

Schedule of Accreditation



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| Organisation Name | Saolta University Health Care Group Galway University Hospital Microbiology |
| Trading As | |
| INAB Reg No | 223MT |
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| Accreditation Standard | EN ISO 15189 |
| Standard Version | 2012 |
| Date of award of accreditation | 07/04/2009 |
| Scope Classification | Microbiology and virology |
| Services available to the public ¹ | |

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 | Head Office | Galway University Hospital, Newcastle Road, Galway |

Scope of Accreditation

Head Office

Microbiology and Virology

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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| 1011 Macroscopic examination and description | Macroscopic examination and description | Sputum Faeces | Macroscopic examination | Based on standard methods | Macroscopic examination | MICSOP010 MICSOP070 |
| 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 including enumeration and description of human cells | Blood cultures Swabs Wound exudates CSFs Fluids/Aspirates Genital tract and associated specimens Corneal lens/scrapings Bronchoalveolar Lavage Bronchial washings Pus Tissue/Biopsy Urine Fluids | Microscopy | Based on standard methods | Microscopic examinations | MICSOP058 MICSOP009 MICSOP010 MICSOP006 MICSOP025 |

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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 - .02 Microscopic examination for parasites | Microscopic examination for parasites | Fluids/Aspirates Faeces Blood Sellotape slides Urine | Microscope | based on standard methods | Microscopic examination | MICSOP025 MICSOP023 MICSOP024 |
| 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 for fungi | Hair/nail/skin clippings | Microscope | Based on standard methods | Microscopic examination | MICSOP048 |
| 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 for mycobacteria | Bronchoalveolar Lavage Bronchial washings Fluids/Aspirates Pus Tissue/Biopsy Sputum Blood cultures | Microscope | Based on standard methods | Microscopic examination | MICSOP007 |
| 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 including blood cultures, urines, CSFs. faeces. Investigation of genital tract and associated specimens. Culture of diagnostic specimens and screening for multi-drug resistant organisms. | Blood cultures Swabs Wound exudates CSFs Fluids/Aspirates Genital tract and associated specimens Corneal lens/scrapings Bronchoalveolar Lavage Bronchial washings Pus Tissue/Biopsy Urine Fluids Faeces | Incubators Bactec FX Blood Culture System | CE marked/ Based on standard methods | Target organisms isolated/ Not isolated | MICSOP009 MICSOP010 MICSOP011 MICSOP013 MICSOP014 MICSOP025 MICSOP045 MICSOP070 MICSOP072 |

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| | | Sputum Swabs including screening swabs for VRE, CPE, MRSA and ESBL Tips IUD | | | | |
| 1013 Culture of organisms in liquid or agar based culture media with visual or instrument monitoring for growth - .02 Culture of fungi | Investigation of Dermatological Specimens for Superficial Mycoses | Hair/nail/skin clippings Skin scrapings Blood cultures | Incubators Bactec FX Blood Culture System | CE marked/ Based on standard methods | Target organisms isolated/ Not isolated | MICSOP048 MICSOP009 |
| 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 | Sputum Bronchoalveolar Lavage Bronchial washings Tissue/Biopsy Pus | Incubators Bactec MGIT 960 Instrument | CE marked/ Based on standard methods | Target organisms isolated/ Not isolated | MICSOP007 |
| 1014 Detection of bacterial, parasite, viral or fungal antigens using specific antibodies and appropriate techniques - .02 Particle agglutination | Identification of S. aureus by latex agglutination. | Bacterial isolates | Particle agglutination | CE marked | Qualitative | MICSOP020 |
| | Qualitative detection of antibodies to T. pallidum in human serum -ASI | Serum | Particle agglutination | Particle agglutination | Qualitative | VIR/SOP/107 |
| | Serological identification of beta haemolytic strep belonging to Lancefield groups A, B,C,D, F and G | Bacterial isolates | Particle agglutination | CE marked | Qualitative | MICSOP020 |
| 1014 Detection of bacterial, parasite, viral or fungal antigens using specific antibodies and appropriate techniques - .03 Enzyme immunoassay, | Detection of C.difficile toxins A and B. Alere | Faeces | Enzyme immunoassay | Ce marked | Qualitative | MICSOP070 |
| | Confirmation of the presence of Hepatitis B | Plasma/Serum | Abbott Architect i1000sr | CE marked | Qualitative | VIR/SOP/071 |

