

Schedule of Accreditation

issued by

United Kingdom Accreditation Service

2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

 <p>UKAS MEDICAL 8213</p> <p>Accredited to ISO 15189:2012</p>	<p align="center">United Kingdom Health Security Agency, an Executive Agency of the Department of Health</p> <p align="center">Issue No: 009 Issue date: 01 October 2021</p>	
	<p>Birmingham Heartlands Hospital Bordesley Green East Birmingham B9 5SS United Kingdom</p>	<p>Contact: Dr Husam Osman Tel: +44 (0)1214243236 Fax: +44 (0)1217726229 E-Mail: phebirmingham@heft.nhs.uk Website: www.phe.gov.uk</p>
<p>Testing performed at the above address only</p>		

DETAIL OF ACCREDITATION

Materials/ Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS AND TISSUES	<u>Microbiology examination activities for the purpose of clinical diagnosis</u>	In House documented methods based on related UK Standards for Microbiology Investigations' (SMIs)' and incorporating manufacturers' instructions where relevant:
Urine	Quantification of white and red cells, bacteria & epithelial cells	In conjunction with manufacturer's instructions using Biomerieux UF1000 and manual plate reading MI.S2022 Use of UF 1000 MI.S1173 Primary processing of urines MI.N1244 Urine manual microscopy
Faeces, Urine, perianal swab of anal area	Examination for the presence of parasites (ova, cysts, trophozoites and worms) of clinical significance	Manual microscopy MI.S1355 Diagnostic Parasitology
Swabs, blood, bodily fluids including CSF & joint fluids, nails skin & hair	Detection & enumeration of white and red blood cells, clinically significant micro-organisms (excluding Trichomonas vaginalis) and crystals	Manual microscopy : MI.S1528 Microscope SOP. MI.S1417 Gram stain MI.S1430 CSF MI.S2128 Investigation of prosthetic joint infection samples MI.S1231 Processing of tissue, fluid & pus samples MI.S1531 Medical Mycology – Microscopy MI.S1288 Processing and Reading of Genito/Urinary Medicine (GUM) Samples



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Microbiology examination activities for the purpose of clinical diagnosis</u> (cont'd)	In House documented methods based on related UK Standards for Microbiology Investigations' (SMIs)' and incorporating manufacturers' instructions where relevant:
Respiratory samples – Sputum, lavages. Swabs/ CSF/ Fluids and Tissues/ Faeces/ Skin/Nails/Hair	General isolation and characterisation of bacterial and fungal isolates of clinical significance	Manual culture and manual plate read MI.S2049 Reading and reporting of respiratory isolates MI.S1430 Examination of CSF MI.S1231 Processing of Tissue, fluid and pus samples MI.S1308 Enteric Specimen preparation and processing MI.S1481 Medical Mycology procedures and techniques
Urine & swabs – ears/eyes/nose/th roat/wounds/ genital	Isolation of micro-organisms of clinical significance	Manual and automated sample processing methods using Copan WASP MI.S3102 Processing of acute bacteriology swab and urine samples using WASP and manual method
Urine & swabs – ears/eyes/nose/th roat/wounds/ genital	Isolation of micro-organisms of clinical significance	Automated sample incubation and reading methods using Copan WASPLab MI.S3104 WASPLab Screening and reading procedure
Whole Blood Sterile Body Fluids	General isolation and characterisation of bacterial and fungal isolates of clinical significance	In conjunction with manufacturer's instructions using BD Bactec FX Blood culture system MI.S3112 BD FX Blood culture system MI.S1191 Processing positive blood cultures MI.S1440 Blood Culture Read
Cultured isolates produced by the laboratory	Identification of bacterial and fungal isolates of clinical significance	Automated - BRUKER/BD Maldi-TOF by Matrix- assisted laser desorption/ionization, in conjunction with manufacturer's instructions. MI.S1492 Microbial species identification by MALDI-TOF



