

# Schedule of Accreditation



|   |  |
|---|--|
| Organisation Name                             | HSE Cork University Hospital   |
| Trading As                                    |  |
| INAB Reg No                                   | 333MT  |
| Contact Name                                  | Paul Cantwell  |
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| Website                                       |  |
| Accreditation Standard                        | ISO 15189  |
| Date Initially Awarded                        | 09/06/2015   |
| Scope Classification                          | Microbiology and virology  |
| Scope Classification                          | Histopathology and cytopathology   |
| Scope Classification                          | Haematology  |
| Scope Classification                          | Chemical pathology   |
| Scope Classification                          | Immunology   |
| Services available to the public <sup>1</sup> | Yes  |

<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  | Head Office | Laboratory Quality Manager, Laboratory Medicine, Cork University Hospital, Wilton, Cork |

# Scope of Accreditation

## Head Office

### Chemical Pathology

Category: A

| Medical pathology field - Test  | Test/assay                                       | Specimen Type       | Technique                               | Equipment/Range of Measurement | Method (CE/Non-CE/In house developed/based on standard method) | Std. Ref & SOP   |
|---|--|---------------------|---|--------------------------------|--|------------------|
| 1061 Clinical Chemistry - .01 Analytes in general use in cardiac, liver function, lipid, renal and other profiles and metabolic studies | Alanine Transaminase (ALT) <sup>1234</sup>       | Plasma/Serum        | IFCC with PNPP                          | AU General Chemistry Analyser  | CE Marked Assay  | PPG-CUH-PAT-1420 |
|   | Albumin <sup>1234</sup>                          | Plasma/Serum /Urine | Bromocresol Green Turbidimetry (Urines) | AU General Chemistry Analyser  | CE Marked Assay  | PPG-CUH-PAT-1420 |
|   | Alkaline Phosphatase <sup>1234</sup>             | Plasma/Serum        | IFCC                                    | AU General Chemistry Analyser  | CE Marked Assay  | PPG-CUH-PAT-1420 |
|   | Ammonia <sup>1234</sup>                          | Plasma              | Enzymatic                               | AU General Chemistry Analyser  | CE Marked Assay  | PPG-CUH-PAT-1420 |
|   | Amylase <sup>1234</sup>                          | Plasma/Serum /Urine | IFCC                                    | AU General Chemistry Analyser  | CE Marked Assay  | PPG-CUH-PAT-1420 |
|   | Angiotensin converting enzyme <sup>1234</sup>    | Serum               | FAPGG                                   | AU General Chemistry Analyser  | CE Marked Assay  | PPG-CUH-PAT-1420 |
|   | Aspartate aminotransferase (AST) <sup>1234</sup> | Plasma/Serum        | IFCC                                    | AU General Chemistry Analyser  | CE Marked Assay  | PPG-CUH-PAT-1420 |
|   | Bicarbonate <sup>1234</sup>                      |                     | Enzymatic                               | AU General Chemistry Analyser  | CE Marked Assay  | PPG-CUH-PAT-121  |
|   | Bile Acids <sup>1234</sup>                       | Serum               | Enzymatic                               | AU General Chemistry Analyser  | CE Marked Assay  | PPG-CUH-PAT-1420 |
|   | Calcium <sup>1234</sup>                          | Plasma/Serum /Urine | Colorimetric                            | AU General Chemistry Analyser  | CE Marked Assay  | PPG-CUH-PAT-1420 |
|   | Chloride <sup>1234</sup>                         |                     | Indirect ISE                            | AU General Chemistry Analyser  | CE Marked Assay  | PPG-CUH-PAT-1420 |
|   | Cholesterol <sup>1234</sup>                      | Plasma/Serum        | Enzymatic                               | AU General Chemistry Analyser  | CE Marked Assay  | PPG-CUH-PAT-1420 |
|   | Creatinine Kinase (CK) <sup>1234</sup>           |                     | IFCC                                    | AU General Chemistry           | CE Marked Assay  | PPG-CUH-PAT-1420 |

|  |                                |                            |                                     |                      |                                  |
|--|--------------------------------|----------------------------|-------------------------------------|----------------------|----------------------------------|
|  |                                |                            | Analysers                           |                      |                                  |
| Creatinine <sup>1234</sup>                           |                                | Enzymatic                  | AU General Chemistry Analyser       | CE Marked Assay      | PPG-CUH-PAT-1420                 |
| Direct Bilirubin <sup>1234</sup>                     |                                | Diazo                      | AU General Chemistry Analyser       | CE Marked Assay      | PPG-CUH-PAT-1420                 |
| Gamma-glutamyl transpeptidase (GGT) <sup>1234</sup>  |                                | IFCC                       | AU General Chemistry Analyser       | CE Marked Assay      | PPG-CUH-PAT-1420                 |
| Glucose (Fasting/Random) <sup>1234</sup>             | Plasma                         | Enzymatic                  | AU General Chemistry Analyser       | CE Marked Assay      | PPG-CUH-PAT-1420                 |
| HDL Cholesterol <sup>1234</sup>                      | Plasma/Serum                   | Enzymatic                  | AU General Chemistry Analyser       | CE Marked Assay      | PPG-CUH-PAT-1420                 |
| Lactate Dehydrogenase (LDH) <sup>1234</sup>          |                                | IFCC                       | AU General Chemistry Analyser       | CE Marked Assay      | PPG-CUH-PAT-1420                 |
| Lactate <sup>1234</sup>                              | Plasma                         | Enzymatic                  | AU General Chemistry Analyser       | CE Marked Assay      | PPG-CUH-PAT-1420                 |
| LDL-Cholesterol <sup>1234</sup>                      | Plasma/Serum                   | Calculated                 | AU General Chemistry Analyser       | CE Marked Assay      | PPG-CUH-PAT-1420                 |
| Magnesium <sup>1234</sup>                            | Plasma/Serum /Urine            | Colorimetric               | AU General Chemistry Analyser       | CE Marked Assay      | PPG-CUH-PAT-1420                 |
| Osmolality <sup>1234</sup>                           | Serum/Urine                    | Freezing Point measurement | Advanced Micro-Osmometer Model 2020 | CE Marked Assay      | PPG-CUH-PAT-195                  |
| Phosphate <sup>1234</sup>                            | Plasma/Serum /Urine            | Ammonium Molybdate         | AU General Chemistry Analyser       | CE Marked Assay      | PPG-CUH-PAT-1420                 |
| Potassium <sup>1234</sup>                            |                                | Indirect ISE               | AU General Chemistry Analyser       | CE Marked Assay      | PPG-CUH-PAT-1420                 |
| Sodium <sup>1234</sup>                               |                                | Indirect ISE               | AU General Chemistry Analyser       | CE Marked Assay      | PPG-CUH-PAT-1420                 |
| Total Bilirubin <sup>1234</sup>                      | Plasma/Serum                   | Diazo Method               | AU General Chemistry Analyser       | CE Marked Assay      | PPG-CUH-PAT-1420                 |
| Total Protein <sup>1234</sup>                        |                                | Colorimetric               | AU General Chemistry Analyser       | CE Marked Assay      | PPG-CUH-PAT-1420                 |
| Triglyceride <sup>1234</sup>                         |                                | GPO-PAP                    | AU General Chemistry Analyser       | CE Marked Assay      | PPG-CUH-PAT-1420                 |
| Urate <sup>1234</sup>                                | Plasma/Serum /Urine            | Enzymatic                  | AU General Chemistry Analyser       | CE Marked Assay      | PPG-CUH-PAT-1420                 |
| Urea <sup>1234</sup>                                 |                                | Enzymatic                  | AU General Chemistry Analyser       | CE Marked Assay      | PPG-CUH-PAT-1420                 |
| Urinary Protein <sup>1234</sup>                      | Urine                          | Pyrogallol Red             | AU General Chemistry Analyser       | CE Marked Assay      | PPG-CUH-PAT-1420                 |
| 1061 Clinical Chemistry - .02 Proteins, quantitative | A1-Antitrypsin <sup>1234</sup> | Serum                      | Immunoturbidimetric                 | AU General Chemistry | CE Marked Assay PPG-CUH-PAT-1420 |