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| | virus Surface Antigen in human serum and plasma, using the Abbott Architect HBsAg Qualitative confirmatory assay | | | | | |
| | Qualitative detection of Hepatitis B virus Surface Antigen in human serum and plasma, using the Abbott Architect HBsAg Qualitative assay | | Abbott Architect i1000sr and i2000sr | CE marked | Qualitative | VIR/SOP/066 |
| 1014 Detection of bacterial, parasite, viral or fungal antigens using specific antibodies and appropriate techniques - .04 Immunochemical methods, | Biotech Lateral Flow Kit for the detection of CTX-M groups 1, 2, 8, 9 & 25 in a bacterial colony obtained from culture | Bacterial isolates | N/A | CE/based on standard method | N/A | MICSOP020 and MICFM089 |
| | Biotech Lateral Flow Kit for the detection of CTX-M groups 1, 2, 8, 9 & 25 in a bacterial colony obtained from culture. NG Biotech | Bacterial isolates | Immunochemical methods | CE marked | Qualitative | MICSOP020 & MICFM089 |
| | Biotech Lateral Flow Kits for detection of CPE | | Lateral flow assay | CE marked | Qualitative | MICSOP072 MICFM274 |
| | H.pylori lateral flow assay for the diagnosis of Helicobacter pylori infection CerTest | Faeces | Lateral flow assay | CE marked | Qualitative | MICSOP053 |
| | Investigation of faeces specimens for Rota and Adenovirus using Coris Bioconcept Combi strip | | Timer | CE marked | Qualitative | MICSOP026 |
| | Qualitative detection of Cryptococcal antigen (CrAg) in cerebral spinal fluid (CSF) specimens | CSF | Lateral flow assay | CE marked | Qualitative | MICSOP014 Investigation of CSF |

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| | Qualitative detection of Legionella Urinary Antigen detection using the Binax NOW kit | Urine | Alere reader | CE marked | Qualitative | VIR/SOP/052 |
| | Qualitative immunochromatographic assay for the rapid detection of penicillin-binding protein 2a (PBP2a) in isolates identified as Staphylococcus aureus Alere | Bacterial isolate | NA | CE marked | Qualitative | MICSOP002 |
| 1015 Detection and/or identification of bacterial, parasite, fungal and viral nucleic acids - .01 Nucleic acid probe hybridization, CE marked commercial systems | Qualitative detection and differentiation of RNA from influenza A virus (flu A), influenza B virus (flu B), Respiratory Syncytial Virus (RSV) and SARS-CoV-2 using the Resp 4-plex AMP kit | Nasopharyngeal swabs | Alinity M | CE marked | Qualitative | VIR/SOP/103 |
| | Qualitative detection of Neisseria gonorrhoeae DNA from Abbott multicollect samples | Abbott multicollect samples | GeneXpert | CE marked | Qualitative | VIR/SOP/088 |
| | Quantitative detection of Hepatitis B virus (HBV) DNA in human plasma or serum | Plasma Serum | Alinity M | CE marked | 5.28 IU/mL to 9.27 IU/mL | VIR/SOP/103 |
| | Quantitative detection of Hepatitis C virus (HCV) RNA in human plasma or serum. | | Alinity M | CE marked | 12 IU/mL to 200,000,000 IU/mL | VIR/SOP/103 |
| | Quantitative detection of Human Immunodeficiency virus type 1 (HIV-1) RNA in human plasma. | Plasma | Alinity M | CE marked | 10 copies/mL to 20,000,000 copies/mL | VIR/SOP/103 |
| 1015 Detection and/or identification of bacterial, parasite, fungal and viral | Detection of Salmonella enterica spp., Shigella spp., | Faeces | Roche Diagnostics Ltd Light cycler 480II Entericbio workstation | CE marked | Qualitative | MICSOP070 |

