

Schedule of Accreditation



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| Organisation Name | Midland Regional Hospital Tullamore |
| Trading As | |
| INAB Reg No | 221MT |
| Contact Name | Orlaith McDonnell |
| Address | Pathology Department, HSE Dublin Mid Leinster, Arden Road, Tullamore, Offaly, R35 Y2D1 |
| Contact Phone No | 057 9357752 |
| Email | Orlaith.McDonnell@hse.ie |
| Website | |
| Accreditation Standard | EN ISO 15189 |
| Standard Version | 2012 |
| Date of award of accreditation | 07/04/2009 |
| Scope Classification | Microbiology and virology |
| Scope Classification | Blood Transfusion Science |
| Scope Classification | Haematology |
| Scope Classification | Histopathology and cytopathology |
| Scope Classification | Chemical pathology |
| Services available to the public ¹ | Yes |

¹ Refer to document on interpreting INAB Scopes of Accreditation

| Sites from which accredited services are delivered | | |
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| (the detail of the accredited services delivered at each site are on the Scope of Accreditation) | | |
| | Name | Address |
| 1 | Quality Office | Pathology Department, Midland Regional Hospital Tullamore, Arden Road, Tullamore, Offaly, Ireland, R35 Y2D1 |

Scope of Accreditation

Quality Office

Blood Transfusion Science

Category: A

| Medical pathology field - Test | Test/assay | Specimen Type | Equipment/Technique | Method (CE/Non-CE/In house developed/based on standard method) | Range of measurement | Std. ref & SOP |
|--|--|----------------------------|---|--|---|---|
| 1020 Transfusion science - .01 Blood grouping including ABO, Rh(D) and other antigens by manual methods | Forward Blood Group, Reverse Blood Group | Red Blood Cells and Plasma | Manual method using tube and Gels cards | CE - based on standard method | Qualitative - Agglutination donates a positive reaction | Section 5.5 - 5.8 of ISO 15189:2012 & BSCH Guidelines, T/BTL/LP/003 |
| 1020 Transfusion science - .02 Blood grouping including ABO, Rh(D) and other antigens by automated methods | | | Automated using Gel cards | CE - based on standard method | Qualitative - Agglutination donates a positive reaction | Section 5.5 - 5.8 of ISO 15189:2012 & BSCH Guidelines, T/BTL/LP/003, T/BTL/EQ/056 |
| 1020 Transfusion science - .03 Blood group antibody screen | Antibody Screen | Plasma | Manual method using Gel Cards Automated using Gel Cards | CE - based on standard method | Qualitative - Agglutination donates a positive reaction | Section 5.5 - 5.8 of ISO 15189:2012 & BSCH Guidelines, T/BTL/LP/003, T/BTL/EQ/056 |
| 1020 Transfusion science - .04 Identification of blood group antibodies | Antibody Identification | | Manual method using Gel Cards Automated using Gel Cards | CE - based on standard method | Qualitative - Agglutination donates a positive reaction | Section 5.5 - 5.8 of ISO 15189:2012 & BSCH Guidelines, |

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| | | | | | | T/BTL/LP/005, T/BTL/EQ/056 |
| 1020 Transfusion science - .05 Cross match compatible donor units | Crossmatch testing | | Manual method using Gel Cards Automated using Gel Cards | CE - based on standard method | Qualitative - Agglutination donates a positive reaction | Section 5.5 - 5.8 of ISO 15189:2012 & BSCH Guidelines, T/BTL/LP/004, T/BTL/EQ/056 |
| 1020 Transfusion science - .06 Red cell phenotyping | Antigen typing - Patients and Donor Cells | Patient and Donor Red Cells | Manual method using tube and Gels cards Automated using Gel Cards | CE - based on standard method | Qualitative - Agglutination donates a positive reaction | Section 5.5 - 5.8 of ISO 15189:2012 & BSCH Guidelines, T/BTL/LP/009, T/BTL/EQ/056 |
| | Extended Antigen Typing - Patient and Door Cells | | Manual method using Gel Cards Automated method using Gel Cards | CE - based on standard method | Qualitative - agglutination donates a positive reaction | Section 5.5 - 5.8 of ISO 15189:2012 & BSCH Guidelines, T/BTL/LP/009, T/BTL/EQ/056 |
| 1020 Transfusion science - .99 Miscellaneous tests | Direct coombs testing/Monospecific coombs test | | Manual method using Gel Cards Automated using Gel Cards | CE - based on standard method | Qualitative - Agglutination donates a positive reaction | Section 5.5 - 5.8 of ISO 15189:2012 & BSCH Guidelines, T/BTL/LP/010, T/BTL/EQ/056 |

