme Immunoassay                         | Stool   | Manual method / Enzyme immuno assay (EIA)   | CE/based on standard method   | N/A | LP-L-SER-HPA   |
| 1014 Detection of bacterial, parasite, viral or fungal antigens using specific antibodies and appropriate techniques - .04 Immunochromatographic methods,        | Coris Rotavirus & Adenovirus Antigen Combi-Strip rapid test  | Faeces  | Manual method / Immuno-chromatographic lateral flow                                       | CE/based on standard method   | N/A | LP-L-SER-ROAD  |
|  | Detection of:<br>- Urinary pneumococcal antigen<br>- Legionella urine antigen                              | Urine   | Binax now streptococcus pneumoniae antigen card / Immunochromatographic assay             | CE/based on standard method   | N/A | LI-L-MIC-LEGAGBIN<br>LP-L-MIC-STPNBIN  |
| 1015 Detection and/or identification of bacterial, parasite, fungal and viral nucleic acids - .03 Nucleic acid amplification tests, CE marked commercial systems | Detection of Influenza A; Influenza A (H1N1) pdm09 & Influenza B   | Nasopharyngeal specimens                                    | Cepheid GeneXpert Influenza A& Influenza B assay / Nucleic acid amplification test        | CE/based on standard method   | N/A | LP-L-SER-XPERTFLU  |
|  | Detection of Norovirus GI and GII  | Faeces  | Serosep EntericBio Norovirus real time PCR  | CE / Based on Standard Method | N/A | LP-L-SER-EBNORO  |
|  | Detection of: Chlamydia trachomatis and Neisseria gonorrhoeae  | Endocervical swab<br>Vaginal swab<br>Urethral swab<br>Urine | M2000sp and M2000rt / PCR (amplification)   | CE/based on standard method   | N/A | LP-L-MIC-CHLAMGC   |
|  | Detection of: Toxigenic Clostridium difficile Salmonella, Shigella, Campylobacter and Verotoxigenic E.coli | Faeces  | Illumipro-10 Roche light cycler 480 / PCR (Amplification)                                 | CE/based on standard method   | N/A | LP-L-MIC-CDTOXILLUM<br>LP-L-MIC-ENTBIO<br>LP-L-MIC-CDIFFENTBIO   |
| 1016 Identification of cultured bacteria and fungi using non-nucleic acid based techniques - .01 Biochemical methods , CE marked commercial systems              | Identification of organisms using: Biochemical methods   | As per specimen type in classification in 1012              | APIs, ARIS, Madli-Tof / Manual, Commercial ID systems, Automated ID systems, Spectroscopy | CE/based on standard method   | N/A | LP-L-MIC-MALDI<br>LP-L-MIC-ARIS<br>EXTMIC-5<br>EXTMIC-6<br>EXTMIC-26<br>EXTMIC-29<br>EXTMIC-31<br>EXTMIC-32<br>EXTMIC-39<br>EXTMIC-43<br>EXTMIC-44 |

|   |   |                        |   |                             |     |   |
|---|---|------------------------|---|-----------------------------|-----|---|
|   |   |                        |   |                             |     | EXTMIC-45   |
| 1016 Identification of cultured bacteria and fungi using non-nucleic acid based techniques - .04 Identification using MALDI-TOF Spectroscopy  | Identification of organisms using: Maldi-Tof Spectroscopy |                        | APIs, ARIS, Madli-Tof / Manual, Commercial ID systems, Automated ID systems, Spectroscopy | CE/based on standard method | N/A | LP-L-MIC-MALDI<br>LP-L-MIC-ARIS<br>EXTMIC-5<br>EXTMIC-6<br>EXTMIC-26<br>EXTMIC-29<br>EXTMIC-31<br>EXTMIC-32<br>EXTMIC-39<br>EXTMIC-43<br>EXTMIC-44<br>EXTMIC-45 |
| 1017 Measurement of antimicrobial activity and application of clinical interpretive criteria to general bacteria (rapidly growing aerobes) - .01 Anaerobes                                    | Aerobes / Anaerobes                                       |                        | Manual / Disc diffusion/Minimum inhibitory concentration                                  | CE/based on standard method | N/A | Anitmicrobial susceptibility testing manual Gradient MIC SOP (LP-L-MIC-EATESTMICQC)   |
| 1017 Measurement of antimicrobial activity and application of clinical interpretive criteria to general bacteria (rapidly growing aerobes) - .03 Yeasts                                       | Yeasts  |                        | Manual / Disc diffusion/Minimum inhibitory concentration                                  | CE/based on standard method | N/A | Anitmicrobial susceptibility testing manual Gradient MIC SOP (LP-L-MIC-EATESTMICQC)   |
| 1017 Measurement of antimicrobial activity and application of clinical interpretive criteria to general bacteria (rapidly growing aerobes) - .05 Other categories of organism (as specified ) | Aerobes   |                        | ARIS sensititre / Breakpoint  | CE/based on standard method | N/A | LP-L-MIC-ARIS   |