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| nucleic acids - .03 Nucleic acid amplification tests, CE marked commercial systems | Campylobacter jejuni/coli/lari, Stx1/Stx2, Cryptosporidium and Giardia DNA using the Enteric Bio Real Time PCR Gastro Panel 2 kit from Serosep. | | | | | |
| | Detection of C. difficile DNA using the Enteric Bio Real Time C. difficile PCR Kit from Serosep. | | Roche Diagnostics Ltd Light cycler 480II Entericbio Workstation | CE marked | Qualitative | MICSOP070 |
| | Detection of M. Tuberculosis complex and Rifampicin resistance using the MTB/RIF Ultra GeneXpert Kit | Sputum specimens | Cepheid GeneXpert Instrument | CE marked | Qualitative | MICSOP062 |
| | Detection of Norovirus genogroup I and II RNA using the Cepheid GeneXpert Kit | Faeces | Cepheid GeneXpert Instrument | CE marked | Qualitative | MICSOP062 |
| | Identification and characterisation of Clostridium difficile using the Cepheid GeneXpert Kit | | Cepheid GeneXpert Instrument | CE marked | Qualitative | MICSOP062 |
| | Qualitative detection and differentiation of SARS-CoV-2, influenza A, influenza B, and respiratory syncytial virus (RSV)viral RNA in upper respiratory specimens | Upper respiratory specimens in VTM | Cepheid GeneXpert Instrument | CE marked | Qualitative | VIR/SOP/088 |
| | Qualitative detection and differentiation of SARS-CoV-2, influenza A, influenza B, and respiratory syncytial virus (RSV)viral RNA in | | GenMark Dx ePLEX System | CE marked | Qualitative | VIR/SOP/104 |

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| | upper respiratory specimens on the RP2 molecular assay | | | | | |
| | Qualitative detection of the plasmid DNA for <i>C. trachomatis</i> and the genomic DNA of <i>N. gonorrhoeae</i> | Urine, endocervical, vaginal swabs and male urethral swab specimens collected in the Abbott multi-Collect Specimen Collection Kit | Abbott m2000sp Abbott m2000rt | CE marked | Qualitative | VIR/SOP/087 |
| 1015 Detection and/or identification of bacterial, parasite, fungal and viral nucleic acids - .04 Nucleic acid amplification tests, in house developed assays | Detection of <i>Pneumocystis jirovecii</i> DNA in respiratory specimens using the AB7500 | Respiratory specimens | Applied Biosystems Real-time PCR System - AB7500 | In house developed | Qualitative | MICSOP061 MICSOP067 MICSOP073 |
| | RT PCR Assay for the detection of <i>bla</i> IMI gene DNA in Gram-Negative isolates. | Bacterial isolates | Applied Biosystems Real-time PCR System - AB7500 Qiagen EZ1 Advanced XL | In house developed | Qualitative | MICLP036 MICSOP061 MICSOP066 MICSOP073 |
| | RT PCR assay for the detection of <i>CoA</i> gene in <i>S.aureus</i> , the detection of Group A Streptococcal DNA, the detection of <i>MecA</i> gene in <i>S.aureus</i> , the detection of <i>S.pneumoniae</i> DNA and determination of penicillin susceptibility and the detection of <i>Neisseria meningitidis</i> DNA | CSF Fluids Tissues Swabs Bacterial isolates | Applied Biosystems Real-time PCR System - AB7500 Qiagen EZ1 Advanced XL | In house developed | Qualitative | MICSOP073 MICSOP061 MICSOP063 MICSOP065 |
| 1016 Identification of cultured bacteria and fungi using non-nucleic acid based techniques - .03 Identification of fungi by microscopic morphology | Investigation of Dermatological Specimens for Superficial Mycoses | Fungal isolates | Microscope | Based on standard methods | Qualitative | MICSOP048 |

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| 1016 Identification of cultured bacteria and fungi using non-nucleic acid based techniques - .04 Identification using MALDI-TOF Spectroscopy | Identification of organisms using the MALDI TOF Sirius instrument | Bacterial, fungal and Mycobacterial isolates | MALDI TOF Sirius | CE marked | Target organisms identified/ Not identified | MICSOP068 |
| | Identification using MALDI-TOF spectroscopy | | Bruker MALDI TOF Microflex | Based on standard methods | Target organisms identified/ Not identified | MICSOP068 |
| 1017 Measurement of antimicrobial activity and application of clinical interpretive criteria to general bacteria (rapidly growing aerobes) - .01 Anaerobes | Antimicrobial resistance testing of bacterial isolates using Disk diffusion and Minimum inhibitory concentration (MIC) testing with MIC strips and broth dilution on the Trek Diagnostic Sensititre instrument using EUCAST and CLSI interpretive guidelines | Bacterial isolates | BIOMIC V3 Trek Diagnostic Sensititre instrument | Based on standard methods | Interpreted as sensitive, resistant and susceptible increased exposure | MICSOP002 MICSOP077 MICSOP030 |
| 1017 Measurement of antimicrobial activity and application of clinical interpretive criteria to general bacteria (rapidly growing aerobes) - .02 Mycobacteria | Antimicrobial resistance testing of Mycobacterial isolates on the BACTEC MGIT | Mycobacterial isolates | Becton Dickinson BACTEC 960 MGIT | CE marked | Interpreted as sensitive or resistant | MICSOP007 |
| 1017 Measurement of antimicrobial activity and application of clinical interpretive criteria to general bacteria (rapidly growing aerobes) - .03 Yeasts | Antimicrobial resistance testing of Yeast isolates using MIC test strips | Yeast isolates | Incubator | Based on standard methods | Interpreted as sensitive, resistant and susceptible increased exposure | MICSOP069 |
| 1017 Measurement of antimicrobial activity and application of clinical interpretive criteria to general bacteria (rapidly growing aerobes) - .05 | Antimicrobial resistance testing of bacterial isolates using Inoclic - a new inoculum standardization device | Bacterial isolates | BIOMIC V3 | Based on standard methods | Interpreted as sensitive, resistant and susceptible increased exposure | MICSOP002 MICSOP038 |

