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Clinical Microbiology
QMC Campus
Derby Road
Nottingham
NG7 2UH

Contact: Rebecca Walker
Tel: +44 (0) 115 924 9924 Ext 84210
E-Mail:Rebecca.walker@nuh.nhs.uk
Website: https://www.nuh.nhs.uk/microbiology

Testing performed at the above address only

DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS AND TISSUES	Microbiology examination activities for the purpose of clinical diagnosis	In house documented methods based on related UK Standards for Microbiology Investigations (PHE SMIs):
Aspirates Cellular and fluid material contained on swabs, cannulae, Faeces Fluids Genital samples Pus Samples from sterile sites Semen Tissues Respiratory samples	General isolation of micro-organisms of clinical significance	Manual inoculation followed by culture using SOPs: General Swabs D Bench – SOP PR 2058 Enteric SOP – SOP PR 2062 Genital Swab Methods SOP PR 2059 Special Bacteriology Methods SOP PR 2056 Investigation of samples for respiratory pathogens SOP PR2070
Whole blood	General isolation of micro-organisms of clinical significance	Automated culture using BacTec FX400 Blood Culture Method SOP PR 2057
Urine	Quantification of white and red blood cells, bacteria and epithelial cells	Automated urine analysis using iQ200Sprint PR2054
Urine	Isolation, identification and antibiotic susceptibility testing of microorganisms of clinical significance	MAST Uriplus Urine Methods SOP PR 2054
	Antimicrobial disk suceptability	Automated methods - inhibition zone size reader on the Biorad Adagio

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HUMAN BODY FLUIDS AND TISSUES (cont'd)	Microbiology examination activities for the purpose of clinical diagnosis (cont'd)	In house documented methods based on related UK Standards for Microbiology Investigations (PHE SMIs):
Cerebral fluid samples, CAPD fluids	Detection and quantification of white and red blood cells Isolation and identification testing of microorganisms of clinical significance	Light Microscopy using a Fuchs Rosenthal and Kova counting chamber for counts and Differentiation of white blood cells using Toludine blue stain or TURKs.: CSF Methods – SOP PR 2055, Special Bacteriology Methods – SOP PR 2056,
Swabs	Isolation of MRSA	Manual culture using: MRSA Bench – SOP PR 2071
Respiratory samples Urine Pus Tissue Fluids CSF	Isolation and presumptive identification of Acid-alcohol fast bacilli (inc. *Mycobacterium* spp.) and routine respiratory culture of clinical significance	Automated culture and microscopy (screening by fluorescent microscopy using Auramine stain, and ZN light microscopy on automated detection) using BD MGIT 960 and BD Bactec FX40; SOP PR2069 Investigation of specimens for respiratory pathogens PR2070
Cultures isolated in house from the above	Identification of clinically significant bacteria	Biochemical profile determination using: Vitek 2 SOP PR 3881 Urine SOP PR 2054 Genital SOP PR 2059 Enteric SOP PR2062 General Swabs D Bench **–** SOP PR 2058
	Identification of clinically significant bacteria and fungi	Automated identification using the Bruker Maldi-ToF platform and SOP PR3362
Serum or plasma	Quantitative detection of β-D-Glucan	Wako β-D-Glucan assay using Toxinometer MT-6500 following SOP PR3912

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HUMAN BODY FLUIDS AND TISSUES (cont'd)	Microbiology examination activities for the purpose of clinical diagnosis (cont'd)	In house documented methods based on related UK Standards for Microbiology Investigations (PHE SMIs):
Cultures isolated in house from the above (cont'd)	Antimicrobial susceptibility testing of clinically significant bacteria	Manual disc diffusion and/or automated methods using EUCAST methodology, including Microscan Walkaway 96 Plus analyser: Antibiotic SOP PR2053 Blood Culture Identification Procedures PR2057 Genital SOP PR 2059 Enteric SOP PR2062
	Identification of clinically significant bacteria	General bacterioogy SOP PR2058 Enteric SOP PR 2062 Special Bacteriology PR2056 Genital bench PR 2059 Respiratory bench PR 2069/2070 Blood cultures bench PR 2057 Mycology SOP PR 2060 Urines bench PR 2054 NUH Microbiology Staining techniques PR2068
Cultures isolated in house from the above	Identification of Staphylococcal isolates	Prolex staph latex PR 2058
Cultures isolated in house from the above	Serological identification of groups A, B, C, D, F and G of the Lancefield groups of Streptococci grown on agar plates	Pro-Lab Strep grouping kit PR 2053, PR 2054, PR 2056, PR 2057, PR 2058, PR 2059
Cultures isolated in house from the above	Detection of *Salmonella* polyvalent 'O' (PSO) and *Salmonella* polyvalent 'H' (PSH); *Shigella* species; *Vibrio* species.	MAST agglutination using Enteric SOP PR 2062
Cultures isolated in house from the above	Identification of *E. coli* O157	E.col O157 Oxoid Latex Test using: Enteric SOP PR 2062
Cultures isolated in house from the above	Identification of *Campylobacter* species and *Yersinia* species	Light microscopy and Carbol Fuchsin stain using: SOP PR 2062