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Cultured isolates produced by the laboratory	Identification of bacterial and fungal isolates of clinical significance	Biomerieux VITEK 2 MI.S2004 Putting up sensitivities on the Vitek 2 Manual identification methods Gram stain, catalase, oxidase, coagulase, latex/particle agglutinations, aesculin production, agglutinating anti-sera, Biochemical tests including API tests & Gonochek MI.S1417 Gram stain MI.S1970 Catalase MI.S1962 Oxidase MI.S1988 Latex test for Staph aureus MI.S1942 Latex test for Streptococcal grouping MI.S1996 Aesculin production MI.S209 Gonochek MI.S2030 Inoculation and reading of API's MI.S1309 Salmonella identification and serological methods
Cultures isolated in house from above methods	Antimicrobial susceptibility testing of bacterial and fungal isolates of clinical significance	In house automated antimicrobial susceptibility testing methods in conjunction with manufacturers instructions using Biomerieux Vitek 2. MI.S2004 Putting up sensitivities on the Vitek 2
Cultures isolated in house from above methods	Antimicrobial susceptibility testing of bacterial and fungal isolates of clinical significance	In house disc diffusion antimicrobial susceptibility testing methods in conjunction with EUCAST guidelines. MI.S1216 Reading & reporting EUCAST sensitivity results MI.S1229 Putting up antimicrobial susceptibility tests by EUCAST MI.S1281 Enteric sensitivity testing and processing of blood cultures suspected of containing hazard group 3 isolates
Cultures isolated in house from above methods	Antimicrobial susceptibility testing of bacterial and fungal isolates of clinical significance	Manual sensitivity testing methods using breakpoint sensitivity strips (MIC strips) MI.S1222 E-test MI.S3110 Neisseria MIC Test Strip (MTS) Susceptibility Testing



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Microbiology examination activities for the purpose of clinical diagnosis</u> (cont'd)	In House documented methods based on related UK Standards for Microbiology Investigations' (SMIs)' and incorporating manufacturers' instructions where relevant:
Faeces	Identification of; Clostridium difficile toxin; Clostridium difficile GDH	Automated processing - in conjunction with manufacturer's instructions using Dynex DS2 MI.S2072 Clostridium difficile EIA investigation
	EIA detection of Helicobacter pylori stool antigen	Premier Platinum HpSA PLUS EIA in conjunction with manufacturer's instructions using DS2 MI.S3105 H.pylori stool antigen EIA testing.
Sputum/lavages/ swabs/ fluids/ tissues/blood/ bone marrow/ urine/CSF/faeces	Isolation, identification and antimicrobial susceptibility testing of Mycobacteria	In house methods and automated processing in conjunction with manufacturer's instructions using : Liquid culture on BD Bactec MIGIT960, BD Bactec MGIT190, BD Bactec 9050 and BD Bactec FX40 MI.S1036 RCM Sample processing MI.S1059 Isolation of mycobacteria from blood and bone marrow MI.S1336 RCM sensitivity testing for M. tuberculosis
Sputum/lavages/ swabs/fluids/ tissues	Identification of Mycobacterium tuberculosis DNA	Cepheid Genexpert MI.S2073 Use of the Xpert MTB/RIF ULTRA assay of Cepheid Genexpert system
Bacterial culture isolates	Molecular detection of Carbapenemase producing Enterobacteriaceae	In house methods in conjunction with manufacturers instructions using PCR Cepheid GeneXpert. MI.S1532 Rapid carbapenemase testing (CPE RT-PCR) SOP
		In house methods in conjunction with manufacturer's instructions using PCR/ABI 3130XL
Culture Isolates produced by the laboratory	Clostridium difficile ribotyping	Sequencer/population sequencing Clostridium difficile PCR - Ribotyping. MI.S3029 Clostridium difficile PCR-Ribotyping MI.S2124 C. difficile Culture MI.S3032 CDRIBO fragment analysis



