

Schedule of Accreditation

issued by

United Kingdom Accreditation Service

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



Accredited to
ISO 15189:2012

Public Health England, an Executive Agency of the Department of Health and Social Care (Trading as Manchester Medical Microbiology Partnership)

Issue No: 006 Issue date: 05 July 2021

Manchester Medical Microbiology
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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>	Documented in-house methods based on related UK Standards for Microbiology Investigations (SMIs) and manufacturer's operating instructions, where relevant, to support clinical diagnosis
Urine, Suprapubic aspirate	Detection and quantification of white blood cells, red blood cells, epithelial cells and bacteria. General isolation and characterisation of bacterial and fungal isolates of clinical significance from urinary specimens	Differential cell count (flow cytometry) using BioMerieux UF1000i with automated plating on chromogenic agar using Previ-Isola. MMMP-BM-PROC18 Investigation of Urine MMMP-BM-PROC110 Use of Sysmex UF1000i urine analyser Differential cell count (flow cytometry) using BioMerieux UF1000i MMMP-BW-PROC74 Investigation of Urine MMMP-BW-PROC7119 Use of Sysmex UF-1000i urine analyser
Blood, Fluids, Aspirates	Culture and detection of microorganisms of clinical significance	BD BacTec FX semi-automated blood culture system: MMMP-BM-PROC3 Investigation of Blood Cultures & Sterile Fluids



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<p>HUMAN BODY FLUIDS AND TISSUES</p> <p>Wound swab, nose swab, throat swab, ear swab, MRSA swabs</p> <p>Superficial and deep-seated wound swabs, tissues, genital specimens, ENT swabs, ocular specimens, biopsies, bone</p>	<p><u>Microbiology examination activities for the purpose of clinical diagnosis</u></p> <p>Isolation and characterisation of microorganisms of clinical significance including MRSA</p> <p>Isolation and characterisation of microorganisms of clinical significance.</p>	<p>Documented in-house methods based on related UK Standards for Microbiology Investigations (SMIs) and manufacturer's operating instructions, where relevant, to support clinical diagnosis</p> <p>WASPLab total laboratory automation, MMMP-BM-PROC23 Investigation of MRSA Screening Swabs using WASP and Traditional Culture</p> <p>Manual inoculation and media culture MMMP-BM-PROC53 Investigation of nose swabs MMMP-BM-PROC54 Investigation of Throat Swabs MMMP-BM-PROC55 Investigation of Specimens for Bordetella Species MMMP-BM-PROC56 Investigations of Ear Swabs and Associated Specimens MMMP-BM-PROC65 Investigation of Skin Superficial & Non-surgical Wound Swabs MMMP-BM-PROC66 Investigation of Abscesses, Pus & Deep-Seated Infections MMMP-BM-PROC85 Investigation of specimens from Burns patients MMMP-BM-PROC64 Investigation of Tissue, Biopsies and Bone MMP-BM-PROC10 Investigation of Genital Tract Specimens MMMP-BM-PROC12 Investigation of GUM Specimens (Genito-urinary med MMMP-BM-PROC51 Investigation of Intraocular Fluids and Corneal Biopsies & Scrapings (routine culture for bacteria) MMMP-BM-PROC99 Investigation of Eye bank specimens MMMP-BM-PROC59 Investigation of Eye Swabs, Canalicular Pus</p>