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

Category: A

| Medical pathology field - Test | Test/assay | Specimen Type | Technique | Equipment/Range of Measurement | Method (CE/Non-CE/In house developed/based on standard method) | Std. Ref & SOP |
|---|----------------------------------|--------------------|----------------------|--------------------------------|--|----------------|
| 1061 Clinical Chemistry - .01 Analytes in general use in cardiac, liver function, lipid, renal and other profiles and metabolic studies | Alanine Aminotransferase (ALT) | serum/plasma | Photometric | Roche Cobas Analyser | Manufacturer CE marked method | T/BIO/LP/069 |
| | Albumin | | Photometric | Roche Cobas Analyser | Manufacturer CE marked method | T/BIO/LP/067 |
| | Albumin/Creatinine Ratio (ACR) | urine | Calculation | Roche Cobas Analyser | Manufacturer CE marked method | T/BIO/LP/007 |
| | Alkaline Phosphatase (ALP) | serum/plasma | Photometric | Roche Cobas Analyser | Manufacturer CE marked method | T/BIO/LP/068 |
| | Amylase | serum/plasma/urine | Photometric | Roche Cobas Analyser | Manufacturer CE marked method | T/BIO/LP/070 |
| | ASOT | serum/plasma | Immunoturbidimetric | Roche Cobas Analyser | Manufacturer CE marked method | T/BIO/LP/071 |
| | Aspartate Aminotransferase (AST) | | Photometric | Roche Cobas Analyser | Manufacturer CE marked method | T/BIO/LP/072 |
| | Bicarbonate | | Photometric | Roche Cobas Analyser | Manufacturer CE marked method | T/BIO/LP/073 |
| | Bilirubin (Direct) | | Photometric | Roche Cobas Analyser | Manufacturer CE marked method | T/BIO/LP/074 |
| | Bilirubin (Total) | | Photometric | Roche Cobas Analyser | Manufacturer CE marked method | T/BIO/LP/075 |
| C reactive Protein (CRP) | Immunoturbidimetric | | Roche Cobas Analyser | Manufacturer CE marked method | T/BIO/LP/087 | |

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| Calcium | serum/plasma/ urine | Photometric | Roche Cobas Analyser | Manufacturer CE marked method | T/BIO/LP/079 |
| Chloride | serum/plasma | ISE | Roche Cobas Analyser | Manufacturer CE marked method | T/BIO/LP/081 |
| Cholesterol | | Photometric | Roche Cobas Analyser | Manufacturer CE marked method | T/BIO/LP/082 |
| Corrected Calcium | | Calculation | Roche Cobas Analyser | Manufacturer CE marked method | T/BIO/LP/007 |
| Creatine Kinase (CK) | | Photometric | Roche Cobas Analyser | Manufacturer CE marked method | T/BIO/LP/083 |
| Creatinine (Enzymatic) | | Photometric | Roche Cobas Analyser | Manufacturer CE marked method | T/BIO/LP/086 |
| Creatinine (Jaffe) | | serum/plasma/urine | Photometric | Roche Cobas Analyser | Manufacturer CE marked method |
| Creatinine Clearance | Calculation | | Roche Cobas Analyser | Manufacturer CE marked method | T/BIO/LP/007 |
| eGFR | serum/plasma | Calculation | Roche Modular Analyser | Manufacturer CE marked method | T/BIO/LP/007 |
| Gamma Glutamyltransferase (GGT) | | Photometric | Roche Cobas Analyser | Manufacturer CE marked method | T/BIO/LP/089 |
| Glucose | serum/plasma/CSF | Photometric | Roche Cobas Analyser | Manufacturer CE marked method | T/BIO/LP/090 |
| HDL | serum/plasma | Photometric | Roche Cobas Analyser | Manufacturer CE marked method | T/BIO/LP/092 |
| High Sensitivity Troponin T (HsTnT) | | Chemiluminescent Immunoassay | Roche Cobas Analyser | Manufacturer CE marked method | T/BIO/LP/103 |
| Lactate DeHydrogenase (LDH) | | Photometric | Roche Cobas Analyser | Manufacturer CE marked method | T/BIO/LP/094 |
| LDL | | Photometric | Roche Cobas Analyser | Manufacturer CE marked method | T/BIO/LP/095 |
| Magnesium | serum/plasma/urine | Photometric | Roche Cobas Analyser | Manufacturer CE marked method | T/BIO/LP/096 |
| Microalbumin | urine | Immunoturbidimetric | Roche Cobas Analyser | Manufacturer CE marked method | T/BIO/LP/097 |