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Molecular microbiology examination activities for the purpose of clinical diagnosis</u>	In house PCR methods in conjunction with manufacturer's instructions using :
Culture Isolates produced by the laboratory	Identification of Escherichia Coli 0157 DNA	In house methods in conjunction with manufacturer's instructions using PCR ABI 7500 fast taqman MI.S2094 Detection of Shiga Toxin Producing E. coli (STEC) Using Real Time PCR SOP
Fluids/ Tissues	Detection and identification of Bacteria DNA from sterile sites	In house methods for extraction by Roche compact, detection on ABI 7500 fast taqman and sequencing on ABI sequencer in conjunction with manufacturer's instructions. MI.S2110 DNA Extraction for 16s PCR MI.S2111 16s PCR MI.S2112 PHE 16s Sequencing MI.S2113 PHE 16s Sequencing Analysis
Faeces	Identification of Clostridium difficile DNA	In house methods in conjunction with manufacturer's instructions using Abacus GenomEra MI.S11009 Use of Abacus GenomEra PCR C. diff testing and reporting
Faeces, urine, blood, cerebrospinal fluid (CSF), eye swabs, nose and/or throat swab, nasopharyngeal aspirates, bronchoalveolar lavage, sputum	Qualitative & quantitative detection of Adenovirus DNA	MI.S2413 Detection and quantification of Adenoviruses using real time PCR on the Roche FLOW system
Blood/Urine/ /tissues, cerebrospinal fluid CSF/Nose &/or Throat swab/ nasopharyngeal aspirates NPA/ bronchoalveolar lavage BAL/Sputum	Qualitative & quantitative detection of Cytomegalovirus DNA	MI.S2414 Detection and Quantification of Cytomegalovirus (CMV) using real time PCR on the Roche FLOW system



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Molecular microbiology examination activities for the purpose of clinical diagnosis</u> (cont'd)	In house real time PCR test in conjunction with manufacturer's instructions on Roche FLOW system according to SOP:
Blood/CSF	Epstein Barr virus DNA	MI.S2417 Detection and Quantification of Epstein-Barr Virus (EBV) using real time PCR on the Roche FLOW system
Blood, cerebrospinal fluid (CSF), swabs, nasopharyngeal aspirates, bronchoalveolar lavage, sputum	Qualitative and quantitative molecular detection of Herpes simplex Virus Type I & II DNA	MI.S2415 Detection of Herpes Simplex Viruses (HSV) using real time PCR on the Roche FLOW system
Blood, cerebrospinal fluid (CSF)	Qualitative and quantitative molecular detection of Human Herpes Virus 6 (HHV6) DNA	MI.S2418 Detection and quantification of Human Herpes Virus 6 (HHV6) using real time PCR on the Roche FLOW system
Blood, cerebrospinal fluid (CSF), urine	Qualitative and quantitative molecular detection of Polyomaviruses DNA	MI.S2424 Detection of Polyomaviruses (BK and JC) using real time PCR on the Roche FLOW system
Skin swabs, cerebrospinal fluid (CSF), tissues, vesicle fluid, mouth swab, blood	Qualitative and quantitative molecular detection of Varicella Zoster (VZV) DNA	MI.S2416 Detection of Enterovirus, Parechovirus and Varicella Zoster Virus (VZV) using Real time PCR on the Roche FLOW system
Pernasal swab, nose and/or throat swabs, nasopharyngeal aspirates, bronchoalveolar lavage and sputum	Qualitative molecular detection of <i>Bordetella pertussis</i> DNA	MI.S2422 Detection of <i>Bordetella species</i> and <i>Bordetella pertussis</i> by real time PCR on the Roche FLOW system
Skin swabs, cerebrospinal fluid (CSF), tissues, fluids, blood, faeces	Qualitative molecular detection of Enteroviruses DNA	MI.S2416 Detection of Enterovirus, Parechovirus and Varicella Zoster Virus (VZV) using Real time PCR on the Roche FLOW system