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| analysis  |  |              |   | Analyser                      |                 |                  |
|   | Anti-Thyroid Peroxidase Ab's <sup>1234</sup> |              | Immunoassay                                       | Architect i2000               | CE Marked Assay | PPG-CUH-PAT-263  |
|   | Ceruloplasmin <sup>1234</sup>                |              | Immunturbidimetric                                | AU General Chemistry Analyser | CE Marked Assay | PPG-CUH-PAT-1420 |
|   | C-Reactive Protein <sup>1234</sup>           | Plasma/Serum | Immunturbidimetric                                | AU General Chemistry Analyser | CE Marked Assay | PPG-CUH-PAT-1420 |
|   | Free Light Chains <sup>1234</sup>            | Serum        | Nephelometric                                     | BNII Nephelometer             | CE Marked Assay | PPG-CUH-PAT-269  |
|   | Haptoglobin <sup>1234</sup>                  |              | Immunturbidimetric                                | AU General Chemistry Analyser | CE Marked Assay | PPG-CUH-PAT-1420 |
|   | Insulin-like Growth Factor 1 <sup>1234</sup> |              | Immunoassay                                       | IDS-isys                      | CE Marked Assay | PPG-CUH-PAT-265  |
|   | NT-proBNP <sup>1234</sup>                    | Serum        | Chemiluminescent microparticle immunoassay (CMIA) | Abbott Architect              | CE Marked Assay | PPG-CUH-PAT-263  |
|   | Troponin I (hs) <sup>1234</sup>              | Serum        | Immunoassay                                       | Architect i2000               | CE Marked Assay | PPG-CUH-PAT-263  |
| 1061 Clinical Chemistry - .03 Proteins, qualitative and semiquantitative analysis | Bence-Jones Protein <sup>1234</sup>          | Urine        | Electrophoresis                                   | Sebia Hydrasys II             | CE Marked Assay | PPG-CUH-PAT-222  |
|   | Electrophoresis <sup>1234</sup>              | Serum        | Electrophoresis                                   | Sebia                         | CE Marked Assay | PPG-CUH-PAT-223  |
|   | Paraprotein Level <sup>1234</sup>            |              | Electrophoresis                                   | Sebia Capillarys II           | CE Marked Assay | PPG-CUH-PAT-223  |
|   | Paraprotein Type (Serum) <sup>1234</sup>     |              | Immuno-fixation                                   | Sebia Hydrasys                | CE Marked Assay | PPG-CUH-PAT-223  |
| 1061 Clinical Chemistry - .06 Blood pH and gas tensions                           | Arterial Blood Gas <sup>1234</sup>           | Whole Blood  | Potentiometric                                    | Gem 4000                      | CE Marked Assay | PPG-CUH-PAT-194  |
|   | Ionized Calcium <sup>1234</sup>              |              | Potentiometric                                    | Gem 4000                      | CE Marked Assay | PPG-CUH-PAT-194  |
| 1061 Clinical Chemistry - .07 Other analytes performed on a blood gas analyser    |  |              |   |                               |                 |                  |
| 1061 Clinical Chemistry - .08 Haemo-related pigments and precursors               | CSF Spectrophotometry <sup>1234</sup>        | CSF          | Spectrophotometric                                | Camspec M550                  | CE Marked Assay | PPG-CUH-PAT-248  |
| 1061 Clinical Chemistry - .10 Drugs for therapeutic monitoring                    | Carbamazepine <sup>1234</sup>                | Serum        | CMIA  | Architect i 1000 System       | CE Marked Assay | PPG-CUH-PAT-1420 |
|   | Cyclosporin <sup>1234</sup>                  | Whole Blood  | CMIA  | Architect i 1000 System       | CE Marked Assay | PPG-CUH-PAT-263  |
|   | Digoxin <sup>1234</sup>                      | Serum        | CMIA  | Architect i 1000 System       | CE Marked Assay | PPG-CUH-PAT-1420 |
|   | Lithium <sup>1234</sup>                      |              | Colorimetric                                      | AU General Chemistry Analyser | CE Marked Assay | PPG-CUH-PAT-1420 |
|   | Methotrexate <sup>1234</sup>                 |              | CMIA  | Architect i 1000 System       | CE Marked Assay | PPG-CUH-PAT-263  |
|   | Paracetamol <sup>1234</sup>                  |              | Enzymatic   | AU General Chemistry Analyser | CE Marked Assay | PPG-CUH-PAT-1420 |
|   | Phenobarbitone <sup>1234</sup>               |              | CMIA  | Architect i 1000 System       | CE Marked Assay | PPG-CUH-PAT-1420 |

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|  | Phenytoin <sup>1234</sup>                          |             | CMIA                | Architect i 1000 System       | CE Marked Assay | PPG-CUH-PAT-1420 |
|  | Tacrolimus <sup>1234</sup>                         | Whole Blood | CMIA                | Architect i 1000 System       | CE Marked Assay | PPG-CUH-PAT-263  |
|  | Theophylline <sup>1234</sup>                       | Serum       | CMIA                | Architect i 1000 System       | CE Marked Assay | PPG-CUH-PAT-1420 |
|  | Valproate <sup>1234</sup>                          |             | CMIA                | Architect i 1000 System       | CE Marked Assay | PPG-CUH-PAT-1420 |
| 1061 Clinical Chemistry - .14 Alcohol for non-legal purposes     | Alcohol <sup>1234</sup>                            | Serum/Urine | Enzymatic           | AU General Chemistry Analyser | CE Marked Assay | PPG-CUH-PAT-1420 |
| 1061 Clinical Chemistry - .15 Drugs for toxicological purposes   | Salicylate (Serum) <sup>1234</sup>                 | Serum       | Enzymatic           | AU General Chemistry Analyser | CE Marked Assay | PPG-CUH-PAT-1420 |
| 1061 Clinical Chemistry - .20 Hormones                           | Cortisol <sup>1234</sup>                           |             | Immunoassay         | Architect i2000               | CE Marked Assay | PPG-CUH-PAT-263  |
|  | Follicle-stimulating hormone (FSH) <sup>1234</sup> |             | Immunoassay         | Architect i2000               | CE Marked Assay | PPG-CUH-PAT-263  |
|  | Free T3 <sup>1234</sup>                            |             | Immunoassay         | Architect i2000               | CE Marked Assay | PPG-CUH-PAT-263  |
|  | Free T4 <sup>1234</sup>                            |             | Immunoassay         | Architect i2000               | CE Marked Assay | PPG-CUH-PAT-263  |
|  | Growth Hormone <sup>1234</sup>                     |             | Immunoassay         | IDS-isys                      | CE Marked Assay | PPG-CUH-PAT-265  |
|  | Luteinizing hormone (LH) <sup>1234</sup>           |             | Immunoassay         | Architect i2000               | CE Marked Assay | PPG-CUH-PAT-263  |
| Oestradiol <sup>1234</sup>                                       | Immunoassay  |             | Architect i2000     | CE Marked Assay               | PPG-CUH-PAT-263 |                  |
| Parathyroid hormone (PTH) <sup>1234</sup>                        | EDTA-Plasma  |             | Immunoassay         | Architect i2000               | CE Marked Assay | PPG-CUH-PAT-263  |
| Progesterone <sup>1234</sup>                                     | Serum  |             | Immunoassay         | Architect i2000               | CE Marked Assay | PPG-CUH-PAT-263  |
| Prolactin <sup>1234</sup>  |  | Immunoassay | Architect i2000     | CE Marked Assay               | PPG-CUH-PAT-263 |                  |
| Sex Hormone-Binding Globulin <sup>1234</sup>                     |  | Immunoassay | Architect i2000     | CE Marked Assay               | PPG-CUH-PAT-263 |                  |
| Testosterone <sup>1234</sup>                                     |  | Immunoassay | Architect i2000     | CE Marked Assay               | PPG-CUH-PAT-263 |                  |
| Thyroid-stimulating hormone (TSH) <sup>1234</sup>                |  | Immunoassay | Architect i2000     | CE Marked Assay               | PPG-CUH-PAT-263 |                  |
| 1061 Clinical Chemistry - .40 Iron studies                       | Iron <sup>1234</sup>                               |             | Ferrazine           | AU General Chemistry Analyser | CE Marked Assay | PPG-CUH-PAT-1420 |
|  | Transferrin <sup>1234</sup>                        |             | Immunoturbidimetric | AU General Chemistry Analyser | CE Marked Assay | PPG-CUH-PAT-1420 |
| 1061 Clinical Chemistry - .47 Vitamin assays                     | Vitamin D <sup>1234</sup>                          |             | Immunoassay         | Architect i 1000 System       | CE Marked Assay | PPG-CUH-PAT-206  |
| 1061 Clinical Chemistry - .50 Protein and peptide tumour markers | Alphafetaprotein <sup>1234</sup>                   |             | Immunoassay         | Architect i2000               | CE Marked Assay | PPG-CUH-PAT-263  |
|  | Ca125 <sup>1234</sup>                              |             | Immunoassay         | Architect i2000               | CE Marked Assay | PPG-CUH-PAT-263  |
|  | Ca15-3 <sup>1234</sup>                             |             | Immunoassay         | Architect i2000               | CE Marked Assay | PPG-CUH-PAT-263  |
|  | Ca19-9 <sup>1234</sup>                             |             | Immunoassay         | Architect i2000               | CE Marked Assay | PPG-CUH-PAT-263  |