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| | NTproBNP | Serum/Plasma | Electrochemiluminescent Assay | Roche Cobas Analyser | Manufacturer CE marked method | T/BIO/LP/109 |
| | Parathyroid Hormone (PTH) | plasma | Chemiluminescent Immunoassay | Roche Cobas Analyser | Manufacturer CE marked method | T/BIO/LP/100 |
| | Phosphate | serum/plasma/urine | Photometric | Roche Cobas Analyser | Manufacturer CE marked method | T/BIO/LP/098 |
| | Potassium | | ISE | Roche Modular Analyser | Manufacturer CE marked method | T/BIO/LP/045 |
| | Protein (Urinary/CSF) | urine/CSF | Immunoturbidimetric | Roche Cobas Analyser | Manufacturer CE marked method | T/BIO/LP/105 |
| | Sodium | serum/plasma/urine | ISE | Roche Cobas Analyser | Manufacturer CE marked method | T/BIO/LP/045 |
| | Total Protein | serum/plasma | Photometric | Roche Cobas Analyser | Manufacturer CE marked method | T/BIO/LP/104 |
| | Triglyceride | | Photometric | Roche Cobas Analyser | Manufacturer CE marked method | T/BIO/LP/106 |
| | Urea | serum/plasma/urine | Photometric | Roche Cobas Analyser | Manufacturer CE marked method | T/BIO/LP/107 |
| | Uric Acid | | Photometric | Roche Cobas Analyser | Manufacturer CE marked method | T/BIO/LP/108 |
| 1061 Clinical Chemistry - .10 Drugs for therapeutic monitoring | Gentamicin | serum/plasma | Enzyme Immunoassay | Roche Cobas Analyser | Manufacturer CE marked method | T/BIO/LP/111 |
| | Vancomycin | | Colourimetric Assay | Roche Cobas Analyser | Manufacturer CE marked method | T/BIO/LP/110 |
| 1061 Clinical Chemistry - .14 Alcohol for non-legal purposes | Ethanol | | Photometric | Roche Cobas Analyser | Manufacturer CE marked method | T/BIO/LP/088 |
| 1061 Clinical Chemistry - .15 Drugs for toxicological purposes | Paracetamol | | Photometric | Roche Cobas Analyser | Manufacturer CE marked method | T/BIO/LP/065 |
| | Salicylate | | Photometric | Roche Cobas Analyser | Manufacturer CE marked method | T/BIO/LP/102 |
| 1061 Clinical Chemistry - .50 Protein and peptide tumour markers | Alpha Feto Protein (AFP) | | Chemiluminescent Immunoassay | Roche Cobas Analyser | Manufacturer CE marked method | T/BIO/LP/066 |

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| | Cancer antigen 125 (CA 125) | | Chemiluminescent Immunoassay | Roche Cobas Analyser | Manufacturer CE marked method | T/BIO/LP/078 |
| | Cancer antigen 15.3 (CA 15.3) | | Chemiluminescent Immunoassay | Roche Cobas Analyser | Manufacturer CE marked method | T/BIO/LP/076 |
| | Cancer antigen 19.9 (CA 19.9) | | Chemiluminescent Immunoassay | Roche Cobas Analyser | Manufacturer CE marked method | T/BIO/LP/077 |
| | CarcinoEmbryonic Antigen (CEA) | | Chemiluminescent Immunoassay | Roche Cobas Analyser | Manufacturer CE marked method | T/BIO/LP/080 |
| | Human Chorionic Gonadotrophin Plus Beta (BHCG) | | Chemiluminescent Immunoassay | Roche Cobas Analyser | Manufacturer CE marked method | T/BIO/LP/091 |
| | Prostate Specific Antigen (PSA) | | Chemiluminescent Immunoassay | Roche Cobas Analyser | Manufacturer CE marked method | T/BIO/LP/099 |
| 1061 Clinical Chemistry - .60 Glycohaemoglobins | HbA1c | Whole Blood | HPLC | Ha-8180 | Manufacturer CE marked method | T/BIO/EQ/017 |
| 1061 Clinical Chemistry - .61 Hb A1c | | | HPLC | Ha-8180 | Manufacturer CE marked method | T/BIO/EQ/017 |
| 1061 Clinical Chemistry - .83 Rheumatoid factor – quantitative assays | Rheumatoid Factor | serum/plasma | Immunoturbidimetric | Roche Cobas Analyser | Manufacturer CE marked method | T/BIO/LP/101 |

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 | Blood | Spectrophotometry, Sheath flow (DC) detection and Fluorescence flow cytometry | Sysmex XN-10/ XN-20 | Automated | T/HAE/LP/025, T/HAE/LP/026, T/HAE/EQ/035, T/HAE/EQ/036, T/HAE/QC/005, T/HAE/IT/004 |
| 1030 Haematology - .02 Visual examination of blood films | Manual WBC Differential & Blood Film Review | | Slide Stainer & Morphological | Wescor Stainer & Sysmex SP-50 | Automated | T/HAE/EQ/015, T/HAE/LP/007, T/HAE/TR/001, T/HAE/LP/026 |
| | | | Slide Stainer & Morphological | Wescor Stainer & Sysmex SP-50 | Automated | T/HAE/EQ/015, T/HAE/LP/007, T/HAE/TR/001, T/HAE/LP/026 |
| 1030 Haematology - .03 Erythrocyte sedimentation rate | ESR | Whole Blood in EDTA | Capillary photometry | TEST 1 Analyser | Based on standard method | T/HAE/LP/021, T/HAE/EQ/012 |
| 1030 Haematology - .05 Automated differential leucocyte counts | White Blood Cell Differential | Blood | Spectrophotometry, Sheath flow (DC) detection and Fluorescence flow cytometry | Sysmex XN-10/ XN-20 | Automated | T/HAE/LP/025, T/HAE/LP/026, T/HAE/EQ/035, T/HAE/EQ/036, T/HAE/QC/005, T/HAE/IT/004 |
| | | | Spectrophotometry, Sheath flow (DC) detection and Fluorescence flow cytometry | Sysmex XN-10/ XN-20 | Automated | T/HAE/LP/025, T/HAE/LP/026, T/HAE/EQ/035, T/HAE/EQ/036, T/HAE/QC/005, T/HAE/IT/004 |