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Molecular microbiology examination activities for the purpose of clinical diagnosis</u> (cont'd)	In house real time PCR test in conjunction with manufacturer's instructions on Roche FLOW system according to SOP:
Nose and/or throat swabs, nasopharyngeal aspirates, bronchoalveolar lavage and sputum	Qualitative molecular detection of human metapneumovirus (hMPV) DNA	MI.S2411 Detection of Respiratory syncytial viruses and human metapneumovirus using real time PCR on the Roche FLOW system
Nose and/or throat swabs, nasopharyngeal aspirates, bronchoalveolar lavage and sputum	Qualitative molecular detection and typing of influenza viruses type A and B, including A(H1)pdm2009 (sH1 and sN1), A(H3), A(H5), A(H7), A(H1) targets DNA	MI.S2410 Detection and differentiation of Influenza viruses using real time PCR on the Roche FLOW system
Throat swabs	Qualitative molecular detection of Measles virus DNA	MI.S2423 Detection of Measles virus using real time PCR on the Roche FLOW system
Nose and/or throat swabs, nasopharyngeal aspirates, bronchoalveolar lavage and sputum	Qualitative molecular detection of parainfluenza viruses DNA	MI,S2412 Detection of parainfluenza viruses and rhinoviruses by real time PCR using the Roche FLOW system
Skin swabs, cerebrospinal fluid (CSF), tissues, vesicle fluid, blood, faeces	Qualitative molecular detection of Parechovirus DNA	MI.S2416 Detection of Enterovirus, Parechovirus and Varicella Zoster Virus (VZV) using Real time PCR on the Roche FLOW system
Nose and/or throat swabs, nasopharyngeal aspirates, bronchoalveolar lavage, sputum and blood	Qualitative molecular detection of <i>Pneumocystis jirovecii</i> DNA	MI.S2420 Detection of <i>Pneumocystis jirovecii</i> using real time PCR on the Roche FLOW system



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Molecular microbiology examination activities for the purpose of clinical diagnosis</u> (cont'd)	In-house methods in conjunction with manufacturer's instructions using real time PCR/ ABI Taqman 7500 fast/ end-point detection using primers and probes :
Nose and/or throat swabs, nasopharyngeal aspirates, bronchoalveolar lavage and sputum	Qualitative molecular detection of Rhinoviruses DNA	MI.S2412 Detection of parainfluenza viruses and rhinoviruses by real time PCR using the Roche FLOW system
Nose and/or throat swabs, nasopharyngeal aspirates, bronchoalveolar lavage and sputum	Qualitative molecular detection of Respiratory Syncytial Virus (RSV) DNA	MI.S2411 Detection of Respiratory syncytial viruses and human metapneumovirus using real time PCR on the Roche FLOW system
Ulcer swabs and cerebrospinal fluid (CSF)	Qualitative molecular detection of <i>Treponema pallidum</i> DNA	MI.S2419 Detection of <i>Treponema pallidum</i> using real time PCR on the Roche FLOW system Real time PCR test in conjunction with manufacturer's instructions. Nucleic acid extraction on Roche MagNAPure 96 and PCR on Taqman 7500 Fast according to SOP
Blood and faeces	Qualitative and quantitative molecular detection of Hepatitis E RNA	MI.S2430 Detection of Hepatitis E Virus (HEV) using the ALTONA real time RT-PCR kit
Guthrie Spots	Qualitative detection of Cytomegalovirus DNA	MI.S1273 Guthrie card extraction using the EZ1 DNA Investigator kit
Faeces/Vomit	Norovirus RNA	MI.S1185 One Step Norovirus RT PCR on the Taqman 7500
Nose & Throat swab/NPA/BAL/ sputum	Pandemic H1N1 2009 Oseltamivir resistance screening	MI.S2023 Pandemic H1N1 2009 Oseltamivir resistance screening assay (1-step Taqman assay)
Nose & Throat swab/NPA/BAL/ sputum	Middle East Respiratory Syndrome Coronavirus (MERS-CoV) RNA	MI.S3015 1-step real-time detection of novel coronavirus 2012 (upE assay)