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<p>HUMAN BODY FLUIDS AND TISSUES</p> <p>Respiratory specimens, sputum, broncho-alveolar lavage, endotracheal specimens, tissue, pleural fluid, cough swabs</p> <p>CSF, PD fluid, Sterile Fluids, Aspirates, Joint Fluids</p> <p>CSF, PD fluids, sterile fluids, aspirates, joint fluids</p>	<p><u>Microbiology examination activities for the purpose of clinical diagnosis</u></p> <p>Isolation and characterisation of microorganisms from respiratory specimens of clinical significance</p> <p>Detection and quantification of white blood cells, red blood cells,</p> <p>Differentiation of different organism types: Gram positive/negative/variable, branching organisms, yeasts</p>	<p>Documented in-house methods based on related UK Standards for Microbiology Investigations (SMIs) and manufacturer's operating instructions, where relevant, to support clinical diagnosis</p> <p>MMMP-BM-PROC17 Investigation of Sputum and associated specimens MMMP-BM-PROC96 Investigation of Sputum and associated specimens from Cystic Fibrosis, PCD and Bronchiectasis patients MMMP-BM-PROC100 Investigation of Post-Mortem samples</p> <p>Manual cell using and SOPs: MMMP-BM-PROC63 Investigation of Sterile Fluids MMMP-BM-PROC15 Investigation of Continuous Ambulatory Peritoneal Dialysis Fluid MMMP-BM-PROC16 Investigation of Cerebrospinal Fluid MMMP-BM-PROC61 Investigations of Sinus Aspirate MMMP-BW-PROC94 Investigation of prosthetic joint infection and prosthetic vascular graft infection samples</p> <p>Gram staining and light microscopy MMMP-BM-PROC63 Investigation of Sterile Fluids MMMP-BM-PROC15 Investigation of Continuous Ambulatory Peritoneal Dialysis Fluid MMMP-BM-PROC61 Investigations of Sinus Aspirate MMMP-BM-PROC16 Investigation of Cerebrospinal Fluid MMMP-BW-PROC94 Investigation of prosthetic joint infection and prosthetic vascular graft infection samples</p>



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Swabs	Isolation and characterisation of carbapenemase producing Enterobacteriaceae	Manual methods using MMMP-BW-PROC-125 Detection of Carbapenemase Producing Enterobacteriaceae
Rectal swabs and bacterial isolates	Molecular detection of carbapenemase producing Enterobacteriaceae	MMMP-BM-PROC130 Cepheid GeneXpert Infinity 48 System for the detection of carbapenemase producing Enterobacteriaceae and MMMP-BM-PROC91 CPE using a Manual Screening method
Sputum, BAL, pus, urine	Isolation and characterisation of mycobacteria	BD MGIT and manual culture on Lowenstein Jenson media. MMMP-BM-PROC14 Investigation of specimens for Mycobacterium species MMMP-BM-PROC121 Examination of specimens for isolation of mycobacteria using BD BACTEC MGIT 960
Blood and bone marrow	Isolation and characterisation of mycobacteria	MMMP-BM-PROC147 Examination of Blood Cultures, Bone Marrow for the Isolation of Mycobacteria-BD Bactec FX40
Sputum, BAL, pus, urine	Molecular detection of mycobacteria	Cepheid GeneXpert PCR and HAIN Geno Type Mycobacteria DNA strip technology
	HAIN for detection of MTB complex, rifampicin and isoniazid resistance	MMMP-BM-PROC69 Molecular Detection of Mycobacterium using HAIN Geno Type Mycobacteria DNA strip technology
	Cepheid for detection of MTB complex, and 13 other Mycobacterium species, and rifampicin resistance	MMMP-BM-PROC115 Cepheid GeneXpert ® MTB/RIF User Guide for the Detection of Mycobacterium Tuberculosis complex



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Sputum, BAL, pus, urine	Detection of acid-fast bacilli	Manual auramine stained smears and fluorescent microscopy MMMP-BM-PROC14 Investigation of specimens for Mycobacterium species MMMP-BM-PROC21 Microscopical preparations and staining techniques
Faeces	Isolation and characterisation of microorganisms of clinical significance	Manual inoculation and media culture MMMP-BM-PROC47 Examination procedure Enterics
Faeces	Detection of the following: Giardia lamblia Cryptosporidium Helicobacter pylori antigen C. difficile GDH and toxin AB	Dynex DS2 automated ELISA processor MMMP-BM-PROC47 Examination procedures Enterics Techlab Giardia Cryptosporidium CHEK Oxoid H. pylori IDEIA Hp STAR Techlab C. difficile CHEK 60 Techlab C. difficile Tox A/BII
Faeces	Detection of the following: Clostridium difficile GDH Clostridium difficile toxin A & B	MMMP-BM-PROC47 Examination procedures Enterics Lateral flow membrane immunoassay, Quik Check MMMP-BM-PROC129 C.difficile Quik Chek Complete Test Procedure MMMP-BM-PROC101 Examination of immunochromatic assays
Faeces, urine, Sellotape slide, pus, fluids, tissue	Identification/confirmation of faecal parasites	Microscopic examination using wet preparation, dry slide and Parasep concentration MMMP-BM-PROC25 Parasitology



