Schedule of Accreditation

Organisation Name	Saolta University Health Care Group Galway University Hospital Microbiology
Trading As	
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Accreditation Standard	EN ISO 15189
Standard Version	2022
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		
(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
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

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 Sputum Swabs including screening swabs for VRE, CPE, MRSA	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

		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 aggluntination	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.difficle toxins A and B. Alere	Faeces	Enzyme immunoassay	Ce marked	Qualitative	MICSOP070
	Confirmation of the presence of Hepatitis B virus Surface Antigen in human serum and plasma, using the Abbott Architect HBsAg	Plasma/Serum	Abbott Architect i1000sr	CE marked	Qualitative	VIR/SOP/071

	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 Immunochromatographic 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 Kits for detection of CPE	Bacterial isolates	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
	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	Bacterial isolate	NA	CE marked	Qualitative	MICSOP002

	Staphylococcus aureus Alere					
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 nucleic acids - .03 Nucleic acid amplification tests, CE marked commercial systems	Dectection of Salmonella enterica spp., Shigella spp., Campylobacter jejuni/coli/lari, Stx1/Stx2, Cryptosporidium and Giardia DNA using the Enteric Bio Real Time PCR Gastro Panel 2 kit from Serosep.	Faeces	Roche Diagnostics Ltd Light cycler 480II Entericbio workstation	CE marked	Qualitative	MICSOP070
	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 and Genexpert MTB/XDR Extended Resistance kit **2,3,4	Sputum specimens	Cepheid GeneXpert Instrument	CE marked	Qualitative	MICSOP062
		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 of Chlamydia trachomatis target on the CT/NG assay on the GeneXpert.	Abbott multicollect samples. Genital, Rectal, Throat, Eye swabs and Urine.	GeneXpert	CE marked	Qualitative	VIR/SOP/088
Qualitative detection of Chlamydia trachomatis target on the CT/NG assay on the GeneXpert **Note 2,3,4		Cepheid GeneXpert	CE Marked	Qualitative	VIR/SOP/088

	Qualitative detection of Chlamydia trachomatis, Neisseria gonorrhoeae, Trichomonas vaginalis, Mycoplasma genitalium.		Alinity M	CE marked	Qualitative	VIR/SOP/103
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
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, funagl 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) - .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	Antimicrobial resistance testing of bacterial	Bacterial isolates	BIOMIC V3	Based on standard methods	Interpreted as sensitive, resistant	MICSOP002 MICSOP038

application of clinical interpretive criteria to general bacteria (rapidly growing aerobes) - .05 Other categories of organism (as specified)	isolates using Inoclic - a new inoculum standardization device				and susceptible increased exposure	
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 ASI RPR card antigen flocculation test **Note 2,3,4	Serum	Particle agglutination	CE Marked	Serum dilution Neat - 520	VIR/SOP/108
	Semi quantitative detection of anti-cardiolipin antibodies using the ASI RPR card antigen flocculation test **Note 2,3,4		Particle agglutination	CE marked	Serum dilution Neat - 520	VIR/SOP/108
	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 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 **Notes 2,3,4	Serum	Biomerieux mini Vidas	CE Marked	Qualitative	VIR/SOP/110
	Qualitative detection of HIV p24 antigen, HIV-1	Serum	Biomerieux Vidas	CE marked	Qualitative	VIR/SOP/110 VIR/SOP/049

antibody and HIV-2 antibody in human serum **Notes 2,3,4					
Qualitative detection of IgG and IgM class antibodies to VlsE1 and pepC10 antigens from Borrelia burgdorferi in human serum using the AccuDiag™ Borrelia VlsE1/pepC10 IgG/IgM ELISA		Microplate reader/washer	CE marked	Qualitative	VIR/SOP/105
		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 Mumps IgG, Measles IgG, Hep C antibody, HIV Ag/Ab **Note 2,3,4		Biomerieux VIDAS KUBE	CE Marked	Qualitative	VIR/SOP/109 VIR/SOP/090 VIR/SOP/099 VIR/SOP/091 VIR/SOP/110
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
Quantitative detection of Rubella IgG antibody	Serum	Biomerieux VIDAS KUBE	CE Marked	Quantitative	VIR/SOP/109 VIR/SOP/084

	using the Biomerieux VIDAS Kube **Note 2,3,4					
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	Plasma/Serum	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
	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		Abbott Architect	CE marked	Qualitative	VIR/SOP/078

	Cytomegalovirus IgM antibodies using the Abbott Architect CMV IgM assay	i2000sr			
	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 using the Abbott Architect HBeAg Assay	Architect i1000sr	CE marked	Qualitative	VIR/SOP/093
	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	Abbott Architect i1000sr and i2000sr	CE marked	Qualitative	VIR/SOP/027
	Qualitative detection of IgG antibody to Hepatitis A virus in human serum and plasma, using the Abbott Architect HAVAb-IgG assay	Abbott Architect i2000sr	CE marked	Qualitative	VIR/SOP/030
	Qualitative detection of IgM antibody to Hepatitis A virus, in human serum and plasma using the Abbott Architect HAVAb-IgM assay	Abbott Architect i2000sr	CE marked	Qualitative	VIR/SOP/106

	Qualitative detection of Rubella virus IgM using the Abbott Architect Rubella IgM assay		Abbott Architect i2000sr	CE marked	Qualitative	VIR/SOP/080
	Qualitative detection of Toxoplasma gondii IgG antibodies in human serum and plasma, using the Abbott Architect Toxoplasma IgG assay		Abbott Architect i2000sr	CE marked	Qualitative	VIR/SOP/072
	Qualitative detection of Toxoplasma gondii IgM antibodies, using the Abbott Architect Toxoplasma IgM assay		Abbott Architect i2000sr	CE marked	Qualitative	VIR/SOP/079
	Qualitative detection of Hepatitis B core IgM using the Abbott Architect anti HBc IgM assay		Abbott Architect i1000sr	CE marked	Qualitative	VIR/SOP/010
	Quantitative detection of Hepatitis B virus Surface Antibody in human serum and plasma, using the Abbott Architect Anti-HBs assay		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	Referigerators 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

The laboratory has been awarded flexible scope in the scope classifications as noted in the scope document and in accordance with the laboratory's approved and documented procedures.
Note 1 - Range may be extended for the test
Note 2 – New parameters/tests may be added
Note 3 – New matrices may be added
Note 4 – Changes to equipment/kits where the underlying methodology does not change
For further details please refer to the laboratory's 'List of flexible scope changes', available directly from the laboratory.