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|  | Carcinoembryonic Antigen (CEA) <sup>1234</sup> |     | Immunoassay         | Architect i2000               | CE Marked Assay | PPG-CUH-PAT-263  |
|  | Human chorionic gonadotropin <sup>1234</sup>   |     | Immunoassay         | Architect i2000               | CE Marked Assay | PPG-CUH-PAT-263  |
|  | PSA (Total) <sup>1234</sup>                    |     | Immunoassay         | Architect i2000               | CE Marked Assay | PPG-CUH-PAT-263  |
| 1061 Clinical Chemistry - .80 Quantitative investigation of immunoglobulins G, A, M and in body fluids | IgA <sup>1234</sup>                            |     | Immunoturbidimetric | AU General Chemistry Analyser | CE Marked Assay | PPG-CUH-PAT-1420 |
|  | IgG <sup>1234</sup>                            |     | Immunoturbidimetric | AU General Chemistry Analyser | CE Marked Assay | PPG-CUH-PAT-1420 |
|  | IgM <sup>1234</sup>                            |     | Immunoturbidimetric | AU General Chemistry Analyser | CE Marked Assay | PPG-CUH-PAT-1420 |
| 1061 Clinical Chemistry - .86 C3 and C4  | Complement C3 <sup>1234</sup>                  |     | Immunoturbidimetric | AU General Chemistry Analyser | CE Marked Assay | PPG-CUH-PAT-1420 |
|  | Complement C4 <sup>1234</sup>                  |     | Immunoturbidimetric | AU General Chemistry Analyser | CE Marked Assay | PPG-CUH-PAT-1420 |
| 1061 Clinical Chemistry - .99 Miscellaneous tests  |  |     |                     |                               |                 |                  |
|  | CSF Glucose <sup>1234</sup>                    | CSF | Enzymatic           | AU General Chemistry Analyser | CE Marked Assay | PPG-CUH-PAT-1420 |
|  | CSF Lactate <sup>1234</sup>                    |     | Enzymatic           | AU General Chemistry Analyser | CE Marked Assay | PPG-CUH-PAT-1420 |
|  | CSF Total Protein <sup>1234</sup>              |     | Pyrogallol Red      | AU General Chemistry Analyser | CE Marked Assay | PPG-CUH-PAT-1420 |

| 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  | White Cell Count <sup>1234</sup><br>Red Cell Count <sup>1234</sup><br>Haemoglobin <sup>1234</sup><br>Haematocrit <sup>1234</sup><br>Mean Cell Volume <sup>1234</sup><br>MCH <sup>1234</sup><br>MCHC <sup>1234</sup><br>Platelet Count <sup>1234</sup> | Whole Blood in EDTA                 | Fluorescent flow Cytometry, Hydrodynamic focusing<br>Light scatter Impedance  | XN series   | CE Marked Assay  | PPG-CUH-PAT-403<br>PPG-CUH-PAT-1571                     |
| 1030 Haematology - .02<br>Visual examination of blood films                             | Differential white cell, red cell morphology and platelet checks <sup>1234</sup>  | Whole blood – films                 | May Grunwald and Giemsa staining  | SP1000i Microscope  | CE Marked Assay  | PPG-CUH-PAT-471<br>PPG-CUH-PAT-473<br>PPG-CUH-PAT-475   |
| 1030 Haematology - .03<br>Erythrocyte sedimentation rate                                | Automated ESR <sup>1234</sup>   | Whole Blood in EDTA                 | Westgren based Sedimentation rate   | Starrsed Compact ESR (Interrliner and RS)                     | CE Marked Assay  | PPG-CUH-PAT-404   |
| 1030 Haematology - .05<br>Automated differential leucocyte counts                       | Neutrophils, Lymphocytes, Monocytes, Eosinophils and Basophils <sup>1234</sup>  |                                     | Fluorescent flow Cytometry, Hydrodynamic focusing<br>Light scatter, Impedance | XN series   | CE Marked Assay  | PPG-CUH-PAT-403<br>PPG-CUH-PAT-1571<br>PPG-CUH-PAT-1971 |
| 1030 Haematology - .06<br>Automated reticulocyte counts                                 | Automated Reticulocyte count <sup>1234</sup>  |                                     | Fluorescent flow Cytometry<br>Impedance                                       | XN series   | CE Marked Assay  | PPG-CUH-PAT-403<br>PPG-CUH-PAT-1571<br>PPG-CUH-PAT-1971 |
| 1030 Haematology - .08<br>Blood film examinations involving special staining procedures | Factor V Leiden and Prothrombin gene mutation   | Whole Blood in EDTA – DNA extracted | PCR   | Cobas 480, PCR  | CE Marked Assay  | PPG-CUH-PAT-1572  |
|   | Iron Stain <sup>1234</sup>  | Bone marrow film                    | Perl's Prussian Blue  | Manual  | Based on a standard method                                     | PPG-CUH-PAT-476   |
| 1030 Haematology - .09<br>Examination of malarial parasites                             | Examination for malaria parasites <sup>1234</sup>   | Whole Blood in EDTA                 | May Grunwald and Giemsa manual staining and Kits                              | Manual and Binax NOW Malaria Ag Screen<br>CareStart Ag Screen | CE Marked Assay  | PPG-CUH-PAT-477<br>PPG-CUH-PAT-478<br>PPG-CUH-PAT-1981  |
|   | Malaria   | Whole blood EDTA                    | PCR   | Illumigene PCR bench top analyser                             | CE Marked Assay  | "PPG-CUH-PAT-477<br>PPG-CUH-PAT-478"                    |
| 1030 Haematology - .20<br>Bone marrow examination                                       | Bone Marrow <sup>1234</sup>   | Bone marrow film                    | May-Grunwald/ Giemsa stain  | SP 1000i, Microscope SP-10 Manual                             | CE Marked Assay  | PPG-CUH-PAT-476<br>PPG-CUH-PAT-471<br>PPG-CUH-          |



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|   |  |                        |   |   |                               | PAT-473<br>PPG-CUH-<br>PAT-475<br>PPG-CUH-<br>PAT-476<br>PPG-CUH-<br>PAT-1971 |
| 1030 Haematology - .30<br>Tests for haemoglobin<br>variants and<br>thalassaemia | Sickle cell test <sup>1234</sup><br>Haemoglobin<br>Electrophoresis on<br>the HYDRASYS<br>System <sup>1234</sup><br>Hb Variants and $\beta$<br>Thalassaemia<br>Screen <sup>1234</sup> | Whole Blood in<br>EDTA | Haemoglobin<br>Solubility test<br>Electrophoresis<br><br>High Performance<br>Liquid<br>Chromatography<br>HPLC | Clin Tech Sickle Cell<br>KitHYDRASYS System<br>Tosoh G8 | CE Marked Assay               | PPG-CUH-<br>PAT-458<br>PPG-CUH-<br>PAT-457<br>PPG-CUH-<br>PAT-453             |
| 1030 Haematology - .31<br>Tests for foetal Hb<br>(Kleihauer)                    | Foetal cells (Acid<br>Elution) <sup>1234</sup>   |                        | Acid elution  | Manual  | Based on a<br>standard method | PPG-CUH-<br>PAT-479   |
| 1030 Haematology - .36<br>Screening tests for<br>G6Pd                           | G6PD screen <sup>1234</sup><br>G6PD assay <sup>1234</sup>  |                        | Fluorescence spot<br>test<br>Ultraviolet, kinetic<br>determination of<br>G6PDH                                | UV Lamp<br>Spectrophotometer<br>CAMSPEC-M550            | CE Marked Assay               | PPG-CUH-<br>PAT-454<br>PPG-CUH-<br>PAT-455                                    |
| 1030 Haematology - .40<br>Limited haemostasis<br>related tests                  | ACTIN FSL <sup>1234</sup>  | Plasma – Citrate       | Clotting  | CS-2500   | CE Marked Assay               | PPG-CUH-<br>PAT-425<br>PPG-CUH-<br>PAT-1972                                   |
|   | Activated Protein C<br>Resistance <sup>1234</sup>  |                        | Clotting  | CS-2500   | CE Marked Assay               | PPG-CUH-<br>PAT-425<br>PPG-CUH-<br>PAT-1972                                   |
|   | Anti Xa Heparin<br>assay <sup>1234</sup>   |                        | Chromogenic   | CS-2500   | CE Marked Assay               | PPG-CUH-<br>PAT-425<br>PPG-CUH-<br>PAT-1972                                   |
|   | Anti-Thrombin III<br>Assay <sup>1234</sup>   |                        | Chromogenic   | CS-2500   | CE Marked Assay               | PPG-CUH-<br>PAT-425<br>PPG-CUH-<br>PAT-1972                                   |
|   | Cardiolipin<br>Antibody <sup>1234</sup>  | Serum sample           | Immunoassay   | DS2   | CE Marked Assay               | PPG-CUH-<br>PAT-438<br>PPG-CUH-<br>PAT-440                                    |
|   | DVVT: Lupus<br>Anticoagulant <sup>1234</sup>   | Plasma – Citrate       | Clotting  | CS-2500   | CE Marked Assay               | PPG-CUH-<br>PAT-425<br>PPG-CUH-<br>PAT-1972                                   |
|   | Factor assays -<br>Intrinsic Factor VIII,<br>IX, XI, XII <sup>1234</sup>   |                        | Clotting  | CS-2500 (CS5100 Factor<br>VIII only)                    | CE Marked Assay               | PPG-CUH-<br>PAT-425<br>PPG-CUH-<br>PAT-1972                                   |
|   | Factor assays –<br>Extrinsic Factor II,<br>VII, X <sup>1234</sup>  |                        | Clotting  | CS-2500   | CE Marked Assay               | PPG-CUH-<br>PAT-421<br>PPG-CUH-<br>PAT-1972                                   |
|   | Free Protein S <sup>1234</sup>   |                        | Immunoassay   | CS-2500   | CE Marked Assay               | PPG-CUH-<br>PAT-425<br>PPG-CUH-<br>PAT-1972                                   |
|   | Protein C Assay <sup>1234</sup>  |                        | Chromogenic   | CS-2500   | CE Marked Assay               | PPG-CUH-<br>PAT-425<br>PPG-CUH-<br>PAT-1972                                   |