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Faeces	Molecular detection of Clostridium difficile	GeneXpert PCR MMMP-BM-PROC112
Clinical isolates cultured in-house (including, bacteria, yeasts, fungi)	Identification of microorganisms of clinical significance.	Bruker Microflex Biotyper (MALDI-TOF), mass spectrometry MMMP-BM-PROC119 Biomerieux Vitek 2XL MMMP-BM-PROC39 Biomerieux Vitek Compact MMMP-BM-PROC39 Biomerieux API identification strips MMMP-BM-PROC13 Identification of Organisms Oxoid Latex agglutination MMMP-BM-PROC6 Identification of E. coli 0157 Biorad Latex agglutination MMMP-BM-PROC105 Identification of Staphylococcus
Clinical isolates cultured in-house (including, bacteria, yeasts, fungi)	Identification of microorganisms of clinical significance.	Prolab Serology Kits MMMP-BM-PROC50 Identification of Salmonella Streptococcal grouping MMMP-BM-PROC13 Identification of Organisms
Skin, hair, nail, swabs, BAL, sputum, CSF, tissues	Isolation and identification of fungi of clinical significance. Presence or absence of fungal elements	Media culture and wet film microscopy using Calcofluor and Indian Ink MMMP-BM-PROC24 Investigation of Mycology specimens



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<p>HUMAN BODY FLUIDS AND TISSUES</p> <p>Bacterial and yeast isolates</p>	<p><u>Microbiology examination activities for the purpose of clinical diagnosis</u></p> <p>Antimicrobial susceptibility testing (AST)</p>	<p>Documented in-house methods based on related UK Standards for Microbiology Investigations (SMIs) and manufacturer's operating instructions, where relevant, to support clinical diagnosis</p> <p>Fully automated Vitek XL using EUCAST breakpoint data Manual antimicrobial susceptibility testing using disc diffusion and EUCAST and BSAC methodology Antibiotic disc diffusion and gradient MIC determination (Etest and Lilofilchem) MMMP-BM-PROC29 Antimicrobial sensitivity testing: Disk testing MMMP-BM-PROC91 Screening bench: resistant enzymes MMMP-BM-PROC102 Antimicrobial sensitivity testing: E-tests</p>



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HUMAN BODY FLUIDS AND TISSUES	<u>Serology examination activities for the purpose of clinical diagnosis</u>	Documented in-house methods based on related UK Standards for Microbiology Investigations (SMIs) and manufacturer's operating instructions, where relevant, to support clinical diagnosis
Serum, plasma, dried blood spot	Qualitative detection of the following: Syphilis (total) HIV antigen & antibody Human T-cell Lymphotropic Virus (HTLV) antibody Hepatitis A IgG & IgM Hepatitis B surface antibody Hepatitis B Core ab (total) Hepatitis B core IgM Hepatitis B surface antigen Hepatitis B e antigen Hepatitis B e antibody Hepatitis C antibody Cytomegalovirus IgG & IgM Rubella IgG & IgM Toxoplasma IgG, IgM & avidity	Roche Cobas 8000 analyser using electrochemiluminescence and MMMP-SEROL-PROC75 MMMP-SERO-PROC 78 MMMP-SEROL-PROC 80 MMMP-SEROL-PROC 95 MMMP-SEROL-PROC28 MMMP-SEROL-PROC85 MMMP-SEROL-PROC86 MMMP-SEROL-PROC84 MMMP-SEROL-PROC89 MMMP-SEROL-PROC90 MMMP-SEROL-PROC 81 MMMP-SEROL-PROC91 MMMP-SEROL-PROC92 MMMP-SEROL-PROC83 MMMP-SEROLPROC 82 MMMP-SEROL-PROC 88 MMMP-SEROLPROC79 MMMP-SEROLPROC87 MMMP-SEROL-PROC96 MMMP-SEROLPROC97 MMMP-SEROL-PROC115 MMMP-SEROLPROC93 MMMP-SEROLPROC94
Serum, plasma	Syphilis confirmation TPPA titre Syphilis confirmation RPR titre	Serodia TPPA using particle agglutination MMMP-SEROL-PROC128 Biokit RPR reditest using microparticle agglutination MMMP-SEROL-PROC128