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| 1030 Haematology - .06 Automated reticulocyte counts | Reticulocyte Count | | Spectrophotometry, Sheath flow (DC) detection and Fluorescence flow cytometry | Sysmex XN-10/ XN-20 | Automated | T/HAE/LP/025, T/HAE/LP/026, T/HAE/EQ/035, T/HAE/EQ/036, T/HAE/QC/005, T/HAE/IT/004 |
| | | | Spectrophotometry, Sheath flow (DC) detection and Fluorescence flow cytometry | Sysmex XN-10/ XN-20 | Automated | T/HAE/LP/025, T/HAE/LP/026, T/HAE/EQ/035, T/HAE/EQ/036, T/HAE/QC/005, T/HAE/IT/004 |
| 1030 Haematology - .09 Examination of malarial parasites | Malaria Parasites Detection | | Qualitative Immunochromatographic Assay and Thick & Thin film | N/A | Manual (CE marked kits) | T/HAE/LP/017, T/HAE/LP/012, T/HAE/LP/013, T/HAE/LP/020 |
| 1030 Haematology - .30 Tests for haemoglobin variants and thalassaemia | Sickle Cell Screening test | | Qualitative Turbidity Solubility Test | N/A | Manual (CE marked kit) | T/HAE/LP/009 |
| 1030 Haematology - .41 General haemostasis related tests | Prothrombin Time (PT), Activated Partial Thromboplastin Time (APTT), Fibrinogen (Derived Fib), Fibrinogen (Clauss Fib), International Normalised Ratio (INR), D-Dimer (D-Dimer) | Plasma | Quantitative, Turbidimetric, Chromogenic and Immunological | ACL Top 550 | Automated | ISO 15189 T/HAE/EQ/026 T/HAE/EQ/028 T/HAE/EQ/029 |
| 1030 Haematology - .57 Screening test for infectious mononucleosis | Infectious Mononucleosis Screen | EDTA, Blood/Serum/Plasma | Immunoassay | Clearview IM II Kit | Manual (CE marked kit) | T/HAE/LP/028 |

Histopathology and Cytopathology

Category: A

| Medical pathology field - Test | Test/assay | Specimen Type | Equipment/Technique | Method (CE/Non-CE/In house developed/based on standard method) | Range of measurement | Std. ref & SOP |
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| 1051 Histopathology - .01 Processing fixed specimens for Histopathological testing | Automated and Manual Haematoxylin and Eosin Staining | Paraffin Section of Human Tissue | Leica Histocore Spectra ST Stainer and Coverlipper | Based on standard method | N/A | T/HIS/LP/049 |
| | Automated and Manual Haematoxylin and Eosin Staining | | Leica Multistainer/ Manual/Automated | Based on standard method | N/A | T/HIS/LP/015, |
| | Coverslipping | Stained Glass Slide containing section of human tissue | Leica Coverslipper/Automated | Based on standard method | N/A | T/HIS/EQ/016 |
| | | | Leica Histocore Spectra ST Stainer and Coverlipper | Based on standard method | N/A | T/HIS/LP/049 |
| | Cut up | Formalin Fixed Human tissue | Dissection table /Manual | Manual -Based on standard method | N/A | T/HIS/LP/002 |
| | Embedding | Paraffin Processed Human tissue | Leica Embedding Station /Manual | Manual- Based on standard method | N/A | T/HIS/EQ/005 , T/HIS/LP/033 |
| | Microtomy | Paraffin Block of Human Tissue | Leica Microtomes/semi automatic | Based on standard method | N/A | T/HIS/LP/010, T/HIS/LP/038 |
| | Tissue processing | Formalin Fixed Human tissue | Leica ASP 300S/ Automated Formalin Fixed Paraffin processing | Based on standard method | N/A | T/HIS/EQ/003,T/HIS/EQ/004 |
| 1051 Histopathology - .02 Processing fresh specimens for frozen section examination | Cut-up | Fresh Human Tissue / Formalin Fixed Human Tissue | Microm Cryostat / Manual | Based on standard method | N/A | T/HIS/LP/010 T/HIS/EQ/039 |