| 1018 Detection of antibody response to infection using appropriate CE marked commercial techniques - .01 Particle agglutination, using CE marked commercial systems                           | Omega Immutrep Rapid Plasmin Reagin (RPR)                 | Blood (serum)          | Manual method / Card test - antigen flocculation  | CE/based on standard method | N/A | LP-L-SER-SYPH-RPR   |
|   | Omega Immutrep TPHA                                       |                        | Manual method / Haem-agglutination assay  | CE/based on standard method | N/A | LP-L-SER-SYPH-TPHA  |
| 1018 Detection of antibody response to infection using appropriate CE marked commercial techniques - .02 Enzyme immunoassay, using CE marked commercial systems                               | Anti-Streptolysin 0 (ASO)                                 | Blood (serum / plasma) | Siemens BNII / Laser nephelometry   | CE/based on standard method | N/A | LP-L-SER-BNII-ASO   |
|   | BIOKIT Bioelisa Syphilis                                  |                        | Manual method & automated method, ETI-MAX 3000 / Enzyme Immunoassay (EIA)                 | CE/based on standard method | N/A | LP-L-SER-SYPH-EIA   |
|   | Biorad Genscreen HIV 1 & 2 Ag / Ab                        |                        | Manual method / Enzyme immuno assay (EIA)   | CE/based on standard method | N/A | LP-L-SER-HIVAg-Ab   |
|   | Biorad Monolisa Anti-HBc Plus                             |                        | Manual method / Enzyme immuno assay   | CE/based on standard method | N/A | LP-L-SER-HBCEIA   |

|   |   |                        |   |                             |     |                           |
|---|---|------------------------|---|-----------------------------|-----|---------------------------|
|   | assay   |                        | (EIA)   |                             |     |                           |
|   | Biorad Monolisa Hepatitis B Surface Antigen (HBsAg) Ultra assay                                       |                        | Manual method / Enzyme immuno assay (EIA)   | CE/based on standard method | N/A | LP-L-SER-HEPBEIA          |
|   | Euroimmun EBNA-1 IgG  |                        | Manual method & automated method, ETI-MAX 3000 / Enzyme Immunoassay (EIA)         | CE/based on standard method | N/A | LP-L-SER-EBNA-1 IgG       |
|   | Euroimmun EBV-CA IgG  |                        | Manual method & automated method, ETI-MAX 3000 / Enzyme Immunoassay (EIA)         | CE/based on standard method | N/A | LP-L-SER-EBVCA-IgG        |
|   | Euroimmun EBV-CA IgM  |                        | Manual method & automated method, ETI-MAX 3000 / Enzyme Immunoassay (EIA)         | CE/based on standard method | N/A | LP-L-SER-EBVCA-IgM        |
|   | Euroimmun Measles IgG   |                        | Manual method & automated method, ETI-MAX 3000 / Enzyme Immunoassay (EIA)         | CE/based on standard method | N/A | LP-L-SER-MEASG            |
|   | Euroimmun Mumps IgG   |                        | Manual method & automated method, ETI-MAX 3000 / Enzyme Immunoassay (EIA)         | CE/based on standard method | N/A | LP-L-SER-MUMPSG           |
|   | Euroimmun VZV IgG   |                        | Manual method & automated method, ETI-MAX 3000 / Enzyme Immunoassay (EIA)         | CE/based on standard method | N/A | LP-L-SER-VZVG             |
|   | Immunitics Lyme C6  | Blood (serum)          | Manual method / Enzyme immuno assay (EIA)   | CE/based on standard method | N/A | LP-L-SER-LYMEC6           |
|   | Microimmune Mumps IgM   | Blood (serum / plasma) | Manual method & automated method, ETI-MAX 3000 / Capture Enzyme Immunoassay (EIA) | CE/based on standard method | N/A | LP-L-SER-MUMPSM           |
|   | Quantitative detection of antibodies to hepatitis B (and-HBs) in serum / plasma by Enzyme Immunoassay |                        | Manual method & automated method, ETI-MAX 3000 / Enzyme Immunoassay (EIA)         | CE/based on standard method | N/A | LP-L-SER-DIASORIN-ANTIHBS |
|   | Syphilis IgM  |                        | Manual method / ELISA   | CE/based on standard method | N/A | LP-L-SER-SYPH-IGMLAB21    |