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Serum, plasma	Detection of HIV 1 and 2 antibodies	Biorad Geenius immunoblot lateral flow device MMMP-SEROL-PROC71
Urine	Detection of Legionella and Streptococcus pneumoniae antigen	Binax NOW kit and immunochromatography, MMMP-SEROL-PROC123
CSF	Detection of Cryptococcal antigen	Latex antigen kit MMMP-SEROL-PROC125
Serum, plasma	Detection of ASD antibodies	BioMerieux ASD by enzyme inhibition MMMP-SEROL-PROC127
Serum, plasma	Qualitative detection of the following: Epstein Barr Virus (EBV)CA IgG, IgM & EBNA IgG Measles IgG & IgM HSV IgG & IgM Parvovirus IgG & IgM Varicella Zoster IgG & IgM Mumps IgG & IgM Chlamydia IgG CMV IgG and avidity Syphilis IgG HIV antigen & antibody Hepatitis B surface antigen Hepatitis delta antibody	Diasorin Liaison XL analyser using chemiluminescence, MMMP-SEROL-PROC57, MMMP-SEROL-PROC28 and MMMP-SEROL-PROC124



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Serum, plasma	Qualitative detection of: HIV P24 antigen Lyme IgG & IgM Hepatitis B Core antibody (total)	BioMerieux automated analyser VIDAS 3 User Guide MMMP-SEROL-PROC74 MMMP-SEROL-PROC98 MMMP-SEROL-PROC99 MMMP-SEROL-PROC100 MMMP-SEROL-PROC102
Serum, plasma	Qualitative detection of: Syphilis IgM Hepatitis C Virus antibody confirmation Hepatitis E Virus (HEV) IgM	Werfen DS2 automated ELISA analyser Trinity Biotech Syph IgM MMMP-SEROL-PROC68 Ortho HCV MMMP-SEROL-PROC65 HEV IgM Fortress Diagnostics MMMP-SEROL-PROC64



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HUMAN BODY FLUIDS AND TISSUES	<u>Molecular examination activities for the purposes of clinical diagnosis</u>	Documented in-house methods based on related UK Standards for Microbiology Investigations (SMIs) and manufacturer's operating instructions, where relevant, to support clinical diagnosis
Blood	Quantitative viral load for: HIV RNA Hepatitis B DNA Hepatitis C RNA	Roche Cobas 6800 MMMP-MOL-PROC-95 MMMP-MOL-PROC-94 MMMP-MOL-PROC-93 PCR using Qiagen MDX extraction and Applied Biosystems 7500 Taqman amplification
Blood, urine	Quantitative detection of CMV DNA	MMMP-MOL-PROC44
Blood	Quantitative detection of EBV DNA	MMMP-MOL-PROC66
Blood, swabs	Quantitative detection of Adenovirus DNA	MMMP-MOL-PROC2
Respiratory sample, nose and throat swabs and CSF	Qualitative detection of Mycoplasma pneumoniae DNA	MMMP-MOL-PROC91
Genital and skin swabs, vitreous fluids, CSF, blood	Varicella zoster DNA	MMMP-MOL-PROC29
Swabs, CSF, fluids	Treponema pallidum DNA	MMMP-MOL-PROC56
Blood, plasma, serum, CSF	Meningococcal (incorporating ctrA gene and serogroup B) and pneumococcal DNA Meningococcal serogroups A, C, Y, W confirmatory assays	MMMP-MOL-PROC40