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HUMAN BODY FLUIDS AND TISSUES (cont'd)	Microbiology examination activities for the purpose of clinical diagnosis (cont'd)	In house documented methods based on related UK Standards for Microbiology Investigations (PHE SMIs):
Faeces	Detection of ova, cysts and parasites (OCP)	Concentration and light microscopic examination using Parasep method: Enteric SOP PR2062
Faeces	Detection of *Cryptosporidium* oocysts	Fluorescent microscopy (Auramine stain) using: Enteric SOP PR2062
Faeces	Detection of *C. difficile* GDH antigen	Faeces specimens are screened for the presence of Clostridium difficile using the RIDA® Quick Clostridium difficile GDH kit (r-Biopharm) which detects the C. difficile antigen, glutamate dehydrogenase enzyme – Lateral flow - PR2062
Faeces	Detection of *C. difficile* toxin A & B	Confirmatory for the presence of C. difficile toxin using the RIDA® Quick Clostridium difficile Tox A/B kit (r-Biopharm) – Lateral flow - PR2062
Faeces	Detection of Rotavirus and Adenovirus antigen	lateral flow (Certest Biotec) kit Enteric SOP – PR 2062

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HUMAN BODY FLUIDS AND TISSUES (cont'd)	Serological activities for the purpose of clinical diagnosis	Documented in house methods incorporating manufacturers' instructions where relevant Documented-in-house methods to meet the requirements of the Infectious Diseases in Pregnancy Screening programme as defined in the 'Infectious Diseases in Pregnancy Screening: laboratory QA evidence requirements' (targets marked*)
Plasma Serum	Detection of: HIV-1 and HIV-2 Antibodies and Antigen (p24)* Hepatitis C Antibody Syphilis total Antibody* Hepatatis B surface Antigen* Anti-HBs Hepatitis B core IgM Hepatitis B core total Antibody Hepatatis B e Antigen Heptatis B e Antibody Hepatitis A IgM Hepatitis A total antibody Rubella IgM Rubella IgG	Alinity I analyser SOP – PR 3784
Serum	Quantification of the following: Hepatitis A IgG antibody Hepatitis A IgM antibody Human T-lymphotropic virus type 1 and 2 (HTLV I/II) Toxoplasma IgG Procalcitonin (PCT) Cytomegalovirus (CMV) IgG Avidity Hepatitis B surface Ag (HBsAg)	Alinity I analyser using Chemiluminescent Microparticle immunoassay SOP PR3784

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HUMAN BODY FLUIDS AND TISSUES (cont'd)	Serological activities for the purpose of clinical diagnosis	Documented in house methods incorporating manufacturers' instructions where relevant Documented-in-house methods to meet the requirements of the Infectious Diseases in Pregnancy Screening programme as defined in the 'Infectious Diseases in Pregnancy Screening: laboratory QA evidence requirements' (targets marked*)
Clotted Blood, Plasma, Serum	Detection of: VZV IgG Parvovirus IgM Parvovirus IgG Measles IgG HTLV I/II IgG *Borrelia* IgG/ Mumps IgG H.pylori	Using Diasorin Liaison XL SOP – PR 3028
Serum	Hepatitis E IgG Hepatitis E IgM	
Serum	Identification of Mycobacteria Tuberculosis	Quantiferon Gold assay on the Diasorin Liaison XL analyser following SOP PR3028
Lithium Heparin, Plasma	H.pylori IgG	Diasorin Liaison XL SOP – PR 3028

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HUMAN BODY FLUIDS AND TISSUES (cont'd)	Serological activities for the purpose of confirmation of clinical diagnosis	Documented in house methods incorporating manufacturers' instructions where relevant
Serum / Plasma / Clotted blood	Syphilis IgM	Dynex DS2 EIA DS2 System manual (PR2051) Syphilis IgM (PR3149)
Serum	Confirmation of Syphilis	Manual methods following SOP PR3106 including: ASI Treponema pallidum haemagglutination (TPHA) kit ASI rapid plasma reagin (RPR)
	Anti streptolysin O titres	Biokit Rheumajet ASO assay, PR2098 - Anti-streptolysin O Titre SOP
Serum / Plasma	HIV 1 and 2 Ab typing	Geenius HIV 1/2 Confirmatory Assay - (PR3145)
Urine	Detection of Legionella pneumophila Antigen	Dynex DS2 EIA Binax Legionella Antigen EIA kit (PR2092);
Urine, CSF	Detection of streptococcus pneumoniae antigen	Binax NOW Pneumococcal Ag for Streptococcus pneumoniae (Urinary Ag SOP PR2092)