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|   | Thrombophilia Screen <sup>1234</sup>  |   | Chromogenic and clotting   | CS-2500  | CE Marked Assay | PPG-CUH-PAT-425<br>PPG-CUH-PAT-1972   |
|   | vW screen: Antigen <sup>1234</sup><br>Ristocetin cofactor <sup>1234</sup>   |   | Immunoassay<br>Aggregometry  | CS-2500  | CE Marked Assay | PPG-CUH-PAT-434<br>PPG-CUH-PAT-435<br>PPG-CUH-PAT-1972  |
|   | Beta 2 Glycoprotein 1 Antibody <sup>1234</sup>  | Serum sample  | Immunoassay  | DS2  | CE Marked Assay | PPG-CUH-PAT-438<br>PPG-CUH-PAT-439  |
| 1030 Haematology - .41<br>General haemostasis related tests           | Prothrombin Time PT <sup>1234</sup> International Normalised Ratio INR <sup>1234</sup><br>Activated Partial Thromboplastin Time APTT and Ratio <sup>1234</sup><br>Fibrinogen <sup>1234</sup><br>D-Dimer <sup>1234</sup>   | Plasma – Citrate                                      | Clotting<br><br>Clotting<br><br>Immuno assay<br>Immuno-turbidimetric | CS-5100 CS-2500<br>Centrifuge                  | CE Marked Assay | PPG-CUH-PAT-442<br>PPG-CUH-PAT-1972   |
| 1030 Haematology - .45<br>Tests of platelet function                  | Platelet Aggregometry <sup>1234</sup>   | Whole blood<br>Plasma – Citrate                       | Optical Impedance  | PFA 100<br>PAP-8                               | CE Marked Assay | PPG-CUH-PAT-437<br>PPG-CUH-PAT-436  |
| 1030 Haematology - .55<br>Iron studies                                | Serum Ferritin <sup>1234</sup>  | Serum sample  | Chemiluminescent immunoassay   | Dxl 800  | CE Marked Assay | PPG-CUH-PAT-501   |
| 1030 Haematology - .57<br>Screening test for infectious mononucleosis | Clearview IM Screening Test for Infectious Mononucleosis <sup>1234</sup>  | EDTA  | Heterophile Antibody   | Alere IM II Kit                                | CE Marked Assay | PPG-CUH-PAT-480   |
| 1030 Haematology - .58<br>Vitamin B12 and folate (serum and red cell) | Serum Folate <sup>1234</sup>  | Serum sample  | Chemiluminescent immunoassay   | Dxl 800  | CE Marked Assay | PPG-CUH-PAT-501   |
|   | Serum Vitamin B12 <sup>1234</sup>   |   | Chemiluminescent immunoassay   | Dxl 800  | CE Marked Assay | PPG-CUH-PAT-501   |
| 1030 Haematology - .70<br>Immunophenotyping                           | Cell Surface Markers <sup>1234</sup><br>CD2, CD3, CD4, CD5, CD7, CD8, CD10, CD11b, CD11c, CD13, CD14, CD15, CD19, CD20, CD22, CD23, CD25, CD33, CD34, CD38, CD41a, CD45, CD56, CD57, CD61, CD64, CD71, CD79b, CD103, CD117, CD138, CD235a, HLADR, FMC7, Kappa, Lambda, IgM, TCR a/b, TCR g/d <sup>1234</sup><br><br>Intracellular Markers <sup>1234</sup><br>cyCD3, cyCD79a, cyIgM, TdT, MPO, | Whole Blood in EDTA<br>or<br>Bone Marrow in EDTA/RPMI | Flow Cytometry   | FACS Lyse Wash Assistant (LWA)<br>FACS Calibur | CE Marked Assay | PPG-CUH-PAT-491<br>PPG-CUH-PAT-492<br>PPG-CUH-PAT-493<br>PPG-CUH-PAT-499<br>PPG-CUH-PAT-494<br>PPG-CUH-PAT-497<br>PPG-CUH-PAT-500 |

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|   | Kappa, Lambda <sup>1234</sup><br>CD4 Assay <sup>1234</sup><br>CD3/8/45/4 <sup>1234</sup>  |                                     |   |   |                 |  |
|   | Enumeration of CD34 cells <sup>1234</sup>   | Whole Blood in EDTA                 | Flow Cytometry                              | FACS Canto II   | CE Marked Assay | PPG-CUH-PAT-498<br>PPG-CUH-PAT-506   |
|   | Multiset Immune Monitoring<br>CD3, CD4, CD8, CD19, CD16/56 <sup>1234</sup><br><br>CD4 Assay <sup>1234</sup><br>CD3/8/45/4 <sup>1234</sup> |                                     | Flow Cytometry                              | FACS Lyse Wash Assistant (LWA) FACS Sample Preparation Assistant SPA III FACS Canto II FACS Calibur | CE Marked Assay | PPG-CUH-PAT-491<br>PPG-CUH-PAT-492<br>PPG-CUH-PAT-497<br>PPG-CUH-PAT-498<br>PPG-CUH-PAT-499<br>PPG-CUH-PAT-500 |
| 1030 Haematology - .80<br>Molecular genetic studies | Factor V Leiden Prothrombin gene mutation   | Whole Blood in EDTA – DNA extracted | Polymerase Chain Reaction PCR               | MagNA Pure DNA Isolation LC<br>MagNA Pure Lightcycler LC 2.0  | CE Marked Assay | PPG-CUH-PAT-1567<br>PPG-CUH-PAT-1570<br>PPG-CUH-PAT-1568<br>PPG-CUH-PAT-1569                                   |
| 1030 Haematology - .99<br>Miscellaneous tests       | Hb A1c <sup>1234</sup>  | Whole Blood in EDTA                 | High Performance Liquid Chromatography HPLC | Tosoh G8  | CE Marked Assay | PPG-CUH-PAT-451<br>PPG-CUH-PAT-452   |
|   | Intrinsic factor antibody <sup>1234</sup>   | Serum sample                        | Chemiluminescent immunoassay                | Dxl 800   | CE Marked Assay | PPG-CUH-PAT-501  |
|   | Pregnancy test <sup>1234</sup>  | Urine                               | Chromographic Immunoassay                   | Alere HCG Cassette  | CE Marked Assay | PPG-CUH-PAT-456  |

| 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 Processing fixed specimens for Histopathological testing | Coverslipping  | Stained slides               | Automated & Manual<br>Automated coverslipper   | Based on standard method                                       | Qualitative test     | PPG-CUH-PAT-622  |
|  | Cut up         | Human Tissue                 | Manual<br>(Knives, scalpels, dyes etc)   | Based on standard method                                       | Qualitative test     | PPG-CUH-PAT-565<br>PPG-CUH-PAT-1118<br>PPG-CUH-PAT-552<br>PPG-CUH-PAT-600<br>PPG-CUH-PAT-684<br>PPG-CUH-PAT-685<br>PPG-CUH-PAT-642<br>PPG-CUH-PAT-918<br>PPG-CUH-PAT-949<br>PPG-CUH-PAT-690<br>PPG-CUH-PAT-691 |
|  | Embedding      | Paraffin infiltrated         | Embedding Centre & Cold Plate<br>Manual  | Based on standard method                                       | Qualitative test     | PPG-CUH-PAT-569<br>PPG-CUH-PAT-655   |
|  | H & E Staining | Paraffin wax tissue sections | Staining machine<br>Automated  | Based on standard method                                       | Qualitative test     | PPG-CUH-PAT-622<br>PPG-CUH-PAT-989   |
|  | Microtomy      | Paraffin wax blocks          | Semi-automated microtome   | Based on standard method                                       | Qualitative test     | PPG-CUH-PAT-590  |
|  | Muscle biopsy  | Muscle                       | Manual<br>Cryostat<br>Microtome<br>Stainer<br>Bondmax  | Based on standard method                                       | Qualitative test     | PPG-CUH-PAT-951  |
|  | Nerve biopsy   | Nerve                        | Manual<br>Cryostat<br>Microtome<br>Stainer<br>Fluorescent Microscope<br>Electron Microscope<br>Bondmax | Based on standard method                                       | Qualitative test     | PPG-CUH-PAT-952  |