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CSF, blood, amniotic fluid	Qualitative detection of Toxoplasma gondii DNA	MMMP-MOL-PROC46 PCR using Qiagen MDX extraction and Applied Biosystems 7500 Taqman amplification
BAL, sputum, CSF, blood, swabs	Qualitative Detection of Candida DNA	MMMP-MOL-PROC8
BAL, sputum, CSF	Qualitative Detection of Aspergillus DNA	MMMP-MOL-PROC8
Genital and skin swabs, CSF, vitreous fluids, blood	Qualitative detection of Herpes simplex 1 & 2 DNA	MMMP-MOL-PROC18
CSF, faeces, blood, swabs, respiratory samples	Qualitative detection of Enterovirus and Parechovirus RNA	MMMP-MOL-PROC59
CSF, blood	Qualitative detection of Human Herpes virus 6 & 7 DNA	MMMP-MOL-PROC14
Throat swabs, urines	Qualitative detection of Measles RNA	MMMP-MOL-PROC35
CSF, urine, serum, blood	Qualitative detection of Polyoma (BK and JC) DNA	MMMP-MOL-PROC3
Blood, tissues, amniotic fluid	Qualitative detection of Parvovirus B19 DNA	MMMP-MOL-PROC23
BAL, sputum, blood	Qualitative detection of Pneumocystis jiroveci DNA	MMMP-MOL-PROC24



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Respiratory samples	Qualitative detection of the following: Respiratory viruses, Influenza A RNA (Pandemic, H1, H3, H5, H7) & B, RSV RNA, Parainfluenza 1 RNA, Parainfluenza 2 RNA, Parainfluenza 3 RNA, Adenovirus DNA, Rhinovirus RNA, Metapneumovirus RNA,	PCR using Qiagen Symphony extraction and Applied Biosystems Taqman amplification
Respiratory specimens, swabs, BAL, sputum	Oseltamivir resistance	MMMP-MOL-PROC34 MMMP-MOL-PROC39 MMMP-MOL-PROC72
Pernasal swab, nose and throat swab, BAL, sputum, nasopharyngeal aspirate	Bordetella pertussis DNA	MMMP-MOL-PROC42 MMMP-MOL-PROC83
Genital swabs, urine, eye swabs, rectal swabs and throat swabs	Detection of Chlamydia trachomatis RNA, Neisseria gonorrhoeae and Trichomonas vaginalis DNA	PCR using Roche Cobas 8800 MMMP-MOL-PROC67 MMMP-MOL-PROC111



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Cervical swabs, biopsies, paraffin wax tissue sections	Qualitative detection of Human Papilloma virus, types 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68	Roche Cobas 8800 PCR MMMP-MOL-PROC106 Detection of high risk Human Papillomavirus using the Cobas 68/8800 System
Nasal and throat swabs in VTM Sputum Bronchoalveolar lavage (BAL)	HPV genotyping (DNA) Papillocheck assay	MMMP-MOL-PROC69
Nasopharyngeal/oropharyngeal, nasal and midturbinate swabs in Viral Transport Medium Sputum	Detection of SARS-CoV-2 virus RNA (COVID-19) specific gene sequences: E, ORF1ab	Roche Cobas 6800/8800 PCR MMMP-MOL-PROC112 Detection of SARS-CoV-2 using the Roche Cobas 68/8800 System
Bronchoalveolar lavage (BAL) Tracheal aspirate from organ transplant patient	Detection of SARS-CoV-2 virus RNA (COVID-19) specific gene targets: E, N2 and ORF1a	MMMP-MOL-PROC114 the Cepheid Xpert Xpress SARS-CoV-2 assay for the rapid detection of COVID 19 using Cepheid Xpert Infinity-48 automated PCR System
Plasma	Detection of the following	Sequencing using Qiagen Symphony extraction and Applied Biosystems ABI 3130 sequencer
	Hepatitis B resistance	MMMP-MOL-PROC58
	Detection of CMV resistance	MMMP-MOL-PROC41
	HIV resistance, integrase, tropism	MMMP-MOL-PROC48, 49, 53
Serum, dried blood spot	Hepatitis C genotyping	BioMerieux EasyMAG extraction and Roche Cobas 4800 qualitative PCR MMMP-MOL-PROC13 MMMP-MOL-PROC100