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS AND TISSUES (cont'd)	Molecular examination activities for the purpose of clinical diagnosis	Documented in house methods incorporating manufacturers' instructions where relevant:
	Detection of:	Alinity m using methods as listed below and PR3784 NUH Microbiology Alinity m SOP:
Urine, Endocervical swab, vaginal swab	*Chlamydia trachomatis* and *Neisseria gonorrhoea*, Trichomonan vaginalis and Mycoplasma genitalium	STI assay using PCR technology with homogenous real-time fluorescence detection
Plasma, serum	HIV-1 RNA	RT-PCR
Plasma, serum	HCV RNA	RT-PCR
Plasma, serum	HBV RNA	RT-PCR
Nasopharangeal swab oropharangeal swab	SARS-COV-2 (RdRp and N genes)	RT-PCR detection of nucleic acid from SARS-CoV-2 virus
Nasopharangeal swab	Influenza A (Matrix gene) Influenza B (Non-structural 1 gene) RSV (Matrix gene) SARS-COV-2 (RdRp and N genes)	RT-PCR 4-plex multiplex assay RT-PCR 4-plex multiplex assay RT-PCR 4-plex multiplex assay RT-PCR 4-plex multiplex assay

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS AND TISSUES (cont'd)	Molecular examination activities for the purpose of clinical diagnosis (cont'd)	Documented in house methods incorporating manufacturers' instructions where relevant:
CSF, Throat Swabs, Whole Blood, Faeces, skin swabs	Detection of neurological viruses: Herpes simplex virus 1 (Human herpes virus 1; all strains) Herpes simplex virus 2 (Human herpes virus 2; all strains) Varicella zoster virus (Human herpes virus 3; all strains) Adenovirus group B, C and E (Includes groups B, C, E and some A, D; excludes hAdV 21) Enterovirus (types A, B, C and D) Parechovirus (types 1-8)	Kingfisher extraction methods (PR3894) PR2958 AusDiagnostics High-Plex system SOP
Serum	Quantitation of CMV	Kingfisher extraction methods (PR3894) (PR2080) AltoStar Automation System AM16 (PR3721)
Serum	Quantitation of EBV	Kingfisher extraction methods (PR3894) AltoStar Automation System AM16 (PR3721)
Throat and Nasal Swabs in Viral Transport Medium (VTM), Bronchoalveolar Lavage (BAL), Bronchial Aspirates and Nasopharyngeal Aspirates (NPA)	Detection and differentiation of lineage β-betacoronavirus (β-βCoV) and SARS-CoV-2 specific RNA. Specifically, E and S gene targets	RealStar SARS-CoV-2 RT-PCR - Manual test using BioMerieux NucliSENS and Kingfisher extraction methods (PR3894)

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
HUMAN BODY FLUIDS AND TISSUES (cont'd)	Molecular examination activities for the purpose of clinical diagnosis (cont'd)	Documented in house methods incorporating manufacturers' instructions where relevant: Using the Cepheid GeneXpert System GX-XVI-16 module using PR3569 and specific methodologies/kits as below
Nasopharyngeal, Throat and Nasal Swabs in Viral Transport Medium (VTM) and Nasopharyngeal Aspirates	Detection and differentiation of lineage β-betacoronavirus (β-βCoV) and SARS-CoV-2 specific RNA. Specifically, E and S gene targets	RealStar SARS-CoV-2 RT-PCR - Automated test using the AltoStar AM16 platform with AltoStar Purification Kit 1.5 and AltoStar internal Control 1.5 on the Bio-Rad CFX96 Real Time PCR system (PR3721)
Nasopharyngeal, Throat and Nasal Swabs in Viral Transport Medium (VTM) Bronchioalveolar lavage (BAL) Endotracheal secretions (ETS) Sputum	Detection of SARS-CoV-2 virus RNA (COVID-19) specific gene sequences E and N2	Rapid, real-time RT-PCR using the Xpert Xpress SARS-CoV-2 rapid molecular test
Nasopharyngeal, Throat swabs	Detection of SARS-COV-2 (Orf1ab and N gene)	Novodiag® COVID-19 RT-PCR test assay SOP PR3669
Endocervical swab, vaginal swab, urine, rectal, conjunctival and pharyngeal swabs	Detection of DNA from Neisseria gonnorrhoae	Real time PCR with Xpert CT/NG kit
Faeces, rectal swabs	Detection of C.difficile DNA	Real time PCR with Xpert C.difficile kit
	Detection of Flu and RSV RNA	Reverse transcription real-time PCR using Xpert Xpress Flu/RSV kit
	Detection of Norovirus RNA	Reverse transcription real-time PCR using Xpert Norovirus kit
Sputum	Detection of Mycobacterium tuberculosis DNA Detection of Rifampacin resistance geneA	PCR Method with MTB/RIF Ultra kit Via Cepheid GeneXpert SOP IN7370

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HUMAN BODY FLUIDS AND TISSUES (cont'd)	Molecular examination activities for the purpose of clinical diagnosis (cont'd)	Documented in house methods incorporating manufacturers' instructions where relevant:
Bacterial Isolates	Detection of Carbapenamase enzymes; VIM1, NDM, KPC, IMP and OXA48	Using the Cepheid GeneXpert System GX-XVI-16 module using PR3569 and PR2053
END		