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|   | Tissue processing   | Formalin fixed | Automated Vacuum Infiltration Processor | Based on standard method             | Qualitative test | PPG-CUH-PAT-626                                       |
| 1051 Histopathology - .02 Processing fresh specimens for frozen section examination | Frozen section/smear  | Human Tissue   | Cryostat Cryotomy                       | Based on standard method             | Qualitative test | PPG-CUH-PAT-576                                       |
| 1051 Histopathology - .03 Histochemistry  | 6.Immunohistochemistry <sup>1234</sup> : Bond Polymer Refine Detection Kit <sup>1234</sup>  |                | Immunostaining Bondmax                  | CE                                   | Qualitative test | PPG-CUH-PAT-926                                       |
|   | 7. Immunohistochemistry <sup>1234</sup> : Dako Envision Detection Kit <sup>1234</sup>   |                | Manual Immunostaining PT Module         | CE                                   | Qualitative test | PPG-CUH-PAT-926                                       |
|   | Immunohistochemistry Antibodies <sup>1234</sup> AE1-3 , AFP, ALK NSCLC , Alk1, AMACR/P504S, AMACR/P63/34 $\beta$ E12 , Arginase , $\beta$ -Catenin,BCL-2, BCL-6 , BER-4, BOB-1 , BRAF Caldesmon, Calcitonin, Calretinin, CAM 5.2 , carbonic anhydrase IX, CD1a , CD3, CD4, CD5, CD7, CD8, CD10, CD15 , CD20, CD21 CD23, CD30, CD31 , CD34, CD43, CD45/CLA, CD45RO/UCHL-1, CD56, CD57, CD68, CD79a, CD99 CD117/C-KIT, CD138, CDX2, CDK4 CEA Poly , Chromogranin A, CK 5/6, CK7 , CK19 , CK20, C-MYC,, CMV, CMYC, CYCLIN D1 , D2-40 / Podoplanin, DESMIN , Dog-1 EBER/EBV, EMA, E-Cad, ER GATA 3, Glycophorin A, Glypican-3, Granzyme B HEPAR 1, HCG, HER2, HER2 DDISH , H Pylori , HMB45 Inhibin, IgG4 , Ki-67, Ki-67/Melan-A Mel A, Mel tri-cocktail , MDM2, MLH1 MMR/MSH6, MMR/PMS2, MNF 116, MOC31 Mum 1, MPO, MSH2 , NF, NSE, OCT2, OCT4 P16, P57, P53 , P63, PAX5, PAX8, Parvovirus, PD1, PD-L1, Perforin PCP, PLAP, PR, Prostein / P501S, PSA, PSAP RCC , SMA, Synapto, S100 , TDT, Thyroglobulin, TTF-1 , Uroplakin II, WT1 Vimentin , SOX 10, SOX 11, 34 $\beta$ E12 |                | Immunostaining Ventana Ultra Bondmax    | CE                                   | Qualitative test | PPG-CUH-PAT-669<br>PPG-CUH-PAT-580<br>PPG-CUH-PAT-926 |
|   | Immunohistochemistry Neuropathology Markers <sup>1234</sup> : Alpha-synuclein, ATRX, B-Amyloid, A4), Brachyury, B-APP, C5b-9, FUS , GFAP , H3K27M,  |                |   | Immunostaining Ventana Ultra Bondmax | CE               | Qualitative test                                      |

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| <p>HIV (P24), HSV 1&amp;2, IDH1, INI1 , MAP2 , MHC1, MBP, Measles, Myosin (fast), Myosin (slow) Myosin (neonatal) , Nestin, NeuN, NF (52/2F11), Olig 2, PHH3, Pre-albumin/ Transthyretin, P62, SMI-31R, SV40, TAU, Tau (RD3), Tau (RD4), TDP43, Toxoplasma, Ubiquitin, Dystrophin1 , Dystrophin2, Dystrophin 3, Alpha-sarcoglycan, Beta-sarcoglycan, Gamma-sarcoglycan, Dystroglycan, Dysferlin, Merosin, Spectrin, Caveolin3, Collagen VI, Alpha-subunit, ACTH, TSH, GH, PRO, LH, FSH , GH</p> |                                  |   |                                 |                         |  |
| <p>Immunohistochemistry<sup>1234</sup><br/>Detection Kit:<br/>1. Optiview<br/>2. Ultraview<br/>3. Ultraview Red Alkaline phosphatase<br/>4. IView Blue ISH<br/>5. (a) Ultraview Red ISH DIG<br/>(b) Ultraview SISH DNP</p>  | <p>Human Tissue/Glass slides</p> | <p>Immunostaining<br/>Insitu Hybridisation<br/>Ventana<br/>Ultra</p>  | <p>CE</p>                       | <p>Qualitative test</p> | <p>PPG-CUH-PAT-669<br/>PPG-CUH-PAT-580<br/>PPG-CUH-PAT-680</p> |
| <p>Muscle stains:<br/>ATP 4.2<br/>ATP 4.6<br/>ATP 10.2<br/>Myophosphorylase<br/>Cytochrome oxidase<br/>Succinic dehydrogenase<br/>Myoadenylate deaminase<br/>NADH<br/>PFK</p>   | <p>Fresh Muscle Tissue</p>       | <p>Manual Oven</p>  | <p>Based on standard method</p> | <p>Qualitative test</p> | <p>PPG-CUH-PAT-988</p>   |
| <p>Non-gynae cytology<br/>Immunohistochemistry: ICC on Cell Blocks and cytocentrifuged samples.</p>   | <p>Human Tissue</p>              | <p>Immunohistochemistry Antibodies<sup>1234</sup><br/>AE1-3 , AFP, ALK NSCLC , Alk1, AMACR/P504S, AMACR/P63/34βE12 , Arginase , β-Catenin, BCL-2, BCL-6 , BER-4, BOB-1 , BRAF Caldesmon, Calcitonin, Calretinin, CAM 5.2 CD1a , CD3, CD4, CD5, CD7, CD8, CD10, CD15 , CD20, CD21 CD23, CD30, CD31 , CD34, CD43, CD45/CLA, CD45RO/UCHL-1, CD56, CD57, CD68, CD79a, CD99 CD117/C-KIT, CD138, CDX2, CDK4 CEA Poly , Chromogranin A, CK</p> | <p>CE</p>                       | <p>Qualitative test</p> | <p>PPG-CUH-PAT-665</p>   |

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|  |  |   | <p>5/6, CK7 , CK19 , CK20,<br/> CMV, CYCLIN D1 , D2-40 / Podoplanin,<br/> DESMIN , Dog-1<br/> EBER/EBV, EMA, E-Cad, ER<br/> GATA 3, Glycophorin A, Glypican-3,<br/> Granzyme B<br/> HEPAR 1, HCG,<br/> HER2, HER2 DDISH ,<br/> H Pylori , HMB45<br/> Inhibin, IgG4 , Ki-67,<br/> Ki-67/Melan-A<br/> Mel A, Mel tri-cocktail ,<br/> MDM2, MLH1<br/> MMR/MSH6,<br/> MMR/PMS2, MNF 116,<br/> MOC31<br/> Mum 1, MPO, MSH2 ,<br/> NF, NSE, OCT2, OCT4<br/> P16, P57, P53 , P63,<br/> PAX5, PAX8, PD1,<br/> Perforin<br/> PCP, PLAP, PR,<br/> Prostein / P501S, PSA,<br/> PSAP<br/> RCC , SMA, Synapto,<br/> S100 , TDT,<br/> Thyroglobulin, TTF-1 ,<br/> WT1<br/> Vimentin , SOX 10,<br/> 34βE12</p> |                          |                  |                                    |
|  | <p>Special Stains:<br/> Artisan: AFB/ZN, Alcian Blue/PAS, Congo Red ,<br/> Elastic stain, Grocott's Methenamine Silver ,<br/> Perl's Masson's Trichrome, PAS ,<br/> PASD (Diastase), Reticulin,</p> <p>Manual Methods:<br/> H &amp; E<br/> Biebrich Scarlet<br/> Congo Red<br/> Rapid Giemsa<br/> MSB<br/> Masson Fontana<br/> Masson Trichrome<br/> PAM<br/> Toluidine Blue<br/> Von Kossa<br/> Elastic Van Gieson<br/> Gallyas<br/> Gram<br/> HVG<br/> LFB-H&amp;E<br/> LFB-Cresyl violet<br/> Oil Red O<br/> PAS/DPAS<br/> Solochrome cyanine<br/> Gomori trichrome stain</p> | Glass slides – tissue sections & smears | Automated Artisan   | Based on standard method | Qualitative test | PPG-CUH-PAT-622<br>PPG-CUH-PAT-989 |
| 1051 Histopathology - .035 Histological Interpretation | Diagnostic Interpretation and reporting of Human tissue specimens  | Stained glass slides – Tissue sections  | H&E<br>- Special Stains<br>- ICC  | Based on standard method | Qualitative test | PPG-CUH-PAT-602                    |