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| | Frozen section cryotomy and staining | | | | | |
| 1051 Histopathology - .03 Histochemistry | Alcian Blue/PAS Stain | Paraffin section on glass slide | Semi-automated Artisan | Non-CE/Based on standard method | N/A | T/HIS/LP/47 T/HIS/EQ/44 |
| | Congo Red | | Dako Artisan/ Automated | CE | N/A | T/HIS/LP/055 |
| | Diastase PAS stain | | Dako Artisan/ Automated | CE | N/A | T/HIS/LP/046 |
| | Gram Twort | | Manual | CE Marked /Based on standard method | N/A | T/HIS/LP/052 |
| | Grocott Methenamine silver | | Dako Artisan/ Automated | CE | N/A | T/HIS/LP/062 |
| | Martius Scarlett Blue | | Manual | Non CE/Based on standard method | N/A | T/HIS/LP/060 |
| | Masson Fontana | | Manual | Non CE/Based on standard method | N/A | T/HIS/LP/058 |
| | Massons Trichrome | | Dako Artisan/ Automated | CE | N/A | T/HIS/LP/050 |
| | May Grunwald Giemsa | Cytology cytospin Slide / Smears | Leica Multistainer/ Manual/Automated | CE Marked /Based on standard method | N/A | T/HIS/LP/029 |
| | PAP (Papanicolou stain) | Cytology Thin Prep Slide | Leica Multistainer/ Manual/Automated | CE Marked /Based on standard method | N/A | T/HIS/LP/030 |
| | PAS Green Stain | Paraffin Section on glass slide | Dako Artisan/ Automated | CE | N/A | T/HIS/LP/100 |
| | PAS Stain | | Dako Artisan/ Automated | CE | N/A | T/HIS/LP/045 |
| | Perls Prussian Blue | | Dako Artisan/ Automated | CE | N/A | T/HIS/LP/048 |
| | Reticulin Nuclear Fast Red | | Dako Artisan/ Automated | CE | N/A | T/HIS/LP/049 |
| | Verhoeff Elastic stain | | Dako Artisan/ Automated | CE | N/A | T/HIS/LP/053 |
| | Warthin and Starry | | Dako Artisan/ Automated | CE | N/A | T/HIS/LP/043 |

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| | Ziehl Neelsen | | Dako Artisan/ Automated | CE | N/A | T/HIS/LP/034 |
| 1051 Histopathology - .04 Histological interpretation- medical renal pathology | Specialist areas excluded: Breast check designated laboratories only Breast screening pathology Medical Renal Pathology Neuropathology Paediatric Pathology Perinatal Pathology | | | | | |
| | Specialist areas included: Diagnostic Interpretation and reporting of Human tissue specimens | Formalin fixed paraffin processed human tissue | Manual | N/A | | T/HIS/LP/077 T/HIS/LP/076 T/HIS/LP/070 T/HIS/LP/078 T/HIS/LP/072 T/HIS/LP/075 T/HIS/LP/073 T/HIS/LP/074 T/HIS/LP/071 T/HIS/LP/079 |
| 1051 Histopathology - .05 Histological interpretation- paediatric pathology | Dual Stain P40/CK5/6 | Paraffin section on glass slide | Automated Benchmark Ultra | N/A | CE Marked | T/HIS/22 T/HIS/EQ/45 |
| 1051 Histopathology - .09 Immunohistochemistry | D2 40-Podoplanin | | | CE | N/A | T/HIS/EQ/045, T/HIS/LP/022 |
| | 34 BE 12, ALK-1, Actin | | Benchmark Benchmark Ultra/ Optiview DAB Kit | CE | N/A | T/HIS/EQ/045, T/HIS/LP/022 |
| | BCL-2, BCL-6, BER EP4, BOB-1 | | Benchmark Ultra/ Optiview DAB Kit | CE | N/A | T/HIS/EQ/045, T/HIS/LP/022 |
| | Calretenin, Cam 5.2 | | Benchmark Ultra/ Optiview DAB Kit | CE | N/A | T/HIS/EQ/045, T/HIS/LP/022 |
| | CD 15,CD 20,CD 23,CD 30 | | Benchmark Ultra/ Optiview DAB Kit | CE | N/A | T/HIS/EQ/045, T/HIS/LP/022 |
| | CD 3,CD 4,CD 5,CD 8,CD 10, | | Benchmark Ultra/ Optiview DAB Kit | CE | N/A | T/HIS/EQ/045, T/HIS/LP/022 |