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| Other categories of organism (as specified) | | | | | | |
| 1018 Detection of antibody response to infection using appropriate CE marked commercial techniques - .01 Particle agglutination, using CE marked commercial systems | Semi quantitative detection of anti-cardiolipin antibodies using the BD RPR card antigen flocculation test | Serum | Particle agglutination | CE marked | Serum dilution Neat - 520 | VIR/SOP/064 |
| | Semi-quantitative detection of antistreptolysin-O antibodies, in human serum, using the Biokit rheumajet ASO Latex agglutination test | | Particle agglutination | CE marked | Serum dilution Neat - 3200 | VIR/SOP/053 |
| 1018 Detection of antibody response to infection using appropriate CE marked commercial techniques - .02 Enzyme immunoassay, using CE marked commercial systems | Qualitative detection of Hepatitis B virus Core Antibody using the Biomerieux VIDAS Anti-HBc Total II assay | Plasma/Serum | Biomerieux Vidas | CE marked | Qualitative | VIR/SOP/048 VIR/SOP/049 |
| | Qualitative detection of Hepatitis C antibody using the Biomerieux VIDAS | Plasma/ Serum | Biomerieux Vidas | CE marked | Qualitative | VIR/SOP/091 |
| | Qualitative detection of HIV p24 antigen, HIV-1 antibody and HIV-2 antibody in human serum and plasma | Plasma/Serum | Biomerieux Vidas | CE marked | Qualitative | VIR/SOP/050 VIR/SOP/049 |
| | Qualitative detection of IgG and IgM class antibodies to VlsE1 and pepC10 antigens from Borrelia burgdorferi in human serum using the AccuDiag™ Borrelia | Serum | Microplate reader/washer | CE marked | Qualitative | VIR/SOP/105 |

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| | VlsE1/pepC10 IgG/IgM ELISA | | Microplate washer/Microplate reader | CE marked | Qualitative | VIR/SOP/105 |
| | Qualitative detection of Measles IgG antibody using the Biomerieux VIDAS | Plasma/Serum | Biomerieux Vidas | CE marked | Qualitative | VIR/SOP/049 VIR/SOP/099 |
| | Qualitative detection of Mumps IgG antibody using the Biomerieux VIDAS | Serum | Biomerieux Vidas | CE marked | Qualitative | VIR/SOP/049 VIR/SOP/090 |
| | Qualitative detection of Varicella zoster IgG antibodies using theVircell Varicella-Zoster Virclia IgG Monotest assay | Plasma/Serum | Virclia | CE marked | Qualitative | VIR/SOP/097 |
| | Quantitative detection of Rubella IgG antibody using the Biomerieux VIDAS | | Biomerieux Vidas | CE marked | 10-400IU/mL | VIR/SOP/049 VIR/SOP/084 |
| 1018 Detection of antibody response to infection using appropriate CE marked commercial techniques - .05 Immunochromatographic methods, using CE marked commercial systems | Immy Cryptococcal antigen lateral flow assay for the detection of cryptococcal antigen in serum samples | | Lateral flow immunoassay | CE marked | Qualitative | VIR/SOP/098 |
| 1018 Detection of antibody response to infection using appropriate CE marked commercial techniques - .07 Chemiluminescent microparticle immunoassay, using CE marked commercial systems | Qualitative detection of antibody to Hepatitis Be virus in human serum and plasma using the Abbott Architect Anti HBe assay | | Abbott Architect i1000sr | CE marked | Qualitative | VIR/SOP/054 |