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|   | Specialist areas excluded:<br>Paediatric Pathology<br>Specialist areas included:<br>(Added as demonstration of<br>EQA participation is<br>presented)                      |   |   |  |                  |  |
| 1051 Histopathology -<br>.04 Histological<br>interpretation-medical<br>renal pathology                                  | Renal Pathology:<br>Neoplastic<br>Non-neoplastic  |   | H&E<br>- Special Stains<br>- ICC  | Based on<br>standard method                | Qualitative test | PPG-CUH-<br>PAT-602  |
| 1051 Histopathology -<br>.06 Histological<br>interpretation-perinatal<br>pathology                                      | Perinatal Pathology:<br>Placentas Products of<br>conception<br>Ectopic pregnancies  | Stained glass<br>slides – Tissue<br>sections  | H&E<br>- Special Stains<br>- ICC  | Based on<br>standard method                | Qualitative test | PPG-CUH-<br>PAT-602  |
| 1051 Histopathology -<br>.07 Histological<br>interpretation-<br>neuropathology  | Neuropathology specimens  |   | C14- H&E<br>- Special Stains<br>- ICC   | Based on<br>standard method                | Qualitative test | PPG-CUH-<br>PAT-602  |
| 1051 Histopathology -<br>.08 Histological<br>interpretation-breast<br>screening pathology<br>(Breastcheck<br>programme) | Breast Specimens  |   | H&E<br>- Special Stains<br>- ICC<br>- ISH   | Based on<br>standard method                | Qualitative test | PPG-CUH-<br>PAT-602  |
| 1051 Histopathology -<br>.11 Chromogenic /<br>bright-field in situ<br>hybridisation                                     | Chromogenic in situ<br>hybridisation method <sup>1234</sup><br>List of probes specific to<br>each laboratory<br>Chromosome 17<br>EBER<br>Her-2 DDISH<br>Kappa<br>Lambda/λ |   | Human Tissue  | Immunostaining<br>Ventana Ultra<br>Bondmax | CE               | Qualitative test   |
| 1051 Histopathology -<br>.12 Electron<br>microscopy   | Electron Microscopy:<br>Preparation and Cut up<br>Fixation and Processing<br>Microtomy and Staining<br>EM<br>Diagnostic Interpretation                                    |   | Manual<br>Ultramicrotomy<br>Manual Staining<br>Electron Microscopy<br>Rotator, Fumehood<br>Fridge<br>60°oven<br>Ultramicrotome<br>Fumehood<br>Electron Microscope | Based on<br>standard method                | Qualitative test | PPG-CUH-<br>PAT-570<br>PPG-CUH-<br>PAT-571<br>PPG-CUH-<br>PAT-568<br>PPG-CUH-<br>PAT-600                       |
| 1051 Histopathology -<br>.13 Molecular testing  | Assay for Somatic Variants<br>in DNA sequences  |   | Idylla<br>Cobas<br>KRAS, NRAS, EGFR,<br>BRAF.   | CE   | Qualitative test | PPG-CUH-<br>PAT-1101<br>PPG-CUH-<br>PAT-1103<br>PPG-CUH-<br>PAT-1104   |
|   | MSI (PCR Assay)   | FFPE Tissue   | "Biocartis Idylla<br>DNA extraction and<br>PCR method for MSI"  | CE marked assay                            | Qualitative test | PPG-CUH-<br>PAT-1101<br>PPG-CUH-<br>PAT-1103   |
| 1052 Cytopathology -<br>.02 Non gynaecological<br>cytology  | Cytopathology, Non-gynae<br>cytology: Preparation   | Joint fluids,<br>Respiratory,<br>FNA, Serous<br>Fluids, Urines,<br>CSF, Other<br>fluids, Cell<br>Blocks | LBC<br>Cytocentrifugation<br>Direct Smear<br>Thin Prep 2000<br>Statspin<br>Cytocentrifuge   | Based on<br>standard method                | Qualitative test | PPG-CUH-<br>PAT-37<br>PPG-CUH-<br>PAT-665<br>PPG-CUH-<br>PAT-664<br>PPG-CUH-<br>PAT-689<br>PPG-CUH-<br>PAT-923 |
|   | Non-gynae cytology:   |   | Automated Acetate   | Based on                                   | Qualitative test | PPG-CUH-   |



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|  | Coverslipping  |  | Sakura Tissue Tek<br>Film Coverslipper   | standard method             |                  | PAT-564                                    |
|  | Non-gynae cytology:<br>Staining<br>PAP and Giemsa<br>Special Stains<br>ICC |  | Manual & Automated<br>staining<br>Manual Giemsa<br>(Rapid)<br>Leica Autostainer<br>(PAP) | Based on<br>standard method | Qualitative test | PPG-CUH-<br>PAT-622<br>PPG-CUH-<br>PAT-580 |
| 1052 Cytopathology -<br>.04 Cytopathological<br>interpretation | Non-gynae cytology:<br>Cytological interpretation                          |  | Microscopic & word<br>processing<br>APEX LIMS  | Based on<br>standard method | Qualitative test | PPG-CUH-<br>602                            |

| 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 - .08<br>Detection of immune complexes in body fluids and biopsy material | Direct Immunofluorescence for skin, renal and nerve biopsies:<br>Poly-FITC,<br>IgG-FITC,<br>IgG4-FITC,<br>IgA-FITC,<br>IgM-FITC,<br>C3-FITC,<br>C1q-FITC,<br>Kappa-FITC,<br>Lambda-FITC,<br>Fibrin-FITC<br><br>Indirect Immunofluorescence:<br>C4d,<br>FITC secondary antibody (polyclonal rabbit anti mouse) | Human Tissue  | Direct Immuno-fluorescence, Fluorescent microscope | Standard Method  | Qualitative method   | PPG-CUH-PAT-687 |
|   |   |               | Indirect Immuno-fluorescenece                      |  |                      |                 |
|   |   |               | Direct Immuno-fluorescence, Fluorescent microscope | Standard Method  | Qualitative method   | PPG-CUH-PAT-687 |
|   |   |               | Indirect Immuno-fluorescenece                      |  |                      |                 |
| 1040 Immunology - .12<br>Detection of autoantibodies in body fluids and biopsy material   | Paraneoplastic screen   | Serum         | Manual Indirect immunofluorescence & Immunoblot    | Standard Method  | Qualitative method   | PPG-CUH-PAT-901 |
|   |   |               | Manual Indirect immunofluorescence & Immunoblot    | Standard Method  | Qualitative method   | PPG-CUH-PAT-901 |

| 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  |
|--|---|---|-------------------------------|--|----------------------|---|
| 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 General bacteriology <sup>1234</sup> | Urine<br>Sputum<br>Brocheoalveolar Lavage Swabs<br>Abscess and pus specimens<br>Tissues and biopsies<br>Intravascular cannulae and associated specimens<br>Normally sterile body fluids<br>Bone and associated soft tissue<br>Prosthetic joint specimens<br>Aqueous and vitreous humour, corneal scrapings<br>Antral washout, sinus aspirate, sinus washout<br>Aspirates from:<br>Bartholin's gland<br>Fallopian tube<br>Tubo-ovarian abscess Pouch of Douglas fluid<br>Intra-uterine contraceptive device (IUCD)<br>Semen<br>Blood Cultures<br>Bone Marrow<br>CSF<br>CSF Shunts<br>Peritoneal Dialysis Fluid | Light/ Fluorescent microscope | Based on standard method                                       | Qualitative test     | PPG-CUH-PAT-776<br>PPG-CUH-PAT-759<br>PPG-CUH-PAT-750<br>PPG-CUH-PAT-751<br>PPG-CUH-PAT-753<br>PPG-CUH-PAT-754<br>PPG-CUH-PAT-707<br>PPG-CUH-PAT-709<br>PPG-CUH-PAT-706 |
|  |   |   | Light/ Fluorescent microscope | Based on standard method                                       | Qualitative test     | PPG-CUH-PAT-776<br>PPG-CUH-PAT-759<br>PPG-CUH-PAT-750<br>PPG-CUH-PAT-751<br>PPG-CUH-PAT-753<br>PPG-CUH-PAT-754  |