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| CD 31,CD 34,CD 45,CD 56 | Benchmark Ultra/Optiview DAB Kit | CE | N/A | T/HIS/EQ/045, T/HIS/LP/022 |
| CD 68,CD 117,CD 138 | Benchmark Ultra/Optiview | CE | N/A | T/HIS/EQ/045, T/HIS/LP/022 |
| CDX 2, CEA, Chromogranin | Benchmark Ultra/Optiview DAB Kit | CE | N/A | T/HIS/EQ/045, T/HIS/LP/022 |
| CK 5/6,CK 7,CK 19,CK 20 | Benchmark Ultra/Optiview DAB Kit | CE | N/A | T/HIS/EQ/045, T/HIS/LP/022 |
| CK AE1/AE3 | Benchmark Ultra/Optiview DAB Kit | CE | N/A | T/HIS/EQ/045, T/HIS/LP/022 |
| CMV, Cyclin D1, Desmin, DOG -1 | Benchmark Ultra/Optiview DAB Kit | CE | N/A | T/HIS/EQ/045, T/HIS/LP/022 |
| DOG-1, BOB-1, TdT, | Benchmark Ultra/Optiview | CE | N/A | T/HIS/EQ/045, T/HIS/LP/022 |
| Dual Stain CD31/AE1/AE3 | Benchmark Ultra/Optiview DAB Kit +Ultraview Red Kit | CE | N/A | T/HIS/EQ/045, T/HIS/LP/022 |
| Dual Stain CD34/AE1-3 | Benchmark Ultra/Optiview DAB Kit + Ultraview Red Kit | CE | N/A | T/HIS/EQ/045, T/HIS/LP/022 |
| Dual stain D2-40/AE1-3 | Benchmark Ultra/Optiview DAB Kit+ Ultraview Red Kit | CE | N/A | T/HIS/EQ/045, T/HIS/LP/022 |
| Dual stain P63/CK5-6 | Benchmark Ultra/Optiview DAB Kit + Ultraview Red Kit | CE | N/A | T/HIS/EQ/045, T/HIS/LP/022 |
| Dual Stain TTF/Napsin | Benchmark Ultra/Optiview DAB Kit + Ultraview Red Kit | CE | N/A | T/HIS/EQ/045, T/HIS/LP/022 |
| E-Cadherin, EMA, ER,GFAP | Benchmark Ultra/Optiview DAB Kit | CE | N/A | T/HIS/EQ/045, T/HIS/LP/022 |
| Glycophorin A | Benchmark Ultra/Optiview | CE | N/A | T/HIS/EQ/045, T/HIS/LP/022 |
| HMB45,Melan A, | Benchmark Ultra/Ultraview Red Kit | CE | N/A | T/HIS/EQ/045, T/HIS/LP/022 |
| HPV 16 Probe | Benchmark Ultra/iView Blue Plus Kit | CE | N/A | T/HIS/EQ/045, T/HIS/LP/022 |

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| | HSA,Ki-67,Napsin-A, Oct 2 | | Benchmark Ultra/ Optiview DAB Kit | CE | N/A | T/HIS/EQ/045, T/HIS/LP/022 |
| | Kappa Probe, Lambda Probe | | Benchmark Ultra/ I View Blue Kit | CE | N/A | T/HIS/EQ/045, T/HIS/LP/022 |
| | MLH-1, MSH2, MSH6, PMS-2 | | Benchmark Ultra/ Optiview DAB Kit | CE | N/A | T/HIS/EQ/045, T/HIS/LP/022 |
| | MOC31, MUM-1, | | Benchmark Ultra/ Optiview DAB Kit | CE | N/A | T/HIS/EQ/045, T/HIS/LP/022 |
| | Napsin-A, PLAP, GFAP | | Benchmark Ultra/ Optiview | CE | N/A | T/HIS/EQ/045, T/HIS/LP/022 |
| | OCT-2 | | Benchmark Ultra/ Optiview | CE | N/A | T/HIS/EQ/045, T/HIS/LP/022 |
| | P16, P40,P53 | | Benchmark Ultra/ Optiview DAB Kit | CE | N/A | T/HIS/EQ/045, T/HIS/LP/022 |
| | P57,P63,P504s, PLAP | | Benchmark Ultra/Optiview DAB Kit | CE | N/A | T/HIS/EQ/045, T/HIS/LP/022 |
| | PAX 8 | | Benchmark Ultra/ Optiview | Non-CE marked | N/A | T/HIS/EQ/045, T/HIS/LP/022 |
| | PR,PSA | | Benchmark Ultra/ Optiview DAB Kit | CE | N/A | T/HIS/EQ/045, T/HIS/LP/022 |
| | S100 Antigen, Synaptophysin | | Benchmark Ultra/ Optiview DAB Kit | CE | N/A | T/HIS/EQ/045, T/HIS/LP/022 |
| | SOX 10 | | Benchmark Ultra/ Optiview | CE | N/A | T/HIS/EQ/045, T/HIS/LP/022 |
| | Tdt, TTF-1 | | Benchmark Ultra/ Optiview DAB Kit | CE | N/A | T/HIS/EQ/045, T/HIS/LP/022 |
| | Thyroglobulin | | Benchmark Ultra/ Optiview | CE | N/A | T/HIS/EQ/045, T/HIS/LP/022 |
| | Vimentin, WT-1 | | Benchmark Ultra/ Optiview DAB Kit | CE | N/A | T/HIS/EQ/045, T/HIS/LP/022 |
| 1052 Cytopathology - .02 Non gynaecological cytology | Cytology sample preparation and description | Human tissue or fluid | Shandon Cytospin/Thinprep Genesis | N/A | N/A | T/HIS/LP/004, T/HIS/LP/006, T/HIS/LP/007, T/HIS/LP011, T/HIS/LP/29,T/HIS/LP/30, T/HIS/LP/36, T/HIS/EQ/002, T/HIS/EQ/036 |