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Nose & Throat swab/NPA/BAL/ sputum	Swine flu screen (H1) RNA	MI.S1123 1-Step taqman detection of Flu A, B and H5 MI.S1199 One-step detection of respiratory viruses
Vitreous Fluids/CSF	Varicella Zoster DNA	MI.S1234 Detection of HSV and VZV DNA using the ABI 7500 fast
Genital swabs/urine	Chlamydia trachomatis & Neisseria gonorrhoeaDNA screen and confirmation	In-house methods in conjunction with manufacturer's instructions for molecular sexually transmitted disease screening using Hologic Panther/ target amplification nucleic acid probe test : MI.S1442 Chlamydia Sample Processing
Blood	Hepatitis B viral load	In-house methods in conjunction with manufacturer's instructions for Quantitative Real- Time/Viral genome copies using Abbott MR2000/ end-point detection using primers and probes:
Blood	Hepatitis C viral load HIV viral load	MI.S2074 HBV viral load testing on the m2000sp MI.S1366 Protocol for HBV DNA testing of Hepatitis B infected health care workers
Blood/Dried blood spots	Hepatitis C genotyping	MI.S2075 Hepatitis C and HIV viral load testing on the m2000sp MI.S2126 Hepatitis C Genotyping on the M2000sp
Blood	Cytomegalovirus UL97 sequencing	In-house Block-based PCR/population screening in conjunction with manufacturer's instructions using ABI 3130XL sequencer :
Blood	Hepatitis B polymerase gene sequencing	MI.S1254 CMV UL97 Genotypic Assay MI.S1260 CMV Sequence Analysis MI.S1256 HBV Polymerase Genotypic Assay MI.S1116 HBV Genotypic Analysis



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Blood	HIV1 Reverse transcriptase & protease gene sequencing	MI.S1109 One step RT HIV reverse transcriptase and protease gene PCR MI.S1115 Analysis and Interpretation of HIV-1 Reverse Transcriptase and Protease Genotypic tests
Blood (plasma)	HIV-1 Co-receptor Tropism Testing (CCR5)	MI.S2052 CCR5 Assay: Amplification of Plasma RNA MI.S2070 Analysis and Interpretation of HIV-1 CCR5 Tropism Genotypic Tests In-house Block-based PCR/population screening in conjunction with manufacturer's instructions using ABI 3130XL sequencer :
Blood (PBMC)	HIV-1 Co-receptor Tropism Testing (CCR5)	MI.S2051 CCR5 Tropism Assay: Amplification of Proviral DNA MI.S2070 Analysis and Interpretation of HIV-1 CCR5 Tropism Genotypic Tests
Blood	HIV1 Integrase gene sequencing	MI.S1925 HIV Integrase PCR MI.S1926 Analysis and Interpretation of HIV-1 Integrase Genotypic Tests Whole genome sequencing of Mycobacterial isolates using :
Positive Mycobacterium culture grown in MGIT or LJ slope	Generation of Mycobacteria Next Generation Sequencing data (sampling through to sequencing) for the purposes of subsequent Mycobacterium Species identification, drug resistance prediction for Rifampicin and Isoniazid of tuberculosis complex isolates	Manual extraction using FastPrep-24 homogeniser, purification by AMPure XP beads, followed by DNA concentration measure by Qubit : MI.S3041 DNA extraction for MiSeq from a positive Mycobacterium culture. Next Generation Sequencing using Mycobacteria DNA libraries : MI.S3035 Nextera XT library preparation without beads. MI.S3036 Preparing of DNA pool and loading onto the MiSeq.