| 1018 Detection of antibody response to infection using appropriate CE marked commercial techniques - .07 Chemiluminescent microparticle immunoassay, using CE marked commercial systems | Abbott Architect Anti-HBc (total)   |                        | Manual method / Enzyme immuno assay (EIA)   | CE/based on standard method | N/A | LP-L-SER-ARCH-HBCII       |
|   | Abbott Architect Anti-HBc IgM   |                        | Abbott Architect i2000SR / Chemiluminescent Microparticle Immunoassay (CMIA)      | CE/based on standard method | N/A | LP-L-SER-ARCH-COREM       |

|  |  |                                |     |                                |
|--|--|--------------------------------|-----|--------------------------------|
| Abbott Architect Anti-HBs  | Abbott Architect i2000SR /<br>Cemiluminescent<br>Microparticle<br>Immunoassay (CMIA) | CE/based on<br>standard method | N/A | LP-L-SER-<br>ARCH-AUSAB        |
| Abbott Architect Anti-HCV  | Abbott Architect i2000SR /<br>Cemiluminescent<br>Microparticle<br>Immunoassay (CMIA) | CE/based on<br>standard method | N/A | LP-L-SER-<br>ARCH-HEPC         |
| Abbott Architect Anti-Hepatitis B e antigen                      | Abbott Architect i2000SR /<br>Cemiluminescent<br>Microparticle<br>Immunoassay (CMIA) | CE/based on<br>standard method | N/A | LP-L-SER-<br>ARCH-AHBE         |
| Abbott Architect CMV IgG   | Abbott Architect i2000SR /<br>Cemiluminescent<br>Microparticle<br>Immunoassay (CMIA) | CE/based on<br>standard method | N/A | LP-L-SER-<br>ARCH-CMVG         |
| Abbott Architect CMV IgM   | Abbott Architect i2000SR /<br>Cemiluminescent<br>Microparticle<br>Immunoassay (CMIA) | CE/based on<br>standard method | N/A | LP-L-SER-<br>ARCH-CMVM         |
| Abbott Architect HCV Ag  | Abbott Architect i2000SR /<br>Cemiluminescent<br>Microparticle<br>Immunoassay (CMIA) | CE/based on<br>standard method | N/A | LP-L-SER-<br>ARCH-HCVAG        |
| Abbott Architect Hepatitis A IgG                                 | Abbott Architect i2000SR /<br>Cemiluminescent<br>Microparticle<br>Immunoassay (CMIA) | CE/based on<br>standard method | N/A | LP-L-SER-<br>ARCH-HAVAB        |
| Abbott Architect Hepatitis A Igm                                 | Abbott Architect i2000SR /<br>Cemiluminescent<br>Microparticle<br>Immunoassay (CMIA) | CE/based on<br>standard method | N/A | LP-L-SER-<br>ARCH-<br>HAVABM   |
| Abbott Architect Hepatitis B e Antigen                           | Abbott Architect i2000SR /<br>Cemiluminescent<br>Microparticle<br>Immunoassay (CMIA) | CE/based on<br>standard method | N/A | LP-L-SER-<br>ARCH-HBE          |
| Abbott Architect Hepatitis B Surface Antigen (HBsAG) Qualitative | Abbott Architect i2000SR /<br>Cemiluminescent<br>Microparticle<br>Immunoassay (CMIA) | CE/based on<br>standard method | N/A | LP-L-SER-<br>ARCH-<br>HEPBQUAL |
| Abbott Architect HIV 1&2 Ag / Ab                                 | Abbott Architect i2000SR /<br>Cemiluminescent<br>Microparticle<br>Immunoassay (CMIA) | CE/based on<br>standard method | N/A | LP-L-SER-<br>ARCH-HIV          |
| Abbott Architect Rubella IgG                                     | Abbott Architect i2000SR /<br>Cemiluminescent<br>Microparticle<br>Immunoassay (CMIA) | CE/based on<br>standard method | N/A | LP-L-SER-<br>ARCH-RUBG         |
| Abbott Architect Rubella IgM                                     | Abbott Architect i2000SR /<br>Cemiluminescent  | CE/based on<br>standard method | N/A | LP-L-SER-<br>ARCH-RUBM         |

|   |                              |       |   |                             |     |                     |
|---|------------------------------|-------|---|-----------------------------|-----|---------------------|
|   |                              |       | Microparticle Immunoassay (CMIA)  |                             |     |                     |
|   | Abbott Architect Syphilis TP |       | Abbott Architect i2000SR / Cemiluminescent Microparticle Immunoassay (CMIA) | CE/based on standard method | N/A | LP-L-SER-ARCH-SYPH  |
|   | Abbott Architect Toxo IgG    |       | Abbott Architect i2000SR / Cemiluminescent Microparticle Immunoassay (CMIA) | CE/based on standard method | N/A | LP-L-SER-ARCH-TOXOG |
|   | Abbott Architect Toxo IgM    |       | Abbott Architect i2000SR / Cemiluminescent Microparticle Immunoassay (CMIA) | CE/based on standard method | N/A | LP-L-SER-ARCH-TOXOM |
| 1029 Miscellaneous - .99<br>Miscellaneous tests | Pregnancy testing            | Urine | Alere hCG cassette / Chromatographic immunoassay                            | CE/based on standard method | N/A | LP-L-MIC-PREGALERE  |