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| 1052 Cytopathology - .04 Cytopathological interpretation | Diagnostic Interpretation and reporting of non- gynae samples | Stained slide prepared from Human Tissue or Fluid | Interpretative / Manual | N/A | N/A | T/HIS/LP/098 |
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Category: A

| Medical pathology field - Test | Test/assay | Specimen Type | Equipment/Technique | Method (CE/Non-CE/In house developed/based on standard method) | Range of measurement | Std. ref & SOP |
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| 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 for general bacteriology purposes | Blood Cultures | Light Microscope | Manual - Microscopy | N/A | T/MIC/LP/006, T/MIC/EQ/007 |
| | | CPE Swab | Light Microscope | Manual - Microscopy | N/A | T/MIC/LP/045, T/MIC/EQ/007 |
| | | CSF | Light Microscope | Manual - Microscopy | N/A | T/MIC/LP/005, T/MIC/EQ/007 |
| | | Ear Swab | Light Microscope | Manual - Microscopy | N/A | T/MIC/LP/050, T/MIC/EQ/007 |
| | | Eye Swab | Light Microscope | Manual - Microscopy | N/A | T/MIC/LP/012, T/MIC/EQ/007 UK Standards for Microbiology Investigations |
| | | Fluids | Light Microscope | Manual - Microscopy | N/A | T/MIC/LP/007, T/MIC/EQ/007 |
| | | Genital Tract | Light Microscope | Manual - Microscopy | N/A | T/MIC/LP/014, T/MIC/EQ/007 |

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| | | Intravascular Cannulae | Light Microscope | Manual - Microscopy | N/A | T/MIC/LP/007, T/MIC/EQ/007 |
| | | MRSA Swab | Light Microscope | Manual - Microscopy | N/A | T/MIC/LP/016, T/MIC/EQ/007 |
| | | Throat and Mouth Swab | Light Microscope | Manual - Microscopy | N/A | T/MIC/LP/012, T/MIC/EQ/007 |
| | | Tissues/Biopsies | Light Microscope | Manual - Microscopy | N/A | T/MIC/LP/007, T/MIC/EQ/007 |
| | | Urine | Sysmex UF-5000 Flow Cytometry | Automated- Microscopy | N/A | T/MIC/LP/008 T/MIC/EQ/027 |
| | | VRE Swab | Light Microscope | Manual - Microscopy | N/A | T/MIC/LP/017, T/MIC/EQ/007 |
| | | Wound Swab | Light Microscope | Manual - Microscopy | N/A | T/MIC/LP/009, T/MIC/EQ/007 |
| 1013 Culture of organisms in liquid or agar based culture media with visual or instrument monitoring for growth - .01 Culture of general bacteria | Microbial Culture | Blood Cultures/Swabs/Fluids/Tissues/Faeces | BacTAlert 3D/Manual Culture | Automated/Manual | N/A | T/MIC/LP/005, T/MIC/LP/006, T/MIC/LP/007, T/MIC/LP/008, T/MIC/LP/009, T/MIC/LP/010, T/MIC/LP/011, T/MIC/LP/012, T/MIC/LP/013, T/MIC/LP/014, T/MIC/LP/016, T/MIC/LP/017, T/MIC/LP/019, T/MIC/LP/020, T/MIC/LP/045, T/MIC/LP/050, T/MIC/EQ/003 |
| 1014 Detection of bacterial, parasite, viral or fungal antigens using specific antibodies and appropriate techniques - .01 Slide agglutination, | S. aureus | Isolate | N/A - Kit | Manual - CE Marked | Qualitative Test | T/MIC/LP/042 |
| 1014 Detection of bacterial, parasite, viral | Streptococcus Groups | | N/A - Kit | Manual - CE Marked | Qualitative Test | T/MIC/LP/042 |