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|  |  |   |                               |                          |                  | PPG-CUH-PAT-707<br>PPG-CUH-PAT-709<br>PPG-CUH-PAT-706 |
| 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 Parasites <sup>1234</sup> | Faeces Duodenal aspirates<br>Sellotape slides<br>Aspirates<br>Worm/ larvae  | Light/ Fluorescent microscope | Based on standard method | Qualitative test | PPG-CUH-PAT-725                                       |
|  |  | Faeces Duodenal aspirates Sellotape slides Aspirates<br>Worm/ larvae,<br>Urine  | Light/ Fluorescent microscope | Based on standard method | Qualitative test | PPG-CUH-PAT-725                                       |
| 1012 Preparation of films on glass slides followed by microscopic examination with or without fixation and staining with dyes as required - .03 Microscopic examination for fungi        | Microscopic examination of Fungi <sup>1234</sup>     | Hair, Nail, Skin  | Light/ Fluorescent microscope | Based on standard method | Qualitative test | PPG-CUH-PAT-761                                       |
|  |  |   | Light/ Fluorescent microscope | Based on standard method | Qualitative test | PPG-CUH-PAT-761                                       |
| 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              | Brocheoalveolar Lavage /Bronchial washings,<br>Blood or bone marrow, CSF, body fluids, aspirates, pus,<br>Gastric lavage fluid, Laryngeal swabs / Other swabs, Skin / tissue biopsy / post-mortem specimens,<br>Sputum, Urine | Light/ Fluorescent microscope | Based on standard method | Qualitative test | PPG-CUH-PAT-766                                       |
|  |  | Sputum,<br>Brocheoalveolar Lavage /Bronchial washings, Blood or bone marrow, CSF, body fluids, aspirates, pus,<br>Skin / tissue biopsy / post-mortem  | Light/ Fluorescent microscope | Based on standard method | Qualitative test | PPG-CUH-PAT-766                                       |

|   |   |   |  |                          |                  |  |
|---|---|---|--|--------------------------|------------------|--|
|   |   | specimens,<br>Sputum, Urine   |  |                          |                  |  |
| 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 <sup>1234</sup>                     | Urine<br>Sputum<br>Brocheoalveolar Lavage<br>Swabs<br>Abscess and pus specimens<br>Tissues and biopsies<br>Intravascular cannulae and associated specimens<br>Normally sterile body fluids<br>Bone and associated soft tissue<br>Prosthetic joint specimens<br>Aqueous and vitreous humour, corneal scrapings<br>Antral washout, sinus aspirate, sinus washout<br>Aspirates from:<br>Bartholin's gland<br>Fallopian tube<br>Tubo-ovarian abscess<br>Pouch of Douglas fluid<br>Intra-uterine contraceptive device (IUCD)<br>Semen<br>Blood Cultures<br>Sterile Fluids<br>Bone Marrow<br>CSF<br>CSF Shunts<br>Peritoneal Dialysis Fluid<br>Faeces | Bactec FX blood culture instrument,<br>Culture media | Based on standard method | Qualitative test | PPG-CUH-PAT-776<br>PPG-CUH-PAT-759<br>PPG-CUH-PAT-750<br>PPG-CUH-PAT-751<br>PPG-CUH-PAT-753<br>PPG-CUH-PAT-754<br>PPG-CUH-PAT-707<br>PPG-CUH-PAT-709<br>PPG-CUH-PAT-706<br>PPG-CUH-PAT-721 |
|   | Microscopic examination of General bacteriology <sup>1234</sup> |   | Bactec FX blood culture instrument,<br>Culture media | Based on standard method | Qualitative test | PPG-CUH-PAT-776<br>PPG-CUH-PAT-759<br>PPG-CUH-PAT-750<br>PPG-CUH-PAT-751<br>PPG-CUH-PAT-753<br>PPG-CUH-PAT-754<br>PPG-CUH-PAT-707<br>PPG-CUH-PAT-709<br>PPG-CUH-PAT-706<br>PPG-CUH-PAT-721 |

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| 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 <sup>1234</sup>                                       | Urine<br>Sputum<br>Brocheoalveolar Lavage<br>Swabs<br>Abscess and pus specimens<br>Tissues and biopsies<br>Intravascular cannulae and associated specimens<br>Normally sterile body fluids<br>Bone and associated soft tissue<br>Prosthetic joint specimens<br>Aqueous and vitreous humour, corneal scrapings<br>Antral washout, sinus aspirate, sinus washout<br>Aspirates from:<br>Bartholin's gland<br>Fallopian tube<br>Tubo-ovarian abscess<br>Pouch of Douglas fluid<br>Intra-uterine contraceptive device (IUCD)<br>Semen<br>Blood Cultures<br>Sterile Fluids<br>Bone Marrow<br>CSF<br>CSF Shunts<br>Peritoneal Dialysis Fluid<br>Hair, Nail, Skin | Bactec FX blood culture instrument,<br>Culture media | Based on standard method | Qualitative test | PPG-CUH-PAT-776<br>PPG-CUH-PAT-759<br>PPG-CUH-PAT-750<br>PPG-CUH-PAT-751<br>PPG-CUH-PAT-753<br>PPG-CUH-PAT-754<br>PPG-CUH-PAT-707<br>PPG-CUH-PAT-709<br>PPG-CUH-PAT-706<br>PPG-CUH-PAT-761 |
| 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  | BAL/Bronchial washings,<br>Blood or bone marrow, CSF, body fluids, aspirates, pus, Gastric lavage fluid, Laryngeal swabs / Other swabs, Skin / tissue biopsy / post-mortem specimens, Sputum, Urine   | MB/ BacT Alert Bactec FX                             | Based on standard method | Qualitative test | PPG-CUH-PAT-764<br>PPG-CUH-PAT-766<br>PPG-CUH-PAT-707  |
| 1014 Detection of bacterial, parasite, viral or fungal antigens using specific antibodies and appropriate techniques - .04                    | Detection of Respiratory Syncytial Virus (RSV) Antigen <sup>1234</sup> | Nasopharyngeal Aspirate   | Immunochromographic Kit                              | CE marked assay          | Qualitative test | PPG-CUH-PAT-832  |

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| Immunochromatographic methods,   |  |  |  |                 |                  |                  |
|  | Detection of Rotavirus and Adenovirus Antigens in Faecal Samples <sup>1234</sup> | Faeces   | Immunochromatographic Kit  | CE marked assay | Qualitative test | PPG-CUH-PAT-726  |
|  | Legionella Urinary Antigen <sup>1234</sup>                                       | Urine  | Immunochromatographic Kit  | CE marked assay | Qualitative test | PPG-CUH-PAT-832  |
|  | TBCheck MPT64  | bacteria grown in liquid medium  | MPT64 kit cartridge Immunochromatographic method   | CE marked assay | Qualitative test | PPG-CUH-PAT-1956 |
|  | Urinary Pneumococcal Antigen <sup>1234</sup>                                     | Urine  | Immunochromatographic Kit  | CE marked assay | Qualitative test | PPG-CUH-PAT-832  |
| 1015 Detection and/or identification of bacterial, parasite, fungal and viral nucleic acids - .03 Nucleic acid amplification tests, CE marked commercial systems | Cepheid GeneXpert® system MTB/RIF Ultra  | sputum samples or concentrated sediments from induced or expectorated sputum | Cepheid GeneXpert® DX system Real time PCR platform  | CE marked assay | Qualitative test | PPG-CUH-PAT-718  |
|  | GeneXpert® Real time PCR for Influenza A and Influenza B                         | Swab or NPA  | Cepheid GeneXpert® DX system Real time PCR platform  | CE marked assay | Qualitative test | PPG-CUH-PAT-718  |
|  | GeneXpert® Real time PCR for Xpert® Carba-R                                      | Rectal swab or Isolate   | Cepheid GeneXpert® DX system Real time PCR platform  | CE marked assay | Qualitative test | PPG-CUH-PAT-718  |
|  | Investigation of Specimens for Mycobacterium Molecular Identification            | Liquid culture medium Isolates from culture medium                           | Hain GenoType system   | CE marked assay | Qualitative test | PPG-CUH-PAT-772  |
|  | Real Time PCR for Chlamydia trachomatis  | Urine Endocervical Swab High Vaginal Swab                                    | Real Time PCR Roche Cobas 4800   | CE marked assay | Qualitative test | PPG-CUH-PAT-738  |
|  | Real Time PCR for Investigation of Faeces Specimens for Clostridium difficile    | Faeces   | EntericBio Detection System epmotion 5070 instrument LightCycler® 480 Real-time PCR system | CE marked assay | Qualitative test | PPG-CUH-PAT-719  |
|  | Real Time PCR for Investigation of Faeces Specimens for Norovirus                |  | EntericBio Detection System epmotion 5070 instrument LightCycler® 480 Real-time PCR system | CE marked assay | Qualitative test | PPG-CUH-PAT-719  |