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| Qualitative detection of antibody to Hepatitis C virus in human serum and plasma using the Abbott Architect Anti HCV assay | Abbott Architect i1000sr and i2000sr | CE marked | Qualitative | VIR/SOP/029 |
| Qualitative detection of antibody to Treponema pallidum, in human serum and plasma, using the Abbott Architect Syphilis TP assay | Abbott Architect i1000sr and i2000sr | CE marked | Qualitative | VIR/SOP/033 |
| Qualitative detection of Cytomegalovirus IgG antibodies in human serum and plasma, using the Abbott Architect CMV IgG assay | Abbott Architect i2000sr | CE marked | Qualitative | VIR/SOP/055 |
| Qualitative detection of Cytomegalovirus IgM antibodies using the Abbott Architect CMV IgM assay | Abbott Architect i2000sr | CE marked | Qualitative | VIR/SOP/078 |
| Qualitative detection of EBNA IgG antibodies, EBV VCA IgG antibodies and EBV VCA IgM antibodies using the Abbott Architect EBV Assays | Abbott Architect i2000sr | CE marked | Qualitative | VIR/SOP/095 |
| Qualitative detection of Hepatitis B Core Antibody, in human serum and plasma, using the Abbott Architect Anti-HBc II assay | Abbott Architect i1000sr and i2000sr | CE marked | Qualitative | VIR/SOP/034 |
| Qualitative detection of Hepatitis Be Antigen | Architect i1000sr | CE marked | Qualitative | VIR/SOP/093 |

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| using the Abbott Architect HBeAg Assay |
| Qualitative detection of HIV p24 antigen, HIV-1 antibody and HIV-2 antibody in human serum and plasma using the Abbott Architect HIV Ag/Ab combo assay |
| Qualitative detection of IgG antibody to Hepatitis A virus in human serum and plasma, using the Abbott Architect HAVAb-IgG assay |
| Qualitative detection of IgM antibody to Hepatitis A virus, in human serum and plasma using the Abbott Architect HAVAb-IgM assay |
| Qualitative detection of Rubella virus IgM using the Abbott Architect Rubella IgM assay |
| Qualitative detection of Toxoplasma gondii IgG antibodies in human serum and plasma, using the Abbott Architect Toxoplasma IgG assay |
| Qualitative detection of Toxoplasma gondii IgM antibodies, using the Abbott Architect Toxoplasma IgM assay |
| Qualitative detection of Hepatitis B core IgM using the Abbott |

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| Abbott Architect i1000sr and i2000sr | CE marked | Qualitative | VIR/SOP/027 |
| Abbott Architect i2000sr | CE marked | Qualitative | VIR/SOP/030a |
| Abbott Architect i2000sr | CE marked | Qualitative | VIR/SOP/106 |
| Abbott Architect i2000sr | CE marked | Qualitative | VIR/SOP/080 |
| Abbott Architect i2000sr | CE marked | Qualitative | VIR/SOP/072 |
| Abbott Architect i2000sr | CE marked | Qualitative | VIR/SOP/079 |
| Abbott Architect i1000sr | CE marked | Qualitative | VIR/SOP/010 |

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| | Architect anti HBc IgM assay | | | | | |
| | Qualitative detection of Parvovirus IgG and IgM on the VirClia | Serum | VirClia | CE marked | Qualitative | VIR/SOP/097 |
| | Quantitative detection of Hepatitis B virus Surface Antibody in human serum and plasma, using the Abbott Architect Anti-HBs assay | Plasma/Serum | Abbott Architect i1000sr and i2000sr | CE marked | 0-1000mIU/ml | VIR/SOP/031 |
| | Quantitative detection of Rubella virus IgG using the Abbott Architect Rubella IgG assay | | Abbott Architect i2000sr | CE marked | 0 -500 IU/ml | VIR/SOP/032 |
| 1024 Preservation of microbial cultures | Preservation of microbial cultures on agar plates and slope and in Protect beads | Microbial cultures | Refrigerators Freezers | Based on standard methods | Qualitative | MICLP020 MICSOP049 |
| 1029 Miscellaneous - .99 Miscellaneous tests | Automated enumeration of clinical parameters including human cells in urine | Urines | UF5000 | CE marked | 1 - 10,000 µl/mL | MICSOP025 |