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| or fungal antigens using specific antibodies and appropriate techniques - .02 Particle agglutination | | | | | | |
| 1014 Detection of bacterial, parasite, viral or fungal antigens using specific antibodies and appropriate techniques - .04 Immunochromatographic methods, | Clostridium difficile | Faeces | N/A - Kit | Manual - CE Marked | Qualitative Test | T/MIC/LP/020 |
| | Helicobacter pylori | | N/A - Kit | Manual - CE Marked | Qualitative Test | T/MIC/LP/023 |
| | Legionella | Urine | N/A - Kit | Manual - CE Marked | Qualitative Test | T/MIC/LP/008 |
| | Rotavirus/Adenovirus | Faeces | N/A - Kit | Manual - CE Marked | Qualitative Test | T/MIC/LP/021 |
| | S. pneumoniae | Urine | N/A - Kit | Manual - CE Marked | Qualitative Test | T/MIC/LP/008 |
| 1015 Detection and/or identification of bacterial, parasite, fungal and viral nucleic acids - .01 Nucleic acid probe hybridization, CE marked commercial systems | Investigation of Nasopharyngeal swabs for SARS-CoV-2 | Nasopharyngeal Aspirates and Nasal Swabs | EasyScreen Assay on QuantStudio Molecular System | CE Marked | N/A | T/MIC/LP/053, T/MIC/EQ/026, T/MIC/EQ/028 |
| | Xpert Xpress Cov-2 Plus kit | NPA and Nasal Swab | GeneXpert | CE Marked | N/A | T/MIC/EQ/023 |
| | | NPA and Nasal Swabs | Gene Xpert | CE Marked | N/A | T/MIC/EQ/023, MRHT/PPPG/MIC/37 |
| | Xpert Xpress SARS-CoV-2 Assay | NPA and Nasal | GeneXpert | CE Marked | N/A | T/MIC/LP/053, T/MIC/EQ/023 |
| | Xpert Xpress SARS-CoV-2/Flu/RSV | | GeneXpert | Standard Method | N/A | T/MIC/LP/048, T/MIC/EQ/023 |
| | Xpert Xpress SARS-CoV-2/Flu/RSV Plus Assay | | GeneXpert | Standard Method | N/A | T/MIC/LP/048, T/MIC/EQ/023 |

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| 1015 Detection and/or identification of bacterial, parasite, fungal and viral nucleic acids - .03 Nucleic acid amplification tests, CE marked commercial systems | C. diff Toxin | Stool | GeneXpert- PCR | Automated | Qualitative Test | T/MIC/LP/020 |
| | Influenza A,B and RSV | Swab | GeneXpert- PCR | CE marked | Qualitative Test | T/MIC/LP/048 |
| | Norovirus G1 and G2 | Stool | GeneXpert- PCR | Automated | Qualitative Test | T/MIC/LP/047 |
| | Screening samples for CPE by PCR | Rectal swab/faeces | Cepheid GeneXpert | Based on standard | Qualitative test | T/MIC/LP/045 |
| | Screening samples for MRSA by PCR | Nasal Groin Swab | Cepheid GeneXpert | Based on standard | Qualitative test | T/MIC/LP/016 |
| | Screening samples for VRE by PCR | Rectal swab/faeces | Cepheid GeneXpert | Based on standard | Qualitative test | T/MIC/LP/017 |
| 1015 Detection and/or identification of bacterial, parasite, fungal and viral nucleic acids - .05 Nucleotide sequencing & analysis | Determination of Minimum Inhibitory Concentrations | Isolate | Gradient Strips | CE marked | N/A | T/MIC/LP/043 |
| 1016 Identification of cultured bacteria and fungi using non-nucleic acid based techniques - .01 Biochemical methods, CE marked commercial systems | Organism Identification | Isolates | Vitek 2 Compact/Biochemical Methods | Automated and Manual CE Marked Kits | N/A | T/MIC/LP/041, T/MIC/LP/042, T/MIC/LP/043 |
| 1017 Measurement of antimicrobial activity and application of clinical interpretive criteria to general bacteria (rapidly growing aerobes) - .01 Anaerobes | | | Susceptibility Testing | Vitek 2 Compact/Biochemical Methods | Automated and Manual CE Marked Kits | N/A |
| 1017 Measurement of antimicrobial activity and application of clinical interpretive criteria to | Antimicrobial Resistance Testing using Disc Diffusion | Isolate | Disk Diffusion | CE marked | N/A | T/MIC/LP/043 |

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| general bacteria (rapidly growing aerobes) - .05 Other categories of organism (as specified) | | | | | | |
| 1018 Detection of antibody response to infection using appropriate CE marked commercial techniques - .07 Chemiluminescent microparticle immunoassay, using CE marked commercial systems | HCV | Blood | Abbot Architect i2000SR: Chemiluminescent microparticle immunoassay | Automated | Qualitative Test | T/MIC/LP/046 |
| | Hepatitis B Core Antibody | | Abbot Architect i2000SR: Chemiluminescent microparticle immunoassay | Automated | Qualitative Test | T/MIC/LP/046 |
| | Hepatitis B Surface Antibodies | | Abbot Architect i2000SR: Chemiluminescent microparticle immunoassay | Automated | Qualitative Test | T/MIC/LP/046 |
| | Hepatitis B Surface Antigen | | Abbot Architect i2000SR: Chemiluminescent microparticle immunoassay | Automated | Qualitative Test | T/MIC/LP/046 |
| | HIV Ag/Ab Combo | | Abbot Architect i2000SR: Chemiluminescent microparticle immunoassay | Automated | Qualitative Test | T/MIC/LP/046 |
| 1024 Preservation of microbial cultures | Preservation of Microbial Cultures | Isolates | N/A | N/A | N/A | T/MIC/RC/007 |