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Blood	Epstein Barr virus (EBV) - screening & confirmation	MI.X021 EBNA Liaison XL
Blood	Hepatitis C IgG confirmation	MI.S074 Diasorin Liaison XL Murex Hepatitis C antibody kit insert MI.S2037 Liaison XL User guide
Blood	Herpes Simplex 1&2 antigen	MI.X019 HSV IgG Liaison XL
Blood	HTLV-1 antibody	MI.X060 HTLV Liaison XL insert
Blood	Measles IgG	MI.X016 Measles IgG Liaison XL
Blood	Measles IgM	MI.X058 Measles IgM Liaison XL
Blood	Mumps IgG	MI.X017 Mumps IgG Liaison XL
Blood	Mumps IgM	MI.X059 Mumps IgM Liaison XL
Blood	Parvovirus IgM	MI.X022 Parvo IgM Liaison XL
Blood	Parvovirus IgG	MI.X023 Parvo IgG Liaison XL
Blood	Treponema pallidum (syphilis) antigen confirmation	MI.X1553 Treponema screen Liaison XL
Blood	Varicella Zoster IgG	MI.X026 Varicella Zoster IgG Liaison XL
Blood	Varicella Zoster IgM	MI.X018 VZ IgM Liaison XL
Blood	Detection of Aspergillus galactomannan antigen	In house methods in conjunction with manufacturer's instructions using Launch DS2 MI.X399 Biorad EIA Galactomannan test MI.S2444 Aspergillus/Galactomannan Antigen EIA
Blood	Hepatitis E IgG Hepatitis E IgM	MI.S1691 Hepatitis E IgG and IgM Fortress ELISA
Urine	Legionella antigen	MI.S1939 Legionella Antigen Detection in urine samples
Blood	Syphilis IgM	MI.S2555 MIKROGEN SYPHILIS IgM EIA



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Blood	Hepatitis B antigen confirmation	MI.S1959 VIDAS HBsAg MI.S1947 VIDAS Processing
Blood	HIV antigen confirmation	In house methods in conjunction with manufacturer's instructions using MI.S1954 VIDAS HIV Ultra and HIV p24 MI.S1947 VIDAS Processing
Blood	Cytomegalovirus (CMV) activity	In-house methods in conjunction with manufacturer's instructions using MI.S1082 VIDAS CMV IgG avidity II (CMVA)
Blood	Streptococcal Antigen	Manual latex agglutination kit with visual interpretation in conjunction with manufacturer's instructions using Instrumentations Laboratory - Rheumatest ASO MI.S1942 Streptococcal Antibody by latex
Blood	Cryptococcal Antigen	Manual latex agglutination kit with visual interpretation in conjunction with manufacturer's instructions using ALPHA Laboratories - Latex assay MI.S1941 Cryptococcal antigen latex test
Blood CSF	Syphilis TPPA	Manual latex agglutination assay with visual interpretation in conjunction with manufacturer's instructions using Serrodia TPPA MI.S1937 Syphilis TPPA
Blood CSF	Treponema pallidum antibodies confirmation	Manual flocculation test on slide with visual interpretation in conjunction with manufacturer's instructions using RPR (rapid plasma reagin) Reditest MI.S1936 Syphilis RPR
Blood	HIV antibody confirmation	Manual immunochromatographic test with visual interpretation in conjunction with manufacturers instructions using Bio-Rad Geenius HIV 1 and 2 confirmatory assay MI.S3054 Geenius HIV 1 and 2 confirmatory assay



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Urine	Legionella antigen	Manual line immunoassay with visual interpretation in conjunction with manufacturer's instructions using – TRU Legionella MI.S1673 TRU Legionella urine antigen
Faeces	Adenovirus antigen Rotavirus antigen	Manual immunoassay test with visual interpretation in conjunction with manufacturer's instructions using the BioNexia test pack MI.S2005 Detection of Rotavirus and Adenovirus by BioNexia test pack
END		