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|  | Real Time PCR for Investigation of Faeces Specimens for Salmonella, Shigella, Campylobacter sp, VTEC, and Cryptosporidium parvum/hominis |  | EntericBio Detection System<br>Epmotion 5070 instrument<br>LightCycler® 480 Real-time PCR system | CE marked assay          | Qualitative test | PPG-CUH-PAT-719  |
|  | Real Time PCR for Neisseria gonorrhoeae  | Urine<br>Endocervical Swab<br>High Vaginal Swab    | Real Time PCR<br>Roche Cobas 4800<br>Cepheid GeneXpert® Dx System                                | CE marked assay          | Qualitative test | PPG-CUH-PAT-738<br>PPG-CUH-PAT-718                                       |
| 1016 Identification of cultured bacteria and fungi using non-nucleic acid based techniques - .01<br>Biochemical methods , CE marked commercial systems           | Identification of Cultured Bacteria and Fungi <sup>1234</sup>  | Liquid culture medium Isolates from culture medium | Biochemical Characterisation kits  | Based on standard method | Qualitative test | PPG-CUH-PAT-859<br>PPG-CUH-PAT-843                                       |
| 1016 Identification of cultured bacteria and fungi using non-nucleic acid based techniques - .03<br>Identification of fungi by microscopic morphology            | Identification of Cultured Fungi <sup>1234</sup>   |  | Biochemical Characterisation kits  | Based on standard method | Qualitative test | PPG-CUH-PAT-761<br>PPG-CUH-PAT-859<br>PPG-CUH-PAT-843<br>PPG-CUH-PAT-865 |
| 1016 Identification of cultured bacteria and fungi using non-nucleic acid based techniques - .04<br>Identification using MALDI-TOF Spectroscopy                  | Identification of Cultured Bacteria <sup>1234</sup>  |  | Mass Spectrometry<br>Bruker Maldi-tof  | Based on standard method | Qualitative test | PPG-CUH-PAT-859<br>PPG-CUH-PAT-843<br>PPG-CUH-PAT-865                    |
| 1017 Measurement of antimicrobial activity and application of clinical interpretive criteria to general bacteria (rapidly growing aerobes) - .01<br>Anaerobes    | Anaerobes <sup>1234</sup>  |  | Qualitative susceptibility testing<br>bioMerieux VITEK 2XL<br>Biomic Manual                      | Based on standard method | Qualitative test | PPG-CUH-PAT-860<br>PPG-CUH-PAT-869<br>PPG-CUH-PAT-864                    |
| 1017 Measurement of antimicrobial activity and application of clinical interpretive criteria to general bacteria (rapidly growing aerobes) - .02<br>Mycobacteria | Mycobacteria   |  | VersaTREK<br>Qualitative susceptibility testing  | Based on standard method | Qualitative test | PPG-CUH-PAT-770  |
| 1017 Measurement of antimicrobial activity and application of clinical   | Yeasts <sup>1234</sup>   |  | Qualitative susceptibility testing<br>bioMerieux VITEK 2XL                                       | Based on standard method | Qualitative test | PPG-CUH-PAT-860<br>PPG-CUH-  |

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| interpretive criteria to general bacteria (rapidly growing aerobes) - .03<br>Yeasts  |   |       | Manual   |                 |  | PAT-869          |
| 1017 Measurement of antimicrobial activity and application of clinical interpretive criteria to general bacteria (rapidly growing aerobes) - .05<br>Other categories of organism (as specified ) | MAST Uriplus <sup>1234</sup>  | Urine | MAST Uriplus imagind analyser<br>MAST Uriwell multipoint inoculator<br>MAST Uriplus breakpoint susceptibility testing. | CE marked assay | No growth, no significant growth or Significant growth with organism identification and susceptibility | PPG-CUH-PAT-3032 |
| 1018 Detection of antibody response to infection using appropriate CE marked commercial techniques - .01 Particle agglutination, using CE marked commercial systems                              | Anti-Streptolysin (ASO) Latex Agglutination Slide Test <sup>1234</sup>  | Serum | Particle Agglutination Kit   | CE marked assay | Qualitative test   | PPG-CUH-PAT-832  |
|  | Syphilis Rapid Plasma Reagin (RPR) and Treponema pallidum Particle Agglutination (TPPA) Tests <sup>1234</sup> |       | Manual Particle Agglutination (TPPA, RPR)  | CE marked assay | Qualitative test   | PPG-CUH-PAT-832  |
| 1018 Detection of antibody response to infection using appropriate CE marked commercial techniques - .07<br>Chemiluminescent microparticle immunoassay, using CE marked commercial systems       |   |       |  |                 |  |                  |
|  | Antibodies to Hepatitis B e Antigen (Anti-HBeAg) Assay <sup>1234</sup>  | Serum | Architect Chemiluminescent Immunoassay   | CE marked assay | Qualitative test   | PPG-CUH-PAT-1960 |
|  | Antibodies to Hepatitis B Surface Antigen (Anti-HBs) Assay <sup>1234</sup>                                    |       | Architect Chemiluminescent Immunoassay   | CE marked assay | 0 to 1,000 mIU/mL  | PPG-CUH-PAT-1960 |
|  | Borrelia Burgdorferi IgG (Lyme) <sup>1234</sup>   |       | Liaison XL Chemiluminescent Immunoassay  | CE marked assay | Qualitative test   | PPG-CUH-PAT-1959 |
|  | Cytomegalovirus IgG Assay <sup>1234</sup>   |       | Architect Chemiluminescent Immunoassay   | CE marked assay | Qualitative test   | PPG-CUH-PAT-1960 |
|  | Cytomegalovirus IgM Assay <sup>1234</sup>   |       | Architect Chemiluminescent Immunoassay   | CE marked assay | Qualitative test   | PPG-CUH-PAT-780  |
|  | Epstein-Barr Virus VCA IgM Assay <sup>1234</sup>  |       | Architect Chemiluminescent Immunoassay   | CE marked assay | Qualitative test   | PPG-CUH-PAT-1960 |
|  | Hepatitis A Virus IgG Assay <sup>1234</sup>   |       | Architect Chemiluminescent   | CE marked assay | Qualitative test   | PPG-CUH-PAT-1960 |

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|   |   |  | Immunoassay                              |                 |                   |                  |
|   | Hepatitis A Virus IgM Assay <sup>1234</sup>                 |  | Architect Chemi-luminescent Immunoassay  | CE marked assay | Qualitative test  | PPG-CUH-PAT-1960 |
|   | Hepatitis B Core Total Antibody <sup>1234</sup> Assay       |  | Architect Chemi-luminescent Immunoassay  | CE marked assay | Qualitative test  | PPG-CUH-PAT-1960 |
|   | Hepatitis B e Antigen (HBeAg) <sup>1234</sup> Assay         |  | Architect Chemi-luminescent Immunoassay  | CE marked assay | Qualitative test  | PPG-CUH-PAT-1960 |
|   | Hepatitis B Surface Antigen (HBsAg) Assay <sup>1234</sup>   |  | Architect Chemi-luminescent Immunoassay  | CE marked assay | Qualitative test  | PPG-CUH-PAT-1960 |
|   | Hepatitis C Virus Antibody (Anti-HCV) Assay <sup>1234</sup> |  | Architect Chemi-luminescent Immunoassay  | CE marked assay | Qualitative test  | PPG-CUH-PAT-1960 |
|   | Hepatitis C Virus Antigen (HCV Ag) Assay <sup>1234</sup>    |  | Architect Chemi-luminescent Immunoassay  | CE marked assay | Qualitative test  | PPG-CUH-PAT-1960 |
|   | HIV Ag/Ab Combo Assay <sup>1234</sup>                       |  | Architect Chemi-luminescent Immunoassay  | CE marked assay | Qualitative test  | PPG-CUH-PAT-1960 |
|   | Rubella IgG Assay <sup>1234</sup>                           |  | Architect Chemi-luminescent Immunoassay  | CE marked assay | 0 to 500 IU/mL    | PPG-CUH-PAT-1960 |
|   | Rubella IgM Assay <sup>1234</sup>                           |  | Architect Chemi-luminescent Immunoassay  | CE marked assay | Qualitative test  | PPG-CUH-PAT-1960 |
|   | Syphilis IgG Antibody Assay <sup>1234</sup>                 |  | Architect Chemi-luminescent Immunoassay  | CE marked assay | Qualitative test  | PPG-CUH-PAT-1960 |
|   | Toxoplasma IgG Assay <sup>1234</sup>                        |  | Architect Chemi-luminescent Immunoassay  | CE marked assay | Qualitative test  | PPG-CUH-PAT-1960 |
|   | Toxoplasma IgM Assay <sup>1234</sup>                        |  | Architect Chemi-luminescent Immunoassay  | CE marked assay | Qualitative test  | PPG-CUH-PAT-1960 |
|   | Varicella-zoster Virus IgG <sup>1234</sup>                  |  | Liaison XL Chemi-luminescent Immunoassay | CE marked assay | Qualitative test  | PPG-CUH-PAT-1959 |
| 1029 Miscellaneous - .99<br>Miscellaneous tests | Amikacin Assay <sup>1234</sup>                              |  | Cobas c311 KIMS                          | CE marked assay | 0.8 to 40.0 mg/L  | PPG-CUH-PAT-821  |
|   | Gentamicin Assay <sup>1234</sup>                            |  | Cobas c311 KIMS                          | CE marked assay | 0.4 to 10.0 mg/L  | PPG-CUH-PAT-821  |
|   | Tobramycin Assay <sup>1234</sup>                            |  | Cobas c311 KIMS                          | CE marked assay | 0.33 to 10.0 mg/L | PPG-CUH-PAT-821  |
|   | Vancomycin Assay <sup>1234</sup>                            |  | Cobas c311 KIMS                          | CE marked assay | 4.0 to 80.0 mg/L  | PPG-CUH-PAT-821  |