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HUMAN BODY FLUIDS AND TISSUES (cont'd)	<u>Molecular examination activities for the purpose of clinical diagnosis</u> (cont'd)	Documented in-house methods based on related UK Standards for Microbiology Investigations (SMIs) and manufacturer's operating instructions, where relevant, to support clinical diagnosis (cont'd)
Nasopharyngeal swabs and aspirates	Detection of Influenza A, B and RSV	GeneXpert Infinity automated PCR system and MMMP-MOL-PROC103
Faeces	Detection of Norovirus GI and GII, Adenovirus 40/41, Astrovirus, Rotavirus, Sapovirus	Roche FLOW RT-PCR system and MMMP-MOL-PROC108
Nose and throat swab, sputum, bronchoalveolar lavage, lung biopsy	Detection of Middle East Respiratory Syndrome Coronavirus (MERS-CoV)	Altona Real Star qualitative RT-PCR and MMMP-MOL-PROC97
Faeces and C difficile isolates	Identification of ribotypes of C difficile	PCR and gel electrophoresis and MMMP-BM-PROC126
	<u>Microbiological examination activities for the purpose of clinical diagnosis</u>	
	Meningococcal reference unit	
Blood, serum, CSF	Detection of antigen to Streptococcus pneumoniae and Neisseria meningitidis	Latex agglutination using Wellcogen kit and MMMP-MRU-PROC8
Bacterial isolates	Sero-grouping and outer membrane typing of Neisseria meningitidis	Dot blot ELISA using MMMP-MRU-PROC10 and 13
	Identification of Neisseria meningitidis	MMMP-MRU-PROC6 Identification of Neisseria
	Antibiotic susceptibility testing (MIC) for Neisseria meningitidis	MIC using E-test and MMMP-MRU-PROC3



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CSF, blood, joint fluid, bacterial isolates	Meningococcal reference unit	MMMP-MRU-PROC18 PorA sequence typing
Blood, serum	Sequence typing of Neisseria meningitidis	
	Vaccine Evaluation Unit	
	Determination of serum bactericidal antibody level for the following Neisseria meningitidis serogroups	Manual serum bactericidal assay and automated colony counter
	A, C, Y, W B	SOP 1069 SOP 1068
	IgG Determination ELISA Serogroups A, C, Y and W	Versamax Automated Microtitre Plate Reader and IgG determination using Enzyme –linked immunosorbent assay (ELISA) SOP 1080
Blood, serum	Serological determination of immune responses to vaccine preventable disease Streptococcus pneumoniae	SOP 1667 Bioplex Array Reader and IgG determination using Flow Analysis Multiplex Bead Assay
	Serotype 1 Serotype 3 Serotype 4 Serotype 5 Serotype 6B Serotype 7F Serotype 9V Serotype 14 Serotype 18C Serotype 19A Serotype 19F Serotype 23F	



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Public Health England, an Executive Agency of the Department of Health and Social Care (Trading as Manchester Medical Microbiology Partnership)

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Testing performed at main address only

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS AND TISSUES Blood, serum	<u>Microbiological examination activities for the purpose of clinical diagnosis</u> Meningococcal reference unit Serological determination of immune response to vaccine by measurement of IgG for the following: Haemophilus influenzae type b Tetanus Diphtheria	Documented in-house methods based on related UK Standards for Microbiology Investigations (SMIs) and manufacturer's operating instructions, where relevant, to support clinical diagnosis Bioplex array reader using Flow Analysis Multiplex Bead Assay and Sop 1646
END		